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, 2021

or

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

Commission File Number: 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

No ☑

As of July 29, 2021, the registrant had 567,852,353 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.

INDEX

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,	
	2021	2020	2021	2020
Revenues:				
Product sales	$ 6,114	$ 5,908	$ 11,706	$ 11,802
Other revenues	412	298	721	565
Total revenues	6,526	6,206	12,427	12,367
Operating expenses:				
Cost of sales	1,637	1,488	3,127	3,001
Research and development	1,082	964	2,049	1,916
Acquired in-process research and development	1,505	—	1,505	—
Selling, general and administrative	1,384	1,295	2,638	2,611
Other	90	136	151	161
Total operating expenses	5,698	3,883	9,470	7,689
Operating income	828	2,323	2,957	4,678
Other income (expense):				
Interest expense, net	(281)	(296)	(566)	(642)
Other income, net	11	3	24	14
Income before income taxes	558	2,030	2,415	4,050
Provision for income taxes	94	227	305	422
Net income	$ 464	$ 1,803	$ 2,110	$ 3,628
Earnings per share:				
Basic	$ 0.81	$ 3.07	$ 3.67	$ 6.16
Diluted	$ 0.81	$ 3.05	$ 3.65	$ 6.12
Shares used in calculation of earnings per share:				
Basic	573	588	575	589
Diluted	576	592	578	593

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net income	$ 464	$ 1,803	$ 2,110	$ 3,628
Other comprehensive (loss) income, net of reclassification adjustments and taxes:				
Gains (losses) on foreign currency translation	14	(3)	(25)	(55)
(Losses) gains on cash flow hedges	(48)	(116)	142	(177)
Losses on available-for-sale securities	—	(2)	—	(21)
Other	(1)	—	—	(2)
Other comprehensive (loss) income, net of taxes	(35)	(121)	117	(255)
Comprehensive income	$ 429	$ 1,682	$ 2,227	$ 3,373

See accompanying notes.

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

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,630	$ 6,266
Marketable securities	1,452	4,381
Trade receivables, net	4,479	4,525
Inventories	4,115	3,893
Other current assets	2,423	2,079
Total current assets	19,099	21,144
Property, plant and equipment, net	4,906	4,889
Intangible assets, net	15,308	16,587
Goodwill	14,676	14,689
Other noncurrent assets	5,784	5,639
Total assets	$ 59,773	$ 62,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,277	$ 1,421
Accrued liabilities	8,984	10,141
Current portion of long-term debt	4,324	91
Total current liabilities	14,585	11,653
Long-term debt	28,458	32,895
Long-term tax liabilities	6,428	6,968
Other noncurrent liabilities	2,055	2,023
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750.0 shares authorized; outstanding—569.6 shares in 2021 and 578.3 shares in 2020	31,877	31,802
Accumulated deficit	(22,762)	(21,408)
Accumulated other comprehensive loss	(868)	(985)
Total stockholders' equity	8,247	9,409
Total liabilities and stockholders' equity	$ 59,773	$ 62,948

See accompanying notes.

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

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2020	578.3	$ 31,802	$ (21,408)	$ (985)	$ 9,409
Net income	—	—	1,646	—	1,646
Other comprehensive income, net of taxes	—	—	—	152	152
Dividends declared on common stock ($1.76 per share)	—	—	(1,012)	—	(1,012)
Issuance of common stock in connection with the Company's equity award programs	0.7	6	—	—	6
Stock-based compensation expense	—	57	—	—	57
Tax impact related to employee stock-based compensation expense	—	(59)	—	—	(59)
Repurchases of common stock	(3.7)	—	(865)	—	(865)
Balance as of March 31, 2021	575.3	31,806	(21,639)	(833)	9,334
Net income	—	—	464	—	464
Other comprehensive loss, net of taxes	—	—	—	(35)	(35)
Issuance of common stock in connection with the Company's equity award programs	0.8	47	—	—	47
Stock-based compensation expense	—	100	—	—	100
Tax impact related to employee stock-based compensation expense	—	(76)	—	—	(76)
Repurchases of common stock	(6.5)	—	(1,592)	—	(1,592)
Other	—	—	5	—	5
Balance as of June 30, 2021	569.6	$ 31,877	$ (22,762)	$ (868)	$ 8,247

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

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2019	591.4	$ 31,531	$ (21,330)	$ (528)	$ 9,673
Cumulative effect of changes in accounting principles, net of taxes	—	—	(2)	—	(2)
Net income	—	—	1,825	—	1,825
Other comprehensive loss, net of taxes	—	—	—	(134)	(134)
Dividends declared on common stock ($1.60 per share)	—	—	(938)	—	(938)
Issuance of common stock in connection with the Company's equity award programs	0.9	10	—	—	10
Stock-based compensation expense	—	52	—	—	52
Tax impact related to employee stock-based compensation expense	—	(68)	—	—	(68)
Repurchases of common stock	(4.3)	—	(933)	—	(933)
Balance as of March 31, 2020	588.0	$ 31,525	$ (21,378)	$ (662)	$ 9,485
Net income	—	—	1,803	—	1,803
Other comprehensive loss, net of taxes	—	—	—	(121)	(121)
Issuance of common stock in connection with the Company's equity award programs	1.0	65	—	—	65
Stock-based compensation expense	—	101	—	—	101
Tax impact related to employee stock-based compensation expense	—	(81)	—	—	(81)
Repurchases of common stock	(2.6)	—	(591)	—	(591)
Other	—	—	(2)	—	(2)
Balance as of June 30, 2020	586.4	$ 31,610	$ (20,168)	$ (783)	$ 10,659

See accompanying notes.

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

	Six months ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net income	$ 2,110	$ 3,628
Depreciation, amortization and other	1,696	1,827
Deferred income taxes	(137)	(261)
Acquired in-process research and development	1,505	—
Other items, net	170	245
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	35	(1,177)
Inventories	(167)	(226)
Other assets	(258)	143
Accounts payable	(156)	(216)
Accrued income taxes, net	(930)	452
Long-term tax liabilities	47	106
Other liabilities	120	455
Net cash provided by operating activities	4,035	4,976
Cash flows from investing activities:		
Cash paid for acquisitions, net of cash acquired	(1,626)	—
Purchases of marketable securities	(8,000)	(2,229)
Proceeds from sales of marketable securities	4,404	2,598
Proceeds from maturities of marketable securities	6,528	238
Purchases of property, plant and equipment	(351)	(300)
Purchases of equity method investments	(3)	(2,648)
Other	(62)	(48)
Net cash provided by (used in) investing activities	890	(2,389)
Cash flows from financing activities:		
Net proceeds from issuance of debt	—	9,002
Repayment of debt	—	(5,000)
Repurchases of common stock	(2,452)	(1,516)
Dividends paid	(2,024)	(1,887)
Other	(85)	(78)
Net cash (used in) provided by financing activities	(4,561)	521
Increase in cash and cash equivalents	364	3,108
Cash and cash equivalents at beginning of period	6,266	6,037
Cash and cash equivalents at end of period	$ 6,630	$ 9,145

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, 2021 and 2020, is unaudited but includes all adjustments (consisting of only normal, recurring adjustments unless otherwise indicated), which Amgen considers necessary for a fair presentation of its condensed consolidated results of operations for those periods. Interim results are not necessarily indicative of results for the full fiscal year.

The condensed consolidated financial statements should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2020, and with our condensed consolidated financial statements and the notes thereto contained in our Quarterly Report on Form 10-Q for the period ended March 31, 2021.

Principles of consolidation

The condensed consolidated financial statements include the accounts of Amgen as well as its majority-owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation and amortization of $9.1 billion and $9.0 billion as of June 30, 2021 and December 31, 2020, respectively.

Recent accounting pronouncements

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

2. Acquisitions

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

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

3. Revenues

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

Revenues were as follows (in millions):

	Three months ended June 30,					
	2021			2020		
	U.S.	ROW	Total	U.S.	ROW	Total
Enbrel® (etanercept)	$ 1,113	$ 31	$ 1,144	$ 1,213	$ 33	$ 1,246
Prolia® (denosumab)	538	276	814	441	218	659
Otezla® (apremilast)	423	111	534	464	97	561
Neulasta® (pegfilgrastim)	434	52	486	520	73	593
XGEVA® (denosumab)	355	133	488	318	117	435
Aranesp® (darbepoetin alfa)	135	232	367	156	231	387
Repatha® (evolocumab)	143	143	286	115	85	200
KYPROLIS® (carfilzomib)	190	90	280	167	86	253
Other products	1,043	672	1,715	1,034	540	1,574
Total product sales[1]	$ 4,374	$ 1,740	6,114	$ 4,428	$ 1,480	5,908
Other revenues			412			298
Total revenues			$ 6,526			$ 6,206

	Six months ended June 30,					
	2021			2020		
	U.S.	ROW	Total	U.S.	ROW	Total
ENBREL	$ 2,007	$ 61	$ 2,068	$ 2,330	$ 69	$ 2,399
Prolia®	1,039	533	1,572	863	450	1,313
Otezla®	789	221	1,010	841	199	1,040
Neulasta®	855	113	968	1,054	148	1,202
XGEVA®	689	267	956	673	243	916
Aranesp®	260	462	722	331	478	809
Repatha®	282	290	572	239	190	429
KYPROLIS®	349	182	531	354	179	533
Other products	2,007	1,300	3,307	2,022	1,139	3,161
Total product sales[1]	$ 8,277	$ 3,429	11,706	$ 8,707	$ 3,095	11,802
Other revenues			721			565
Total revenues			$ 12,427			$ 12,367

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

4. Income taxes

The effective tax rates for the three and six months ended June 30, 2021, were 16.8% and 12.6%, respectively, compared with 11.2% and 10.4%, respectively, for the corresponding periods of the prior year.

The increase in our effective tax rate for the three and six months ended June 30, 2021, was primarily due to the non-deductible IPR&D expense arising from the acquisition of Five Prime. The effective tax rates differ from the federal statutory rate primarily as a result of foreign earnings from the Company's operations conducted in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, that are subject to a tax incentive grant through 2035. In addition, the Company's operations conducted in Singapore are subject to a tax incentive grant through 2034. These earnings are also subject to U.S. tax at a reduced rate of 10.5%.

The U.S. territory of Puerto Rico imposes an excise tax on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico. The rate of 4% is effective through December 31, 2027. We account for the excise tax as a manufacturing cost that is capitalized in inventory and expensed in cost of sales when the related products are sold. For U.S. income tax purposes, the excise tax results in foreign tax credits that are generally recognized in our provision for income taxes when the excise tax is incurred.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes may arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. In 2017, we received a Revenue Agent Report (RAR) and a modified RAR from the Internal Revenue Service (IRS) for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations and pursued a resolution with the IRS administrative appeals office. As previously reported, we were unable to reach resolution with the IRS appeals office. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for 2010, 2011 and 2012 that we received in May and July 2021. The duplicate Notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately $3.6 billion, plus interest. Any additional tax that could be imposed would be reduced by up to approximately $900 million of repatriation tax previously accrued on our foreign earnings. In any event, we firmly believe that the IRS's positions in the Notices are without merit and we will vigorously contest the Notices through the judicial process.

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico, similar to those proposed for the years 2010, 2011 and 2012. We disagree with the proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. We are currently under examination by the IRS for the years 2016, 2017 and 2018. We are also currently under examination by a number of other state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our condensed consolidated financial statements. We are no longer subject to U.S. federal income tax examinations for the years ended on or before December 31, 2009.

During the three and six months ended June 30, 2021, the gross amounts of our unrecognized tax benefits (UTBs) increased $50 million and $110 million, respectively, as a result of tax positions taken during the current year. Substantially all of the UTBs as of June 30, 2021, if recognized, would affect our effective tax rate.

5. Earnings per share

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

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Income (Numerator):				
Net income for basic and diluted EPS	$ 464	$ 1,803	$ 2,110	$ 3,628
Shares (Denominator):				
Weighted-average shares for basic EPS	573	588	575	589
Effect of dilutive securities	3	4	3	4
Weighted-average shares for diluted EPS	576	592	578	593
Basic EPS	$ 0.81	$ 3.07	$ 3.67	$ 6.16
Diluted EPS	$ 0.81	$ 3.05	$ 3.65	$ 6.12

For the three and six months ended June 30, 2021 and 2020, 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, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury notes	$ 51	$ 1	$ —	$ 52
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,707	—	—	5,707
Other short-term interest-bearing securities	—	—	—	—
Total interest-bearing securities	$ 7,158	$ 1	$ —	$ 7,159

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

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

Condensed Consolidated Balance Sheets locations	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 5,707	$ 5,464
Marketable securities	1,452	4,381
Total interest-bearing securities	$ 7,159	$ 9,845

Cash and cash equivalents in the above table excludes bank account cash of $923 million and $802 million as of June 30, 2021 and December 31, 2020, respectively.

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

Contractual maturities	June 30, 2021	December 31, 2020
Maturing in one year or less	$ 7,159	$ 9,795
Maturing after one year through three years	—	50
Total available-for-sale investments	$ 7,159	$ 9,845

For the three and six months ended June 30, 2021 and 2020, realized gains and losses on interest-bearing securities were not material. Realized gains and losses on interest-bearing securities are recorded in Other income, net, in the Condensed Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

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

Equity securities

We held investments in equity securities with readily determinable fair values (publicly traded securities) of $403 million and $477 million as of June 30, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. For the three months ended June 30, 2021 and 2020, net unrealized gains on publicly traded securities were $25 million and $80 million, respectively. For the six months ended June 30, 2021 and 2020, net unrealized gains and losses on publicly traded securities were a $31 million net loss and a $5 million net gain, respectively. Realized gains and losses on publicly traded securities for the three and six months ended June 30, 2021 and 2020, were not material.

We held investments of $245 million and $203 million in equity securities without readily determinable fair values as of June 30, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. Gains and losses recognized on these securities, including adjustments to the carrying values of these securities, were not material for the three and six months ended June 30, 2021.

Equity method investments

Limited partnerships

We held limited partnership investments of $616 million and $496 million as of June 30, 2021 and December 31, 2020, respectively, which are included in Other assets in the Condensed Consolidated Balance Sheets. These investments, primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of June 30, 2021, unfunded additional commitments to be made for these investments during the next several years were not material. For the three months ended June 30, 2021 and 2020, net unrealized losses from our limited partnership investments were $43 million and $10 million, respectively. For the six months ended June 30, 2021 and 2020, net unrealized gains from our limited partnership investments were $165 million and $10 million, respectively.

BeiGene, Ltd.

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

During the three and six months ended June 30, 2021, the carrying value of our equity investment was adjusted by our share of BeiGene's net income of $14 million and net loss of $83 million, respectively, and amortization of the basis difference of $42 million and $84 million, respectively. In addition, during the three and six months ended June 30, 2021, the carrying value increased by $21 million and $38 million, respectively, from the impact of BeiGene ownership transactions. As of June 30, 2021, the carrying value and fair value of our investment in BeiGene totaled $2.8 billion and $6.4 billion, respectively. As of June 30, 2021, we believe the carrying value of our equity investment in BeiGene is fully recoverable.

7. Inventories

Inventories consisted of the following (in millions):

	June 30, 2021	December 31, 2020
Raw materials	$ 641	$ 486
Work in process	2,443	2,437
Finished goods	1,031	970
Total inventories	$ 4,115	$ 3,893

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, 2021
Beginning balance	$ 14,689
Currency translation adjustment	(13)
Ending balance	$ 14,676

Other intangible assets

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

	June 30, 2021			December 31, 2020		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 25,584	$ (11,673)	$ 13,911	$ 25,591	$ (10,564)	$ 15,027
Licensing rights	3,766	(2,886)	880	3,743	(2,791)	952
Marketing-related rights	1,363	(1,079)	284	1,367	(1,041)	326
Research and development technology rights	1,308	(1,105)	203	1,317	(1,065)	252
Total finite-lived intangible assets	32,021	(16,743)	15,278	32,018	(15,461)	16,557
Indefinite-lived intangible assets:						
In-process research and development	30	—	30	30	—	30
Total other intangible assets	$ 32,051	$ (16,743)	$ 15,308	$ 32,048	$ (15,461)	$ 16,587

Developed-product-technology rights consists of rights related to marketed products. Licensing rights primarily consists of contractual rights to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and upfront payments associated with royalty obligations for marketed products. Marketing-related rights primarily consists of rights related to the sale and distribution of marketed products. Research and development (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, 2021 and 2020, we recognized amortization associated with our finite-lived intangible assets of $652 million and $713 million, respectively. During the six months ended June 30, 2021 and 2020, we recognized amortization associated with our finite-lived intangible assets of $1.3 billion and $1.4 billion, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Condensed Consolidated Statements of Income. The total estimated amortization for our finite-lived intangible assets for the remaining six months ending December 31, 2021, and the years ending December 31, 2022, 2023, 2024, 2025 and 2026, are $1.2 billion, $2.5 billion, $2.4 billion, $2.4 billion, $2.2 billion and $1.8 billion, respectively.

9. Financing arrangements

Our borrowings consisted of the following (in millions):

	June 30, 2021	December 31, 2020
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	$ 1,482	$ 1,527
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	1,500	1,500
3.625% notes due 2022 (3.625% 2022 Notes)	750	750
0.41% CHF700 million bonds due 2023 (0.41% 2023 Swiss franc Bonds)	757	791
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
1.90% notes due 2025 (1.90% 2025 Notes)	500	500
3.125% notes due 2025 (3.125% 2025 Notes)	1,000	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	889	916
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	657	649
2.20% notes due 2027 (2.20% 2027 Notes)	1,750	1,750
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	968	957
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
6.375% notes due 2037 (6.375% 2037 Notes)	478	478
6.90% notes due 2038 (6.90% 2038 Notes)	254	254
6.40% notes due 2039 (6.40% 2039 Notes)	333	333
3.15% notes due 2040 (3.15% 2040 Notes)	2,000	2,000
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	2,250	2,250
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(1,174)	(1,188)
Fair value adjustments	424	566
Other	16	5
Total carrying value of debt	32,782	32,986
Less current portion	(4,324)	(91)
Total long-term debt	$ 28,458	$ 32,895

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

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

10. Stockholders' equity

Stock repurchase program

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

	2021		2020	
	Shares	Dollars	Shares	Dollars
First quarter	3.7	$ 865	4.3	$ 933
Second quarter	6.5	1,592	2.6	591
Total stock repurchases	10.2	$ 2,457	6.9	$ 1,524

In March 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion. As of June 30, 2021, $3.9 billion of authorization remained available under our stock repurchase program.

Dividends

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

Accumulated other comprehensive income (loss)

The components of Accumulated other comprehensive income (loss) (AOCI) were as follows (in millions):

	Foreign currency translation	Cash flow hedges	Available-for-sale securities	Other	AOCI
Balance as of December 31, 2020	$ (709)	$ (263)	$ 1	$ (14)	$ (985)
Foreign currency translation adjustments	(39)	—	—	—	(39)
Unrealized gains	—	108	—	—	108
Reclassification adjustments to income	—	133	—	—	133
Other	—	—	—	1	1
Income taxes	—	(51)	—	—	(51)
Balance as of March 31, 2021	(748)	(73)	1	(13)	(833)
Foreign currency translation adjustments	14	—	—	—	14
Unrealized losses	—	(31)	—	—	(31)
Reclassification adjustments to income	—	(28)	—	—	(28)
Other	—	—	—	(1)	(1)
Income taxes	—	11	—	—	11
Balance as of June 30, 2021	$ (734)	$ (121)	$ 1	$ (14)	$ (868)

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

Components of AOCI	Three months ended June 30, 2021	2020	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract (losses) gains	$ (18)	$ 68	Product sales
Cross-currency swap contract gains	46	51	Other income, net
	28	119	Income before income taxes
	(6)	(26)	Provision for income taxes
	$ 22	$ 93	Net income
Available-for-sale securities:			
Net realized gains	$ —	$ —	Other income, net
	—	—	Provision for income taxes
	$ —	$ —	Net income

Components of AOCI	Six months ended June 30, 2021	2020	Condensed Consolidated Statements of Income locations
Cash flow hedges:			
Foreign currency contract (losses) gains	$ (19)	$ 117	Product sales
Cross-currency swap contract losses	(86)	(82)	Other income, net
	(105)	35	Income before income taxes
	22	(8)	Provision for income taxes
	$ (83)	$ 27	Net income
Available-for-sale securities:			
Net realized gains	$ —	$ 33	Other income, net
	—	(7)	Provision for income taxes
	$ —	$ 26	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 the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the abilit 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, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

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

Fair value measurement as of June 30, 2021, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 52	$ —	$ —	$ 52
U.S. Treasury bills	1,400	—	—	1,400
Money market mutual funds	5,707	—	—	5,707
Other short-term interest-bearing securities	—	—	—	—
Equity securities	403	—	—	403
Derivatives:				
Foreign currency contracts	—	62	—	62
Cross-currency swap contracts	—	182	—	182
Interest rate swap contracts	—	45	—	45
Total assets	$ 7,562	$ 289	$ —	$ 7,851
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 119	$ —	$ 119
Cross-currency swap contracts	—	305	—	305
Interest rate swap contracts	—	90	—	90
Contingent consideration obligations	—	—	48	48
Total liabilities	$ —	$ 514	$ 48	$ 562

Fair value measurement as of December 31, 2020, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury notes	$ 130	$ —	$ —	$ 130
U.S. Treasury bills	4,948	—	—	4,948
Money market mutual funds	4,765	—	—	4,765
Other short-term interest-bearing securities	—	2	—	2
Equity securities	477	—	—	477
Derivatives:				
Foreign currency contracts	—	28	—	28
Cross-currency swap contracts	—	255	—	255
Interest rate swap contracts	—	66	—	66
Total assets	$ 10,320	$ 351	$ —	$ 10,671
Liabilities:				
Derivatives:				
Foreign currency contracts	$ —	$ 237	$ —	$ 237
Cross-currency swap contracts	—	318	—	318
Interest rate swap contracts	—	15	—	15
Contingent consideration obligations	—	—	33	33
Total liabilities	$ —	$ 570	$ 33	$ 603

Interest-bearing and equity securities

The fair values of our U.S. Treasury securities, money market mutual funds and equity securities are based on quoted market prices in active markets, with no valuation adjustment.

Derivatives

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

During the three and six months ended June 30, 2021 and 2020, there were no material remeasurements to the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair values of other financial instruments

Cash equivalents

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

Borrowings

We estimated the fair values of our borrowings by using Level 2 inputs. As of June 30, 2021 and December 31, 2020, the aggregate fair values of our borrowings were $37.9 billion and $39.4 billion, respectively, and the carrying values were $32.8 billion and $33.0 billion, respectively.

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, 2021 and December 31, 2020, we had outstanding foreign currency forward contracts with aggregate notional amounts of $5.2 billion and $5.1 billion, respectively. We have designated these foreign currency forward contracts, which are primarily euro based, as cash flow hedges. Accordingly, we report the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to Product sales in the Condensed Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

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

The notional amounts and interest rates of our cross-currency swaps as of June 30, 2021, were as follows (notional amounts in millions):

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

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Condensed Consolidated Balance Sheets and are amortized into Interest expense, net, in the Condensed Consolidated Statements of Income over the lives of the associated debt issuances. Amounts recognized in connection with forward interest rate swaps during the six months ended June 30, 2021, and amounts expected to be recognized during the subsequent 12 months are not material.

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

	Three months ended June 30,		Six months ended June 30,	
Derivatives in cash flow hedging relationships	**2021**	**2020**	**2021**	**2020**
Foreign currency contracts	$ (46)	$ (101)	$ 137	$ 138
Cross-currency swap contracts	15	71	(60)	(330)
Total unrealized (losses) gains	$ (31)	$ (30)	$ 77	$ (192)

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 June 30, 2021 and December 31, 2020, we had interest rate swap contracts with aggregate notional amounts of $7.4 billion and $5.9 billion, respectively, that hedge certain portions of our long-term debt issuances. During the three months ended June 30, 2021, we entered into $1.5 billion of interest rate swap contracts to hedge portions of our 2.45% 2030 Notes and 2.30% 2031 Notes (see Note 9, Financing arrangements).

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

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

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
Condensed Consolidated Balance Sheets locations	**June 30, 2021**	**December 31, 2020**	**June 30, 2021**	**December 31, 2020**
Current portion of long-term debt	$ 844	$ 89	$ 94	$ 89
Long-term debt	$ 6,857	$ 6,258	$ 330	$ 477

(1) Current portion of long-term debt includes $89 million of carrying value with discontinued hedging relationships as of both June 30, 2021 and December 31, 2020. Long-term debt includes $481 million and $525 million of carrying value with discontinued hedging relationships as of June 30, 2021 and December 31, 2020, respectively.

(2) Current portion of long-term debt includes $89 million of hedging adjustments on discontinued hedging relationships as of both June 30, 2021 and December 31, 2020. Long-term debt includes $381 million and $425 million of hedging adjustments on discontinued hedging relationships as of June 30, 2021 and December 31, 2020, respectively.

Impact of hedging transactions

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

	Three months ended June 30, 2021			Six months ended June 30, 2021		
	Product sales	Other income, net	Interest expense, net	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 6,114	$ 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)

	Three months ended June 30, 2020			Six months ended June 30, 2020		
	Product sales	Other income, net	Interest expense, net	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Condensed Consolidated Statements of Income	$ 5,908	$ 3	$ (296)	$ 11,802	$ 14	$ (642)
The effects of cash flow and fair value hedging:						
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:						
Foreign currency contracts	$ 68	$ —	$ —	$ 117	$ —	$ —
Cross-currency swap contracts	$ —	$ 51	$ —	$ —	$ (82)	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:						
Hedged items[1]	$ —	$ —	$ (30)	$ —	$ —	$ 180
Derivatives designated as hedging instruments	$ —	$ —	$ 53	$ —	$ —	$ (137)

[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, 2021, the net gains expected to be reclassified on our foreign currency and cross-currency swap contracts out of AOCI and into earnings during the next 12 months are not material.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of June 30, 2021 and December 31, 2020, the total notional amounts of these foreign currency forward contracts were $0.8 billion and $1.0 billion, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the three and six months ended June 30, 2021 and 2020.

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

	Derivative assets		Derivative liabilities	
June 30, 2021	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 62	Accrued liabilities/ Other noncurrent liabilities	$ 119
Cross-currency swap contracts	Other current assets/ Other assets	182	Accrued liabilities/ Other noncurrent liabilities	305
Interest rate swap contracts	Other current assets/ Other assets	45	Accrued liabilities/ Other noncurrent liabilities	90
Total derivatives designated as hedging instruments		$ 289		$ 514

	Derivative assets		Derivative liabilities	
December 31, 2020	**Condensed Consolidated Balance Sheets locations**	**Fair values**	**Condensed Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other assets	$ 28	Accrued liabilities/ Other noncurrent liabilities	$ 237
Cross-currency swap contracts	Other current assets/ Other assets	255	Accrued liabilities/ Other noncurrent liabilities	318
Interest rate swap contracts	Other current assets/ Other assets	66	Accrued liabilities/ Other noncurrent liabilities	15
Total derivatives designated as hedging instruments		$ 349		$ 570

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

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

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, 2020, Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020; and in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021.

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

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020; or in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, in which we could incur a liability, our opponents seek an award of a not-yet-quantified amount of damages or an amount that is not material. In addition, a number of the matters pending against us are at very early stages of the legal process, which in complex proceedings of the sort we face often extend for several years. As a result, none of the matters described in this filing; in Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020; or in Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, in which we could incur a liability, have progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate a range of possible loss, if any, or such amounts are not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below:

Abbreviated New Drug Application (ANDA) Patent Litigation

Otezla® ANDA Patent Litigation

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

On May 5, 2021, based on a joint request by Amgen and Cipla Limited (Cipla Ltd), the U.S. District Court for the District of New Jersey (the New Jersey District Court) entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Cipla Ltd's apremilast product during the term of U.S. Patent Nos. 6,962,940 (the '940 Patent); 7,427,638 (the '638 Patent), 7,659,302 (the '302 Patent), 8,455,536 (the '536 Patent), 9,724,330 (the '330 Patent) and 10,092,541 (the '541 Patent), unless authorized pursuant to a confidential settlement agreement. On May 14, 2021, based on a joint request by Amgen and Torrent Pharmaceuticals Ltd. (Torrent), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Torrent's apremilast product during the term of the U.S. Patent Nos. 7,893,101 (the '101 Patent), 9,872,854 (the '854 Patent) and the '638 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 19, 2021, based on a joint request by Amgen and Alkem Laboratories Ltd. (Alkem), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Alkem's apremilast product during the term of the '940, '638, '302, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On May 25, 2021, based on a joint request by Amgen and MSN Laboratories Private Limited (MSN), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of MSN's apremilast product during the term of the '940, '638, '302, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On June 11, 2021, based on a joint request by Amgen and Pharmascience Inc. (Pharmascience), the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of Pharmascience's apremilast product during the term of U.S. Patent No. 9,018,243 (the '243 Patent) and the '940, '638, '302, '101, '536, '330 and '541 Patents, unless authorized pursuant to a confidential settlement agreement. On June 17, 2021, based on a joint request by Amgen and Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) , the New Jersey District Court entered a consent judgment and injunction prohibiting the making, using, selling, offering to sell, or importing of DRL's

apremilast product during the term of the ’638, ’101, ’536 and ’541 Patents, unless authorized pursuant to a confidential settlement agreement.

Trial on the consolidated patent infringement action was held at the New Jersey District Court from June 14 to 25, 2021 with closing arguments on July 28, 2021. The remaining defendants are Sandoz Inc. and Zydus Pharmaceuticals (USA) Inc.

ENBREL Patent Litigation

Immunex Corporation, et al. v. Sandoz Inc., et al.

On May 17, 2021, the U.S. Supreme Court denied the petition of Sandoz Inc., Sandoz International GmbH and Sandoz GmbH for certiorari seeking review of the Federal Circuit Court’s affirmance of the validity of U.S. Patent Nos. 8,063,182 and 8,163,522.

Repatha® Patent Litigation

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

On June 21, 2021, the Federal Circuit Court denied our petition for rehearing en banc of the Federal Circuit Court’s ruling that claims 19 and 29 of our U.S. Patent No. 8,829,165 and claim 7 of our U.S. Patent No. 8,859,741 are invalid for failing to meet the enablement requirement.

NEUPOGEN® (filgrastim)/Neulasta® Patent Litigation

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

On June 11, 2021, after having held a claim construction hearing, the U.S. District Court for the District of Delaware (Delaware District Court) determined that the term at issue required no construction, and on July 14, the Delaware District Court set a briefing schedule for summary judgment motions.

Patent Trial and Appeal Board (PTAB) Challenge

Lupin PTAB Challenge

On July 12, 2021, the PTAB of the U.S. Patent and Trademark Office issued a decision denying institution of Lupin Limited’s petition for inter partes review of U.S. Patent No. 9,856,287.

Apotex PTAB Challenge

On June 21, 2021, the U.S. Supreme Court decided *United States v. Arthrex, Inc.* On June 28, 2021, the Supreme Court granted the government’s pending certiorari petition and vacated and remanded the Federal Circuit Court’s judgment for further consideration under *Arthrex.*

Breach of Contract Action

Novartis Pharma AG v. Amgen Inc.

On June 2, 2021, the parties executed agreements to settle two claims in the litigation, relating to the 2018 budget overrun dispute and certain counterclaims alleging breaches by Novartis Pharma AG (Novartis) of the 2015 and 2017 collaboration agreements related to the development and commercialization of Aimovig® (erenumab-aooe), and to amend and restate the 2017 collaboration agreement. As part of the agreement, Amgen paid $48 million to Novartis to resolve the 2018 budget dispute, and Novartis is in the process of transitioning U.S. commercial operations to Amgen.

Antitrust Class Action

Sensipar® (cinacalcet) Antitrust Class Actions

On April 27, 2021, plaintiffs filed their oppositions to defendants’ (including Amgen’s) motion to dismiss, and defendants’ reply was filed on May 25, 2021. A hearing on defendants’ motion to dismiss was held in the Delaware District Court on July 13, 2021.

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.

14. Subsequent events

On June 1, 2021, Amgen and Kyowa Kirin Co., Ltd. (KKC) announced a collaboration and licensing agreement to jointly develop and commercialize KHK4083, an anti-OX40 fully human monoclonal antibody, worldwide, except in Japan. The transaction closed on July 30, 2021, upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. Amgen will make an upfront payment of $400 million to KKC, to be recognized as R&D expense in the third quarter of 2021.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to and should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2020, and our Quarterly Report on Form 10-Q for the period ended March 31, 2021. Our results of operations discussed in MD&A are presented in conformity with GAAP. Amgen operates in one business segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the Securities and Exchange Commission (SEC) contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Item 1A. Risk Factors in Part II herein and in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31, 2021. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources, trends, planned dividends, stock repurchases, collaborations and effects of pandemics. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

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

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

COVID-19 pandemic

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

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

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

At this time, the clinical trials that paused at the onset of the pandemic to ensure subject safety or data integrity have resumed. Study enrollment was most affected negatively in the second quarter of 2020 but by the end of the year resumed to around pre-pandemic levels. We are continuously monitoring COVID-19 infection rates and working to mitigate effects on future study enrollment. We remain focused on supporting our active clinical sites in their providing care for patients and in our providing investigational drug supply. In addition, our organization is supporting efforts to combat the COVID-19 pandemic, including by manufacturing therapeutic antibodies in a supply arrangement with Eli Lilly and Company (Lilly) and joining a public–private partnership between leading companies in our industry and U.S. government health agencies to develop a strategy for a coordinated research response.

Despite the ongoing pandemic and business impacts noted above, we believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures and debt service requirements as well as to engage in the capital-return and other business initiatives that we plan to pursue. For a discussion of risks the COVID-19 pandemic presents to our results, see Risk Factors in Item 1A. Risk Factors in Part II herein and in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31, 2021.

Significant developments

Following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report on Form 10-Q for the period ended March 31, 2021. For additional developments or for a more comprehensive discussion of certain developments discussed below, see our Annual Report on Form 10-K for the year ended December 31, 2020, and our Quarterly Report on Form 10-Q for the period ended March 31, 2021.

Business Development

Kyowa Kirin Co., Ltd. collaboration

- In June 2021, we and KKC, announced an agreement to jointly develop and commercialize KKC's potential first-in-class, phase 3-ready anti-OX40 fully human monoclonal antibody in development for the treatment of atopic dermatitis, with potential in other autoimmune diseases. The transaction closed on July 30, 2021, upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Teneobio, Inc. acquisition

- In July 2021, we and Teneobio, Inc. (Teneobio), announced an agreement under which Amgen will acquire Teneobio, a privately held, clinical stage biotechnology company developing a new class of biologics called Human Heavy-Chain Antibodies. Under the terms of the agreement, Amgen will acquire all outstanding shares of Teneobio at closing in exchange for a $900 million upfront cash payment, as well as future contingent milestone payments to Teneobio equity holders potentially worth up to an additional $1.6 billion in cash. The acquisition is subject to customary closing conditions, including applicable regulatory approvals. The transaction is expected to close in the second half of 2021.

Products/Pipeline

Inflammation

Otezla®

- In May 2021, we announced that the U.S. Food and Drug Administration (FDA) accepted for review the supplemental New Drug Application for Otezla® for the treatment of adults with mild-to-moderate plaque psoriasis who are candidates for phototherapy or systemic therapy. The FDA has set a Prescription Drug User Fee Act (PDUFA) date of December 19, 2021.

Tezepelumab

- In May 2021, Amgen announced that its partner AstraZeneca had submitted a Biologics License Application to the FDA for tezepelumab, a potential first-in-class medicine in severe asthma. The submission is supported by positive clinical trial results including a phase 3 trial, which demonstrated a statistically significant and clinically meaningful reduction in the annualized asthma exacerbation rate (AAER) in patients with severe, uncontrolled asthma compared to placebo.

- In July 2021, we announced that the FDA had granted Priority Review for tezepelumab in the treatment of asthma. The PDUFA date for a decision by the FDA is during the first quarter of 2022.

Oncology/Hematology

LUMAKRAS™ (sotorasib)

- In May 2021, we announced that the FDA had approved LUMAKRAS™ for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. LUMAKRAS™ received accelerated approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial or trials.

Operations

New manufacturing facilities

We announced plans to expand our United States-based manufacturing footprint:

- In June 2021, we announced plans to build an advanced assembly and packaging plant in Ohio. The new facility will assemble and package vials and syringes to support the growing demand for our medicines.

- In August 2021, we announced plans to build a drug substance plant in North Carolina that will increase our manufacturing network capacity to reliably supply more medicines for patients.

We expect that both of these facilities will be built faster and at a lower cost than traditional plants. Once completed, both will also utilize cutting-edge technologies to be more efficient and environmentally friendly than traditional plants.

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,		
	2021	2020	Change	2021	2020	Change
Product sales						
U.S.	$ 4,374	$ 4,428	(1)%	$ 8,277	$ 8,707	(5)%
ROW	1,740	1,480	18 %	3,429	3,095	11 %
Total product sales	6,114	5,908	3 %	11,706	11,802	(1)%
Other revenues	412	298	38 %	721	565	28 %
Total revenues	$ 6,526	$ 6,206	5 %	$ 12,427	$ 12,367	— %
Operating expenses	$ 5,698	$ 3,883	47 %	$ 9,470	$ 7,689	23 %
Operating income	$ 828	$ 2,323	(64)%	$ 2,957	$ 4,678	(37)%
Net income	$ 464	$ 1,803	(74)%	$ 2,110	$ 3,628	(42)%
Diluted EPS	$ 0.81	$ 3.05	(73)%	$ 3.65	$ 6.12	(40)%
Diluted shares	576	592	(3)%	578	593	(3)%

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

Total product sales increased for the three months ended June 30, 2021, primarily driven by higher unit demand for certain brands, including Prolia®, Repatha®, XGEVA® and MVASI®, partially offset by declines in the net selling prices of certain products. Total product sales decreased for the six months ended June 30, 2021, primarily driven by declines in the net selling price of certain products, partially offset by higher unit demand for certain brands, including Prolia®, Repatha® and MVASI®. There has been gradual recovery through the second quarter of 2021 in patients resuming their treatments and in new patient starts, although overall both remain below pre-COVID-19 levels.

During the initial stages of the COVID-19 pandemic in early 2020, we experienced changes in demand for some of our products. The pandemic interrupted many physician–patient interactions, which led to delays in diagnoses and treatments, with varying degrees of impact across our portfolio. In general, sales of negatively affected products fell the most in the early part of the second quarter of 2020, with product demand beginning to show some recovery in the second half of 2020. In the first half of the current year, demand has been recovering compared with pre-pandemic levels as patients return to doctors' offices. The cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business during the second half of the year. Given the unpredictable nature of the pandemic, we expect there could be ongoing intermittent disruptions in physician–patient interactions, and as a result, we continue to expect quarter-to-quarter variability. See Risk Factors in Part II, Item 1A. of this Form 10-Q and Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. Risk Factors of our Quarterly Report on Form 10-Q for the period ended March 31, 2021.

In addition, other changes in the healthcare ecosystem have the potential to introduce variability into product sales trends. For example, we expect changes in U.S. employment to lead to changes to the insured population. Growth in numbers of Medicaid enrollees and uninsured individuals may have a negative impact on product demand and sales. Overall, uncertainty remains around the timing and magnitude of our sales during the COVID-19 pandemic.

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

Operating expenses increased for the three and six months ended June 30, 2021, primarily driven by IPR&D expense related to the bemarituzumab program acquired as part of the Five Prime acquisition.

Although changes in foreign currency exchange rates result in increases or decreases in our reported international product sales, the benefit or detriment that such movements have on our international product sales is partially offset by corresponding increases or decreases in our international operating expenses and our related foreign currency hedging activities. Our hedging activities seek to offset the impacts, both positive and negative, that foreign currency exchange rate changes may have on our net income by hedging our net foreign currency exposure, primarily with respect to product sales denominated in euros. The net impact from changes in foreign currency exchange rates was not material for the three and six months ended June 30, 2021 and 2020.

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,		
	2021	2020	Change	2021	2020	Change
ENBREL	$ 1,144	$ 1,246	(8)%	$ 2,068	$ 2,399	(14)%
Prolia®	814	659	24 %	1,572	1,313	20 %
Otezla®	534	561	(5)%	1,010	1,040	(3)%
Neulasta®	486	593	(18)%	968	1,202	(19)%
XGEVA®	488	435	12 %	956	916	4 %
Aranesp®	367	387	(5)%	722	809	(11)%
Repatha®	286	200	43 %	572	429	33 %
KYPROLIS®	280	253	11 %	531	533	— %
Other products	1,715	1,574	9 %	3,307	3,161	5 %
Total product sales	$ 6,114	$ 5,908	3 %	$ 11,706	$ 11,802	(1)%

Future sales of our products will depend in part on the factors discussed below and in the following sections of this report: (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview and Selected Financial Information; and (ii) Part II, Item 1A. Risk Factors; and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2020: (i) Item 1. Business—Marketing, Distribution and Selected Marketed Products, (ii) Item 1A. Risk Factors and (iii) Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview, and Results of Operations—Product Sales, as well as in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, in (i) Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Product Sales; and (ii) Part II, Item 1A. Risk Factors.

ENBREL

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
ENBREL — U.S.	$ 1,113	$ 1,213	(8)%	$ 2,007	$ 2,330	(14)%
ENBREL — Canada	31	33	(6)%	61	69	(12)%
Total ENBREL	$ 1,144	$ 1,246	(8)%	$ 2,068	$ 2,399	(14)%

The decrease in ENBREL sales for the three and six months ended June 30, 2021, was primarily driven by lower net selling price and unfavorable changes to estimated sales deductions. For the remainder of 2021, we expect the trend of net selling price declines to continue compared with the prior year.

We are involved in patent litigation with a company seeking to market its FDA-approved biosimilar version of ENBREL. See Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020, and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report. Companies with approved biosimilar versions of ENBREL may seek to enter the U.S. market if we are not ultimately successful in our litigations, or even earlier. Other companies are also developing proposed biosimilar versions of ENBREL.

Prolia®

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Prolia® — U.S.	$ 538	$ 441	22 %	$ 1,039	$ 863	20 %
Prolia® — ROW	276	218	27 %	533	450	18 %
Total Prolia®	$ 814	$ 659	24 %	$ 1,572	$ 1,313	20 %

The increase in global Prolia® sales for the three and six months ended June 30, 2021, was primarily driven by higher unit demand. Although disruptions from the effects of the COVID-19 pandemic on new and repeat patient visits have decreased, we anticipate that such disruptions will continue to affect demand in 2021—but to a lesser degree than that experienced in 2020.

Otezla®

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Otezla® — U.S.	$ 423	$ 464	(9)%	$ 789	$ 841	(6)%
Otezla® — ROW	111	97	14 %	221	199	11 %
Total Otezla®	$ 534	$ 561	(5)%	$ 1,010	$ 1,040	(3)%

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

For a discussion of ongoing litigation related to Otezla®, see Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020, and Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, and Note 13, Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report.

Neulasta®

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Neulasta® — U.S.	$ 434	$ 520	(17)%	$ 855	$ 1,054	(19)%
Neulasta® — ROW	52	73	(29)%	113	148	(24)%
Total Neulasta®	$ 486	$ 593	(18)%	$ 968	$ 1,202	(19)%

The decrease in global Neulasta® sales for the three and six months ended June 30, 2021, was driven by the impact of biosimilar competition on net selling price and unit demand, partially offset by favorable changes to estimated sales deductions.

Increased competition in the United States and Europe as a result of biosimilar versions of Neulasta® has had and will continue to have a significant adverse impact on brand sales, including additional net price erosion. We also expect other biosimilar versions to be approved in the future. For a discussion of ongoing patent litigations related to these and other biosimilars, see Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020, Note 12, Contingencies and commitments, to the condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the period ended March 31, 2021, and 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,		
	2021	2020	Change	2021	2020	Change
XGEVA® — U.S.	$ 355	$ 318	12 %	$ 689	$ 673	2 %
XGEVA® — ROW	133	117	14 %	267	243	10 %
Total XGEVA®	$ 488	$ 435	12 %	$ 956	$ 916	4 %

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

Aranesp®

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Aranesp® — U.S.	$ 135	$ 156	(13)%	$ 260	$ 331	(21)%
Aranesp® — ROW	232	231	— %	462	478	(3)%
Total Aranesp®	$ 367	$ 387	(5)%	$ 722	$ 809	(11)%

The decrease in global Aranesp® sales for the three months ended June 30, 2021, was driven by lower net selling price due to competition. The decrease in global Aranesp® sales for the six months ended June 30, 2021, was primarily driven by lower net selling price and unit demand due to competition.

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

Repatha®

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Repatha® — U.S.	$ 143	$ 115	24 %	$ 282	$ 239	18 %
Repatha® — ROW	143	85	68 %	290	190	53 %
Total Repatha®	$ 286	$ 200	43 %	$ 572	$ 429	33 %

The increase in global Repatha® sales for the three and six months ended June 30, 2021, was driven by higher unit demand, partially offset by lower net selling price. We expect further reduction in the net selling price on a sequential basis as the number of Medicare Part D patients receiving Repatha® increases.

For a discussion of ongoing litigation related to Repatha®, see Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020; Note 12, Contingencies and commitments, to the condensed consolidated financial statements for the period ended March 31, 2021; and 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,		
	2021	2020	Change	2021	2020	Change
KYPROLIS® — U.S.	$ 190	$ 167	14 %	$ 349	$ 354	(1)%
KYPROLIS® — ROW	90	86	5 %	182	179	2 %
Total KYPROLIS®	$ 280	$ 253	11 %	$ 531	$ 533	— %

The increase in global KYPROLIS® sales for the three months ended June 30, 2021, was primarily driven by higher unit demand and an increase in net selling price. Global KYPROLIS® sales for the six months ended June 30, 2021 remained relatively flat compared with the prior period.

We are engaged in litigation with two companies that are challenging certain of our patents related to KYPROLIS® and that are seeking to market generic carfilzomib products. Separately, we have entered into confidential settlement agreements with other companies developing generic carfilzomib products, and the court has entered consent judgments enjoining those companies from infringing certain of our patents, subject to terms of the confidential settlement agreements. See Note 19, Contingencies and commitments, to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020; Note 12, Contingencies and commitments, to the condensed consolidated financial statements for the period ended March 31, 2021, and Note 13; Contingencies and commitments, to the condensed consolidated financial statements in this Quarterly Report. The FDA has reported that it has granted tentative or final approval of ANDAs for generic carfilzomib products filed by a number of companies. The date of approval of those ANDAs for generic carfilzomib products is governed by the Hatch-Waxman Act and any applicable settlement agreements between the parties.

Other products

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
MVASI® — U.S.	$ 206	$ 149	38 %	$ 430	$ 257	67 %
MVASI® — ROW	88	23	*	158	30	*
Nplate® — U.S.	136	107	27 %	248	234	6 %
Nplate® — ROW	109	86	27 %	224	177	27 %
Vectibix® — U.S.	92	79	16 %	171	159	8 %
Vectibix®— ROW	147	116	27 %	259	238	9 %
KANJINTI® — U.S.	132	101	31 %	262	197	33 %
KANJINTI® — ROW	24	22	9 %	55	45	22 %
EPOGEN® — U.S.	130	161	(19)%	255	316	(19)%
EVENITY® — U.S.	79	40	98 %	136	77	77 %
EVENITY®— ROW	52	61	(15)%	102	124	(18)%
BLINCYTO® — U.S.	62	56	11 %	127	113	12 %
BLINCYTO® — ROW	46	37	24 %	88	74	19 %
AMGEVITA™ — ROW	107	62	73 %	213	148	44 %
Parsabiv® — U.S.	37	160	(77)%	83	306	(73)%
Parsabiv® — ROW	34	26	31 %	67	55	22 %
Aimovig® — U.S.	82	98	(16)%	148	169	(12)%
NEUPOGEN® — U.S.	36	28	29 %	54	73	(26)%
NEUPOGEN® — ROW	15	21	(29)%	31	41	(24)%
Sensipar® — U.S.	4	32	(88)%	4	74	(95)%
Sensipar®/Mimpara™ — ROW	20	49	(59)%	43	130	(67)%
Other — U.S.	47	23	*	89	47	89 %
Other — ROW	30	37	(19)%	60	77	(22)%
Total other products	$ 1,715	$ 1,574	9 %	$ 3,307	$ 3,161	5 %
Total U.S. — other products	$ 1,043	$ 1,034	1 %	$ 2,007	$ 2,022	(1)%
Total ROW — other products	672	540	24 %	1,300	1,139	14 %
Total other products	$ 1,715	$ 1,574	9 %	$ 3,307	$ 3,161	5 %

* Change in excess of 100%.

Operating expenses

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

	Three months ended June 30,			Six months ended June 30,		
	2021	2020	Change	2021	2020	Change
Operating expenses:						
Cost of sales	$ 1,637	$ 1,488	10 %	$ 3,127	$ 3,001	4 %
% of product sales	26.8 %	25.2 %		26.7 %	25.4 %	
% of total revenues	25.1 %	24.0 %		25.2 %	24.3 %	
Research and development	$ 1,082	$ 964	12 %	$ 2,049	$ 1,916	7 %
% of product sales	17.7 %	16.3 %		17.5 %	16.2 %	
% of total revenues	16.6 %	15.5 %		16.5 %	15.5 %	
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	$ 1,384	$ 1,295	7 %	$ 2,638	$ 2,611	1 %
% of product sales	22.6 %	21.9 %		22.5 %	22.1 %	
% of total revenues	21.2 %	20.9 %		21.2 %	21.1 %	
Other	$ 90	$ 136	(34)%	$ 151	$ 161	(6)%

NM - Not meaningful

Cost of sales

Cost of sales increased to 25.1% and 25.2% of total revenues for the three and six months ended June 30, 2021, respectively, primarily driven by unfavorable product mix and by higher profit share and royalty expenses, partially offset by lower amortization expense from acquisition-related assets.

Research and development

The increases in R&D expense for the three and six months ended June 30, 2021, were primarily driven by higher research and early pipeline spend and late-stage program support, including recent business development activities.

Acquired in-process research and development

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

Selling, general and administrative

The increase in Selling, general and administrative (SG&A) expense for the three months ended June 30, 2021, was driven by higher marketed-product support.

The increase in SG&A expense for the six months ended June 30, 2021, was driven by higher marketed-product support, partially offset by favorable adjustments to estimated U.S. healthcare reform federal excise fees.

Other

Other operating expenses for the three and six months ended June 30, 2021, consisted primarily of expenses related to cost savings initiatives. Other operating expenses for the three and six months ended June 30, 2020, consisted of legal settlement expenses.

Nonoperating expense/income and income taxes

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Interest expense, net	$ (281)	$ (296)	$ (566)	$ (642)
Other income, net	$ 11	$ 3	$ 24	$ 14
Provision for income taxes	$ 94	$ 227	$ 305	$ 422
Effective tax rate	16.8 %	11.2 %	12.6 %	10.4 %

Interest expense, net

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

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

Other income, net

The increase in Other income, net, for the three months ended June 30, 2021, was primarily due to lower losses in connection with our BeiGene investment, partially offset by gains recognized on our investments in limited partnerships in the prior year period.

The increase in Other income, net, for the six months ended June 30, 2021, was primarily due to higher gains recognized on our investments in limited partnerships in the current year, partially offset by gains recognized in the prior year period on our interest-bearing securities.

Income taxes

The increase in our effective tax rate for the three and six months ended June 30, 2021, was primarily due to the non-deductible IPR&D expense arising from the acquisition of Five Prime.

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

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

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico, similar to those proposed for the years 2010, 2011 and 2012. We disagree with the proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. We are currently under examination by the IRS for the years 2016, 2017 and 2018. We are also currently under examination by a number of other state and foreign tax jurisdictions.

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

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

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 8,082	$ 10,647
Total assets	$ 59,773	$ 62,948
Current portion of long-term debt	$ 4,324	$ 91
Long-term debt	$ 28,458	$ 32,895
Stockholders' equity	$ 8,247	$ 9,409

Cash, cash equivalents and marketable securities

Our balance of cash, cash equivalents and marketable securities was $8.1 billion at June 30, 2021. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

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

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

We also returned capital to stockholders through our stock repurchase program. During the six months ended June 30, 2021, we executed trades to repurchase $2.5 billion of common stock. As of June 30, 2021, $3.9 billion of authorization remained available under our stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we have an accumulated deficit as of June 30, 2021 and December 31, 2020. Our accumulated deficit is not anticipated to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our continuing profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, to meet capital expenditure and debt service requirements, to fund our plans to pay dividends and repurchase stock and to fulfill other business initiatives we expect to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, equity markets and borrowings (including commercial paper and/or syndicated credit facilities and access to other domestic and foreign debt markets). See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement includes a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the credit agreement. We were in compliance with all applicable covenants under these arrangements as of June 30, 2021.

Cash flows

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

	Six months ended June 30,	
	2021	**2020**
Net cash provided by operating activities	$ 4,035	$ 4,976
Net cash provided by (used in) investing activities	$ 890	$ (2,389)
Net cash (used in) provided by financing activities	$ (4,561)	$ 521

Operating

Cash provided by operating activities is expected to be our primary recurring source of funds. Cash provided by operating activities during the six months ended June 30, 2021, decreased primarily due to a difference in the timing of payments to tax authorities and the monetization of interest rate swaps in the prior year, partially offset by the timing of collections from customers, in part, as a result of the impact of the Otezla® acquisition in the prior year.

Investing

Cash provided by investing activities during the six months ended June 30, 2021, was primarily due to net cash inflows related to marketable securities of $2.9 billion, partially offset by the acquisition of Five Prime for $1.6 billion and capital expenditures of $351 million. Cash used in investing activities during the six months ended June 30, 2020, was primarily due to our $2.6 billion equity investment in BeiGene and capital expenditures of $300 million, partially offset by net cash inflows related to marketable securities of $607 million. We currently estimate 2021 spending on capital projects to be approximately $900 million.

Financing

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. Cash provided by financing activities during the six months ended June 30, 2020, was primarily due to net proceeds from the issuance of debt of $9.0 billion, partially offset by the repayment of debt of $5.0 billion, the payment of dividends of $1.9 billion and payments to repurchase our common stock of $1.5 billion. See Note 9, Financing arrangements, and Note 10, Stockholders' equity, to the condensed consolidated financial statements for further discussion.

Critical accounting policies

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information about our market risk is disclosed in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2020, and is incorporated herein by reference. Except as discussed below, there were no material changes during the six months ended June 30, 2021, to the information provided in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2020.

Interest rate sensitive financial instruments

To achieve a desired mix of fixed and floating interest rate debt, we entered into additional interest rate swap contracts with an aggregate notional amount of $1.5 billion during the three months ended June 30, 2021. As of June 30, 2021, an aggregate notional amount of $7.4 billion of interest rate swap contracts was outstanding. These interest rate swap contracts effectively converted a fixed interest rate coupon to a floating-rate LIBOR-based coupon over the life of the respective notes. A hypothetical 100 basis point increase in interest rates relative to interest rates at June 30, 2021, would have resulted in a reduction in fair value of approximately $390 million on our interest rate swap contracts on that date. The analysis for the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair value of debt that these interest-rate-sensitive instruments were designed to offset.

Item 4. CONTROLS AND PROCEDURES

We maintain “disclosure controls and procedures,” as such term is defined under the Securities Exchange Act Rule 13a-15(e) that are designed to ensure that information required to be disclosed in Amgen’s Exchange Act reports gets recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information gets accumulated and communicated to Amgen’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to facilitate timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen’s management necessarily was required to apply its judgment in evaluating the cost–benefit relationship of possible controls and procedures. We carried out an evaluation under the supervision and with the participation of our management, including Amgen’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen’s disclosure controls and procedures. Based on their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2021.

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

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Notes 12 and 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, 2021 and June 30, 2021, respectively, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 19, Contingencies and commitments, to the consolidated financial statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance, and they involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below we provide in supplemental form the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, of our Annual Report, on Form 10-K for the year ended December 31, 2020, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

The COVID-19 pandemic, and the effort to mitigate the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, manufacturing, supply chains, distribution systems, product development, product sales, business and results of operations.

The novel coronavirus identified in late 2019, SARS-CoV-2, which causes the disease known as COVID-19, is an ongoing global pandemic that has resulted in public and governmental efforts to contain or slow the spread of the disease, including widespread shelter-in-place orders, social distancing interventions, quarantines, travel restrictions and various forms of operational shutdowns. The COVID-19 pandemic and the resulting measures implemented in response to the pandemic are adversely affecting, and are expected to continue to adversely affect, our business (including our R&D, clinical trials, operations, manufacturing, supply chains, distribution systems, product development and sales activities), the business activities of our suppliers, customers, third-party payers and our patients. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations*; see also *Our current products and products in development cannot be sold without regulatory approval*; and see also *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Due to the pandemic and these measures and their effects, we have experienced, and expect to continue to experience, unpredictable reductions in demand for certain of our products, exacerbated by COVID-19 surges resulting in repeated shut-downs and/or disruptions in certain geographies.

Federal, state and local, and international governmental policies and initiatives designed to reduce the transmission of COVID-19 also have resulted in the cancellation or delay of diagnostic, elective, specialty and other procedures and appointments to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19. These measures and challenges will likely continue to varying degrees for the duration of the pandemic and have significantly reduced patient access to, and administration of, certain of our drugs. For example, Prolia® requires administration by a healthcare provider in doctors' offices or other healthcare settings that are affected by COVID-19. The U.S. label for Prolia® instructs healthcare professionals who discontinue Prolia® to transition the patient to an alternative antiresorptive, including oral treatments that do not require administration by a healthcare provider. Further, as a result of COVID-19, oncology patients, in consultation with their doctors, may be selecting therapies that are less immunosuppressive or therapies that do not require administration in a hospital setting, potentially adversely affecting certain of our products. Also, new patients have been, and are expected to continue to be, less likely to be diagnosed and/or to start therapeutics during the pandemic, and these effects, together with the lower treatment rates

during the pandemic, have had, and are expected to continue to have, a cumulative negative effect on the commercial performance of our business. The decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business during the second half of the year. Once the pandemic subsides, we anticipate there could be a backlog of patients seeking appointments with physicians relating to a variety of medical conditions, and as a result, patients seeking treatment with certain of our products may have to navigate lower provider capacity, and this lower provider capacity could have a continued adverse effect on our sales following the opening up of various geographies and/or the end of the pandemic. Further, the effects of the COVID-19 pandemic may result in long-term shifts in preferences among healthcare professionals and patients toward treatments that do not require administration by healthcare professionals or visits to medical facilities.

As the pandemic continues, and if conditions worsen or if the duration of the pandemic extends significantly, we expect to experience additional adverse effects on our development, operational and commercial activities, customer purchases and our collections of accounts receivable. It remains uncertain the degree to which these adverse effects would impact our future operational and commercial activities, customer purchases and our collections as conditions begin to improve. There has been a resurgence in COVID-19 infections in numerous jurisdictions in the first half of 2021, resulting in the reinstatement of stricter restrictions and shutdowns in a number of jurisdictions, including in the U.S., Europe and Asia Pacific regions. It is expected that the pandemic will continue to ebb and flow, with different jurisdictions having higher levels of infections than others over the course of the pandemic. New variants of the SARS-CoV-2 virus have emerged, and have been shown to be present in many geographies, and appear to spread more easily and quickly than other variants. Further, although some studies suggest that antibodies generated with currently authorized vaccines may be effective against these variants, it remains uncertain whether currently available vaccines will retain their efficacy against current and/or future variants of the virus. Jurisdictions may implement, continue or reinstate border closures, impose or reimpose prolonged quarantines and further restrict travel and business activity, which could significantly affect our ability to support our operations and customers and the ability of our employees to get to their workplaces to discover, study, develop and produce our product candidates and products, disrupt the movement of our products through the supply chain, and further prevent or discourage patients from participating in our clinical trials, seeking healthcare services and the administration of certain of our products. Further, in connection with the global outbreak and spread of COVID-19 and in an effort to increase the wider availability of needed medical products, we or our suppliers may elect to, or governments may require us or our suppliers to, allocate manufacturing capacity (for example pursuant to the U.S. Defense Production Act) in a way that adversely affects our regular operations, customer relationships and financial results. In the U.S., on January 21, 2021, President Biden issued an Executive Order instructing federal agencies to use all available legal authorities, including the Defense Production Act, to improve current and future pandemic response and biological threat preparedness. The rapid reallocation of resources for the treatment and prevention of COVID-19 (including the production of COVID-19 vaccinations or related therapies, such as our agreement to contribute to the production of Lilly's COVID-19 antibody therapies) and/or disruptions and shortages in the global supply chain caused by the pandemic, could also result in increased competition for, or reduced availability of, materials used in the development, manufacturing, distribution, or administration of our products. For example, during the second quarter of 2021, an industry-wide shortage of certain lab kit supplies necessary for some activities that support our clinical trials has developed that we are actively monitoring and managing. In addition, unpredictable increases in demand for certain of our products could exceed our capacity to meet such demand, which could adversely affect our financial results and customer relationships.

The COVID-19 pandemic and the volatile global economic conditions stemming from it may precipitate or amplify the other risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, which could materially adversely affect our business, operations and financial conditions and results. For example, if a natural disaster or other potentially disruptive event occurs concurrently with the COVID-19 pandemic, such disaster or event could deplete our inventory levels and we could experience a disruption to our manufacturing or ability to supply our products. Further, the global pandemic has exacerbated geopolitical tensions, and some countries, such as China, may be especially vulnerable to such dynamics. If relations between the United States and China or other governments deteriorates, our business and investments in China or other such markets may also be adversely affected. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*Our sales and operations are subject to the risks of doing business internationally, including in emerging markets.*

The rapid development and fluidity of the pandemic preclude any prediction as to the ultimate effect of COVID-19 on us. The duration of the measures being taken by the authorities to mitigate against the spread of COVID-19 (including the distribution and/or availability of vaccines), and the extent to which such measures are effective, if at all, remain highly uncertain. The magnitude and degree of COVID-19's adverse effect on our business (including our product development, product sales, operating results and resulting cash flows) and financial condition will be driven by the severity and duration of the pandemic, the pandemic's effect on the United States and global economies and the timing, scope and effectiveness of federal, state, local and international governmental responses to the pandemic. If mitigation of the pandemic continues to require further shelter-in-place and shut-down orders and/or restrictions on individual and/or group conduct, any adverse effects of the COVID-19 pandemic will likely grow and could be enduring and our business and financial position could be materially

adversely affected.

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

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

Our information technology systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems makes them potentially vulnerable to breakdown or other service interruptions. Our systems are also subject to frequent cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. We have also experienced unsuccessful denial of service attacks against our network, and although such attacks did not succeed, there can be no assurance that our efforts to guard against the wide and growing variety of potential attack techniques will be successful in the future. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the European Medicines Agency (EMA)) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products in certain markets were negatively affected. In December 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1A. Risk Factors—*The COVID-19 pandemic, and the public and governmental effort to mitigate against the spread of the disease, have had, and are expected to continue to have, an adverse effect, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, product sales, business and results of operations* for a discussion of the cyberattack on the EMA.

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

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we may acquire may face similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data or sensitive personal information. For example, in 2019, two vendors that perform testing and analytical services that we use in developing and manufacturing our products have experienced cyberattacks, and in April and September of 2020, vendors that provide us with information technology services and clinical data services, respectively, each experienced ransomware attacks. Although there was no breach of our systems,

each of these incidents required us to disconnect our systems from those vendors' systems. While we were able to reconnect our systems following restoration of these vendor's capabilities without significantly affecting product availability, a more extended service outage affecting these or other vendors, particularly where such vendor is the single source from which we obtain the services, could have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients.

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

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

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

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

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

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

A substantial portion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See our Annual Report on Form 10-K for the year ended December 31, 2020, Part I, Item 1. Business—Reimbursement. Our business has been and will continue to be affected by legislative actions changing U.S. federal reimbursement policy. Congress has been focused on drug pricing reforms and oversight since 2018, and that activity continues today. For example, in 2020, Amgen participated in House Oversight and Reform Committee hearings on drug pricing practices. Additionally, in 2019 and 2020, a number of other Congressional committees debated drug pricing reform proposals. For example, in 2019, the Senate Finance Committee advanced a bill that would, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B

and/or D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries and require higher/additional manufacturer discounts in Medicare Part D. Additionally, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), includes a penalty for failing to reach agreement with the government and requires that manufacturers offer these negotiated prices to other payers. We expect H.R. 3 to again be debated by Congress in the coming months. Most recently, Congress passed the American Rescue Plan Act of 2021 to provide additional stimulus money and support for COVID relief. As part of that legislation, a provision that is expected to be implemented in 2024 was included that has the effect of increasing the Medicaid rebate liability for some medicines that increase prices in excess of inflation. There are other outstanding proposals that have been introduced by the prior Administration that, if enacted and implemented in whole or in part, could also affect access to and sales of our products, including, but not limited to, proposals to allow importation of prescription medications from Canada or other countries and to set Medicare payment rates using international price referencing. Further, in mid-2020, the prior Administration announced a number of Executive Orders intended to reduce the cost of biopharmaceuticals for patients, including a most favored nation (MFN) policy for Medicare Parts B and D, under which the Health & Human Services (HHS) was directed to take steps to implement payment models that set Medicare purchase prices based on the lowest price available in economically comparable countries for certain Part B and Part D medicines. In September 2020, in response to the corresponding Executive Order, HHS released a final rule to allow states (or other nonfederal government entities) to submit proposals to the FDA allowing for the importation of certain nonbiologic prescription drugs from Canada. Currently, the rule is being challenged by litigation, however, should such litigation be unsuccessful and should the Secretary of HHS authorize state proposals for importation, this rule could allow the importation of Canadian versions of certain of Amgen's products (including Otezla®), that could have a material adverse effect on Amgen's business. Further, in November 2020, also in response to the corresponding Executive Order, HHS released an interim final rule to implement the MFN pricing approach. If implemented, the MFN rule would set the reimbursement rate for 50 Medicare Part B drugs (including our products, such as Prolia®, XGEVA®, KYPROLIS®, Neulasta®, Nplate®, EPOGEN® and Aranesp®) equal to the lowest adjusted price for such products of the 22 OECD nations. Lawsuits have been filed by certain trade groups challenging the implementation of this MFN rule based on, among other things, procedural defects. Late in 2020, in the case filed by the Biotechnology Innovation Organization (BIO) and others, the U.S. District Court for the Northern District of California issued a preliminary injunction preventing the rule from taking effect nationwide, pending the government's completion of required administrative procedures. The case was subsequently stayed by the court. On July 29, 2021, the court granted the parties' request for the stay to remain in place and ordered the parties to file their joint status report by September 27, 2021. Another case, filed by the Pharmaceutical Research and Manufacturers of America and others in the U.S. District Court for the District of Maryland, was also stayed until either a final rule based on the MFN interim rule is published in the Federal Register, or until the court orders a lifting of the stay based on, among other things, the status of the nationwide preliminary injunction issued in the BIO case. Notwithstanding these stays, the MFN rule's approach to drug pricing and other similar approaches, remain of interest. Further, despite the change in Administration, we expect continued significant focus on healthcare and similar drug pricing proposals for the foreseeable future, including proposals similar to the MFN rule or other proposals that would grant the HHS secretary the authority to negotiate drug prices directly with manufacturers.

Our business has been, and is expected to continue to be, affected by changes in U.S. federal reimbursement policy resulting from federal regulations and federal demonstration projects. Over the past three years, federal agencies, including the Centers for Medicare & Medicaid Services (CMS), announced a number of recommendations, policies, proposals and demonstration projects addressing drug pricing. CMS is the federal agency responsible for administering Medicare and overseeing state Medicaid programs and Health Insurance Marketplaces and has substantial power to implement policy changes or demonstration projects that can quickly and significantly affect how drugs, including our products, are covered and reimbursed. CMS issued guidance to allow certain Medicare plans offered by private insurance companies to require that patients receiving Medicare Part B drugs first try a drug preferred by the plan before covering another therapy (Step Therapy) and lowered reimbursement rates for new Medicare Part B drugs. Further, HHS issued a final rule under Medicare Part D revising the regulations under the federal antikickback statute to encourage Pharmacy Benefit Managers (PBMs) to use rebates received from biopharmaceutical manufacturers to reduce patient cost-sharing at the point of sale. While the implementation date for the rule is January 1, 2023, the rule remains subject to litigation, there are numerous logistical hurdles to overcome before it can be effectively implemented, and it is unclear how PBMs will respond and what the current Administration's position is on such rule. Further, while the prior Administration finalized a rule (effective January 1, 2022) mandating price and cost-sharing transparency for almost all health plans and insurers in the individual and group commercial markets, it also is unclear how the current Administration views this rule and how plans and PBMs may respond when it goes into effect. Separately, the Administration is seeking information on how best to implement new reporting requirements relating to the cost of pharmacy benefits, including premiums for drug coverage, manufacturer rebates and the most utilized drugs under group health plans. Such reporting requirements begin no later than December 27, 2021. It is unclear how group health plans and health insurers may respond. The Administration also could develop and seek to advance a range of policy proposals that could impact U.S. federal reimbursement policy for drugs and biologics, including changes to Medicare Part B.

CMS policy changes and demonstration projects to test new care, delivery and payment models can significantly affect how drugs, including our products, are covered and reimbursed. In end-stage renal disease (ESRD), CMS uses bundled payment rates. Between 2018 and 2020, Sensipar® and Parsabiv®, our calcimimetics that are used in dialysis clinics, were eligible for temporary drug add-on payment adjustments (TDAPA) to the bundled rate. In November 2020, CMS released its final rule ending the TDAPA for calcimimetics and adjusting ESRD Prospective Payment System bundled rates on January 1, 2021 by $9.93 per dialysis treatment for calcimimetics. As a result, sales of Parsabiv® have been materially adversely affected by this rule change. Additionally, CMS created a new mandatory payment model, effective January 1, 2021, focused on encouraging greater use of home dialysis and kidney transplants for ESRD patients that could result in changes to treatment of dialysis patients, including reduction of the use of our ESAs. Further, in November 2019, CMS announced additional voluntary payment models for nephrologists and dialysis facility partners that also seek to encourage home dialysis and preemptive transplantation through increased risk sharing, but the start date of such programs has been pushed back to January 1, 2022. CMS has also solicited suggestions regarding other potential care models. In 2016, CMS initiated the Oncology Care Model demonstration, which provides participating physician practices with performance-based financial incentives that aim to manage or reduce Medicare costs without negatively affecting the efficacy of care, that has been extended by one year (to 2022) due to COVID-19. We believe the Oncology Care Model has reduced utilization of certain of our oncology products by participating physician practices and expect it to continue to do so in the future. Additionally, in late 2019, CMS announced a request for information on the Oncology Care First model, a new voluntary model that builds on the Oncology Care Model. CMS has indicated a continued interest in exploring demonstrations of mandatory models, and may propose both new mandatory payment models in the future that could adversely affect our business. CMS recently finalized a rule that, starting January 1, 2023, unless a manufacturer can ensure that the full amount of manufacturer patient assistance programs is passed on to the patient, such amount will be treated as a price reduction that will be taken into account when reporting our Best Price and/or Average Manufacturer Price. Given the use by PBMs and insurers of copay accumulator adjustment programs to apply such patient assistance for the benefit of such companies and not to defray costs to patients, it could be difficult to impossible for manufacturers to ensure that the full value of such amounts is being passed on to the patient. This new policy, if implemented, would have significant implications for our ability to offer copay assistance programs.

In this dynamic environment, particularly in light of the pressures on healthcare budgets as a result of the pandemic, we are unable to predict which or how many federal policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our U.S. products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations.

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

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

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

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes can arise with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts, and such tax authorities (including the IRS) are becoming more aggressive in their audits and are particularly focused on such matters. In 2017, we received a RAR and a modified RAR from the IRS for the years 2010, 2011 and 2012 proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. As previously reported, we disagreed with the proposed adjustments and calculations and pursued a resolution with the IRS administrative appeals office. However, we were unable to reach resolution with the IRS appeals office. In July 2021, we filed a petition in the U.S. Tax Court to contest two duplicative Notices for 2010, 2011 and 2012 that we received in May and July 2021 which seek to increase our U.S. taxable income. We firmly believe that the IRS' positions set forth in the Notices are without merit, and we will vigorously contest the Notices through the judicial

process. See Note 4, Income taxes, to the condensed consolidated financial statements.

In addition, in 2020, we received an RAR and a modified RAR from the IRS for the years 2013, 2014 and 2015 also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010, 2011 and 2012. We disagree with the 2013, 2014 and 2015 proposed adjustments and calculations and are pursuing resolution with the IRS administrative appeals office. We are currently under examination by the IRS for the years 2016, 2017 and 2018. We are also currently under examination by a number of other state and foreign tax jurisdictions.

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

Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The Tax Cuts and Jobs Act (the 2017 Tax Act) is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act. The Administration and Congress are considering significant changes to existing tax law, including an increase in the corporate tax rate and the tax rate on foreign earnings. These changes could substantially increase U.S. taxation of our operations both in and outside the United States, including the U.S. territory of Puerto Rico. Further, the OECD recently reached agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. If enacted, this agreement could result in tax increases in both the United States and foreign jurisdictions. Changes to existing tax law in the U.S., the U.S. territory of Puerto Rico, or other jurisdictions that would likely result in tax increases where we do business and could have a material adverse effect on the results of our operations.

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

During the three months ended June 30, 2021, we had one outstanding stock repurchase program, under which the repurchase activity was as follows:

Period	Total number of shares purchased	Average price paid per share [1]	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program[2]
April 1 - 30	1,912,921	$ 244.13	1,912,921	$ 5,044,280,273
May 1 - 31	2,425,697	$ 248.21	2,425,697	$ 4,442,191,440
June 1 - 30	2,180,367	$ 239.80	2,180,367	$ 3,919,349,391
Total	6,518,985	$ 244.20	6,518,985	

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

(2) In March 2021, our Board of Directors increased the amount authorized under our stock repurchase program by an additional $3.4 billion.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 25, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.2	Amendment No. 1 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 8-K on October 17, 2019 and incorporated herein by reference.)
2.3	Amendment No. 2 to the Asset Purchase Agreement, dated October 17, 2019, by and between Amgen Inc. and Celgene Corporation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.4	Letter Agreement, dated November 21, 2019, by and between Amgen Inc. and the parties named therein re: Treatment of Certain Product Inventory in connection with Amgen's acquisition of Otezla®. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
2.5	Irrevocable Guarantee, dated August 25, 2019, by and between Amgen Inc. and Bristol-Myers Squibb Company. (Filed as an exhibit to Form 8-K on August 26, 2019 and incorporated herein by reference.)
2.6	Agreement and Plan of Merger, dated as of March 4, 2021, by and among Amgen Inc., Franklin Acquisition Sub, Inc. and Five Prime Therapeutics, Inc. (Filed as an exhibit to Form 8-K on March 4, 2021 and incorporated herein by reference.)
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)

4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including form of the Company's 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including form of the Company's 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including form of the Company's 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including form of the Company's 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 3.625% Senior Notes due 2022 and 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	Officers' Certificate of Amgen Inc., dated May 22, 2014, including form of the Company's 3.625% Senior Notes due 2024. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.21	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 2.700% Senior Notes due 2022, 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including forms of the Company's 1.250% Senior Notes due 2022 and 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.23	Form of Permanent Global Certificate for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.24	Terms of the Bonds for the Company's 0.410% bonds due 2023. (Filed as an exhibit on Form 8-K on March 8, 2016 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.26	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.250% Senior Notes due 2023 and 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of May 11, 2017 including form of the Company's 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated herein by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050. (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)

4.30	Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031. (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
4.31	Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.32	Registration Rights Agreement, dated as of August 17, 2020, by and among Amgen Inc., BofA Securities, Inc. and J.P. Morgan Securities LLC, as lead dealer managers, and BNP Paribas Securities Corp., Deutsche Bank Securities Inc., RBC Capital Markets, LLC, Blaylock Van, LLC and Siebert Williams Shank & Co., LLC, as co-dealer managers. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
10.1+	Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 8, 2013 and incorporated herein by reference.)
10.2+	First Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 4, 2015. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2015 on April 27, 2015 and incorporated herein by reference.)
10.3+	Second Amendment to Amgen Inc. Amended and Restated 2009 Equity Incentive Plan, effective March 2, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2016 on May 2, 2016 and incorporated herein by reference.)
10.4+	Form of Grant of Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.5+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on December 12, 2017.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2017 on February 13, 2018 and incorporated herein by reference.)
10.7+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 15, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on October 21, 2020.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.9+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.10+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.11+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen 2009 Director Equity Incentive Program. (As Amended on December 11, 2019.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.12+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.13+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.14+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan (As Amended and Restated effective October 23, 2019). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.15+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)

10.16+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.17+	First Amendment to the Amgen Inc. Executive Incentive Plan, effective December 13, 2012. (Filed as an exhibit to Form 10-K for the year ended December 31, 2012 on February 27, 2013 and incorporated herein by reference.)
10.18+	Second Amendment to the Amgen Inc. Executive Incentive Plan, effective January 1, 2017. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.19+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.20+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.21+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2020). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.22+	Agreement between Amgen Inc. and Murdo Gordon, dated July 25, 2018. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2018 on October 31, 2018 and incorporated herein by reference.)
10.23+	Agreement between Amgen Inc. and Peter Griffith, dated October 18, 2019. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.24	Second Amended and Restated Credit Agreement, dated December 12, 2019, among Amgen Inc., the Banks therein named, Citibank, N.A., as administrative agent, and JPMorgan Chase Bank, N.A., as syndication agent. (Filed as an exhibit to Form 8-K on December 12, 2019 and incorporated herein by reference.)
10.25	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted pursuant to a request for confidential treatment) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K/A for the year ended December 31, 2012 on July 31, 2013 and incorporated herein by reference.)
10.26	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.27	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.28	Collaboration Agreement, dated April 22, 1994, by and between Bayer Corporation (formerly Miles, Inc.) and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 by Onyx Pharmaceuticals, Inc. on May 10, 2011 and incorporated herein by reference.)
10.29	Amendment to Collaboration Agreement, dated April 24, 1996, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.30	Amendment to Collaboration Agreement, dated February 1, 1999, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2006 by Onyx Pharmaceuticals, Inc. on May 10, 2006 and incorporated herein by reference.)
10.31	Settlement Agreement and Release, dated October 11, 2011, by and between Bayer Corporation, Bayer AG, Bayer HealthCare LLC and Bayer Pharma AG and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)

10.32	Fourth Amendment to Collaboration Agreement, dated October 11, 2011, by and between Bayer Corporation and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2011 by Onyx Pharmaceuticals, Inc. on February 27, 2012 and incorporated herein by reference.)
10.33	Side Letter Regarding Collaboration Agreement, dated May 29, 2015, by and between Bayer HealthCare LLC and Onyx Pharmaceuticals, Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2015 on August 5, 2015 and incorporated herein by reference.)
10.34	Side Letter Regarding Collaboration Agreement and Stivarga Agreement, dated February 13, 2020, by and between Onyx Pharmaceuticals, Inc. and Bayer HealthCare LLC. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2020 on May 1, 2020 and incorporated herein by reference.)
10.35	Sourcing and Supply Agreement, dated January 6, 2017, by and between Amgen USA Inc., a wholly owned subsidiary of Amgen Inc., and DaVita Inc. (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2017 on April 27, 2017 and incorporated herein by reference.)
10.36	Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.37	Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.38	Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2017 on July 26, 2017 and incorporated herein by reference.)
10.39*	Amended and Restated Collaboration Agreement, dated June 2, 2021, by and between Amgen Inc. and Novartis Pharma AG (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed).
10.40	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.41	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.42	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.43	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.44	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.45	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2012 on May 8, 2012 and incorporated herein by reference.)
10.46	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted pursuant to a request for confidential treatment). (Filed as an exhibit to Form 10-K for the year ended December 31, 2014 on February 19, 2015 and incorporated herein by reference.)

10.47	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.48	Amendment No. 7 to the Collaboration Agreement, dated December 18, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.49*	License and Collaboration Agreement, dated June 1, 2021, by and between Amgen Inc. and Kyowa Kirin Co., Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed).
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 3, 2021

By: /s/ PETER H. GRIFFITH

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

Exhibit 10.39

EXECUTION VERSION

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.

Amended and Restated Collaboration Agreement

By and Between

Amgen Inc.

and

Novartis Pharma AG

Dated

June 2, 2021

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Table of Contents

Page

Amended and Restated Collaboration Agreement

Preamble

This Amended and Restated Collaboration Agreement (this "*Agreement*"), effective as of June 2, 2021 (the "*Restated Effective Date*"), is by and between Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, U.S.A. ("*Amgen*"), and Novartis Pharma AG, a Swiss company having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland ("*Novartis*"). Amgen and Novartis are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties.*"

Recitals

WHEREAS, Amgen and Novartis are parties to that certain Exclusive License and Collaboration Agreement, dated as of August 28, 2015, pursuant to which (i) the Parties are Developing the Product (as defined below) globally, and (ii) Amgen granted to Novartis and Novartis obtained from Amgen, certain license rights to commercialize the Product outside the United States, Canada and Japan (the "*Global Agreement*"); and

WHEREAS, Amgen and Novartis are parties to that certain Collaboration Agreement, dated as of April 21, 2017 (the *"Original Effective Date")*, as amended March 20, 2018 and August 19, 2020 (as amended, the "*Original US Agreement*"), pursuant to which the Parties are collaborating with respect to the Commercialization of and Medical Affairs Activities (each as defined below) with respect to the Product in the Field in the United States (each as defined below);

WHEREAS, Amgen and Novartis now desire to amend and restate the Original US Agreement to transition the Commercialization and performance Medical Affairs Activities with respect to the Product in the Field in the United States to be conducted solely by Amgen in accordance with the terms and conditions hereof; and

WHEREAS, simultaneously herewith, the Parties are entering into a Letter Agreement in respect of certain clarifications to the Global Agreement resulting from entry into this Agreement.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereto agree as follows:

1. Definitions

Capitalized terms herein that are not otherwise defined herein shall have the meanings ascribed to such terms in the Global Agreement; *provided* that any references to "Licensed Product" in any such definition shall, for purposes of this Agreement, mean the Product.

1.1 [***]

1.2 "*Adjusted Cap*" has the meaning set forth in Section 8.6.2.3(e).

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

1.4 "*Alliance Managers*" has the meaning set forth in Section 2.6 (Alliance Managers).

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

1.6 "*Amgen Assumed Item*" has the meaning set forth in Section 9.2.3 (Amgen Secondary Prosecution).

1.7 "*Amgen Headquarter Marketing FTE Costs*" means the Costs for Amgen's headquarter marketing FTEs working with respect to the Product in a Calendar Year, calculated at the applicable FTE Rate, [***]

1.8 [***]

1.9 [***]

1.10 "*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 Amgen Product Trademarks, Novartis Housemarks 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.

1.11 "*Amgen Indemnitees*" has the meaning set forth in Section 13.2 (Indemnification by Novartis).

1.12 "*Amgen Know-How*" means, with respect to the Product, Information Controlled by Amgen or its Affiliates (including Amgen Development Data), as of the Original Effective Date or thereafter during the Term, that is [*] for Novartis to conduct Medical Affairs Activities with respect to or Commercialize the Product in the Field in the United States.

1.13 "*Amgen Patents*" means, with respect to the Product, those patents and patent applications set forth on the Amgen Patent Schedule, as well as any continuation, divisional, substitution, continuation-in-part, reissue, reexamination, provisional and converted provisional application thereof, as well as any Patent in the United States Controlled by Amgen or its Affiliates on or after the Original Effective Date (including an interest in a patent or Joint Patent pursuant to Section 9.1 (Ownership and Cooperation)) that (i) would (absent the licenses granted herein) be infringed by the Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Product in the Field in the United States or (ii) would be [*] for the Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Product in the Field in the United States. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be infringed if issued as then currently set forth in the patent application.

1.14 "*Amgen Patent Schedule*" means the schedule of Amgen Patents attached hereto as Schedule 1, which may be updated by Amgen from time to time upon reasonable notice to Novartis.

1.15 "*Amgen Product Trademarks*" means, with respect to the Product, any trademark rights Controlled or adopted by Amgen or its Affiliates on or after the Original Effective Date for use with the Product in the Field in the United States (not including any Housemarks and not including any such marks to the extent such marks would conflict with any right of any Third Party).

1.16 "*Amgen Technology*" means (i) the Amgen Know-How and (ii) the Amgen Patents.

1.17 "*Amgen Territory*" means (i) during the term of the Global Agreement, Japan and any other country removed from the Territory (as defined in the Global Agreement) in accordance with the terms of the Global Agreement, and (ii) from and after the expiration or earlier termination of the Global Agreement, worldwide other than the United States.

1.18 "*Amgen Territory Patents and Trademarks*" has the meaning set forth in Section 9.3.2 (Amgen Territory Patents and Trademarks).

1.19 [***]

1.20 "*Biennial Cap Adjustment*" has the meaning set forth in Section 8.6.2.3.

1.21 "*Biosimilar Product*" means, with respect to the Product in the United States, after Regulatory Approval of the Product in the United States, any other biological product designated for human use which (i) contains the same principal molecular structural features as (but not necessarily all of the same structural features as) the Product, (ii) has a purity, potency and safety profile that has no clinically meaningful difference from the purity, potency and safety profile of the Product, (iii) is approved for use pursuant to a regulatory approval process in the United States that is based on reliance, at least in part, on the Product, whether or not such regulatory approval was based upon data generated by either Party filed with the applicable Governmental Authority in the United States or was obtained using an abbreviated, expedited or other process, and (iv) is sold in the United States by any Third Party.

1.22 "*Cap*" means, on a Calendar Year-by-Calendar Year basis, the maximum aggregate amount of Commercialization Costs shared by the Parties in such Calendar Year in accordance with Section 8.6.1.5(b), as calculated pursuant to Section 8.6.2 and subject to the Biennial Cap Adjustment.

1.23 "*Cap Schedule*" means the schedule illustrating the methodology for calculating the Cap, Cap Discount Factor and Biennial Cap Adjustment, attached hereto as Schedule 2, which may be updated from time to time in accordance with Section 8.6.2.3.

1.24 "*Cap Discount Factor*" has the meaning set forth in Section 8.6.2.2.

1.25 "*CIA*" means a corporate integrity agreement or similar arrangement entered into between a Party and a Governmental Authority in the United States.

1.26 "*Claims*" has the meaning set forth in Section 13.2 (Indemnification by Novartis).

1.27 "*CMC*" means, for a given product, the chemistry, manufacturing and controls for such product, as submitted to or specified by the FDA.

1.28 "*CMC Core Dossier*" has the meaning set forth in Section 6.3 (Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities).

1.29 "*Commercialization Costs*" means all Costs incurred by Amgen and its Affiliates during the Term in connection with Commercialization activities undertaken hereunder in a manner consistent with the applicable United States Brand Plan, including without limitation, (i) selling expenses, or other direct and indirect costs and expenses associated with marketing of the Product for Commercialization in the Field in the United States, including Sales Force Costs calculated in accordance with Section 8.6.6 (Calculation of Sales Force Costs); (ii) costs for preparing and reproducing Detailing aids, Product promotional materials and other promotional materials, costs of professional education, product related public relations, relationships with opinion leaders and professional societies, market research (before and after Regulatory Approval for the Product in the United States, but excluding research relating to product naming), healthcare economics studies and other similar activities directly related to the Product; and (iii) the cost of activities related to obtaining market access, reimbursement from payers, costs of sales and marketing data, costs associated with training of the sales representatives incurred in accordance with Section 5.3 (Training), sales meetings, samples, sales call reporting, work on managed care accounts, costs related to customer service and other sales and customer service-related expenses; in each case ((i) through (iii)) to the extent [***]. Such costs may also include actual out-of-pocket costs for outside services and expenses (e.g., consultants, agency fees, meeting costs, etc.). Commercialization Costs excludes the Costs of activities that promote Amgen's therapeutic franchise or business as a whole, except to the extent a portion of such Costs is reasonably allocated to the Product in accordance with Amgen's cost accounting policies, as consistently applied across Amgen's entire portfolio and [***]. For the avoidance of doubt, Commercialization Costs shall exclude Medical Affairs Activities Costs, Novartis Headquarter Marketing FTE Costs and Amgen Headquarter Marketing FTE Costs.

1.30 "*Commercialize*" means any and all processes and activities conducted to establish and maintain sales for the Product, including to market, advertise, promote, import, export, offer to sell (including pricing and reimbursement activities), Detail, and/or sell the Product and/or conduct other commercialization activities, and "*Commercialization*" shall have the correlative meaning with respect to such activities; *provided, however*, that Commercialize shall exclude Medical Affairs Activities and Development and Manufacturing activities (including Manufacturing activities related to Commercialization).

1.31 "*Commercially Reasonable Efforts*" means, with respect to the efforts to be expended by Amgen with respect to any objective under this Agreement, reasonable, diligent, good-faith efforts to accomplish such objective as [***] would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to the Manufacture, conduct of Medical Affairs Activities with respect to, and Commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by [***] for a product owned by it or to which it has rights, which product is of similar market and economic potential as the Product, and at a similar stage in its Development or product life as the Product, taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of Regulatory Approval given the regulatory

structure involved, the profitability, and other relevant factors commonly considered in similar circumstances, in any event exercising reasonable business judgment. It is anticipated that the level of effort may change over time, reflecting changes in the status of the aforementioned attributes and potential of the Product.

1.32 "*Confidential Information*" has the meaning set forth in Section 10.1 (Confidentiality; Exceptions).

1.33 "*Contract Interest Rate*" means [***] annually plus the [***] day U.S. Dollar LIBOR or SOFR rate, as applicable, 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 Law.

1.34 "*Control*" means, with respect to any Information or intellectual property, that the applicable Party or any of its Affiliates owns or has a license to such Information or intellectual property and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense, or requiring any payment (whether or not then due and payable) unless the other Party agrees in writing to be responsible for its share of such payments hereunder or it is subject to Section 8.7 (Sublicense Payments).

1.35 "*Copyright*" means all right, title and interest in and to all copyrightable works and any copyright registration or corresponding legal right, other than copyrights included under Trademarks.

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

1.37 "*Detail*" means an interactive, one-on-one, meeting (via face-to-face, teleconference, or videoconference) in an individual or group practice setting, between one or more healthcare professionals having prescribing authority and one Amgen (or its Affiliate's) sales representative during which uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of the Product are discussed in an effort to increase prescribing preferences of the Product for its approved uses. Details will not include (i) activities conducted by medical support staff (such as Medical Liaisons) or (ii) unless the Parties otherwise mutually agree in writing, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing interactive sales calls or not specifically trained with respect to a pharmaceutical product. When used as a verb, "*Detail*" or "*Detailing*" shall mean to engage in a Detail.

1.38 "*Development Lead*" has the meaning set forth in Section 4.1 (Responsibility for Development).

1.39 [***]

1.40 "*Field*" means any and all uses for the diagnosis, prevention or treatment of any disease or condition in all indications in humans.

1.41 "*First Commercial Sale*" means, with respect to the Product, the first sale in the United States to a Third Party of the Product by or under the authority of the Parties or their Affiliates or sublicensees after receipt of Regulatory Approval for the Product in the United States, which occurred on May 17, 2018. Sales for clinical study purposes or compassionate, named patient or similar use shall not constitute a First Commercial Sale.

1.42 "*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.

1.43 "*First Position Detail Equivalent Basis*" has the meaning set forth in Section 8.6.6 (Calculation of Sales Force Costs).

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

1.45 "*FTE*" means a full-time equivalent person (i.e., one fully-dedicated or multiple partially-dedicated employees aggregating to one full-time employee employed or contracted by Amgen based upon a total of [***] per year undertaken in connection with the conduct of Commercialization in a manner consistent with activities contemplated under the United States Brand Plan, or other activities, including Medical Affairs Activities, in accordance with the Development Plan). Overtime, and work on weekends, holidays and the like [***] be counted [***] toward the number of hours that are used to calculate the FTE contribution.

1.46 "*FTE Rate*" means the rates agreed by the Parties in writing as of the Restated Effective Date as set forth on Schedule 7 with respect to FTEs , each per FTE per year (as of the Restated Effective Date), increasing by [***] of the then-current FTE Rate on [***] and each subsequent Calendar Year; *provided*, that Amgen's contract sales force costs shall (i) be Amgen's actual pass-through cost and (ii) in no event exceed amounts equal to the Sales Force Costs calculated in accordance with Section 8.6.6 (Calculation of Sales Force Costs) (i.e., contract sales force costs for a contract sales representative shall in no event exceed the costs associated with a sales representative in Amgen's internal sales force).

1.47 "*Global Agreement*" has the meaning set forth in the Recitals.

1.48 "*Global Brand Plan*" means, with respect to the Product, the strategic and high-level tactical, cross-functional Commercialization plan jointly developed by Amgen and Novartis (including through the JSC) for the Product, including the Global Payer Plan and Global Pricing Policy.

1.49 "*Global Payer Plan*" means, with respect to the Product, the global plan for the Product jointly prepared by Amgen and Novartis (including through the JSC) that sets forth the strategic direction, positioning, value proposition, [***], value evidence generation plan, economic modeling strategy and reimbursement for the Product.

1.50 "*Global Pricing Policy*" means, with respect to the Product, the global plan for the Product jointly prepared by Amgen and Novartis (including through the JSC) that sets forth, globally and by region, the [***] target population and [***] target for the Product.

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

1.52 "*Housemark Transition Period*" has the meaning set forth in Section 3.5.1.

1.53 "*Housemarks*" means the Novartis Housemarks or the Amgen Housemarks, as the case may be.

1.54 "*IND*" means an Investigational New Drug Application as defined in applicable regulations promulgated by the FDA and filed with the FDA for human clinical testing of a drug.

1.55 "*Indemnified Party*" has the meaning set forth in Section 13.4 (Claim for Indemnification).

1.56 "*Indemnifying Party*" has the meaning set forth in Section 13.4 (Claim for Indemnification).

1.57 "*Joint Patent*" means any invention, patent or patent application jointly owned by the Parties pursuant to Section 9.1 (Ownership and Cooperation).

1.58 "*Joint Project Team*" *or* "*JPT*" has the meaning set forth in Section 2.3.2 (Joint Project Teams).

1.59 "*JSC*" means the Joint Steering Committee under the Global Agreement established pursuant to Article 3 (Collaboration Scope and Governance) of the Global Agreement.

1.60 "*Liability*" has the meaning set forth in Section 13.1 (Sharing of Liability Expenses).

1.61 [***]

1.62 "*Losses*" has the meaning set forth in Section 13.2 (Indemnification by Novartis).

1.63 "*MA*" or "*Marketing Authorization*" means an MAA that has been approved by the applicable Governmental Authority to market the Product in the United States.

1.64 "*MAA*" means a BLA in the United States.

1.65 "*Manufacturing Lead*" has the meaning set forth in Section 6.1 (Responsibility for Manufacturing).

1.66 "*Material Safety Issue*" means a Party's good faith belief that, after reviewing applicable safety data and other relevant safety factors, the Product should not [***].

1.67 "*Medical Affairs Activities*" means, design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further clinical studies regarding, the Product, as established by Amgen's internal policies and procedures and approved by the JSC, which includes by way of example: (i) activities of Medical Liaisons; (ii) grants to support continuing independent medical education (including independent symposia and congresses); and (iii) development, publication and dissemination of scientific and clinical information in support of an approved indication for the Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing representatives or received by letter, phone call or email or other means of communication.

1.68 "*Medical Affairs Activities Costs*" means Costs incurred by Amgen and its Affiliates during the Term and pursuant to this Agreement associated with Medical Affairs Activities in the United States to the extent incurred in accordance with the applicable Development Budget. For the avoidance of doubt, Medical Affairs Activities Costs shall be included in Development Costs.

1.69 "*Medical Liaisons*" means those health care professionals employed or engaged by Amgen with sufficient health care experience to engage in in-depth dialogues with physicians regarding medical issues associated with the Product, and are not sales representatives or otherwise engaged in direct selling or promotion of the Product.

1.70 "*MSL Cap*" has the meaning set forth in Section 8.6.1.3.

1.71 "*Net Sales*" means with respect to a given period and the Product, the gross invoiced sales for the Product sold by or on behalf of Amgen or any of its Affiliates or sublicensees hereunder in the United States for use in the United States to Third Parties other than sublicensees in bona fide, arms-length transactions, less the following charges or expenses as recorded on an accrual basis, as determined in accordance with Amgen's Accounting Standards as consistently applied:

(i) normal trade and cash discounts allowed and taken by the Third Party;

(ii) amounts repaid or credited by reasons of defects, rejections, Recalls or returns;

(iii) rebates and chargebacks to customers and managed healthcare organizations, federal, state, provincial, local and other governments, their agencies and purchasers and reimbursers and similar Third Parties (including, without limitation, [***]);

(iv) any amounts recorded in gross revenue associated with goods provided to customers for free;

(v) amounts provided or credited to customers through coupons and other discount programs;

(vi) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates;

(vii) fee for service payments to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information);

(viii) sales taxes (such as VAT or its equivalent) and excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities and [***] imposed upon the sale of the Product to Third Parties; and

(ix) following such deductions in (i) through (viii) above, less a deduction of [***] for direct expenses related to the sales of the Product, distribution and warehousing expenses, and uncollectible amounts on previously sold products.

In addition, (a) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party and sales between or among Amgen and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales; (b) if the Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Amgen's Accounting Standards are met; and (c) in the event that the Product is sold in the United States together with one or more other therapeutically active ingredients or therapies not constituting the Product for a single price (regardless of their packaging) (a "*Combination Product*"), the Product shall be deemed to be sold in the United States for an amount equal to the product of (i) the price at which the Combination Product was sold in the United States and (ii) the fraction A/(A+B), where A is the weighted (by sales volume) average sale price in the United States during the applicable reporting period of the Product when sold alone, and B is the weighted average sale price (by sales volume) in the United States during the applicable reporting period of each other therapeutically active ingredient or therapy included in the Combination Product when sold alone. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages of the Product or other therapeutically active ingredients or therapies than those that are included in the Combination Product, then Amgen shall be entitled to make a proportional adjustment to such prices in calculating the royalty-bearing Net Sales of the Combination Product. If the weighted average sale price cannot be determined for the Product or other therapeutically active ingredients or therapies, the calculation of Net Sales for Combination Products will be agreed by the Parties based on the relative fair market value contributed by each component (each Party's agreement not to be unreasonably withheld or delayed).

Any disposal of Product at no charge for, or use of the Product without charge in, clinical or preclinical trials shall not be included in Net Sales.

1.72 "*Non-Promotional Materials*" means all written materials relating to the Product or Product indication under development, including technology related thereto, that are not considered Promotional Materials and are intended for use with an external audience to appropriately inform through scientific exchange the public or healthcare community regarding the Product or an indication under development therefor or disease awareness materials relating to the applicable therapeutic area in the Field. Such materials include scientific congress booth materials, media communications, Medical Affairs Activities materials and similar documents, but exclude materials described in Section 10.4 (Terms and Conditions Confidential) hereof and Section 11.6 (Publications and Presentations) of the Global Agreement.

1.73 "*Non-Specialty Targets*" means those physicians and nurse practitioners, other than Specialty Targets, that are reasonably expected to treat patients for migraine headaches or other approved indications of the Product for Detailing the Product, which list may include: (i) primary care physicians and nurse practitioners and (ii) physicians and nurse practitioners practicing in the area [***].

1.74 "*Novartis*" has the meaning set forth in the Preamble.

1.75 "*Novartis Branded Materials*" has the meaning set forth in Section 3.4.1.

1.76 "*Novartis Group*" has the meaning set forth in Section 11.2.3.

1.77 "*Novartis Housemarks*" means (i) the corporate logo of Novartis, (ii) the trademark "Novartis", (iii) any other trademark, trade name or service mark (whether registered or unregistered) containing the word "Novartis", and (iv) any other trademark or service mark associated with goods or services of Novartis or its Affiliates, but excluding the Amgen Product Trademarks, Amgen Housemarks 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.

1.78 "*Novartis Indemnitees*" has the meaning set forth in Section 13.3 (Indemnification by Amgen).

1.79 "*Novartis Know-How*" means, with respect to the Product, Information Controlled, as of the Original Effective Date or thereafter during the Term, by Novartis or its Affiliates (including Novartis Development Data) that is a Novartis Improvement or is [***] for Amgen to conduct Medical Affairs Activities with respect to or Commercialize the Product within the United States in the Field or Manufacture the Product within or outside the United States in the Field.

1.80 "*Novartis Headquarter Marketing FTE Costs*" means the Costs for Novartis's headquarter marketing FTE working with respect to the Product [***] calculated at the applicable FTE Rate, [***]

1.81 "*Novartis Patents*" means, with respect to the Product, Patents Controlled by Novartis or its Affiliates on or after the Original Effective Date (including an interest in a patent or Joint Patent pursuant to Section 9.1 (Ownership and Cooperation)) that Cover the Product or a Novartis Improvement that (i) would (absent the licenses granted herein) be infringed by the conduct of Medical Affairs Activities with respect to, Manufacture or Commercialization of the Product in the Field or (ii) would be [***] for the conduct of Medical Affairs Activities with respect to or Commercialization of the Product within the United States in the Field or Manufacture the Product within or outside the United States in the Field. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be infringed if issued as then currently set forth in the patent application.

1.82 [***]

1.83 "*Novartis Technology*" means (i) the Novartis Know-How and (ii) the Novartis Patents.

1.84 "*Novartis Transitional Commercialization Activities*" has the meaning set forth in Section 2.9.3.

1.85 "*Novartis Transitional Medical Affairs Activities*" has the meaning set forth in Section 2.9.3.

1.86 "*Obligations*" has the meaning set forth in Section 11.2.3.

1.87 "*Original Effective Date*" has the meaning set forth in the Recitals.

1.88 "*Original US Agreement*" has the meaning set forth in the Recitals.

1.89 "*Other Costs*" means (i) Costs incurred by a Party and its Affiliates in the prosecution and maintenance of Patents and Trademarks pursuant to Section 9.2 (Prosecution and Maintenance); (ii) Costs incurred by a Party and its Affiliates in the defense and settlement of infringement and other suits pursuant to Section 9.3 (Defense and Settlement of Third Party Claims); (iii) Costs incurred by a Party and its Affiliates in enforcing Patents and Trademarks pursuant to Sections 9.4.2 (Amgen Primary Enforcement), 9.4.4 (Novartis Primary Enforcement and 9.4.5 (Amgen Secondary Enforcement); (iv) subject to Section 8.7 (Sublicense Payments), Third Party license fees, milestones, royalties or other payments owed with respect to the Product (or its components, including devices) in the United States or uses thereof (or its components, including devices), on intellectual property (other than [***]) related to the Product (or its components, including devices) that is licensed by either Party after the Original Effective Date; (v) subject to Sections [***] and 8.7 (Sublicense Payments), Third Party license fees, milestones, royalties or other payments owed with respect to [***] of the Product for the United States that is licensed by either Party after the Original Effective Date, including with respect to [***]; and (vi) Costs incurred by the Parties pursuant to Section 13.1 (Sharing of Liability Expenses).

1.90 "*OSE Costs*" means Commercialization Costs excluding Sales Force Costs.

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

1.92 "*Party Representatives*" has the meaning set forth in Section 11.5.2.

1.93 "*Product*" means Amgen's proprietary monoclonal antibody against calcitonin gene-related peptide (CGRP) receptor, known as AMG 334 or erenumab.

1.94 "*Program Costs*" means, with respect to the Product in the United States for any Calendar Quarter, the following expenses that are incurred by a Party and any of its Affiliates: (i) Commercialization Costs; (ii) Amgen Headquarter Marketing FTE Costs; (iii) Novartis Headquarter Marketing FTE Costs; and (iv) Other Costs; *provided* that, in clause (i) above such costs shall be included within "Program Costs" for the Product to the extent consistent with the applicable United States Brand Plan. The components of Program Costs shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement. Development Costs (including Medical Affairs Activities Costs) are not included in Program Costs and vice versa. If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as Program Costs with respect to one of those activities.

1.95 "*Promotional Materials*" means, collectively and including translations, all written sales, educational, promotional and advertising materials relating to the Product in the United States, and other media and materials used in the United States to promote the Product or educate patients, consumers and healthcare professionals regarding an indication treated with the Product.

1.96 "*Recoveries*" means all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party in connection with the final judgment, award or settlement of any enforcement with respect to any Amgen Technology, Amgen Product Trademark, Novartis Technology, Novartis Product Trademark, Joint Patent, Copyrights pertaining to Promotional Materials, Non-Promotional Materials or training materials for the

Product, or Amgen Housemarks and Novartis Housemarks jointly used by the Parties, each of the foregoing with respect to the Product in the Field in the United States.

1.97 "*Regulatory Lead*" has the meaning set forth in Section 4.2.1 (Regulatory Responsibility, Communications and Filings).

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

1.99 "*Safety Agreement*"means that certain Pharmacovigilance Agreement, dated as of December 10, 2019, between the Parties.

1.100 "*Sales Force Costs*" means the allocable share of Amgen's or any of its Affiliates' or contractors' sales force costs for sales representatives that Detail the Product in the Field in the United States in accordance with this Agreement, calculated in accordance with Section 8.6.6 (Calculation of Sales Force Costs); *provided*, that Amgen's contract sales force costs shall (i) be Amgen's actual pass-through cost and (ii) in no event exceed amounts equal to the Sales Force Costs calculated in accordance with Section 8.6.6 (Calculation of Sales Force Costs) (i.e., contract sales force costs for a sales representative shall in no event exceed the costs associated with a sales representative in Amgen's internal sales force).

1.101 "*Sales Force FTE*" means a full-time equivalent sales representative (i.e., one fully-dedicated or multiple partially-dedicated sales representatives aggregating to one full-time sales representative employed or contracted by Amgen based upon a total of [***] days per Calendar Year and [***] Details per day undertaken in connection with the conduct of Details in a manner consistent with the applicable United States Brand Plan. Overtime, and work on weekends, holidays and the like [***] be counted [***] toward the number of hours that are used to calculate the Sales Force FTE contribution.

1.102 "*Sales Milestone*" has the meaning set forth in Section 8.2.3.

1.103 "*Sales Milestone Threshold*" has the meaning set forth in Section 8.2.3.

1.104 "*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 the Product) and/or the second most predominant portion of time is devoted to the Detailing of such pharmaceutical product.

1.105 "*Service Period*" has the meaning set forth in the Transition Services Agreement.

1.106 "*Shared Liability Losses*" has the meaning set forth in Section 13.1 (Sharing of Liability Expense).

1.107 "*Specialty Targets*" means (i) [***] and (ii) physicians and nurse practitioners practicing in the area of [***], that (in the case of (i) and (ii)) are approved by Amgen on a periodic basis, no less than annually, for Detailing the Product.

1.108 [***]

1.109 [***]

1.110 [***]

1.111 "*Steady State Salesforce*" means [***] of Amgen's steady state salesforce for the Product in the United States.

1.112 "*Staffed Up*" means sufficient sales representatives to staff at least [***] of Amgen's expected post-Restated Effective Date personnel additions to its salesforce for the Product in the United States with the expectation of achieving the Steady State Salesforce.

1.113 "*Steady State Sales Force Costs*" means the annualized dollar amount for Amgen's post-transition, Steady State Salesforce as calculated on a Sales Force FTE basis at the applicable FTE Rates as of the earlier of (i) [***] and (ii) [***], it being understood and agreed that the number of sales representatives added by Amgen to its salesforce as of [***], shall be deemed to satisfy the definition of Staffed Up; *provided*, [***].

1.114 "*Targets*" means Non-Specialty Targets and/or Specialty Targets, as the context admits.

1.115 "*Technology*" means Information and Patents.

1.116 "*Term*" means the period beginning on the Original Effective Date and continuing for as long as the Product is Commercialized by Amgen in the Field in the United States, unless otherwise terminated pursuant to Article 14 (Term and Termination).

1.117 "*Termination Date*" has the meaning set forth in Section 14.3.3.1 (Additional Termination Effects).

1.118 "*Third Position Detail*" means a Detail in which the applicable pharmaceutical product is Detailed in the third position (i.e., no more than two (2) other products are presented to or discussed with the healthcare professional before the Product) and/or the third most predominant portion of time is devoted to the Detailing of such pharmaceutical product.

1.119 "*Transition Period*" means the period of time from the Restated Effective Date until the last to expire Service Period under the Transition Services Agreement.

1.120 "*Transition Services Agreement*" or "*TSA*" means the Transition Services Agreement entered into between Novartis and Amgen on the Restated Effective Date, in the form attached hereto as Schedule 5, relating to transition services to be provided by or on behalf of Novartis to Amgen or its Affiliates.

1.121 [***]

1.122 "*United States*" or "*U.S.*" means the United States of America, including its territories and possessions (including the District of Columbia and Puerto Rico).

1.123 "*United States Brand Plan*" means, with respect to the Product, the United States-specific strategic and high-level tactical, cross-functional Commercialization plan developed by Amgen (subject to review and approval through the JSC) for the Product in the United States and consistent with the Global Brand Plan.

1.124 "*United States Novartis Patents*" has the meaning set forth in Section 9.2.2 (Novartis Primary Prosecution).

1.125 "*United States Patents and Trademarks*" has the meaning set forth in Section 9.2.1 (Amgen Primary Prosecution).

1.126 "*US Biosimilar Entry Date*" has the meaning set forth in Section 8.3.2 (Royalty Reduction for Biosimilar Competition).

1.127 "*US Collaboration*" has the meaning set forth in Section 2.1 (Conduct of the Collaboration).

2. Collaboration Scope, Governance and Transition Planning

2.1 Conduct of the Collaboration. The Parties shall cooperate to permit Amgen to solely conduct Medical Affairs Activities with respect to the Product in the Field in the United States, and to solely Commercialize the Product in the Field in the United States, in each case in accordance with the terms and conditions of this Agreement (the "*US Collaboration*") and subject to Section 2.9 of this Agreement and the TSA.

2.2 Disbandment of Certain US Committees. In connection with the transition of the Commercialization and Medical Affairs Activities with respect to the Product in the Field in the United States solely to Amgen, each of the Joint US Leadership Team, US Collaboration Team, US Medical Affairs JPT, US Committee and Joint Compliance Contacts (each, as defined in the Original US Agreement) shall be disbanded as of the Restated Effective Date.

2.3 JSC.

2.3.1 *JSC*. The JSC shall (i) review and approve plans and strategies for, and the conduct and progress of, activities by Amgen relating to Commercialization in the United States with respect to the Product, including the applicable United States Brand Plan; (ii) monitor Amgen's activities under this Agreement pursuant to the United States Brand Plan; (iii) review sales forecasts for the Product in the United States; (iv) review any anticipated disruption to supply of the Product in the United States; (v) direct and oversee any JPT, sub-committee and collaboration team established by the JSC, on all significant issues that fall within the responsibilities of such JPTs, sub-committees and collaboration team; (vi) attempt to resolve issues presented to it by, and disputes within the JPTs, sub-committees and collaboration team in accordance with Section 2.4 (Decision Making); and (vii) make such determinations as are expressly delegated to it under the terms of this Agreement. Amgen shall keep the JSC reasonably informed of the progress and results of its activities under the United States Brand Plan through its members on the JSC and as otherwise provided herein. Amgen shall prepare the first draft of the United States Brand Plan for presentation to the JSC.

2.3.2 *Joint Project Teams*. From time to time, the JSC may establish permanent or ad hoc cross-functional or function-specific joint project teams to undertake initiatives or analyses and such joint project teams will be constituted as the JSC approves (each, a "Joint Project Team" or "JPT"). If any JPT is unable to reach a decision on any matter after endeavoring in good faith to do so, such matter shall be referred to the JSC for resolution as provided in Section 2.4 (Decision Making).

2.3.3 *Other Sub-Committees and Teams*. The JSC may also establish other committees, sub-committees or collaboration teams as it deems appropriate.

2.4 Decision Making. Other than as set forth herein, in order to make any decision required of it hereunder, the Joint Steering Committee and the Joint Management Committee

must have present (in person, by videoconference or telephonically) at least the Co-Chair of each Party (or his/her designee for such meeting). The Parties will endeavor to make decisions where required of the Joint Steering Committee and the Joint Management Committee by mutual agreement of the Co-Chairs. The Parties will endeavor to make decisions within a Joint Project Team by mutual agreement. If a dispute arises which cannot be resolved within a Joint Project Team, the Co-Chairs of either Party may cause such dispute to be referred to the Joint Steering Committee for resolution. Within the JSC, the Amgen Co-Chair shall have the deciding vote with respect to (i) all Manufacturing matters for the Product (ii) the United States Brand Plan and (iii) all Commercialization matters for the Product in the United States; *provided* that any such decision must be consistent with the Global Brand Plan (including, for clarity, the Global Pricing Policy). For clarity, all Development, regulatory and Medical Affairs Activities matters will be discussed and resolved at the JSC or JMC, as applicable, pursuant to Section 3.5 (Decision Making) of the Global Agreement.

2.5 Interactions between the JSC, Joint Project Teams, Sub-Committees and Collaboration Teams. The Parties recognize that while the JSC may establish Joint Project Teams, sub-committees and collaboration teams for the purposes hereof, each Party maintains internal structures (including its own committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. The Parties shall establish procedures to facilitate communications between the JSC, Joint Project Teams, sub-committees and collaboration teams hereunder and the relevant internal committees, teams or boards within each Party in order to maximize the efficiency of the Parties' activities pursuant to this Agreement.

2.6 Alliance Managers. Following the Original Effective Date, each of Amgen and Novartis appointed one or more senior representatives who possess a general understanding of Development, regulatory, Manufacturing, Medical Affairs Activities and Commercialization matters to act as its respective alliance manager(s) for the US Collaboration (each, an "*Alliance Manager*"). Each Party may replace its respective Alliance Manager(s) at any time upon written notice to the other in accordance with this Agreement. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among the JSC, Joint Project Teams, sub-committees and collaboration teams. Consistent with Section 2.4 (Decision Making), each Alliance Manager will also be responsible for:

2.6.1 providing a single point of communication for seeking consensus both within the respective Party's organization and together with the other Party regarding key strategy and plan issues; and

2.6.2 identifying and raising disputes to the JSC or JMC for discussion in a timely manner.

During the term of the Global Agreement, the Alliance Managers appointed under the Global Agreement shall also serve as the Alliance Managers under this Agreement. The Alliance Managers shall be entitled to attend all JSC meetings, and shall have the right to attend all JPT, sub-committee and collaboration team meetings. Consistent with Section 2.4 (Decision Making), each Alliance Manager may bring any matter to the attention of the JSC, where such Alliance Manager reasonably believes that such matter requires attention of the JSC.

In the event that Novartis undergoes any change of control or restructuring or any transfer or disposition of all or substantially all of its assets or personnel outside of Novartis and its wholly-owned subsidiaries, the Alliance Managers shall discuss in good faith the implications thereof on this Agreement and the activities and obligations contemplated hereby; *provided, however*, that Novartis and its Affiliates shall be permitted to redact any competitively sensitive information included in any documents or correspondence provided to Amgen pursuant to the foregoing.

2.7 Amgen Territory. Unless expressly set forth in this Agreement or the Global Agreement otherwise, Amgen shall have the sole decision-making authority with regard to Development, regulatory, Medical Affairs Activities, Manufacturing and Commercialization of the Product in the Amgen Territory. Unless expressly permitted in this Agreement or the Global Agreement, Novartis and its Affiliates shall not Develop or Commercialize or conduct Medical Affairs Activities with respect to the Product in any country in the Amgen Territory.

2.8 Limitations of Authority. The Joint Steering Committee and the Joint Management Committee, and each Joint Project Team, committee, sub-committee or collaboration team has only the powers expressly assigned to it in this Article 2 (or otherwise under the Global Agreement) and does not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement.

2.9 Transition Planning. Except as contemplated in this Section 2.9 or otherwise in accordance with the terms of the Transition Services Agreement, Novartis and its Affiliates shall not Commercialize or conduct Medical Affairs Activities with respect to the Product in the United States. Notwithstanding anything to the contrary, those definitions and sections which applied to Novartis in the Original Agreement but apply only to Amgen in this Agreement, will be interpreted to apply to Novartis for the purposes of fulfilling Novartis' obligations during the Transition Period hereunder and under the Transition Services Agreement.

2.9.1 During the Transition Period, the Parties shall cooperate generally and use Commercially Reasonable Efforts to transition to Amgen (i) all ongoing Medical Affairs Activities with respect to the Product in the United States and (ii) all Commercialization activities with respect to the Product in the United States, all in accordance with the Transition Services Agreement.

2.9.2 Novartis shall take such actions reasonably requested by Amgen to facilitate such transition, and the Parties shall conduct such transition expeditiously and as reasonably necessary to minimize disruption in the Medical Affairs Activities with respect to and Commercialization of the Product in the United States.

2.9.3 Notwithstanding anything in this Agreement to the contrary, during the Transition Period, Novartis will continue to use Commercially Reasonable Efforts to conduct (i) all Medical Affairs Activities with respect to the Product in the United States assigned to Novartis under the Development Plan as such activities may be modified by the Transition Services Agreement (such Novartis Medical Affairs Activities, the "*Novartis Transitional Medical Affairs Activities*") and (ii) all Commercialization activities with respect to the Product in the United States assigned to Novartis under the Commercialization Plan (as such term was defined in the Original US

Agreement) as such activities may be modified by the Transition Services Agreement (such Novartis Commercialization activities, the "*Novartis Transitional Commercialization Activities*").

2.9.4 The Costs of the Novartis Transitional Commercialization Activities will be included in Program Costs for both Parties during Calendar Year [***], as calculated in accordance with Section 8.6.1.4 and Section 8.6.6(b).

2.9.5 The Costs of the Novartis Transitional Medical Affairs Activities from the Restated Effective Date until [***] shall be considered Medical Affairs Activities Costs under this Agreement.

3. Grant of License

3.1 Amgen Technology.

1.1.1 Amgen hereby grants to Novartis, during the Transition Period, effective as of the Restated Effective Date, a [***] license (i.e., [***]) under the Amgen Technology and Amgen's interest in the Joint Patents to conduct Medical Affairs Activities with respect to and Commercialize the Product in the Field in the United States, in each case to the extent [***]to perform its obligations and exercise its rights in accordance with the terms of this Agreement. Such license shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.1.2 Effective as of the date on which Novartis is entitled to bring and prosecute an action pursuant to Section 9.4.3, and subject to Section 11.6.2, Amgen hereby grants to Novartis and its Affiliates, during the remainder of the Term, a [***] license (i.e., [***]) under the Amgen Technology and Amgen's interest in the Joint Patents.

3.1.3 In the event of any termination of this Agreement by Amgen pursuant to and as set forth in Section 7.4 of the Global Agreement, (a) the licenses granted to Novartis under Sections 4.1 (Licensed Amgen Patents and Know-How) and 4.5 (Grant to Novartis) and under Sections 3.1 (Amgen Technology) and 3.5.2 (Grant to Novartis) of the Original US Agreement (in each case, solely to the extent such intellectual property has been or is incorporated into or used in the Development, Medical Affairs Activities, regulatory activities or Commercialization of the Product as of the date of termination) shall survive and (b) the sections of the Original US Agreement cross-referenced in clause (a) above shall be deemed to survive for purposes of this Section 3.1.3 and shall remain as cross-references to the Original US Agreement and not be deemed cross-references to the this Agreement.

3.2 Novartis Technology. Novartis hereby grants to Amgen, effective as of the Restated Effective Date, (a) a [***], license (i.e., [***]), (b) [***], perpetual license, in each case under the Novartis Technology and Novartis' interest in the Joint Patents to sell, import, conduct Medical Affairs Activities with respect to, and otherwise Commercialize the Product in the Field in the United States and to Manufacture the Product inside or outside of the United States. Such licenses shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.3 Sublicensing. Each Party shall have the right to sublicense the rights granted to it hereunder solely to permitted (pursuant to Section 7.4 (Use of Affiliates and Third Party Contractors)) contractors, agents or other Third Parties performing activities under this

Agreement on behalf of such Party or its Affiliates, subject to the terms and conditions of this Section 3.3 (Sublicensing). Each Party shall have the right to sublicense the rights granted it hereunder (i) as mutually agreed by the Parties; and (ii) unless, notwithstanding the JSC decision-making provisions of the Global Agreement, mutually agreed by the Parties at the JSC, to subcontractors in the ordinary course of business consistent with the United States Brand Plan, provided that [***]. Amgen shall also have the right to sublicense the rights granted to it hereunder to those parties to which Amgen (or its Affiliate or licensee) is also granting licenses to Amgen patents or know-how relating to the Product or the use thereof (other than a global sublicense of all rights to Develop the Product). The Party granting the sublicense hereunder will remain responsible for the full and complete performance of all of such Party's obligations and duties under this Agreement and compliance of any such Third Party and sublicense with the terms of this Agreement. Each Party shall promptly notify the other Party of the grant of each sublicense (other than a sublicense relating to Manufacturing). Any such sublicense agreement shall obligate the sublicensee to comply with all relevant restrictions, limitations and obligations in this Agreement including those relating to confidentiality of the other Party's Confidential Information. Each Party shall provide the other Party a copy of each final executed sublicense agreement (other than a sublicense to a contractor (including for clarity any contract sales organization)), redacted for information not pertinent to this Agreement. Any use by a Party of a Third Party (including contractors) to perform obligations under this Agreement shall be pursuant to a written agreement that is materially as protective of the other Party and its intellectual property and proprietary rights as the terms of this Agreement.

3.4 Trademarks.

3.4.1 *Grant to Amgen*. Novartis hereby grants to Amgen [***], royalty-free license to use the Novartis Housemarks solely as set forth in the Promotional Materials, Non-Promotional Materials, packaging materials and other materials provided to it by Novartis or otherwise approved by the Amgen and Novartis joint Materials Approval Committee prior to the Restated Effective Date (the "*Novartis Branded Materials*"), and solely to sell, import, conduct Medical Affairs Activities with respect to, and otherwise Commercialize the Product in the Field in the United States in a manner consistent with the United States Brand Plan and this Agreement and consistent with the provisions of the Transition Services Agreement for a period not to exceed: (a) with respect to the packaging and labeling of the Product, the date on which all inventory of packaging and labeling materials bearing the Novartis Housemarks (existing as of the Restated Effective Date or produced by Amgen up to [***] following the Restated Effective Date) has been sold; (b) with respect to demonstration kits for the Product, the date on which all inventory of demonstration kits bearing the Novartis Housemarks (existing as of the Restated Effective Date) has been distributed in the normal course of business; (c) with respect to Novartis Branded Materials in an electronic format, [***] days after the Restated Effective Date; and (d) with respect to Novartis Branded Materials in a hard copy (other than those contemplated in clauses (a) and (b), [***] after the Restated Effective Date (clauses (a)-(d) collectively, the "*Housemark Transition Period*"). Such licenses shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.4.2 *Grant to Novartis*. Amgen hereby grants to Novartis, effective as of the Restated Effective Date (without any further action by either Party), [***], royalty-free right and license

during the Transition Period, subject to the terms and conditions hereof, solely to conduct Medical Affairs Activities with respect to and Commercialize the Product in the Field in the United States under Amgen Product Trademarks designated by Amgen for use with the Product solely in connection with the Transitional Medical Affairs Activities and Transitional Commercialization Activities or otherwise as needed in connection with activities under the Transition Services Agreement. Amgen hereby grants to Novartis [***], royalty-free license during the Transition Period to use the Amgen Housemarks solely as set forth in the Promotional Materials, Non-Promotional Materials and other materials provided to it by Amgen, and solely to sell, import, conduct Medical Affairs Activities with respect to and otherwise Commercialize the Product in the Field in the United States solely in connection with the Transitional Medical Affairs Activities and Transitional Commercialization Activities or otherwise as needed in connection with activities under the Transition Services Agreement. Such licenses shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.4.3 *Trademark and Housemark Quality Standards*. Each Party shall (i) maintain such reasonable quality standards for the Trademarks and Housemarks of the other Party as it maintains for its own Trademarks and Housemarks of a similar nature and shall comply with the other Party's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time); (ii) not use any Trademark or Housemark of the other Party in a manner that suggests any connection with any product or service, other than use associated with the Product or any service associated with the Product (including use associated with the Product or service associated with the Product that may also include another product or a product promoted together with the Product); and (iii) not use or display the Trademarks or Housemarks of the other Party in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any Trademark or Housemark of the other Party, the Party that owns such Trademark or Housemark shall provide to the other Party a guideline for use of such Trademark or Housemark, including the review procedure and timing. From time to time, upon request by the Party that owns such Trademark or Housemark, the other Party shall provide copies of the usage of such Trademark or Housemark used in the marketing or promotion of the Product in order to review such usage. Unless otherwise stated hereinafter, each Party agrees that it shall not seek to register or obtain ownership rights in any Novartis Housemark (in the case of Amgen) or any Amgen Product Trademark or any Amgen Housemark (in the case of Novartis) (or confusingly similar trademark) as a Trademark anywhere in the United States.

3.4.4 *Domain Names.* Novartis shall be [***] entitled to register, own and use any Domain Names corresponding to or containing a Novartis Housemark in any generic Top Level Domains (gTLDs), including the new and to be introduced gTLDs, and in any country code Top Level Domains (ccTLDs). Novartis shall own all goodwill associated with all Domain Names corresponding to or containing a Novartis Housemark throughout the world. Amgen shall be exclusively entitled to register, own and use any Domain Names corresponding to a nonproprietary name of the Product or containing an Amgen Product Trademark or Amgen Housemark in any generic Top Level Domains (gTLDs), including the new and to be introduced gTLDs, and in any country code Top Level Domains (ccTLDs). Amgen shall own all goodwill associated with all Domain Names corresponding to or containing a nonproprietary name of the Product or an Amgen Product Trademark or Amgen Housemark throughout the world. Each

Party shall have the option to request to the other Party, which shall give due consideration to such request, an authorization to register, own and/or use any of the Domain Names mentioned hereinabove and containing the nonproprietary name of the Product or other Party's Trademark but excluding the other Party's Housemark.

3.4.5 *Housemarks*. As soon as reasonably practicable in Amgen's normal course of business after the Restated Effective Date but in no event longer than [***] after the Restated Effective Date, the Novartis Housemarks shall be removed from the electronic formats of the Novartis Branded Materials and Amgen will not print any new Promotional Materials that includes the Novartis Housemarks any later than [***] after the Restated Effective Date. After the Housemark Transition Period, Amgen shall have no right to use any Novartis Housemarks; provided, for clarity, (a) Amgen shall have the right to produce inventory of Product packaging and labeling materials bearing the Novartis Housemarks for up to [***] following the Restated Effective Date and (b) to the extent Product packaging and labeling is already in distribution channels at the conclusion of the Housemark Transition Period, Novartis authorizes the continued use of such Novartis Housemarks on or within such Product packaging and labeling in such distribution channels.

3.5 Retained Rights and Limitations. No rights to either Party's Patents, Trademarks, Housemarks or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved. Notwithstanding the licenses granted in this Article 3 (Grant of License), each Party retains rights to perform (itself or through its Affiliates or contractors) its obligations under this Agreement and the Global Agreement.

4. Development, Regulatory and Medical Affairs Activities

4.1 Responsibility for Development. Except as otherwise set forth in this Section 4.1 (Responsibility for Development), from and after the Original Effective Date, responsibility for Development shall be as set forth in the Global Agreement. Amgen will be the "*Development Lead*" for the Product for the United States and shall have primary responsibility for Development activities for the Product in the United States in accordance with the applicable Development Plan and Development Budget, and Novartis shall provide both strategic input and operational support for such activities as agreed in the applicable Development Plan and Development Budget. For clarity, without the prior written consent of Novartis, Amgen shall not undertake any Development activities in the Amgen Territory that would [***] or the US Collaboration.

4.2 Regulatory Matters.

4.2.1 *Regulatory Responsibility, Communications and Filings*. Subject to this Section 4.2.1 (Regulatory Responsibility, Communications and Filings), Amgen shall be the regulatory lead in the United States (the "*Regulatory Lead*") and shall have primary responsibility for regulatory activities relating to the Product in the United States, including preparing, submitting and maintaining all Regulatory Filings in the United States in accordance with the Development Plan, and Novartis shall provide strategic input for such activities therefor as set forth in the Development Plan. Unless [***] is required with respect to such Regulatory Filing or a material communication with a Governmental Authority in the United States with respect to the Product, the Regulatory Lead shall provide the other Party with draft copies of material Regulatory

Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) in the United States prior to submission within a reasonable amount of time and [***] comments of such other Party (but in the event of a disagreement between the Parties with respect to such comments and proposed revisions, such matter shall be escalated to the JSC for review). The Regulatory Lead shall consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all Regulatory Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) it submits in the United States, Governmental Authority review of any such Regulatory Filings, and all Regulatory Approvals that it obtains with respect to the Product in the United States. The Regulatory Lead shall provide to the other Party copies of all final Regulatory Filings it submits in the United States promptly after the submission (but, with respect to Regulatory Filings other than MAAs, MAs and INDs, in no event later than [***] days after submission, and with respect to MAAs, MAs and INDs, within such time period as agreed by the Parties). Notwithstanding the foregoing, Amgen shall have no obligation to share with the non-Regulatory Lead the contents of the CMC Core Dossier. Amgen shall be the regulatory lead in the Amgen Territory and shall have responsibility for regulatory activities relating to the Product in the Amgen Territory, including preparing, submitting and maintaining all Regulatory Filings in the Amgen Territory in accordance with the Development Plan, and Novartis shall provide strategic input for such activities therefor as set forth in the Development Plan; *provided* that the Parties acknowledge and agree that such obligations of Novartis shall not apply (i) with respect to Japan except to the extent included in the Development Plan or (ii) from and after expiration or earlier termination of the Global Agreement.

4.2.2 *Regulatory Meetings.* The Regulatory Lead shall consult with the other Party reasonably in advance of the date of any anticipated meeting with a Governmental Authority in the United States with respect to the Product and shall consider any timely recommendations made by such other Party in preparation for such meeting. Based on the discussions between the Regulatory Lead and the non-Regulatory Lead, the Regulatory Lead shall create an agenda for such meeting and use good faith judgment to assign roles to each of the Regulatory Lead and non-Regulatory Lead, as appropriate based on the expertise of such participants. One or more (up to [***]) representatives of the non-Regulatory Lead [***] scheduled meetings between the Regulatory Lead and the applicable Governmental Authority in the United States with respect to the Product, and shall participate in such meetings consistent with the agenda for the meeting created by the Regulatory Lead and the role(s) assigned to the non-Regulatory Lead by the Regulatory Lead thereunder, in each case to the extent permissible by such Governmental Authority. The Regulatory Lead shall inform the other Party of any unscheduled teleconferences and meetings (other than teleconferences and meetings that are solely administrative in nature) with Governmental Authorities in the United States with respect to the Product reasonably promptly after they occur. Notwithstanding the foregoing, Novartis shall not have any right to attend any portions of meetings between Amgen and the applicable Governmental Authority in the United States with respect to Product manufacturing or CMC information (or any such meetings solely with respect to Product manufacturing or CMC information).

4.2.3 *Ownership of Regulatory Filings and Regulatory Approvals.* Unless the Parties agree otherwise, Amgen or its Affiliate shall own all right, title and interest in and to any and all Regulatory Filings and Regulatory Approvals with respect to the Product in the United States

and all such Regulatory Filings and Regulatory Approvals shall be held in the name of Amgen or its Affiliate, and Novartis shall execute all documents and take all actions as are reasonably requested by Amgen to vest such title in Amgen or its Affiliate, subject to Section 5.5 (Safety Matters) of the Global Agreement, the Safety Agreement and Section 6.3 (Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities).

4.2.4 *Right of Reference*. From and after the Original Effective Date, upon the request of Amgen, Novartis shall provide a sublicensable right of reference to any requested Regulatory Filings or Regulatory Approvals for the Product (*provided* that Novartis shall not grant a right of reference to Novartis [***] Data and any Regulatory Filings or Regulatory Approvals specific to Novartis [***] Data), as [***] for Amgen's (i) Manufacture within or outside the United States, or (ii) conduct of regulatory activities and Medical Affairs Activities with respect to, or Commercialization of, the Product in the Field in the United States as permitted hereunder.

4.2.5 *Material Safety Issue*. In the event that either Party believes in good faith that there is a Material Safety Issue with respect to the Product in the United States, and the other Party disagrees with such belief, either Party may request that the issue be discussed at the JSC for resolution. If the JSC cannot resolve such matter within [***] Business Days following referral to the JSC, notwithstanding Section 3.5 (Decision Making) of the Global Agreement, the Co-Chair (as defined in the Global Agreement) of either Party at the JSC may cause such matter to be referred to the Alliance Managers for escalation to the JMC (as defined in the Global Agreement) for resolution. If the JMC cannot resolve such matter within [***] Business Days following referral to the JMC, notwithstanding anything to the contrary set forth herein or in the Global Agreement, the Co-Chair (as defined in the Global Agreement) of Amgen at the JMC shall have the deciding vote with respect to such matter. Notwithstanding the foregoing, [***] in the event that [***] a Material Safety Issue with respect to the Product in the United States.

4.3 Safety Agreement. The operating procedures respecting adverse event reporting and safety information exchange with respect to the Product set forth in the Safety Agreement shall apply.

4.4 Cooperation Generally. From and after the Original Effective Date, subject to the oversight of the JSC, the Parties shall provide each other with any cooperation reasonably requested by the other with respect to the Regulatory Approval for the Product in the United States.

4.5 Medical Affairs Activities. Subject to the oversight of the JSC and the performance of the Parties under the Transition Services Agreement, Amgen shall be solely responsible for determining (including, for clarity, determining the number of Medical Liaisons performing, subject to Section 8.6.1.3) and providing all Medical Affairs Activities relating to the Product in the Field in the United States. Except as expressly set forth herein or in the Global Agreement, Amgen shall be solely responsible for the conduct of Medical Affairs Activities with respect to the Product in the Amgen Territory and Novartis shall have no rights with respect thereto.

5. Commercialization

5.1 Responsibility for Commercialization. Consistent with this Section 5.1 (Responsibility for Commercialization), Amgen will solely (i) develop objectives and strategy

for Commercialization in accordance with applicable Laws and regulations and (ii) oversee Commercialization activities with respect to all indications for the Product in the Field in the United States. On and after the Restated Effective Date, and subject to the performance of the Parties under the Transition Services Agreement, Amgen shall have sole responsibility for the Commercialization of the Product in the Field in the United States including conducting all Detailing, in a manner consistent with the United States Brand Plan. Such Commercialization shall be conducted in accordance with the then-current United States Brand Plan. Subject to the foregoing, Amgen's responsibilities on and after the Restated Effective Date with respect to the Product shall include: (i) determination of commercial strategies (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch and post-launch marketing and promotion, market access and field sales force optimization); (ii) determination of packaging and labeling; (iii) creation of promotional materials regarding the Product which are intended for distribution to Third Parties (including medical professionals) and to Amgen's sales force (subject to Section 3.4.3 (Trademark and Housemark Quality Standards) and Section 5.2 (Materials)); and (iv) determining and conducting promotion activities. Amgen shall book sales (*i.e.*, recognizing all revenue) and conduct all sales and distribution activities, including pricing, taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables, call reporting, government price reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Amgen shall have authority to [***], and shall [***].

5.2 Materials. Amgen solely owns all right, title and interest in and to any and all Promotional Materials, Non-Promotional Materials and training materials for the Product in the United States (except with respect to any Novartis Housemarks included in any Promotional Materials, Non-Promotional Materials and training materials). All Promotional Materials, Non-Promotional Materials and training materials shall comply with applicable Law, FDA requirements and any CIA.

5.3 Training. The training of Amgen's sales forces and other customer facing personnel for Commercialization of the Product in the United States shall be conducted using only training materials and programs approved by Amgen. Amgen shall train its respective sales representatives and other customer facing personnel with respect to the promotion of the Product in the United States (and update such training from time to time as appropriate) which training will include healthcare compliance training as appropriate.

5.4 Information Concerning the Product. Neither Party will make any claim or representation in the United States that does not represent an accurate summary or explanation of the labeling of the Product.

5.5 Commercialization in the Amgen Territory. Except as expressly set forth herein or in the Global Agreement, Amgen shall be solely responsible for the Commercialization of the Product in the Amgen Territory and Novartis shall have no rights with respect thereto.

5.6 Detailing Reports and Audit Rights.

5.6.1 *Reporting*. Within [***] calendar days after the end of each [***], Amgen will provide Novartis with a report setting forth the following information during the prior [***]:

(i) the total number of Details made by Amgen's sales force in the United States, including a breakdown by First Position Details, Second Position Details and Third Position Details by target, and frequency of Detail by date and by individual representative; and (ii) such other information as may be agreed upon by the Parties. Notwithstanding the foregoing, in the event that any Detail(s) conducted by Amgen in a given [***] were not included in Amgen's report for such [***], Amgen shall [***] and the costs for such Detail(s) shall be [***]. Notwithstanding the foregoing, the Parties may, by mutual written agreement, modify the timing, frequency or required content of the reports contemplated by this Section 5.6.1 (Reporting).

5.6.2 *Audits*. Each Party will keep complete and accurate records of its Detailing of the Product in the United States in sufficient detail to permit the other Party to audit its performance of Details hereunder. During regular business hours, with not less than [***] Business Days' advance written notice and under reasonable obligations of confidentiality which are in any event no less stringent than those confidentiality obligations set forth in Article 10 (Confidentiality), a Party will permit an independent, internationally recognized certified public accounting firm, selected by the other Party to: (i) have access to the records of Detailing activities in the United States maintained by such Party for purposes of verifying the accuracy of reports described in Section 5.6.1 (Reporting); and (ii) audit such records; *provided* that such audits may not be performed on behalf of 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 [***] 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 5.6.2 (Audits) will be performed at the sole and exclusive expense of the auditing Party and will not be included in Commercialization Costs; *provided* that if an audit reveals an overstatement of Details in the United States 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.

6. Manufacture and Supply

6.1 Responsibility for Manufacturing. Except as otherwise set forth in this Section 6.1 (Responsibility for Manufacturing), Amgen will be the "*Manufacturing Lead*" for the Product for the United States and shall have sole responsibility for the supply and Manufacturing of the Product for the United States. If the Manufacturing Lead elects to cease Manufacturing the Product for the United States, the Manufacturing Lead shall select a Third Party commercial manufacturer to Manufacture the Product for the United States, [***]; *provided*, *however*, that [***].

6.2 Distribution. Amgen shall be solely responsible for distribution of the Product in the United States.

6.3 Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities. The Manufacturing Lead shall have sole responsibility for preparing the draft of the [***] Marketing Application Core Dossier for the United States (the "*CMC Core Dossier*"). As between the Parties, the Manufacturing Lead shall have responsibility for the assessment by Governmental Authorities of change control records of post-approval changes with respect to the Product. Solely the Manufacturing Lead shall have the right to participate in inspections by a Governmental Authority of any facility where the Product is Manufactured for

the United States, whether prior to or after Regulatory Approval of the Product in the United States.

6.4 Supply [***]. If at any point during the Term after First Commercial Sale of the Product in the United States, Amgen [***] [***] (a "*Supply [***]*"), [***] a Supply [***] purposes of this Section 6.4 (Supply [***]) [***] then Amgen shall provide Novartis written notice thereof within [***] of the occurrence of such Supply Shortfall. Amgen shall also provide Novartis prompt written notice [***] percent ([***]%) [***] ("*[***]*"). Amgen's notice [***] shall include [***]. If a Supply [***] Novartis shall [***].

7. Diligence

7.1 Commercially Reasonable Efforts. On and after the Restated Effective Date, Amgen shall use Commercially Reasonable Efforts to (i) conduct Medical Affairs Activities for the Product in the Field in the United States as contemplated by this Agreement; (ii) Manufacture the Product for the United States; and (iii) Commercialize the Product in the Field in the United States; *provided* that Amgen agrees that such Commercialization activities shall be consistent with the United States Brand Plan and the Global Brand Plan.

7.2 Proper Conduct Practices Standards. Each Party will conduct, and ensure that each of its Affiliates conducts, all of its and their activities with respect to the Manufacture, Medical Affairs Activities and Commercialization of the Product for the United States in accordance with this Agreement, accepted national and international pharmaceutical industry codes of practices in and for the United States, and applicable Law. The non-Regulatory Lead will provide the Regulatory Lead with all reasonably requested cooperation to enable the Regulatory Lead to comply with its legal and compliance obligations to Governmental Authorities with respect to the Product. Notwithstanding anything to the contrary contained herein, neither Party hereto (nor its Affiliates) shall be required to perform any obligation hereunder to the extent that (i) such Party reasonably believes that the performance of such obligation would be prohibited by, or would otherwise not comply with, applicable Law or any CIA, (ii) such Party reasonably believes that there is a Material Safety Issue with respect to the performance of such obligation, or (iii) such Party reasonably believes it would infringe an issued Patent of a Third Party in the applicable jurisdiction(s) for which no exemption is available and no license has been obtained; *provided, however*, that the provisions of this Section 7.2 (Proper Conduct Practices Standards) shall not limit a Party's payment obligations under this Agreement.

7.3 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 agreed to by the Parties with respect thereto, subject to applicable Law relating to employment or privacy matters. The Party employing any personnel that violates applicable Law or applicable national or international pharmaceutical industry codes of practices shall cause such personnel to cease to perform activities under this Agreement.

7.4 Use of Affiliates and Third Party Contractors.

7.4.1 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, notwithstanding the JSC decision-making provisions of the Global Agreement, subject to the mutual agreement of the Parties at the JSC; *provided* that, (i) Amgen shall have the right to perform its activities hereunder through subcontractors in the ordinary course of business in a manner consistent with the United States Brand Plan, (ii) in the event that any Third Parties are performing Commercialization activities with respect to the Product in the United States on behalf of Amgen or Novartis immediately prior to the Restated Effective Date, Amgen shall have the right to continue to perform such activities through such Third Parties, and (iii) Amgen shall have the right to use contract sales organizations (or other similar contractors) [***]. 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.

7.4.2 Except as expressly contemplated in Section 7.4.1, [***]

8. Payment

8.1 Upfront Payment. As partial consideration for the rights granted to Novartis hereunder, pursuant to the Original US Agreement, Novartis paid Amgen, as full satisfaction of the payment provided for in this Section 8.1, a one-time [***] upfront payment of [***] within [***] following acceptance by the FDA of the first BLA for the Product submitted by or on behalf of Amgen.

8.2 Milestone Payments. As partial consideration for the rights granted to Novartis hereunder:

1.1.1 Pursuant to the Original US Agreement, Novartis paid Amgen, as full satisfaction of the payment provided for in this Section 8.2.1, a one-time [***] payment of [***] within [***] following First Commercial Sale of the Product in the United States.

8.2.2 Pursuant to the Original US Agreement, Novartis paid Amgen, as full satisfaction of the payment provided for in this Section 8.2.2, a one-time [***] payment of [***] within [***] days following the date that cumulative gross invoiced sales of the Product in the United States (for clarity, regardless of the Calendar Year in which such sales occur) equaled or exceeded [***].

8.2.3 Novartis shall pay to Amgen a one-time non-creditable, non-refundable payment of [***] (the "*Sales Milestone*") within [***] days following the later of (i) the date that the aggregate of all Net Sales of the Product in the United States in a given Calendar Year equals or exceeds [***] (the "*Sales Milestone Threshold*") and (ii) the date [***]

8.2.4 Notwithstanding the foregoing, [***]

[***] For clarity, the Sales Milestone payments set forth under Section 8.2.3 and 8.2.4 8.2.4are alternative milestones and not cumulative milestones, only one of which, but not both, shall be paid by Novartis, meaning the total maximum Sales Milestone payment payable under Sections 8.2.3 and 8.2.4 is [***].

8.3 Royalty Payments and Royalty Reduction for Biosimilar Competition.

8.3.1 *Royalty Payments*. As partial consideration for the rights granted to Amgen hereunder, subject to Section 8.3.2 (Royalty Reduction for Biosimilar Competition), Amgen shall pay Novartis a royalty on annual Net Sales of the Product in the United States for each Calendar Year (or portion thereof) during the Term at a rate of [***].

8.3.2 *Royalty Reduction for Biosimilar Competition*. Notwithstanding the foregoing, if, following the date of First Commercial Sale of a Biosimilar Product in the United States (the "*US Biosimilar Entry Date*"), aggregate Net Sales of the Product in the United States in any [***] consecutive Calendar Quarter period are less than Net Sales of the Product in the United States in the [***] month period immediately preceding the US Biosimilar Entry Date, the applicable royalty rate set forth in Section 8.3.1 (Royalty Payments) shall be reduced by [***] for every [***] percent ([***]%) reduction of aggregate Net Sales of the Product in the United States in any [***] consecutive Calendar Quarter period after the US Biosimilar Entry Date; *provided* the applicable royalty rate set forth in Section 8.3.1 (Royalty Payments) shall in no event be reduced by more than [***] in the aggregate (*i.e.*, the royalty rate on annual Net Sales of the Product in the United States will in no case be less than [***] percent ([***]%)). The reduced royalty rate, if any, shall apply to Net Sales of the Product in the United States commencing on the first day of the Calendar Quarter following the last Calendar Quarter in the [***] consecutive Calendar Quarter period that triggers the reduction in the royalty rate. For clarity, and by way of example only, [***] percent ([***]%) [***]

8.4 Reports.

8.4.1 Beginning with the Calendar Quarter in which the First Commercial Sale of the Product in the United States occurs and thereafter for each Calendar Quarter until the expiration of the Term, reports of the sale of the Product for each Calendar Quarter will be delivered by Amgen to Novartis under this Agreement within [***] days after the end of each such Calendar Quarter. Such report shall state: (i) Net Sales of the Product in the United States by or on behalf of Amgen, its Affiliates or sublicensees during the applicable Calendar Quarter; and (ii) a calculation of the royalty payment due from Amgen hereunder for such Calendar Quarter. In the event of Combination Product(s), the aforementioned report shall include a reasonably detailed calculation of how Net Sales were calculated in relation to such Combination Product(s).

8.4.2 Based on the reports received by Novartis from Amgen pursuant to Section 8.4.1 and without prejudice to Section 8.9 (Audits), Novartis shall issue an invoice to Amgen for the amount of the royalty payments indicated in the Calendar Quarter report. Following receipt of such invoice, to the extent that Amgen does not dispute, in good faith, the amount set forth on such invoice, Amgen shall pay the amount of the royalty payments indicated on such invoice within [***] to an account designated by Novartis.

8.4.3 Any reports which contain currency conversions shall provide the details and background information used to calculate such conversions. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, such Net Sales invoiced or expenses incurred shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by the Party recording Net Sales (or an Affiliate) uses for purposes

of calculating its financial reports. Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.

8.5 No Wrongful Reductions. Amgen shall not attempt to reduce compensation rightly due to Novartis hereunder by shifting compensation otherwise payable to Amgen from a Third Party with respect to the Product to another product or service for which no royalties are payable by it hereunder.

8.6 Cost Allocation.

8.6.1 *Allocation of Recoveries, Development Costs and Program Costs*. Each Party shall account for Program Costs and Development Costs in accordance with its Accounting Standards.

8.6.1.1 Each Party shall be entitled to share in fifty percent (50%) of Recoveries;

8.6.1.2 Each Party shall pay fifty percent (50%) of Program Costs other than (1) Commercialization Costs, (2) Amgen Headquarter Marketing FTE Costs, and (3) Novartis Headquarter Marketing FTE Costs; *provided* that in any given Calendar Year, [***]. For clarity, [***] (i) [***] and (ii) [***] percent ([***]%) [***] percent ([***]%) [***];

8.6.1.3 Novartis shall pay [***] ([***]%) of Development Costs (including Medical Affairs Activities Costs) until such time as such Development Costs (including Medical Affairs Activities Costs) not otherwise payable by Novartis under the Global Agreement with respect to the Product equal [***] [***] in the aggregate, after which time each Party shall pay fifty percent (50%) of all Development Costs (including Medical Affairs Activities Costs) in excess of those Development Costs (including Medical Affairs Activities Costs) otherwise payable by Novartis with respect to the Product under the Global Agreement, *provided* that Novartis shall have no obligation to fund Development Costs (a) solely relating to Development of the Product for Regulatory Approval in Japan to the extent such costs are not included in the Development Budget as of the Original Effective Date or (b) [***]. For clarity, (1) [***] and (2) following such payment by Novartis of such [***] in Development Costs (including Medical Affairs Activities Costs) with respect to the Product, subject to [***], Novartis will effectively pay [***] of all Development Costs (including Medical Affairs Activities Costs) for the Product, which includes (i) [***] percent ([***]%) of all Development Costs (including Medical Affairs Activities Costs) (pursuant to Section 9.7.1 (Development Cost Sharing) of the Global Agreement) for the Product and (ii) [***] percent ([***]%) of all Development Costs (including Medical Affairs Activities Costs) in excess of those Development Costs otherwise payable by Novartis with respect to the Product under the Global Agreement.

8.6.1.4 For Calendar Year 2021, each Party shall pay [***] percent ([***]%) of the Commercialization Costs, Amgen Headquarter Marketing FTE Costs, and Novartis Headquarter Marketing FTE Costs; provided:

(a) Novartis Headquarter Marketing FTE Costs will not exceed [***] in total for Calendar Year 2021;

(b) the Amgen Headquarter Marketing FTE Costs will not exceed [***] in total for Calendar Year 2021;

(c) Novartis' OSE Costs will not exceed [***] in total for Calendar Year 2021, other than OSE Costs incurred by Novartis during the Transition Period pursuant to the Transition Services Agreement, to the extent the incurrence of such costs causes Novartis' OSE Costs for Calendar Year 2021 [***]; and

(d) The sum of Novartis' OSE Costs and Amgen's OSE Costs will not exceed [***] in total for Calendar Year 2021.

8.6.1.5 For Calendar Year 2022 and for each Calendar Year thereafter, Novartis shall reimburse Amgen for [***] percent ([***]%) of:

(a) the lesser of (i) [***] for such Calendar Year or (ii) [***]; provided, Novartis' reimbursement obligation with respect to [***] are limited to the [***] and Amgen shall pay [***] percent ([***]%) of the [***] in excess of the [***] in any such Calendar Year; and

(b) the lesser of (i) the Commercialization Costs for such Calendar Year or (ii) the sum of (1) the [***] for such Calendar Year and (2) the [***], if any, for such Calendar Year (such sum, the "*Commercial Costs Limit*"); *provided*, Amgen shall pay [***] percent ([***]%) of (and Novartis will [***]) the Commercialization Costs in excess of the Commercial Costs Limit in any such Calendar Year. For clarity, the [***].

8.6.2 *Cap Calculation.*

8.6.2.1 *Baseline Cap.* By [***], Amgen shall provide written notice to Novartis of a good faith, non-binding estimate of the number of sales representatives anticipated for the [***]. Upon the earlier of (i) [***] and (ii) the [***], the "*Baseline Cap*" shall be calculated as the sum of (1) the [***] and (2) the [***]. The Baseline Cap will reflect the baseline upon which the [***] for each of Calendar Years [***] through [***] will initially be calculated (until a new Cap calculation is required as a result of a Biennial Cap Adjustment) and from which the Cap Discount Factor will be derived.

8.6.2.2 *Cap Discount Factor*. The "*Cap Discount Factor*" means the annual weighted average of (1) a [***] percent ([***]%) annual decrease applied to the [***] and (2) a [***] percent ([***]%) annual increase applied to the [***]. The Cap Discount Factor will be calculated one time only at the time the Baseline Cap is established and, except as contemplated in Section 8.6.2.3 with respect to the Biennial Cap Adjustment resulting in an Adjusted Cap, will not be subject to re-calculation in later years during the Term. [***].

8.6.2.3 *Biennial Cap Adjustment*. Effective as of [***] of each of Calendar Years [***], the Cap for such Calendar Year shall be [***] as follows based on the [***] by measuring the [***] (each a "*Biennial Cap Adjustment*").

(a) For every [***], the Cap Discount Factor applied to the Cap of the prior Calendar Year (and for clarity, that Calendar Year only) will be [***].

(b) For every [***], the Cap Discount Factor applied to the Cap of the prior Calendar Year (and for clarity, that Calendar Year only) will be [***].

(c) If the [***], then the Cap for the then-current Calendar Year will remain unchanged.

(d) For clarity, the Cap Discount Factor resulting from the Biennial Cap Adjustment will be increased or decreased by fractional percentages rounded to the nearest hundredth of a percent.

(e) The Cap for the then-current Calendar Year resulting from the application of the modified Cap Discount Factor to the Cap of the prior Calendar Year shall be known as the "*Adjusted Cap*".

(f) Upon any Biennial Cap Adjustment, the Adjusted Cap will thereafter be the basis upon which the [***] is applied in the calculation of the Caps for the subsequent Calendar Years until [***].

After each Biennial Cap Adjustment, the illustrative Cap Schedule shall be updated for each remaining Calendar Year until [***] to reflect any modifications as a result of the Adjusted Cap. The Parties will discuss and share the Cap Schedule every [***] Calendar Years as updated in accordance with this Agreement.

8.6.2.4 *Caps for Calendar Years [***] and beyond during the Term*. Prior to [***], the Parties shall negotiate in good faith the Caps for Calendar Years [***] and beyond. If the Parties cannot agree on Caps for Calendar Years [***] and beyond during the Term, the Cap Discount Factor and Biennial Cap Adjustment shall continue to apply for such Calendar Years and the Parties shall update the Cap Schedule in accordance with such Cap Discount Factor and Biennial Cap Adjustment for such Calendar Years.

8.6.2.5 *Amgen's Discretion within the Cap*.

(a) For clarity, during the course of each Calendar Year, Amgen may, in its sole discretion (but subject to acting consistently with the US Brand Plan) (i) allocate the [***] amongst the [***], provided that the overall

Cap for such Calendar Year will continue to apply and (ii) [***], but doing so will in no event increase the Cap.

(b) During the Term, Amgen shall use reasonable efforts to communicate to Novartis if Amgen [***] that the Commercialization Costs in a Calendar Year will be less than [***] of the applicable Cap to assist Novartis with its internal budgeting and planning; provided, for clarity any such communication by Amgen would not trigger a recalculation of the Cap or modify Novartis' cost sharing obligations under Section 8.6.1.5 or otherwise under this Agreement.

8.6.2.6 In the event the economic outlook for the Product in the United States [***], the Parties will discuss in [***] revisions to the Cap in present and future affected Calendar Years to enable appropriate Commercialization activities with the intent to optimize brand performance in light of such changed economic outlook for the Product.

8.6.3 *Payment of Costs*. Subject to reconciliation as provided in Section 8.6.5 (Payments), the Party initially incurring Development Costs and Program Costs shall be responsible for and pay for all such Development Costs and Program Costs so incurred. Each Party shall maintain the books and records referred to in Section 8.9 (Audits) and shall accrue all Development Costs and Program Costs in accordance with the terms and conditions hereof and in accordance with its Accounting Standards.

8.6.4 *Reports.* Without limitation of Section 5.6 (Detailing Reports and Audit Rights), within [***] after the end of each Calendar Quarter, each Party shall provide the other Party with a report specifying in reasonable detail Program Costs (broken down by category as set forth in the definition of Program Costs) incurred by such Party in such Calendar Quarter, as well as any other Costs for which such Party is entitled to reimbursement hereunder; *provided* that in the event that Sales Force Costs for any Detail(s) conducted by Amgen in a given Calendar Quarter [***], Amgen shall [***] such Sales Force Costs, and such Sales Force Costs shall [***]. Such Program Costs shall be attributed by Amgen to the Calendar Quarter in which they are expensed. For clarity, the reporting obligations of the Parties with respect to Development Costs shall be governed by Section 9.7.3 (Reports) of the Global Agreement.

8.6.5 *Payments.* Within [***] after the end of each Calendar Quarter, Amgen will prepare a reconciliation report setting forth the total amounts of Program Costs incurred by each Party in such Calendar Quarter based on the reports submitted by the Parties pursuant to Section 8.6.4 (Reports), the allocation of the total amounts of each category of costs within Program Costs between the Parties in accordance with Section 8.6.1 (Allocation of Recoveries, Development Costs and Program Costs), and the calculation of the amount payable by the applicable Party to the other Party in order to achieve such allocation. Based on such reconciliation report, the Party to whom a payment is owed in order to achieve such allocations shall issue an invoice to the other Party for the appropriate amount in accordance with Section 8.8 (Payment Method) and the owing Party shall make the applicable payment within [***] after receiving such invoice. For clarity, reconciliation payments with respect to Development Costs shall be governed by Section 9.7.4 (Payments) of the Global Agreement.

8.6.6 *Calculation of Sales Force Costs*. Sales Force Costs will be calculated as follows:

(a) For each Party with respect to Commercialization activities in the United States prior to the Restated Effective Date, in accordance with the provisions of the Original US Agreement;

(b) (i) for Novartis with respect to the Novartis Transitional Commercialization Activities and (ii) for Amgen in the United States [***], in each case for a given period of time, Sales Force Costs will be determined by including in Commercialization Costs the product of (A) the [***] of such Party supporting the Product in the United States multiplied by (B) the [***] prorated for such period of time and utilizing a First Position Detail Equivalent Basis; provided, however, (1) the Sales Force Costs attributable to Novartis with respect to the Novartis Transitional Commercialization Activities will not exceed [***] and (2) the Sales Force Costs attributable to Amgen in the United States [***] will not exceed [***].

(c) For Amgen in the United States during Calendar Year [***], for a given Calendar Quarter, will be determined by including in Commercialization Costs the Sales Force Costs of Details (as illustrated in [***]) performed by Amgen or any of its Affiliates or contractors in the United States utilizing a First Position Detail Equivalent Basis as follows: (i) [***]percent ([***]%) if such sales representative Details the Product as a First Position Detail as set forth in the United States Brand Plan and details no other products; (ii) [***] percent ([***]%) if such sales representative Details the Product as the First Position Detail as set forth in the United States Brand Plan and details only one (1) other product; (iii) [***] percent ([***]%) if such sales representative Details the Product as a First Position Detail as set forth in the United States Brand Plan and details only [***] other products; (iv) [***] percent ([***]%) if such sales representative Details the Product as a Second Position Detail and details only [***] other product(s); and (v) [***] percent ([***]%) if such sales representative Details the Product as a Third Position Detail [***] ((i) through (v), as applicable, the "*First Position Detail Equivalent Basis*"). Notwithstanding the foregoing, in case that, notwithstanding the JSC decision-making provisions of the Global Agreement, the Parties mutually agree at the JSC ([***]) that the Detailing under this Agreement, for any given Calendar Quarter, shall be or has been significantly impacted such that Amgen's call plan consistent with the United States Brand Plan will not be achieved due to causes beyond Amgen's reasonable control, which shall include but not be limited to

pandemics and other outbreak of illness or public health events, (A) the product of the [***] supporting the Product on behalf of Amgen in the United States multiplied by the [***] prorated for such Calendar Quarter shall be deemed the applicable Sales Force Costs for Amgen for inclusion into the Commercialization Costs or (B) the determination of Amgen's applicable Sales Force Costs shall be handled as may otherwise be agreed upon by the Parties in writing.

For clarity, with respect to any period for which Amgen is determining its Sales Force Costs on an "FTE-basis" (e.g., as contemplated in clause (b)), Amgen shall [***] as described in this Section 8.6.6. Amgen represents and warrants to Novartis that [***] and Amgen shall use commercially reasonable efforts to onboard and train Sales Force FTEs within such period so that such Sales Force FTEs may commence Detailing the Product at the end of such [***] period.

8.7 Sublicense Payments. Each Party shall be responsible for any Third Party license fees, milestones, royalties or other payments owed with respect to the Product or uses or methods of Manufacture thereof (or of its components), on intellectual property that is licensed by such Party prior to or as of the Original Effective Date. For the avoidance of doubt, such sublicense payments shall not be included in any calculation of Development Costs.

8.8 Payment Method. All amounts in this Agreement are expressed in U.S. Dollars. All payments made hereunder between the Parties shall be made in U.S. Dollars except as set forth in Section 8.10 (Blocked Currency). Any sales incurred in a currency other than U.S. Dollars shall be converted to the U.S. Dollar equivalent using the applicable Party's then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into U.S. Dollars. Each Party shall pay all sums due hereunder, on invoice, by check, wire transfer, or electronic funds transfer (EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.12 (Withholding) and Section 8.13 (VAT)).

8.9 Audits. Each Party shall keep complete and accurate records showing (i) the expenses incurred by it in performing its Commercialization activities, (ii) its Program Costs, (iii) Net Sales of the Product in the United States and the calculation of royalty payments due and (iv) calculation of the License Payments, during the three (3) preceding Calendar Years, which books and records shall be in sufficient detail to confirm the accuracy of all payments due hereunder. Such records of each Party shall be open (in such form as may be available or reasonably requested by an internationally recognized certified public accounting firm in accordance with this Section 8.9 (Audits)) to inspection for three (3) years following the end of the period to which they pertain. Each Party shall have the right, at its own expense, to have an

independent, internationally recognized certified public accounting firm, selected by it review the records of the other Party upon reasonable notice and during regular business hours, with not less than ten (10) Business Days' advance written notice and under reasonable obligations of confidentiality which are in any event no less stringent than those confidentiality obligations set forth in Article 10 (Confidentiality). The report of such accounting firm shall be made available to both Parties simultaneously, promptly upon its completion; *provided*, *however*, that the Party being audited shall have the right to review and comment on the final draft version of the report prior to it being finalized. Such review and comment period shall extend for four (4) weeks after the audited Party's receipt of such draft report. Each Party's audit rights with respect to any Calendar Year shall expire three (3) years after the end of such year and the books and records for any particular Calendar Year shall only be subject to one (1) audit. Should the inspection lead to the discovery of a discrepancy to the auditing Party's detriment, then the other Party shall pay to the auditing Party the amount of the discrepancy. Should the inspection lead to the discovery of a discrepancy to the detriment of the Party being audited, then the auditing Party shall pay to the Party being audited the amount of the discrepancy. The auditing Party shall pay the full cost of the inspection unless the discrepancy is to the detriment of the auditing Party and is greater than [***] percent ([***]%) of the amount actually paid for the audited period, in which case the Party being audited shall pay the cost of such inspection. For clarity, the audit rights of the Parties with respect to Development Costs shall be governed by Section 9.11 (Audits) of the Global Agreement.

8.10 Blocked Currency. If at any time legal restrictions prevent the prompt remittance of any payments with respect to sales therein, the Party making payment shall 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 designated by such other Party.

8.11 Taxes. All Taxes levied on account of a payment pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 8.12 (Withholding). Except as otherwise provided, each Party will be responsible for its own taxes, fees, duties or similar amounts levied on account of any payments made to it under this Agreement.

8.12 Withholding. In the event that Law requires either Party to pay or withhold Taxes with respect to any payment to be made by such Party pursuant to this Agreement, such Party shall notify the other Party in writing of such payment or withholding requirements prior to making the payment and provide such assistance to the other Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary to claim an exemption from or reduction of such Taxes. The Party making payment will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes within fifteen (15) Business Days following obtaining the relevant payment certificate. If Taxes are paid to a tax authority, each Party shall provide such assistance to the other Party as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. Further, the Parties agree that no gross up mechanism or similar type adjustment will apply to such net payment. Notwithstanding the foregoing, in the event that a Party unilaterally restructures the payment of any monies payable to the other Party under this Agreement such that such first Party or any of its Affiliates makes the payment of such monies payable to the other Party under this

Agreement and solely as a result of such unilateral restructuring said amount is subject to withholding and further, such other Party is not able to recover or credit all or part of such withheld amount(s), such first Party agrees to compensate the other Party without interest for the corresponding economic impact of such non-recoverable or non-creditable amount. Such compensation must be made within a reasonable timeframe, upon request of such other Party. For the avoidance of doubt, the preceding sentence shall apply only in respect of a unilateral restructuring of payments by such first Party and shall not apply (x) in the event of a change in applicable Law or circumstance, (y) as the result of such other Party's inability to recover or credit such withholding on a current or future basis due to such other Party's taxable income (loss) position or other tax attributes in a given year, or (z) for any other reason beyond the exclusive control of such first Party.

8.13 VAT. All payments due pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable upon receipt of a valid VAT invoice).

8.14 Late Payment. Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate calculated on the number of days such payment is delinquent. This Section 8.14 (Late Payment) shall in no way limit any other remedies available to either Party.

8.15 Appropriate Measure of Value. Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including intellectual property of various types, access to Development and Commercialization expertise, clinical data and other financial and non-financial consideration and that the royalty payments set forth in Section 8.3 (Royalty Payments) are intended to capture such value as an aggregate. Therefore, the increase, decrease or lapse of any particular items or rights shall not affect the amount of such royalty, and the Parties agree that both the amount and duration of the royalty payments set forth in this Article 8 (Payment) are reasonable.

9. Intellectual Property

9.1 Ownership and Cooperation.

9.1.1 *Ownership of Technology*. Except to the extent expressly specified to the contrary in this Agreement: (i) each Party shall retain and own all right, title and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party; (ii) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created jointly by the Parties pursuant to the US Collaboration and, subject to the provisions of this Agreement and the Global Agreement, neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit, license or assign such intellectual property rights; and (iii) inventorship and authorship of any invention, or work of authorship conceived or created by either Party or jointly by the Parties pursuant to the US Collaboration, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the U.S. (without reference to any conflict of law principles). Notwithstanding the foregoing, any Copyrights pertaining to Promotional Materials, Non-Promotional Materials or training materials for the Product in the United States shall be owned solely by the Amgen.

9.1.2 *Notification.* Each Party shall promptly notify the other upon becoming aware (i) of any actual, suspected or threatened material infringement of any Amgen Technology, Novartis Technology, Amgen Product Trademarks or Joint Patents; (ii) of any claim that either Party's exercise of the rights granted under any Amgen Technology, Novartis Technology, Amgen Product Trademarks or Joint Patents infringes any rights or patents of a Third Party; (iii) of any claims of alleged patent or trademark infringement by Amgen or Novartis with respect to the Manufacture, use, sale, offer for sale or importation of Product; (iv) of any threatened, suspected or actual material misappropriation of Amgen Know-How or Novartis Know-How; and/or (v) of any actual, suspected or threatened material infringement or dilution of the Amgen Product Trademarks Amgen Housemarks as used with the Product or Novartis Housemarks as used with the Product, all of the foregoing, (i) through (v), anywhere in the world.

9.2 Prosecution and Maintenance.

9.2.1 *Amgen Primary Prosecution.* Amgen shall control, itself or through outside counsel reasonably acceptable to Novartis and directed by Amgen, Patent and Trademark Matters with respect to Amgen Patents, Amgen Product Trademarks and Joint Patents (in the case of Joint Patents, the prosecution will be in the name of both Parties), in each case solely in the United States (collectively, the "*United States Patents and Trademarks*"), as well as preparation and filing for any patent term extensions or similar protections therefor. From and after the Original Effective Date, with respect to United States Patents and Trademarks specific to the Product, (i) Amgen shall provide Novartis with copies of and an opportunity to review and comment upon the text of the applications relating to such United States Patents and Trademarks as soon as practicable (but in no event less than [***] for new patent application filings and [***] for all other filings or correspondence before submission thereof) before filing, (ii) Amgen shall provide Novartis with a copy of each submission made to and document received from a patent or trademark authority, court or other tribunal regarding any such United States Patents and Trademarks reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within such United States Patents and Trademarks as filed together with notice of its filing date and application number, (iii) Amgen shall keep Novartis advised of the status of all material communications, actual and prospective filings or submissions regarding such United States Patents and Trademarks, and shall give Novartis copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent or trademark authority or judicial body, and (iv) Amgen shall reasonably consider in good faith Novartis' comments on the communications, filings and submissions for such United States Patents and Trademarks. Amgen shall not abandon or fail to (a) maintain any patent, trademark or application within such United States Patents and Trademarks or (b) defend against any post-grant challenges, including without limitation inter-partes reviews or post-grant reviews filed with respect to any patent, trademark or application within such United States Patents and Trademarks, in each case, without the prior written consent of Novartis and Novartis shall respond to Amgen's request for a consent within [***] of receipt of such request.

9.2.2 *Novartis Primary Prosecution.* Novartis shall control, itself or through outside counsel reasonably acceptable to Amgen and directed by Novartis, Patent and Trademark Matters with respect to Novartis Patents solely in the United States (collectively, the "*United*

States Novartis Patents"), as well as preparation and filing for any patent term extensions or similar protections therefor. From and after the Original Effective Date, with respect to United States Novartis Patents specific to the Product, (i) Novartis shall provide Amgen with copies of and an opportunity to review and comment upon the text of the applications relating to such United States Novartis Patents as soon as practicable (but in no event less than [***] for new patent application filings and [***] for all other filings or correspondence before submission thereof) before filing, (ii) Novartis shall provide Amgen with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any such United States Novartis Patents reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within such United States Novartis Patents as filed together with notice of its filing date and application number, (iii) Novartis shall keep Amgen advised of the status of all material communications, actual and prospective filings or submissions regarding such United States Novartis Patents, and shall give Amgen 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) Novartis shall reasonably consider in good faith Amgen's comments on the communications, filings and submissions for such United States Novartis Patents.

9.2.3 *Amgen Secondary Prosecution.* From and after the Original Effective Date, with respect to United States Novartis Patents specific to the Product, if Novartis proposes to abandon or fail to maintain any patent or application within such United States Novartis Patents, it shall give Amgen reasonable notice thereof (with sufficient time for Amgen to assume control thereof and continue the prosecution or maintenance of such patent or application) and thereafter Amgen may, upon written notice to Novartis, control Patent and Trademark Matters with respect to such patent or application within such United States Novartis Patents thereafter in accordance with this Section 9.2.3 (Amgen Secondary Prosecution) (any patent or application so assumed, an "*Amgen Assumed Item*"). Amgen shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Amgen, Patent and Trademark Matters with respect to Amgen Assumed Items in the United States, as well as preparation and filing for any patent term extensions or similar protections therefor. Amgen shall provide Novartis with a copy of each material submission made to and document received from a patent authority regarding any Amgen Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Amgen Assumed Items as filed together with notice of its filing date and application number.

9.2.4 *Amgen Territory*. Except to the extent expressly provided otherwise in the Global Agreement, in the Amgen Territory, Amgen shall control and be solely responsible for all Patent and Trademark Matters with respect to (i) its patent rights, trademark rights and other intellectual property and (ii) Joint Patents. Notwithstanding the other provisions of this Section 9.2.4 (Amgen Territory), without the prior written consent of Novartis, Amgen shall not take any action (or fail to take any action) with respect to such intellectual property or Joint Patents [***] that would reasonably be expected to [***] on the Amgen Patents, the Novartis Patents or the conduct of Medical Affairs Activities with respect to or Commercialization of the Product [***].

9.2.5 *Expenses*. Costs incurred in connection with Patent and Trademark Matters in accordance with this Section 9.2 (Prosecution and Maintenance) in the United States will be included as Other Costs.

9.3 Defense and Settlement of Third Party Claims.

9.3.1 *United States Patents and Trademarks.* From and after the Original Effective Date, if a Third Party asserts that a patent right or other right owned by it is infringed by the Manufacture, use, sale, offer for sale or importation of the Product by either Party in the United States, such Party shall have the sole right to defend against any such assertions. The other Party shall reasonably assist such first Party and cooperate in any such litigation at such first Party's request. Subject to such control, the other Party may join any defense and settlement pursuant to this Section 9.3 (Defense and Settlement of Third Party Claims). The Party defending the Third Party claim shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, each Party shall keep the other advised of all material communications and actual and prospective filings or submissions regarding such action, and shall provide the other Party with (i) copies of and an opportunity to review and comment on any such communications, filings and submissions and (ii) Calendar Quarterly updates on estimated and actual Costs incurred in connection therewith. Neither Party shall settle or consent to the entry of any judgment in any such action without the other Party's prior written consent, not to be unreasonably withheld or delayed, unless such settlement (a) includes a complete release from liability with respect to the Third Party claim and (b) does not include any admission of wrongdoing by such other Party. Each Party shall keep the other fully informed of all claims and actions governed by this Section 9.3 (Defense and Settlement of Third Party Claims). In the event either Party becomes engaged in: (1) settlement discussions with a Third Party that has specifically asserted that a patent right or Trademark of such Third Party would be infringed by the Manufacture, use, sale, offer for sale or importation of the Product in the United States; (2) settlement discussions of an interference involving a patent right or Trademark of such Party corresponding to a Patent or Trademark that is subject to the licenses granted hereunder; or (3) cross-license discussions with respect to a patent right or Trademark corresponding to a Patent or Trademark that is subject to the licenses granted hereunder: (A) such Party shall keep the other reasonably informed of the status of such discussions; and (B) such Party shall consider in good faith any comments or suggestions of the other Party. Costs incurred in connection with such defense and settlement of Third Party claims in accordance with this Section 9.3.1 (United States Patents and Trademarks) (including under Section 9.5 (Cooperation)) will be included as Other Costs (other than Costs incurred by a Party in fulfilling its indemnification obligations hereunder). In the event that a Third Party asserts that a patent right or other right owned by it is infringed by the sale, offer for sale or importation of the Product by both Parties in the United States, the Parties shall discuss and develop a joint strategy with respect to the defense against any such assertions. For clarity, notwithstanding the foregoing or anything to the contrary contained herein, Amgen shall have no obligation to share with Novartis any Product manufacturing or CMC information or any information related to products other than the Product.

9.3.2 *Amgen Territory Patents and Trademarks*. From and after the Original Effective Date, with respect to Amgen Patents, Amgen Product Trademarks and Joint Patents, in each case

in the Amgen Territory (collectively, the "*Amgen Territory Patents and Trademarks*") specific to the Product, if a Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, offer for sale, sale, or importation of the Product in the Amgen Territory by Amgen, except to the extent expressly provided otherwise in the Global Agreement, Amgen shall have the sole right to defend against any such assertions at its sole cost. Novartis shall reasonably assist Amgen and cooperate in any such litigation at Amgen's request, and Amgen shall reimburse Novartis any reasonable, documented, out-of-pocket costs (including legal fees) incurred in connection therewith. Subject to such control, Novartis may join any defense and settlement pursuant to this Section 9.3 (Defense and Settlement of Third Party Claims), with its own counsel at its sole cost. Amgen shall seek and reasonably consider Novartis' comments before determining the strategy for such matter. Without limiting the foregoing, Amgen shall keep Novartis advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Novartis copies of and an opportunity to review and comment on any such communications, filings and submissions. Amgen shall not settle or consent to the entry of any judgment in any such action that would reasonably be expected to [***] the Amgen Patents, the Amgen Product Trademarks or the conduct of Medical Affairs Activities with respect to or Commercialization of the Product in [***].

9.3.3 *Mutual Provisions*. Each Party shall have the right to redact any information disclosed to the other Party pursuant to this Section 9.3 (Defense and Settlement of Third Party Claims) relating to any product other than the Product.

9.4 Infringement Notice; Enforcement.

9.4.1 *Notice.* Each Party shall promptly notify the other Party in writing if it reasonably believes that any United States Patents and Trademarks or United States Novartis Patents are infringed or misappropriated by a Third Party in the United States.

9.4.2 *Amgen Primary Enforcement.* From and after the Restated Effective Date, with respect to United States Patents and Trademarks specific to the Product, Amgen shall have:

(a) the first right, but not the obligation, to enforce such United States Patents and Trademarks against any actual, alleged or threatened infringement or misappropriation by any Third Party with respect to a Biosimilar Product in the United States, subject to Section 9.5 (Cooperation); and

(b) subject to clause (a), the sole right, but not the obligation, to enforce such United States Patents and Trademarks against any actual, alleged or threatened infringement or misappropriation by any Third Party with respect to any product other than a Biosimilar Product in the United States, subject to Section 9.5 (Cooperation).

In the event Amgen elects to bring and prosecute such an action, Novartis shall reasonably assist Amgen and cooperate in any such action at Amgen's request, and Amgen shall seek and reasonably consider Novartis' comments before determining the strategy. Without limiting the foregoing, Amgen shall keep Novartis advised of all material communications, actual and

prospective filings or submissions regarding such action, including with respect to actions set forth under 42 U.S.C. § 262(*l*), shall provide Novartis copies of and an opportunity to review and comment on any such material communications, filings and submissions (*provided* that Amgen shall have the right to redact any Amgen Manufacturing information and any information relating to any product other than the Product from any such materials), and will consult with Novartis regarding the reasons for not seeking to enforce any particular United States Patents and Trademarks against such Third Party to the extent permitted by any existing protective orders or other agreements prohibiting the disclosure of Third Party information.

9.4.3 *Novartis Secondary Enforcement.* From and after the Restated Effective Date, with respect to United States Patents and Trademarks specific to the Product, in the event Amgen does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any such United States Patents and Trademarks with respect to a Biosimilar Product marketed in the United States pursuant to Section 9.4.2(a), including with respect to actions set forth under 42 U.S.C. § 262(*l*), within [***] after Novartis requests Amgen to do so in writing (or, if later, within [***] after such action can viably be brought by Law (as, for example, in the case of expiration of a clinical trial exception to patent infringement, and, if sooner, by such time as it would no longer be possible to bring such action due to delay)), Novartis shall be entitled to bring and prosecute such an action, including actions set forth under 42 U.S.C. § 262(*l*), and Amgen will cooperate with Novartis. If Novartis elects to bring and prosecute such an action, then Novartis shall seek and reasonably consider Amgen's comments on strategy. Without limiting the foregoing, Novartis shall keep Amgen advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions (*provided* that Novartis shall have the right to redact any information relating to any product other than the Product from any such materials). Novartis shall not settle, or consent to any judgment in, any action under this Section 9.4.3 (Novartis Secondary Enforcement) [***].

9.4.4 *Novartis Primary Enforcement.* From and after the Original Effective Date, with respect to United States Novartis Patents specific to the Product, Novartis shall have the first right, but not the obligation, to enforce such United States Novartis Patents against any actual, alleged or threatened infringement or misappropriation by Third Parties in the United States, subject to Section 10.5 (Cooperation). In the event Novartis elects to bring and prosecute such an action, Amgen shall reasonably assist Novartis and cooperate in any such action at Novartis' request, and Novartis shall seek and reasonably consider Amgen's comments before determining the strategy. Without limiting the foregoing, Novartis shall keep Amgen advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions.

9.4.5 *Amgen Secondary Enforcement.* From and after the Original Effective Date, with respect to United States Novartis Patents specific to the Product, in the event Novartis does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any such United States Novartis Patents within [***] after Amgen requests Novartis to do so in writing (or, if later, within [***] after such action can viably be brought by

Law (as, for example, in the case of expiration of a clinical trial exception to patent infringement, and, if sooner, by such time as it would no longer be possible to bring such action due to delay)), Amgen shall be entitled to bring and prosecute such an action and Novartis will cooperate with Amgen. If Amgen elects to bring and prosecute such an action, then Amgen shall seek and reasonably consider Novartis' comments on strategy. Without limiting the foregoing, Amgen shall keep Novartis advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Novartis copies of and an opportunity to review and comment on any such material communications, filings and submissions (*provided* that Amgen shall have the right to redact any information relating to any product other than the Product from any such materials). Amgen shall not settle, or consent to any judgment in, any action under this Section 9.4.5 (Amgen Secondary Enforcement), without Novartis' prior written consent, not to be unreasonably withheld or delayed.

9.4.6 *Enforcement Costs*. Costs incurred in connection with enforcement activities pursuant to this Section 9.4 (Infringement Notice; Enforcement) (including under Section 9.5 (Cooperation) but excluding Section 9.4.7 (Amgen Territory) and 9.4.8 (Novartis Intellectual Property Rights Outside the United States)) shall be included as Other Costs.

9.4.7 *Amgen Territory.* Except to the extent expressly provided otherwise in the Global Agreement, Amgen shall have the sole right, but not the obligation, to enforce its patent rights, trademark rights and other intellectual properties, and the Joint Patents in the Amgen Territory against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Amgen Territory, and to settle any such matters in its sole discretion subject to Section 9.3 (Defense and Settlement of Third Party Claims). Except to the extent expressly provided otherwise in the Global Agreement, Novartis shall have no right to enforce such rights in the Amgen Territory.

9.4.8 *Novartis Intellectual Property Rights Outside the United States.* Novartis shall have the sole right, but not the obligation, to enforce Novartis Patents outside the United States against any actual, alleged or threatened infringement or misappropriation by Third Parties outside the United States, and to settle any such matters in its sole discretion. Amgen shall have no right to enforce such rights outside the United States.

9.5 Cooperation. When either Party is bringing or defending an action of the type described in Section 9.3 (Defense and Settlement of Third Party Claims) or Section 9.4 (Infringement Notice; Enforcement), then upon reasonable request by such a Party, the other Party will reasonably assist in the defense against or enforcement of such action, including if required or desirable to bring, maintain or prove damages in such action, furnishing a power of attorney, furnishing documents and information, providing employee witnesses, and executing all necessary documents as such Party may reasonably request.

9.6 Patent Term Extensions. From and after the Original Effective Date, with respect to United States Patents and Trademarks and United States Novartis Patents, in each case specific to the Product, each Party shall provide reasonable assistance to the other Party in connection with obtaining patent term extensions for such Amgen Patents, Novartis Patents and Joint Patents consistent with the rights of the other Party to control such matters as specified in Section 9.2 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such patent term extension in the United States, each Party shall make

available to the other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the patent term extension in the United States.

9.7 Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement or being given access to Amgen Technology or Novartis Technology or the Confidential Information of the other Party, each employee, consultant or agent of Novartis or Amgen, respectively, shall have either signed or shall be bound to a non-disclosure and invention assignment agreement pursuant to which each such person shall agree to comply with all of the obligations of Novartis or Amgen, as appropriate, substantially including: (i) promptly reporting any Information, as appropriate; (ii) assigning to Novartis or Amgen, as appropriate, all of his or her right, title and interest in and to any such Information or be bound by applicable Law to assign to Novartis or Amgen, as appropriate, all of his or her right, title and interest in and to any such Information; (iii) cooperating in the preparation, filing, prosecution, maintenance, enforcement and defense of any intellectual property rights; (iv) performing all acts and signing, executing, acknowledging and delivering any and all papers, documents and instruments required for effecting the obligations and purposes of this Agreement; and (v) abiding by the obligations of confidentiality and non-use set forth in this Agreement. It is understood and agreed that any such non-disclosure and invention assignment agreement need not be specific to this Agreement, and that the operation of a collective employment policy sufficient to achieve the intent of the foregoing shall be sufficient to satisfy such obligation. Each Party shall be responsible for any compensation and any other payments due to its own inventors of any patent right.

10. Confidentiality

10.1 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 shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "*Confidential Information*"). Novartis shall have no right to and shall not utilize any Confidential Information of Amgen except as required to enforce its rights under this Agreement or as expressly permitted under the Global Agreement. For clarity, Confidential Information of a Party shall include all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

10.1.1 was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;

10.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

10.1.3 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 in breach of this Agreement;

10.1.4 was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence prepared contemporaneously with such independent development; or

10.1.5 was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

10.2 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) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, and (b) to the extent such disclosure is reasonably necessary or useful in conducting Development, Manufacture, Commercialization or Medical Affairs Activities under this Agreement; (ii) 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 the Product, or otherwise required by Law; *provided*, *however*, that if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it shall, 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, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; or (iv) to the extent mutually agreed to by the Parties. For purposes of clarity, in each case ((i) through (iv)), Novartis shall ensure that manufacturing technology related Confidential Information is not shared with any of its or its Affiliates' personnel (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the United States): (i) [***]; and (ii) [***].

10.3 Use of Confidential Information and Data with Distracting Programs. Each Party acknowledges the value of Confidential Information and other data provided by the other Party hereunder and agrees that it shall not utilize any such information to benefit its programs or products other than the Product or, in the case of Amgen, subject to the Global Agreement, Franchise Product 2 and Franchise Product 3.

10.4 Terms and Conditions Confidential. Neither Party shall disclose the terms and conditions of this Agreement except as may be required by Law. 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 shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Each Party shall have the right to issue press releases in regard to this Agreement or the Product with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [***] Business Days' notice to the other Party and reasonably considering comments provided by such other Party within [***] Business Days after such notice, or such shorter notice and comment time periods as the disclosing Party may reasonably require). Notwithstanding the foregoing, Amgen may issue one or more public announcements to the health care community providing certain details of the transition of Commercialization activities and Medical Affairs Activities to Amgen as contemplated by this Agreement in the general form attached hereto as Schedule 3; thereafter, Novartis and Amgen may each disclose to Third Parties the information contained in such announcement without the need for further approval by the other Party. This Agreement supersedes the Confidential Disclosure Agreement between Amgen and Novartis or its Affiliates dated [***], including any written requests thereunder, (the "*Prior Agreement*") with respect to information disclosed thereunder relating to the Product and the research and Development related thereto. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Agreement.

10.5 Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (i) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (ii) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (iii) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (iv) intend that after the Original Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

11. Representations, Warranties and Covenants

11.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as follows:

11.1.1 As of the Restated Effective Date, it is duly organized and validly existing under the Laws 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;

11.1.2 As of the Restated Effective Date, 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 the Agreement by such Party does not conflict with any agreement,

instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of the Restated Effective Date violate any Law; and the person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

11.1.3 To its knowledge, as of the Restated Effective Date no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or shall be necessary for, or in connection with, the entering into of this Agreement or the transaction contemplated by this Agreement, or (except for FDA or other Regulatory Approvals, licenses, clearances and the like necessary for the research, Development, conduct of Medical Affairs Activities with respect to, Manufacture, sales or marketing of pharmaceutical products and except for any required filing with the U.S. Securities and Exchange Commission) for the performance by it of its obligations under this Agreement;

11.1.4 As of the Restated Effective Date, it has not been debarred or excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;

11.1.5 To its knowledge, as of the Restated Effective Date, it and its Affiliates have not committed any Material Anti-Corruption Law Violation, other than, in the case of Novartis, the activities identified in the Settlement Agreement entered into between Novartis and the Office of the Inspector General of the United States Health and Human Services in the United States Department of Justice in September 2010 and the Settlement Agreement entered into between Novartis and the Office of the Inspector General of the United States Health and Human Services in the United States Department of Justice in November 2015 and, in the case of Amgen, the mis-promotion activities preceding the Corporate Integrity Agreement, entered into between Amgen and the Office of the Inspector General of the United States Health and Human Services in the United States Department of Justice in December 2012; and

11.1.6 As of the Restated Effective Date, it has not knowingly used in connection with the conduct of Medical Affairs Activities, Manufacture or Commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred, excluded or disqualified or the subject of debarment, exclusion or disqualification proceedings by any Governmental Authority.

11.2 Novartis Representations and Warranties. Novartis hereby represents that, as of the Original Effective Date:

11.2.1 Novartis has the right to grant the rights granted to Amgen under this Agreement, and no rights granted to Amgen pursuant to this Agreement are in violation of any agreement between Novartis or any of its Affiliates and any Third Party;

11.2.2 As of the Original Effective Date, it has sufficient legal and/or beneficial title and ownership under the Novartis Technology and Novartis Housemarks to grant the licenses to the other Party as purported to be granted pursuant to this Agreement; and

11.2.3 Novartis is part of the Novartis AG group of companies ("*Novartis Group*"), Novartis AG owns, directly or indirectly, all of the shares and ownership interests in Novartis, and Novartis [***].

11.3 Amgen Representations and Warranties. Amgen hereby represents that, as of the Original Effective Date:

11.3.1 Amgen has the right to grant the rights granted to Novartis under this Agreement, and no rights granted to Novartis pursuant to this Agreement are in violation of any agreement between Amgen or any of its Affiliates and any Third Party;

11.3.2 Amgen has sufficient legal and/or beneficial title and ownership under the Amgen Technology, Amgen Product Trademarks and Amgen Housemarks to grant the licenses to the other Party as purported to be granted pursuant to this Agreement;

11.3.3 Amgen Controls the Amgen Patents listed on the Amgen Patents Schedule, free of any Liens. The Amgen Patents in the United States listed on the Amgen Patents Schedule constitute a true and complete list of all Patents Controlled by Amgen in the United States specific to the Product in the United States.

11.3.4 Amgen has not received any written notice from any Third Party asserting or alleging that the Manufacture, use or sale of the Product in or for the United States infringes rights of such Third Party;

11.3.5 Amgen has not received any written notice of any opposition or challenge against any Amgen Patent in the United States;

11.3.6 All data and information relating to the Product filed by Amgen with the FDA are true and accurate in all material respects;

11.3.7 Amgen has filed with the FDA all [***] relating to the Product in Amgen's possession that are required to be filed, and has made available to Novartis, all such [***]; and

11.3.8 Amgen has not received any written notice that any Governmental Authority has commenced any investigation or any action to withdraw any Regulatory Filing with respect to the Manufacture, conduct of Medical Affairs Activities with respect to or Commercialization of the Product in the United States, [***].

11.4 Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 11 (REPRESENTATIONS, WARRANTIES AND COVENANTS) OR ARTICLE 12 (REPRESENTATIONS, WARRANTIES AND COVENANTS) OF THE GLOBAL AGREEMENT, NOVARTIS AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE US COLLABORATION, THE PRODUCT, THE AMGEN TECHNOLOGY, AMGEN PRODUCT TRADEMARKS, AMGEN HOUSEMARKS, NOVARTIS TECHNOLOGY, NOVARTIS HOUSEMARKS, 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. Except as set forth in this Article 11 (Representations, Warranties and Covenants) or Article 12 (Representations, Warranties and Covenants) of the Global Agreement, all licenses by Novartis to Amgen under the Novartis Technology and Novartis Housemarks shall be granted "as-is" and all licenses by Amgen to Novartis under the Amgen Technology, Amgen Product Trademarks and Amgen Housemarks shall be granted "as-is".

11.5 Mutual Covenants. Each of the Parties hereby covenants to the other Party as follows:

11.5.1 It shall not knowingly use in connection with the conduct of Medical Affairs Activities, Manufacture or Commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred, excluded, disqualified or the subject of debarment, exclusion or disqualification proceedings by any Governmental Authority;

11.5.2 Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors acting for or on behalf of such Party in connection with the subject matter of this Agreement (together with the Party, the "*Party Representatives*") that in connection with the conduct of Medical Affairs Activities, Manufacture or Commercialization to take place pursuant to this Agreement:

11.5.2.1 Each Party's respective Party Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize such payment, offer or promise of, any money or anything else of value, to any Person or Government Official for the purpose of influencing the acts of such Person or Government Official to induce them to use their influence with any Governmental Authority, or obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Anti-Corruption Laws.

11.5.2.2 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.

11.5.2.3 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 [***] years thereafter each Party shall maintain complete and accurate books, accounts, invoices and reasonably detailed records related to this Agreement or any work conducted for or on behalf of Amgen under this Agreement including all records required to establish compliance with Sections 11.5.2.1 and 11.5.2.2 above.

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

(i) 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 11.5.2.1 and 11.5.2.2.

(ii) 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.

11.5.3 If either Party requests that the other Party complete a compliance certification certifying compliance with Section 11.5.2.1, which request shall occur no more than once per Calendar Year, such other Party shall promptly complete and deliver such compliance certification truthfully and accurately;

11.5.4 If either Party requests, in connection with a CIA, that the other Party complete a compliance certification certifying adherence to and compliance with such other Party's code of

conduct and compliance program with respect to such other Party's activities under this Agreement, which request shall occur no more than once per Calendar Year, such other Party shall cooperate with the first Party to promptly complete and deliver such compliance certification truthfully and accurately, and should there be reasonable additional requests of such other Party as a result of a CIA of the requesting Party, such other Party shall comply with such requests;

11.5.5 It shall carry out its activities hereunder in compliance with Law (including relevant Laws relating to economic sanctions, bribery and data protection and privacy, and including the Prescription Drug Marketing Act of 1987 (PDMA), the Federal Drug and Cosmetic Act, the Medicare/Medicaid anti-kickback statute, and the Health Insurance Portability and Accountability Act (HIPAA)) and shall use commercially reasonable efforts to comply in all material respects with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice (and implementing regional or national codes thereof) or similar applicable code and the PhRMA Code on Interactions with Healthcare Professionals, the Accreditation Council for Continuing Medical Education (ACCME) requirements for continuing medical education, and the American Medical Association (AMA) Ethical Guidelines on Gifts to Physicians from Industry, as the same may be amended from time to time, and each Party shall promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports with respect to the Detailing and Commercialization of the Product submitted to or received from the PhRMA, the ACCME or the AMA relating to the foregoing;

11.5.6 If sampling is directed or contemplated in the US Brand Plan, each Party shall conform its practices and procedures relating to Product sampling in the United States to sampling practices and procedures it follows with respect to its other similar prescription products, which practices and procedures shall be in compliance with the Prescription Drug Marketing Act of 1987 (PDMA), as may be amended from time to time, and each Party shall promptly provide the other Party with any correspondence or other reports submitted to or received from the FDA related to Product sampling;

11.5.7 Each Party shall not grant any right to any Third Party that conflicts with the rights granted to the other Party hereunder; and

11.5.8 [***]

11.6 Novartis Covenants.

1.1.1 Novartis shall [***]

11.6.2 [***]

12. Limitations of Liability; Insurance

12.1 Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE

AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 12.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 13 (Indemnification); (ii) Section 10.1 (Confidentiality; Exceptions) or Section 10.2 (Authorized Disclosure); (iii) Section 12.2 (Insurance) or (iv) the gross negligence or willful misconduct of a Party.

12.2 Insurance. During the Term and for [***] years thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry (or reasonable self-insurance sufficient to provide materially the same level and type of protection). The foregoing requirement may be satisfied by a program of self-insurance.

13. Indemnification

13.1 Sharing of Liability Expenses. Except where caused by the gross negligence or willful misconduct of a Party seeking reimbursement, the Parties shall share equally (50%/50%) all losses, damages, liabilities, settlements, penalties, fines and Costs (including, without limitation, reasonable attorneys' fees and expenses) ("*Shared Liability Losses*") arising out of or caused by the conduct of Medical Affairs Activities with respect to or Manufacture or Commercialization of the Product under this Agreement, including product liability claims and Costs associated with any Recalls and returns of the Product in the Field in the United States, other than to the extent the responsibility for any such loss, damage, liability, settlement, penalty, fine or Cost ("*Liability*") is covered by the indemnification provisions of Sections 13.2 (Indemnification by Novartis) or 13.3 (Indemnification by Amgen) and except in the case that Amgen reasonably requests Novartis or its Affiliates or licensees to take prompt mitigating actions (including conducting a Recall) with respect to Product delivered that failed to be Manufactured in compliance with cGMP or to meet the applicable specifications at time of delivery, in which case (i) Amgen shall be responsible for the Costs related to such mitigating actions and (ii) Novartis shall be responsible for Liabilities with respect to Product for which Novartis or its Affiliates or licensees declines to take such requested actions.

13.2 Indemnification by Novartis. Subject to the remainder of this Article 13 (Indemnification), Novartis shall defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, "*Amgen Indemnitees*"), at Novartis' cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (collectively, "*Losses*") (including reasonable legal expenses and attorneys' fees incurred by any Amgen Indemnitees until such time as Novartis has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) arising out of any claim, action, lawsuit, or other proceeding (collectively, "*Claims*") brought against any Amgen Indemnitee by a Third Party to the extent such Losses result from (i) the gross negligence or willful misconduct of Novartis, its Affiliates or agents in performing under this Agreement; or (ii) a breach by Novartis of this Agreement, including any failure of Novartis' representations or warranties in Section 11.1 (Mutual Representations and Warranties) or Section 11.2 (Novartis Representations and Warranties) to be true; in each case excluding such Losses to the extent they arise from the gross negligence or

willful misconduct of Amgen or any Amgen Indemnified Party, or by the breach of this Agreement by Amgen.

13.3 Indemnification by Amgen. Subject to the remainder of this Article 13 (Indemnification), Amgen shall defend, indemnify, and hold harmless Novartis, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, "*Novartis Indemnitees*"), at Amgen's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any Novartis Indemnitees until such time as Amgen has acknowledged and assumed its indemnification obligation hereunder with respect to the applicable Claim) arising out of any Claim brought against any Novartis Indemnitee by a Third Party to the extent such Losses result from (i) the gross negligence or willful misconduct of Amgen, its Affiliates or agents in performing under this Agreement; (ii) a breach by Amgen of this Agreement, including any failure of Amgen's representations or warranties in Section 11.1 (Mutual Representations and Warranties) or Section 11.3 (Amgen Representations and Warranties) to be true; or (iii) the death or injury of a person caused by the failure of Product manufactured by Amgen, its Affiliates or its licensees (other than Novartis, its Affiliates or its licensees) to be Manufactured in compliance with cGMP or to meet the applicable specification at time of delivery; in each case excluding such Losses to the extent they arise from the gross negligence or willful misconduct of Novartis or any Novartis Indemnified Party, or by the breach of this Agreement by Novartis.

13.4 Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Novartis Indemnitee or an Amgen Indemnitee (the "*Indemnified Party*") may seek indemnification under this Article 13 (Indemnification), the Indemnified Party shall promptly notify the other Party (the "*Indemnifying Party*") of the Claim or Loss and, when known, the facts constituting the basis for the Claim; *provided, however*, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 13.4 (Claim for Indemnification) shall 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. Except as set forth below in this Section, the Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense The Indemnifying Party shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to the Indemnified Party and shall cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party. The Indemnified Party shall not settle or compromise such Claim for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Article 10 (Confidentiality). The

Indemnified Party shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. Notwithstanding the foregoing, 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 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; *provided* that in no event will the Indemnifying Party be required to pay fees and expenses under this sentence for more than one (1) firm of attorneys in any jurisdiction in any one (1) legal action or group of related legal actions. In such event, the Indemnified Party shall not settle or compromise such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

14. Term and Termination

14.1 Term. This Agreement shall come into effect as of the Original Effective Date and, unless otherwise terminated pursuant to the provisions of Article 14 (Term and Termination), shall remain in effect during the Term.

14.2 Termination. This Agreement may be terminated as follows:

14.2.1 *Termination for Breach.* If either Party believes that the other Party is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. If the breaching Party (or its Affiliate) fails to cure such material breach within [***] days after the receipt of such notice (or [***] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [***] days after the end of such cure period and effective upon delivery; *provided*, *however*, if the breaching Party notifies the other Party within such [***] day period that it disagrees in good faith with such asserted basis for termination, this Agreement shall not terminate unless and until the matter has been finally resolved in accordance with Section 15.3 (Governing Law; Jurisdiction); *provided further* 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.

14.2.2 *Termination for Insolvency*. A Party shall have the right to terminate this Agreement, upon written notice thereof to the other Party, if the other Party suffers an Insolvency Event.

14.2.3 *Termination for Challenge*. Amgen shall have the right to terminate this Agreement should Novartis, its Affiliate or its or their licensee under the Amgen Patents or Amgen Product Trademarks bring or join any challenge to the validity or enforceability of any Amgen Patent or Amgen Product Trademark and Novartis, its Affiliate or its or their licensee has not withdrawn from such challenge within [***] days following receipt of a written notice from Amgen to withdraw.

14.2.4 *Termination for Convenience*. Novartis shall have the right to terminate this Agreement from and after [***] upon [***] prior written notice to Amgen. For clarity, Novartis

may provide written notice of termination to Amgen at any time from or after [***], such that this Agreement may be terminated by Novartis effective any time from or after [***].

14.2.5 *Termination for [***]*. Novartis shall have the right to [***] terminate this Agreement upon written notice to Amgen [***].

14.2.6 *Termination for [***]*. Novartis shall have the right to [***] terminate this Agreement upon written notice to Amgen [***].

14.2.7 *Termination [***]*. Amgen shall have the right to terminate this Agreement upon [***] days' prior written notice to Novartis pursuant to [***] of the [***].

14.3 Effect of Termination. Termination of this Agreement shall have the following effects with regard to the Product:

14.3.1 *General*. In the event of any termination of this Agreement, unless otherwise expressly provided, any liabilities previously accrued (including the obligation of Amgen to pay royalties pursuant to Section 8.3 (Royalty Payments and Royalty Reduction for Biosimilar Competition)) with respect to sales of the Product made prior to the effective date of such termination shall survive. In addition, in the event of termination of this Agreement, each Party shall return to the other Party or destroy (and certify such destruction to such other Party) all Confidential Information of the other Party (*provided* that each Party shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by applicable Law or regulatory requirement).

14.3.2 *Termination Effects*. In the event of any termination of this Agreement, (i) Novartis shall use reasonable efforts to, to the extent permitted by Law and requested by Amgen, assign any contracts solely to the extent related to the Product in the United States to Amgen or its designee (including by requesting and using good faith efforts to obtain any required consents, provided that Novartis shall be under no obligation to make any payments or incur any liabilities in order to obtain such consent); (ii) ; (ii) the Parties shall cooperate to promptly transition sole responsibility for the prosecution, maintenance and enforcement in the United States of United States Patents and Trademarks and United States Novartis Patents specific to the Product to Amgen; (iii) all sublicenses granted by Novartis shall terminate; (iv) Amgen shall have the right to control all Recalls of the Product in the United States, and in each case Novartis shall provide any reasonable assistance requested by Amgen in connection therewith; (v) Section 3.2 (Novartis Technology) (solely to the extent such intellectual property has been or is incorporated into or used in the Development, Manufacture, Medical Affairs Activities, regulatory activities or Commercialization of the Product as of the date of termination) shall survive [***]; and (vi) the Parties shall cooperate to promptly transfer ownership of all Domain Names and Domain Name registrations (including in each case with respect to nonproprietary names for the Product) related to the Product held by Novartis to Amgen, save as to any Domain Names and Domain Name registrations that contain any Novartis Housemarks; *provided* that [***] shall bear any expenses incurred in connection with any such transfer except that, in the event of termination by Amgen pursuant to Section [***] or by Novartis pursuant to Section [***], [***] shall bear such expenses.

14.3.3 *Additional Termination Effects*. In addition to the effects of termination set forth in Section 14.3.2 (Termination Effects), the following will apply:

14.3.3.1 in the event of termination of this Agreement by Novartis pursuant to Section [***], Amgen shall pay to Novartis, commencing on the effective date of termination (the "*Termination Date*") and continuing [***], a royalty on annual Net Sales of the Product in the United States for each Calendar Year (or portion thereof) at the following rates: (a) [***] percent ([***]%) if the Termination Date occurs [***], (b) [***] percent ([***]%) if the Termination Date occurs [***], (c) [***] percent ([***]%) if the Termination Date occurs on or after [***].

14.3.3.2 in the event of termination of this Agreement by Novartis pursuant to Section [***]commencing on the Termination Date and continuing until [***], Amgen shall pay to Novartis a royalty on annual Net Sales of the Product in the United States for each Calendar Year (or portion thereof) at the following rates: (i) [***] percent ([***]%) if the Termination Date occurs [***], (ii) [***] percent ([***]%) if the Termination Date occurs [***] and (iii) [***] percent ([***]%) if the Termination Date occurs [***].

14.3.3.3 in the event of any termination of this Agreement, other than a termination by Novartis pursuant to Section [***], [***].

14.4 Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 14.3 (Effect of Termination) and the provisions that are expressly stated to survive termination, in the event of any termination of this Agreement the following provisions shall survive: Article 1 (Definitions) (to the extent defined terms are contained in the following surviving Articles and Sections), Article 10 (Confidentiality); Articles 12 (Limitations of Liability; Insurance); 13 (Indemnification); 14 (Term and Termination) and 15 (Miscellaneous); Section 5.6 (Detailing Reports and Audit Rights) (with respect to Details made prior to such termination), Sections 8.1 (Upfront Payment) and 8.2.1 [***]; Sections 8.3 (Royalty Payments and Royalty Reduction for Biosimilar Competition) through 8.5 (No Wrongful Reductions) (inclusive) (with respect to sales made prior to such termination); Section 8.6 (Cost Allocation) (with respect to Program Costs and Development Costs reasonably incurred prior to such termination and for Recoveries with respect to periods prior to termination); Sections 8.8 (Payment Method) through 8.14 (Appropriate Measure of Value); 9.1.1 (Ownership of Technology); and 11.4 (Disclaimer of Warranties).

15. Miscellaneous

15.1 Affiliates. Each Party shall 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 shall be responsible for its Affiliates' performance hereunder.

15.2 Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign this Agreement and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale to a Third Party of all or substantially all of the business of, in the case of Amgen,

Amgen, and in the case of Novartis, [***]. Any assignment not in accordance with this Agreement shall be void ab initio. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

15.3 Governing Law; Jurisdiction. This Agreement shall 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.

15.4 Construction. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “or” is used in the inclusive sense (and/or). The word “will” shall be construed to have the same meaning and effect as the word “shall”. 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 shall 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 shall 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 Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended; (iii) any reference herein to any person shall be construed to include the person’s permitted successors and assigns; (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall 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, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.

15.5 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall 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.

15.6 Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits and the Safety Agreement and together with the Global Agreement, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

15.7 Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest ("*Force Majeure*"); *provided, however*, 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 further provided* that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.

15.8 Further Assurances. Each Party agrees to do and perform all such further acts and things and shall 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.

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

15.10 No Set-Off. Except as expressly set forth in this Agreement, no Party shall 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).

15.11 Notices. Any notice required or permitted to be given by this Agreement shall be in writing, in English, and shall 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: [***]
Facsimile: [***]

If to Novartis: Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel
Switzerland
Attention: [***]
Facsimile: [***]

With a copy to:
Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel
Switzerland
Attention: [***]
Facsimile: [***]

Any such notice shall 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).

15.12 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Novartis and Amgen as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15.13 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.14 Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or Novartis Indemnities in Article 13 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.

15.15 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall 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 shall be valid or effective unless in writing and signed by all Parties hereto.

****

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Collaboration Agreement as of the Restated Effective Date.

NOVARTIS PHARMA AG

By: /s/ Maximiliano Bricchi

Name: Maximiliano Bricchi

Title: Worldwide Head of Neuroscience Franchise

AMGEN INC.

By: /s/ Murdo Gordon

Name: Murdo Gordon

Title: EVP Global Commercial Ops

NOVARTIS PHARMA AG

By: /s/ Gregor Von Arx

Name: Gregor Von Arx

Title: Global Head Legal Neuroscience Franchise

[Signature Page to Amended and Restated Collaboration Agreement]

List of Exhibits and Schedules Omitted from the Amended and Restated Collaboration Agreement
Referenced in Exhibit 10.39 Above

Pursuant to Regulation S-K, Item 601(b)(2), the Exhibits and Schedules to the Amended and Restated Collaboration Agreement referenced in Exhibit 10.39 above, as listed below, have not been filed. The Registrant agrees to furnish supplementally a copy of any omitted Exhibit or Schedule to the Securities and Exchange Commission (the "Commission") upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

Schedules

Schedule 1 Amgen Patents
Schedule 2 Cap Calculation
Schedule 3 Amgen HCP Communication
Schedule 4 Specified Patent
Schedule 5 Transition Services Agreement
Schedule 6 Calculation of Sales Force Costs
Schedule 7 FTE Rates

Exhibit 10.49

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.

AMGEN INC.

and

KYOWA KIRIN CO., LTD.

Dated June 1, 2021

LICENSE AND COLLABORATION AGREEMENT

CONTENTS

Page

SCHEDULES

Excluded Patents Schedule
European Union Member States Schedule
Global Pricing Policy Considerations Schedule
Standard Contractual Clauses Schedule
Information Security Requirements Schedule
Licensed KKC Patents Schedule
Press Releases Schedule
Privacy and Data Protection Schedule

EXHIBITS

Compliance Certification

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this "Agreement") is entered into as of June 1, 2021 (the "Execution Date") by and between Amgen Inc., a Delaware corporation with a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320 USA ("Amgen") and Kyowa Kirin Co., Ltd., a Japanese corporation with a principal place of business at 1-9-2 Otemachi, Chiyoda-ku, Tokyo, 100-0004 Japan ("KKC"). Amgen and KKC are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Amgen is a global biopharmaceutical company that researches, develops, manufactures and commercializes therapeutic products, including in the Amgen Territory (as defined below) to treat grievous illness;

WHEREAS, KKC is a global biopharmaceutical company and is engaged in research, development, manufacturing and commercialization of pharmaceutical products;

WHEREAS, KKC has developed and is developing the Product (as defined below) for the treatment of certain inflammation-related diseases and conditions;

WHEREAS, Amgen and KKC desire to collaborate on the continued global development of the Product; and

WHEREAS, Amgen desires to secure the right to commercialize the Product in the Amgen Territory, and KKC desires to grant such right.

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:

Article I.

DEFINITIONS

Section 1.1 "Affected Party" has the meaning set forth in Section 10.3 (Distracting Transactions; Notice).

Section 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. Notwithstanding the foregoing, for the purposes of Article X (Distracting Products) and Section 1.53 (Distracting Transaction) only, the ownership threshold included in the definition of "control" will be fifty percent (50%) or more, rather than more than fifty percent (50%).

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

Section 1.4 "Alliance Manager" has the meaning set forth in Section 2.5 (Alliance Managers).

Section 1.5 "Allocable Manufacturing Overhead" means, with respect to the Manufacturing Actual Costs for any Products intended for the Amgen Territory, the Costs incurred by a Party or for its account, in accordance with GAAP, including [***]and which are specifically allocated (and properly attributable) to such Product's Manufacturing activity (pursuant to this Agreement) within a given company department(s) based on a properly allocable portion of space occupied or headcount or other activity-based method consistent with such Party's internal accounting principles consistently and properly applied by such Party, or a standard rate if agreed by the Parties. "Allocable Manufacturing Overhead" shall not include [***].

Section 1.6 "Amgen" has the meaning set forth in the Preamble.

Section 1.7 "Amgen Assumed Item" has the meaning set forth in Section 11.2(a)(ii) (Amgen Secondary Prosecution).

Section 1.8 "Amgen Assumed Joint Patent Item" has the meaning set forth in Section 11.2(c)(ii) (Amgen Secondary Prosecution of Joint Patents in the KKC Territory).

Section 1.9 "Amgen Co-Promote Medical Liaisons" has the meaning set forth in Section 6.4.7 (Medical Affairs Activities).

Section 1.10 "Amgen Commercialization Costs" has the meaning set forth in Section 8.3.2 (Amgen Costs)

Section 1.11 "Amgen Development Costs" has the meaning set forth in Section 8.2.2 (Amgen Costs).

Section 1.12 "Amgen Development Data" means the preclinical and clinical data generated by or on behalf of Amgen or its Affiliates in the course of its Development and any other data generated in connection with Amgen's Development activities hereunder, on or after the Effective Date of this Agreement.

Section 1.13 "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 Licensed Amgen Trademarks and trademarks, trade names or service marks associated with and used solely in connection with goods or services outside the scope of this Agreement; and all intellectual property rights residing in any of the foregoing.

Section 1.14 "Amgen Improvement" means any improvement, modification, enhancement to or novel use of the Product that (a) either Covers or specifically relates to the

Product or (b) is developed by or on behalf of, or becomes Controlled by, Amgen or its Affiliates during the Term in the research, conduct of Medical Affairs Activities with respect to, Development, Commercialization or Manufacture of the Product or any of the activities contemplated hereunder.

Section 1.15 "Amgen Indemnitees" has the meaning set forth in Section 14.1 (Indemnity by KKC).

Section 1.16 "Amgen Territory" means all countries in the world with the exception of Japan.

Section 1.17 "Anti-Corruption Laws" means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including the U.S. Foreign Corrupt Practices Act (FCPA), Criminal Law, Anti-Unfair Competition Law and similar laws intended to prohibit corruption and bribery, regardless of whether those laws pertain to corruption and bribery involving public or private individuals or entities.

Section 1.18 "Applicable Law" 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, including, to the extent applicable, Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), including all applicable data protection and privacy laws, rules and regulations, Anti-Corruption Laws and Healthcare Compliance Requirements.

Section 1.19 "Assisting Party" has the meaning set forth in Section 14.4 (Defense of Third Party Claims).

Section 1.20 "Audited Party" has the meaning set forth in Section 9.4.1 (Accounting).

Section 1.21 "Auditing Party" has the meaning set forth in Section 9.4.1 (Accounting).

Section 1.22 "Backup Manufacturer" has the meaning set forth in Section 5.1.3 (Backup Manufacturing Rights).

Section 1.23 "Biosimilar Product" means, with respect to the Product in a particular country, after Regulatory Approval of the Product in such country, any other therapeutic drug product designated for human use which (i) contains the same or highly similar principal molecular structural features as (but not necessarily all of the same structural features as) the Product except for minor differences in clinically inactive components, (ii) has no clinically meaningful differences from the Product in terms of purity, potency, safety, mechanism of action, route of administration, dosage form and strength, (iii) is approved for use pursuant to a

Regulatory Approval process in such country that is based on the indications and conditions of use on an unrelated party's previously approved version of that same product (i.e., a product meeting the standards set forth in the foregoing clauses (i) and (ii)), whether or not such regulatory approval was based upon data generated by the Parties filed with the applicable governmental authority in such country or was obtained using an abbreviated, expedited or other process, and (iv) is authorized for sale or sold in the same country (or is commercially available in the same country via import from another country) as the Product by a Party or any Third Party, as applicable.

Section 1.24 "BLA" means a Biologic Licensing Application, including all supplements and amendments thereto, for the approval to market the Product by the FDA.

Section 1.25 "Business Day" means a day that is not a Saturday, Sunday or a day on which banking institutions in New York, New York U.S.A. or Tokyo, Japan, are authorized by Applicable Law to remain closed.

Section 1.26 "Challenged KKC Patents" has the meaning set forth in Section 11.2(b)(i) (Amgen Primary Prosecution).

Section 1.27 "Change of Control" with respect to a Party, is deemed to have occurred if any of the following occurs after the Effective Date:

(a) any "person" or "group" (as such terms are defined below) who (i) becomes or acquires the right to become (including, by way of a tender or exchange offer) the "beneficial owner" (as such term is defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("Voting Stock") of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party, (ii) acquires the power, directly or indirectly, to elect a majority of the members of the Party's board of directors, or similar governing body ("Board of Directors"), or (iii) otherwise has the ability to direct or cause the direction of the management or operation of the Party; or

(b) such Party enters into any merger, consolidation, other business combination or similar transaction with another Person (whether or not such Party is the surviving entity), unless immediately after such merger, consolidation, other business combination or similar transaction (i) the members of the Board of Directors of such Party constituting at least a majority of the members of the Board of Directors of such Party immediately prior to such transaction continue to constitute a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction and (ii) the Persons that beneficially owned, directly or indirectly, at least a majority of the shares of Voting Stock of such Party immediately prior to such transaction continue to beneficially own (either by such shares remaining outstanding or by their being converted into shares of voting capital stock of the surviving Person), directly or indirectly, shares of Voting Stock of such Party

representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction; or

(c) the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change of Control, (i) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act, (ii) a "beneficial owner" is determined in accordance with Rule 13d-3 under the aforesaid Act, (iii) the terms "beneficially owned" and "beneficially own" have meanings correlative to that of "beneficial owner", and (iv) the term "Party" means both the Party and the Person that controls such Party (as "control" is defined in the definition of "Affiliate").

Section 1.28 "Clinical Study" means a research study (including interventional and observational studies) in which data from one or more human subjects is collected to evaluate health-related biomedical outcomes, including a Phase 4 Study.

Section 1.29 "CMC" means chemistry, manufacturing and controls.

Section 1.30 "Co-Detail Percentage" means the percentage of Total FPDE Details for which KKC (or, with respect to Detailing activities in the U.S., KKUS) is responsible pursuant to Section 6.4 (Co-Promotion Activities).

Section 1.31 "Co-Detail and Field Medical Liaison Plan" means a rolling strategic and operational Commercialization plan focusing on Detailing and field Medical Affairs Activities created and updated by Amgen in accordance with Section 6.4.5 (Co-Detail and Field Medical Liaison Plan) consistent with the Global Pricing Policy, for the Product in the Co-Promotion Territory, which plan shall set forth, [***].

Section 1.32 "Co-Promotion Territory" means the U.S. and any other territories for which KKC has opted in to co-promote in accordance with Section 6.4.2 (Co-Promotion Outside of U.S. Generally) and Section 6.4.3 (KKC Co-Promotion Right).

Section 1.33 "Collaboration Territory" means the Amgen Territory and the KKC Territory.

Section 1.34 "Commercialization" and "Commercialize" means any and all processes and activities conducted to establish and maintain sales for a Product, including to market (including pre-launch activities), advertise, promote, store, transport, distribute, import, export, offer to sell (including pricing and reimbursement activities), Detail, and/or sell the Product and/or conduct other commercialization activities, and "Commercialization" shall have the correlative meaning with respect to such activities; *provided*, *however*, that Commercialize shall exclude Development and Manufacturing activities (including Manufacturing activities related to

Commercialization). For purposes of this Agreement and for ease of management of the Collaboration only, "Commercialize" shall also include Medical Affairs Activities.

Section 1.35 "Commercialization Budget" means the applicable budget prepared by Amgen for review by the JCS and approval by the JSC for the Commercialization of the Product in the Amgen Territory in accordance with the applicable Commercialization Plan (which budget will be updated by Amgen no less than annually and reviewed and discussed by the JCS in accordance with Section 2.2.8 (Joint Commercialization Committee) and approved by the JSC, and will cover a period of at least [***] and will include quarterly budgets for a period of at least [***] for the current year).

Section 1.36 "Commercial Lead" has the meaning set forth in Section 6.1 (Commercialization Activities.).

Section 1.37 "Commercialization and Related Costs" means all Costs incurred by a Party and its Affiliates during the Term in connection with the Commercialization of Products in the U.S., including:

(a) selling expenses, or other Costs and expenses associated with marketing of the Product for Commercialization in the U.S., including Sales Force Costs calculated in accordance with Section 6.9(a) (Calculation of Sales Force Costs and Other Personnel Costs);

(b) costs for preparing and reproducing Commercialization materials, including [***];

(c) Costs of sales and marketing data, costs associated with training of the sales representatives, sales activity reporting and work on target customer accounts in the U.S.;

(d) [***];

(e) marketing Costs and Medical Affairs Activities Costs incurred in connection with launch readiness activities in or for the U.S. prior to commercialization and during commercialization;

(f) all Costs incurred by the Parties or their respective Affiliates associated with any recalls of a Product in or for the U.S.;

(g) all Costs incurred by the Parties or their respective Affiliates with respect to product liability claims for Products in the U.S.;

(h) all Costs incurred by the Parties or their respective Affiliates associated with any returns and withdrawals of a Product in the U.S.;

(i) all Costs incurred by the Parties or their respective Affiliates in performing [***];

(j) all defense, enforcement, settlement and cooperation Costs incurred by the Parties or their respective Affiliates, to the extent such defense, enforcement, settlement and cooperation are conducted in or for the U.S., in accordance with Section 14.4 (Defense of Third Party Claims), (but, in each case, not including defense Costs incurred by a Party in fulfilling its indemnification obligations); and

(k) all Costs incurred by the Parties or their respective Affiliates in connection with Prosecution and Maintenance of Licensed Amgen Patents, Licensed Amgen Know-How and Licensed Amgen Trademarks and Licensed KKC Patents, Licensed KKC Know-How and Licensed KKC Trademarks, to the extent such Prosecution and Maintenance are conducted in or for the U.S., in accordance with Section 11.2 (Prosecution and Maintenance).

in each case solely to the extent (i) not previously deducted from gross invoiced amounts in determining Net Revenues hereunder, included as part of Global Development Costs, or otherwise subject to adjustment and (ii) with respect to (a) through (e), (i) and (k), included in the Commercialization Plan and Commercialization Budget, but (iii) excluding the Manufacturing Actual Cost for commercial supply of Products in the U.S.

Such Costs may include all Costs for outside services and expenses (e.g., consultants, agency fees, etc.). Commercialization and Related Costs shall not include [***] or any Cost subject to an indemnification obligation under Article XIV (Indemnification and Insurance).

Section 1.38 "Commercialization Plan" means a rolling strategic and operational commercialization plan for the applicable Product in the Collaboration Territory (which plan will be a detailed plan for the first year and a rolling [***] high level plan for all subsequent years and will be updated by the JCS and approved by the JSC on a periodic basis but no less than annually), which sets forth, among other things, (i) a multi-year Commercialization strategy that includes plans for [***], (ii) timing of launch sequence of the Product in each country in the Collaboration Territory, (iii) a multi-year communications strategy that includes plans for [***], and (iv) an operating plan for the implementation of such strategies on an annual basis, including information related to [***], all as developed by the JCS and approved by the JSC.

Section 1.39 "Commercially Reasonable Efforts" means, with respect to a Party and/or its Affiliates and an activity under this Agreement, the efforts and expenditures that would be employed, in good faith and in accordance with Applicable Law, by a reasonably prudent company in the biopharmaceutical industry, which prudent company is performing such activity for their own biopharmaceutical products that are of a similar stage of development or commercialization and similar scientific and commercial potential to the Product, but in no event less than the standards and level, consistent with commercially reasonable practices, commonly applied by other reasonably prudent biopharmaceutical companies to their biopharmaceutical products of a similar stage of development or commercialization and similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the safety, efficacy, intellectual property profile, commercial potential, actual or anticipated Governmental Authority approved labeling,

competitiveness of the Product or alternative products that are in the marketplace or under development by Third Parties, and cost and likelihood of obtaining Regulatory Approval, but specifically excluding (i) [***] and (ii) [***]. Without limiting the foregoing, Commercially Reasonable Efforts generally requires, with respect to such obligations, that the Party:[***]

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Section 1.40 "Confidential Information" has the meaning set forth in Section 12.1 (Confidentiality; Exceptions).

Section 1.41 "Contract Interest Rate" means [***], or, if lower, the maximum rate permitted by Applicable Law.

Section 1.42 "Control" or "Controlled" means, with respect to any intellectual property right, that a Party owns or has a license (other than a license granted to such Party under this Agreement) to such right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to such other Party on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense. For clarity, KKC shall be deemed to not Control [***]. If Amgen notifies KKC that Amgen has determined that [***] would be reasonably necessary for the use, research, Manufacture, Development or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Product, the Parties shall [***].

Section 1.43 "Copyrights" means all right, title, and interest in and to all copyrightable works and any copyright registration or corresponding legal right.

Section 1.44 "Costs" means both internal and external costs and expenses (including the cost of allocated FTEs at the applicable FTE Rate).

Section 1.45 "Cover" means (a) with respect to Information, such Information was used in the Exploitation of the product, and (b) with respect to a Patent, a Valid Claim would (absent a license thereunder or ownership thereof) be infringed by the Exploitation of the product; *provided*, *however*, that in determining whether a Valid Claim that is a claim of a pending application would be infringed, it shall be treated as if issued as then currently being prosecuted. Cognates of the word "Cover" shall have correlative meanings.

Section 1.46 "Critical Matters" means: (i) agreement of the initial versions of each of the [***], (ii) any material updates or changes to [***], (iii) decisions that would reasonably be expected to: [***], (iv) a decision to conduct [***] and (v) any material decision with respect to [***].

Section 1.47 "DCSI" has the meaning set forth in Section 4.9 (Ownership of Core Data Sheet and Global Safety Database).

Section 1.48 "Defending Party" has the meaning set forth in Section 14.4 (Defense of Third Party Claims).

Section 1.49 "Designated Officer" means with respect to each of KKC and Amgen, (a) with respect to commercial matters, [***] and (b) with respect to all other matters, [***].

Section 1.50 "Detail" means an interactive, one-on-one, face-to-face or virtual meeting, in an individual or group practice setting, between one or more healthcare professionals having prescribing authority or who is able to influence prescribing decisions and one Amgen or KKC (or their respective Affiliates or Amgen's permitted contractors) sales representative during which uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of the Product are discussed in an effort to increase prescribing preferences of the Product for its approved uses. Details will not include (i) [***] or (ii) [***]. When used as a verb, "Detail" or "Detailing" shall mean to engage in a Detail.

Section 1.51 "Development" means all activities required and/or useful to obtain and maintain Regulatory Approval of the Product for use in the Lead Indication or any other indication, and generate pre-clinical and clinical evidence to support Commercialization and Manufacturing activities, including research, non-clinical and preclinical testing and trials, clinical testing and trials, including Clinical Studies, toxicology testing, modification, optimization and animal efficacy testing of pharmaceutical compounds, statistical analysis, publication and presentation of study results and reporting, preparation and submission to regulatory authorities of applications relating to the Product; *provided, however*, that Development shall exclude Commercialization and Manufacturing activities.

Section 1.52 "Development Lead" has the meaning set forth in Section 4.1 (Development Matters).

Section 1.53 "Development Records" has the meaning set forth in Section 4.4 (Development Records).

Section 1.54 "Dispute" has the meaning set forth in Section 16.5.2.

Section 1.55 "Distracted Party" means a Party that either itself or its Affiliate conducts or participates in, advises, assists, or enables any Third Party to conduct or participate in, any Distracting Program or enters into any Distracting Transaction.

Section 1.56 "Distracting Product" means any pharmaceutical or biologic product, other than the Product, that [***].

Section 1.57 "Distracting Program" means [***] of any Distracting Product.

Section 1.58 "Distracting Program Restriction" has the meaning set forth in Section 10.1 (General).

Section 1.59 "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 either (i) becomes an Affiliate of such Party or any of its Affiliates or (ii) sells, transfers or assigns all or substantially all of its assets to such Party or any of its Affiliates.

Section 1.60 "Distracting Transaction Notice" has the meaning set forth in Section 10.3 (Distracting Transactions; Notice).

Section 1.61 "Divest" means, with respect to any Distracting Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to such Distracting Program, including technology, Information, intellectual property and other assets materially relating thereto, to an independent Third Party, without the retention or reservation of any rights or interest (other than solely an economic interest, reversion rights or other similar rights typical of a licensor in an exclusive license agreement) in such Distracting Program by the relevant Party or its Affiliates. When used as a noun, each of "Divestiture" and "Divestment" has a corresponding meaning.

Section 1.62 "Effective Date" has the meaning set forth in Section 15.1 (Term).

Section 1.63 "Excluded Patents" means the Patents set forth in the Excluded Patents Schedule.

Section 1.64 "Exploit" means, with respect to the Product, to research, develop (including to conduct any Development activities), Commercialize, make (including to conduct any Manufacturing activities), have made, use, market, offer for sale, sell, import, export, manufacture, have manufactured or otherwise exploit, distribute, promote, transfer possession of or title in the Product. Cognates of the word "Exploit" shall have correlative meanings.

Section 1.65 "Ex-U.S. Amgen Territory" has the meaning set forth in Section 6.4.9 (Responsibility for KKC's Detailing and Medical Liaison Costs and Expenses).

Section 1.66 "Ex-U.S. Amgen Territory Commercialization Costs" means, collectively, (a) the Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs and (b) the Ex-U.S. Amgen Territory Commercialization Costs – Other Costs.

Section 1.67 "Ex-U.S. Amgen Territory Commercialization Costs – Other Costs" has the meaning set forth in Section 6.10 (Other KKC Ex-U.S. Amgen Territory Commercialization Costs).

Section 1.68 "Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs" has the meaning set forth in Section 6.9 (Calculation of Sales Force Costs and Other Personnel Costs).

Section 1.69 "FDA" means the U.S. Food and Drug Administration, and any successor agency thereto.

Section 1.70 "First Commercial Sale" means, with respect to any compound or product, the first sale for end use or consumption of such compound or product after Regulatory Approval and Pricing Approval have been granted.

Section 1.71 "First Party" has the meaning set forth in Section 9.6.4(b).

Section 1.72 "First Position Detail" means a Detail in which the Product is Detailed before any other product and/or the predominant portion of time is devoted to the Detailing of the Product.

Section 1.73 "First Position Detail Equivalent Basis" means (i) [***] if the Product is Detailed in a First Position Detail and [***] other products are detailed in such encounter, (ii) [***] if Product is Detailed as a First Position Detail and [***] other product is detailed in such encounter, and (iii) [***] if the Product is Detailed in a Second Position Detail and [***] other product is detailed in such encounter.

Section 1.74 "Force Majeure" has the meaning set forth in Section 16.9 (Force Majeure).

Section 1.75 "FTE" means, with respect to a person, the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of (i) [***] weeks or (ii) [***] hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. No one person shall be permitted to account for more than one FTE.

Section 1.76 "FTE Rate" means for any employee of KKC or Amgen (i) conducting Development Activities, [***], increasing by [***] each January 1st beginning on January 1, 2022 and (ii) conducting Commercialization activities (excluding Sales Force activities but including Other Personnel activities, [***], increasing by [***] each January 1st beginning on January 1, 2022 . The FTE Rate includes costs associated with salaries, payroll taxes, bonuses, benefits, recruiting, relocation, employee stock option programs or stock grants, retirement programs, and applicable overhead (e.g., facilities, operating supplies, travel and training). No one person shall be permitted to account for more than one FTE.

Section 1.77 "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.

Section 1.78 "GCC Countries" means the United Arab Emirates, Saudi Arabia, Qatar, Oman, Kuwait and Bahrain.

Section 1.79 "Global Development Budget" means the applicable budget prepared by Amgen and reviewed at the JSC for the Development of each Product in the Amgen Territory in accordance with the applicable Global Development Plan (which budget will be updated by Amgen no less than [***] and will be reviewed and discussed by the JDS in accordance with Section 2.2.7 (Joint Development Subcommittee) and approved by the JSC and will cover a period of at least [***] years).

Section 1.80 "Global Development Cost Balancing Report" has the meaning set forth in Section 8.2.4 (Balancing Payment for Global Development Costs).

Section 1.81 "Global Development Cost-Share Payments" has the meaning set forth in Section 8.2.3 (Global Development Cost Share).

Section 1.82 "Global Development Costs" means all Costs incurred by Amgen or KKUS and their Affiliates during the Term in connection with the Development of the Product in the Amgen Territory in accordance with the Global Development Plan and Global Development Budget, including:

(a) all Costs incurred in performing development activities which have been designated to Amgen in furtherance of the Global Development Plan (including [***];

(b) all Costs associated with obtaining, maintaining and renewing Regulatory Filings and Regulatory Approvals pertaining to a Product;

(c) all manufacturing Costs not otherwise included in Manufacturing Standard Costs or Manufacturing Actual Costs, including [***];

(d) for any clinical supply of Products, (i) the Manufacturing Standard Cost, if it is manufactured in a Party's (or its designee's) clinical manufacturing facility, or (ii) the Manufacturing Actual Costs, if it is manufactured in a Party's (or their designee's) nonclinical (i.e., commercial) manufacturing facility;

(e) Medical Affairs Activities Costs to the extent relevant to clinical development;

(f) [***]; and

(g) all Costs incurred for other materials (such as nonParty comparator drugs and placebo) obtained or made for use in Clinical Studies of or related to a Product.

For clarity, Global Development Costs shall include Costs incurred to manage any of (a) through (g) above to the extent performed by any contract research organization by or on behalf of Amgen or KKUS or their Affiliates, but shall exclude any Cost subject to an indemnification obligation under Article XIV (Indemnification and Insurance) and shall also exclude any Cost included in Commercialization and Related Costs or otherwise deducted from the calculation of Net Revenues. For the avoidance of doubt, KKC shall bear the costs of any Development costs related to the KKC Territory, including, without limitation, the Development costs incurred in connection with the Japan portion of a Global Phase 3 Registrational Studies or any other global clinical study.

Section 1.83 "Global Development Plan" means the applicable global plan prepared by Amgen no less than [***] and will be reviewed and discussed by the JDS and approved by the JSC, consistent with the Global Product Strategy, as such Global Development Plan may be updated from time to time in accordance with the terms of this Agreement, covering, among other things: (i) the Development of the Product (both in the Amgen Territory and in the KKC Territory), including [***], (ii) the preparation and submission of Regulatory Filings, and

(iii) the obtaining and maintenance of Regulatory Approvals and Pricing Approvals of the Product.

Section 1.84 "Global Phase 3 Registrational Study" means a registration or pivotal Clinical Study performed in accordance with Applicable Laws and conducted in subjects which is designed to establish the efficacy and safety of the Product for the [***] given its intended use and to define warnings, precautions and adverse events that are associated with such Product in the dosage range intended to be prescribed.

Section 1.85 "Global Pricing Policy" means the global plan for the Product jointly developed by the Parties and approved by the JSC, consistent with the Global Product Strategy, that sets forth, globally and by region both in the Amgen Territory and in the KKC Territory [***] as such Global Pricing Policy may be amended and updated from time to time in accordance with Section 6.2 (Global Pricing Policy). Attached as the Global Pricing Policy Considerations Schedule is the alignment of the Parties as of the Effective Date as to the concepts and escalation procedures to be included in the Global Pricing Policy.

Section 1.86 "Global Product Strategy" means the global plan for the Product prepared by Amgen and reviewed and approved by the JSC that sets forth the high level strategy for the Development and Commercialization of Product in the Collaboration Territory.

Section 1.87 "Governmental Authority" means any government or supranational administrative agency, commission or other governmental or supranational authority, regulatory body or other instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.

Section 1.88 "Government Official" means (i) any official or employee of any Governmental Authority, or any department, agency, or instrumentality thereof (including commercial entities owned or controlled, directly or indirectly, by a Governmental Authority), (ii) any political party or official thereof, or any candidate for political office, in the Amgen Territory or any other country, or (iii) any official or employee of any public international organization, or any family member of any of the foregoing individuals identified in the foregoing clauses (i), (ii) and (iii).

Section 1.89 "Healthcare Compliance Requirements" means the healthcare fraud and abuse laws and regulations and industry codes of conduct (for the Collaboration Territory) related to promotional and nonpromotional activities concerning a company's pipeline and approved pharmaceutical, biologic and medical device products, transparency and reporting of relationships with and transfers of value to healthcare providers and other members of the healthcare community, coverage, reimbursement, pricing and price reporting for approved pharmaceutical, biologic and medical device products and interactions with healthcare professionals and members of the healthcare community.

Section 1.90 "Housemarks" means the Amgen Housemarks or the KKC Housemarks, as the case may be.

Section 1.91 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. § 18a).

Section 1.92 "HSR Filing" means a filing by each of Amgen and KKC with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

Section 1.93 "IND" means (i) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (ii) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "Clinical Trial Application" in the European Union, and (iii) all supplements and amendments to any of the foregoing.

Section 1.94 "Indemnified Party" has the meaning set forth in Section 14.3 (Claim for Indemnification).

Section 1.95 "Indemnifying Party" has the meaning set forth in Section 14.3 (Claim for Indemnification).

Section 1.96 "Indirect Taxes" means value added taxes, sales taxes, consumption taxes and other similar taxes, and any surcharge levied on such taxes pursuant to Applicable Law.

Section 1.97 "Information" means all tangible and intangible techniques, information, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms. "Information" excludes tangible materials such as biological compounds, chemical compounds, and reagents, and excludes Trademarks and Housemarks.

Section 1.98 "Initial Global Development Plan" means that certain Global Development Plan prepared by Amgen and KKC and separately agreed upon by the Parties as of the Effective Date.

Section 1.99 "Initial Medical Liaison Notice" has the meaning set forth in Section 6.4.7 (Medical Affairs Activities).

Section 1.100 "Insolvency Event" means, with respect to any Party, the occurrence of any of the following: (i) such Party shall commence a voluntary case concerning itself under any bankruptcy, liquidation or insolvency code, (ii) an involuntary case is commenced against such Party and the petition is not dismissed within [***] after commencement of the case, (iii) a court-supervised custodian is appointed for, or takes charge of, all or substantially all of the property of such Party or such Party commences any other proceedings under any reorganization,

arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect relating to such Party or there is commenced against such Party any such proceeding which remains undismissed for a period of [***], (iv) any order of relief or other order approving any such case or proceeding is entered, (v) such Party is adjudicated insolvent or bankrupt, (vi) such Party suffers any appointment of any court-appointed custodian, receiver or the like for it or all or substantially all of its property to continue undischarged or unstayed for a period of [***], (vii) such Party makes a general assignment for the benefit of creditors, (viii) the governing body or executive management of such Party shall make a duly authorized statement that it is unable to pay, or shall be unable to pay, its debts generally as they become due, or (ix) such Party shall call a meeting of its creditors generally with a view to arranging a compromise or adjustment of its debts, or (x) any corporate, limited liability company, partnership or individual action, as applicable, is taken by such Party for the specific purpose of effecting any of the foregoing.

Section 1.101 "International Trade Laws" means all applicable import, export, reexport and foreign trade control statutes, laws, regulations, enactments, directives and ordinances of any Governmental Authority with jurisdiction over any operations or activities of a Party under this Agreement then in effect.

Section 1.102 "Investigator Sponsored Study" means an investigator sponsored Clinical Study using the Product.

Section 1.103 "Investigator Sponsored Data" means the preclinical and clinical data generated in the course of an Investigator Sponsored Study.

Section 1.104 "Joint Claim" has the meaning set forth in Section 14.4 (Defense of Third Party Claims).

Section 1.105 "Joint Commercialization Subcommittee" or "JCS" has the meaning set forth in Section 2.2.8 (Joint Commercialization Subcommittee).

Section 1.106 "Joint Development Subcommittee" or "JDS" has the meaning set forth in Section 2.2.7 (Joint Development Subcommittee).

Section 1.107 "Joint Operations Subcommittee" or "JOS" has the meaning set forth in Section 2.2.9 (Additional Joint Project Teams).

Section 1.108 "Joint Patents" means any invention, patent or patent application jointly owned by the Parties pursuant to Section 11.1 (Ownership and Cooperation).

Section 1.109 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.2.1 (Formation).

Section 1.110 "Key Regulatory Filings and Material Communications" means Regulatory Filings and correspondence with Regulatory Authorities intended to apply to data driven submissions in contrast to administrative correspondence.

Section 1.111 "KKC" has the meaning set forth in the Preamble.

Section 1.112 "KKC Assumed Item" has the meaning set forth in Section Section 11.2(b)(ii) (KKC Secondary Prosecution).

Section 1.113 "KKC Assumed Joint Patent Item" has the meaning set forth in Section 11.2(c)(iv) (KKC Secondary Prosecution of Joint Patents in the Amgen Territory).

Section 1.114 "KKC Co-Detail Sales Force" has the meaning set forth in Section 6.4.4 (Detailing).

Section 1.115 "KKC Co-Promote Medical Liaisons" has the meaning set forth in Section 6.4.7 (Medical Affairs Activities).

Section 1.116 "KKC Housemarks" means (i) the corporate logo of KKC, (ii) the trademark "Kyowa Kirin," (iii) any other trademark, trade name or service mark (whether registered or unregistered) containing the word "Kyowa Kirin," and (iv) any other trademark or service mark associated with goods or services of KKC or its Affiliates, but excluding the Licensed KKC Trademarks and trademarks, tradenames or service marks associated with and used solely in connection with goods or services outside of the scope of this Agreement; and all intellectual property rights residing in any of the foregoing.

Section 1.117 "KKC Improvement" means any improvement, modification, enhancement to or novel use of the Product that (a) either Covers or specifically relates to the Product or (b) is developed by or on behalf of, or becomes Controlled by, KKC or its Affiliates during the Term in the research, conduct of Medical Affairs Activities with respect to, Development, Commercialization or Manufacture of the Product or any of the activities contemplated hereunder.

Section 1.118 "KKC Indemnitees" has the meaning set forth in Section 14.2 (Indemnity by Amgen).

Section 1.119 "KKC Development Data" means the preclinical and clinical data and any other data generated by or on behalf or in possession of KKC or its Affiliates in the Collaboration Territory in the course of (i) its Development, on or after the Effective Date of this Agreement, and (ii) the preclinical and clinical Development of the Product, before the Effective Date of this Agreement.

Section 1.120 "KKC Territory" means Japan.

Section 1.121 "KKUS" means Kyowa Kirin Inc.

Section 1.122 "KKUS Commercialization Costs" has the meaning set forth in Section 8.3.1 (KKUS Costs).

Section 1.123 "KKUS Development Costs" has the meaning set forth in Section 8.2.1 (KKUS Costs).

Section 1.124 "Lead Indication" means [***].

Section 1.125 "Licensed Amgen IP" has the meaning set forth in Section 11.2(b)(i) (Amgen Primary Prosecution).

Section 1.126 "Licensed Amgen Know-How" means Information Controlled during the Term by Amgen or its Affiliates that is reasonably necessary for KKC to use, research, Manufacture, Develop, conduct Medical Affairs Activities with respect to or Commercialize the Product, as contemplated in this Agreement. Licensed Amgen Know-How shall include Amgen Development Data and Amgen Improvements that are reasonably necessary for KKC to use, research, Manufacture, Develop, conduct Medical Affairs Activities with respect to or Commercialize the Product, as contemplated in this Agreement.

Section 1.127 "Licensed Amgen Patents" means those Patents Controlled on or after the Effective Date by Amgen or its Affiliates (including an interest in a patent or Joint Patent pursuant to Section 11.1 (Ownership and Cooperation)) that (i) would (absent the licenses granted herein) be infringed by the use, research, Development or Commercialization or Manufacture of, or the conduct of Medical Affairs Activities with respect to, the Product or (ii) would be reasonably necessary for the use, research, Development, Commercialization or Manufacture of, or the conduct of Medical Affairs Activities with respect to, the Product. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be infringed if issued as then currently set forth in the patent application, which application has not been pending for more than [***] since its earliest claimed priority date.

Section 1.128 "Licensed Amgen Trademarks" means any Trademarks Controlled and adopted by Amgen or its Affiliates on or after the Effective Date for use with the Product in the Amgen Territory (not including any Amgen Housemarks).

Section 1.129 "Licensed KKC IP" has the meaning set forth in Section 11.2(a)(i) (KKC Primary Prosecution).

Section 1.130 "Licensed KKC Know-How" means Information Controlled by KKC or its Affiliates, as of the Effective Date or thereafter during the Term, that is reasonably necessary for Amgen to use, research, Manufacture, Develop, conduct Medical Affairs Activities with respect to or Commercialize the Product, as contemplated in this Agreement. Licensed KKC Know-How shall include KKC Development Data and KKC Improvements that are reasonably necessary for Amgen to use, research, Manufacture, Develop, conduct Medical Affairs Activities with respect to or Commercialize the Product, as contemplated in this Agreement.

Section 1.131 "Licensed KKC Patents" means those patents and patent applications set forth on the Licensed KKC Patents Schedule, as well as any continuation, divisional, substitution, continuation-in-part, reissue, reexamination, provisional and converted provisional application thereof, and any Patent in the Amgen Territory Controlled by KKC or its Affiliates on or after the Effective Date (including an interest in a patent or Joint Patent pursuant to Section 11.1 (Ownership and Cooperation)) that (i) would (absent the licenses granted herein) be

infringed by the use, research, Manufacture, Development or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Product or (ii) would be reasonably necessary for the use, research, Manufacture, Development or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Product. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be infringed if issued as then currently set forth in the patent application, which application has not been pending for more than [***] since its earliest claimed priority date.

Section 1.132 "Licensed KKC Patent Opposition" means the notice of opposition received by KKC relating to certain Licensed KKC Patents in the EU.

Section 1.133 "Licensed KKC Patent Schedule" means the schedule of Licensed KKC Patents attached hereto, which may be updated by KKC from time to time upon reasonable notice to Amgen.

Section 1.134 "Licensed KKC Trademarks" means any Trademark rights Controlled by KKC or its Affiliates in the Amgen Territory on or after the Effective Date and corresponding to any Trademarks adopted by KKC for use with the Product in the KKC Territory (not including any Housemarks, and not including any such marks to the extent such marks would conflict with any right of any Third Party inside the Amgen Territory).

Section 1.135 "Losses" has the meaning set forth in Section 14.1 (Indemnity by KKC).

Section 1.136 "MA" or "Marketing Authorization" means an MAA that has been approved by the applicable Governmental Authority to market the applicable product in a country or group of countries.

Section 1.137 "MAA" means, with respect to any product, (i) in the U.S., a BLA and (ii) outside the U.S., a Regulatory Filing for the authorization to market such product in any country or group of countries outside the U.S., as defined in the applicable laws and regulations and filed with the Regulatory Authority of such country or group of countries.

Section 1.138 "Manufacture" means all activities related to the manufacturing of the Product, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of the Product or any component or ingredient thereof, and regulatory activities related to all of the foregoing.

Section 1.139 "Manufacturing Actual Costs" means, with respect to a Product (i) the actual Costs (including, without limitation, Allocable Manufacturing Overhead and [***]) to Manufacture such Product including [***] and (ii) [***]. Manufacturing Actual Costs will be calculated consistently with other products manufactured by the applicable Party and in accordance with GAAP. For clarity, (a) in the event that a Party uses a contract manufacturer to

perform any manufacturing activities under this Agreement, Manufacturing Actual Costs for such activities will be the price such Party pays such contract manufacturer for such activities (which price shall be on bona fide arm's length terms and not, by way of example, transfer pricing for such Products), plus the Costs to manage and to process materials obtained from such contract manufacturer, (b) to the extent that any Manufacturing Actual Cost relates to a Product and any other product(s) of a Party, the Manufacturing Actual Cost will be properly allocated by Amgen among such Product and other product(s) in accordance with customary accounting principles consistent with the calculation of Allocable Manufacturing Overhead for such Product.

Section 1.140 "Manufacturing Standard Costs" means, with respect to a Product, the clinical standard cost for such Product as of the time of manufacture as calculated in a manner consistent with a Party's other products. For clarity, (i) Amgen's internal clinical standard cost methodology for clinical product is calculated [***], and (ii) in the event that a Party uses a contract manufacturer to perform any Manufacturing activities under this Agreement, Manufacturing Standard Cost for such activities will be the price such Party pays such contract manufacturer for such activities, plus the Costs to manage and to process materials obtained from such contract manufacturer

Section 1.141 "Manufacturing Transfer" has the meaning set forth in Section 5.2 (Transfer of Manufacturing Technology).

Section 1.142 "Marketing Authorization Holder" means the party holding the Marketing Authorization.

Section 1.143 "Material Safety Issue" means a Party's good faith belief that there is an unacceptable risk of harm to humans based upon (i) pre-clinical Safety Data, including data from animal toxicology studies or (ii) the observation of adverse effects in humans following the Product having been administered to or taken by humans.

Section 1.144 "Medical Affairs Activities" means design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or support clinical studies regarding, the Product, which includes by way of example: (i) evidence generation activities pertaining to but not limited to Phase 4 Studies, activities intended to obtain real world evidence, health economics and outcomes research studies and Investigator Sponsored Studies, (ii) activities of Medical Liaisons, (iii) grants to support continuing independent medical education (including independent symposia and congresses), and (iv) development, publication and dissemination of scientific and clinical information in support of an approved indication for the Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing representatives or received by letter, phone call or email or other means of communication agreed by the Parties in writing.

Section 1.145 "Medical Affairs Activities Costs" means Costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement associated with Medical Affairs Activities in the Collaboration Territory to the extent incurred in accordance with the applicable Global Development Budget and Commercialization Budget. For the avoidance of doubt,

Medical Affairs Activities Costs with respect to a Product shall be included in [***] until the First Commercial Sale of the Product in [***] and, for [***], shall be included as [***] thereafter.

Section 1.146 "Medical Affairs Percentage" means [***] percent ([***]%).

Section 1.147 "Medical Liaisons" means those health care professionals employed or engaged by a Party with sufficient health care experience to engage in in-depth dialogues with health care professionals regarding medical issues associated with the Product and are not sales representatives or otherwise engaged in direct selling or promotion of the Product.

Section 1.148 "Medical Liaison Change Notice" has the meaning set forth in Section 6.4.7 (Medical Affairs Activities).

Section 1.149 "Milestone Payment" has the meaning set forth in Section 8.10 (Milestone Payments).

Section 1.150 "Multiple Product Offering" has the meaning set forth in Section 8.11.3 (Multiple Product Offerings).

Section 1.151 "Net Revenues" means, with respect to a certain period of time, the aggregate of the gross invoiced sales prices for the Product sold or transferred for value by or for Amgen, its Affiliates or sublicensees (including, for clarity, any Sublicense Income) in arms-length transactions to unaffiliated Third Parties for the Amgen Territory (but not including sales relating to transactions between Amgen or its Affiliates and agents (including Amgen's sublicensees)) during such time period, less the total of the following charges or expenses as determined in accordance with GAAP and each to the extent not already deducted when calculating Manufacturing Actual Costs (regardless of the period in which such amounts are incurred or paid) and not included as part of the applicable Party's Global Development Cost or Commercialization and Related Costs:

(a) trade, cash, prompt payment and/or quantity discounts;

(b) returns, allowances, rebates, chargebacks and fees paid on a bona fide arm's length basis or payments to government agencies, including any amounts imposed or due under Section 9008 of the U.S. Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48);

(c) retroactive price reductions applicable to sales of the Product;

(d) 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 on a bona fide arm's length basis;

(e) credits or allowances for product replacement, whether cash or trade;

(f) non-recovered Indirect Taxes (such as VAT or its equivalent) and excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities and any other governmental charges imposed upon the sale of such Product to Third Parties;

(g) [***] included in the gross invoiced sales price; and

(h) [***] percent [***] of gross sales to cover items such as bad debt, freight or other transportation charges, insurances charges, additional special packaging, and other governmental charges.

Section 1.152 "Other Personnel" means any personnel other than Sales Force Representatives performing Commercialization activities as well as Medical Liaisons and access and pricing and field based marketing personnel in or for the Amgen Territory in accordance with this Agreement.

Section 1.153 "Party" or "Parties" has the meaning set forth in the Preamble.

Section 1.154 "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 or divisional applications, 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).

Section 1.155 "Patent and Trademark Matters" has the meaning set forth in Section 11.2(a)(i) (KKC Primary Prosecution).

Section 1.156 "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.

Section 1.157 "Personal Information" means any information that relates to, describes or is capable of being associated with or linked to an individual, by direct or indirect means, including without limitation classes, categories and other types of information that may identify an individual as specified by Applicable Law.

Section 1.158 "Pharmacovigilance Agreement" means any pharmacovigilance agreements between the Parties regarding adverse event management with respect to the Product.

Section 1.159 "Phase 4 Study" means any non-registrational clinical study initiated in any jurisdiction in the Amgen Territory for the Product following the first Regulatory Approval

for the sale of such Product in the applicable jurisdiction for the indication being studied. Phase 4 Studies may include [***], as well as [***].

Section 1.160 "Pricing Approval" means, with respect to any country where a Governmental Authority authorizes reimbursement, or approves or determines pricing, for pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

Section 1.161 "PMDA" means the Pharmaceuticals and Medical Device Agency.

Section 1.162 "Product" means KHK4083, an afuscosylated anti-OX40 monoclonal antibody, and any back-ups directed to the same target as KHK4083 with antagonistic activity.

Section 1.163 "Program Notice" has the meaning set forth in Section 10.2 (Allowed Activities).

Section 1.164 "Promotional Materials" has the meaning set forth in Section 6.6 (Promotional Materials).

Section 1.165 "Proper Conduct Practices" means, in relation to any Person, such Person and each of its Representatives, not, directly or indirectly, (i) making, offering, authorizing, providing or paying anything of value in any form, whether in money, property, services or otherwise to any Government Official or Governmental Authority, or other Person charged with similar public or quasi-public duties, or to any customer, supplier, or any other Person, or to any employee thereof, or failing to disclose fully any such payments in violation of the laws of any relevant jurisdiction to (a) obtain favorable treatment in obtaining or retaining business for it or any of its Affiliates, (b) pay for favorable treatment for business secured, (c) obtain special concessions or for special concessions already obtained, for or in respect of it or any of its Affiliates, in each case which would have been in violation of any Applicable Law, (d) influence an act or decision of the recipient (including a decision not to act) in connection with the Person's or its Affiliate's business, (e) induce the recipient to use his or her influence to affect any government act or decision in connection with the Person's or its Affiliate's business or (f) induce the recipient to violate his or her duty of loyalty to his or her organization, or as a reward for having done so, (ii) engaging in any transactions, establishing or maintaining any fund or assets in which it or any of its Affiliates shall have proprietary rights that have not been recorded in the books and records of it or any of its Affiliates, (iii) making any unlawful payment to any agent, employee, officer or director of any Person with which it or any of its Affiliates does business for the purpose of influencing such agent, employee, officer or director to do business with it or any of its Affiliates, (iv) violating any provision of applicable Anti-Corruption Laws, (v) making any payment in the nature of bribery, fraud, or any other unlawful payment under the Applicable Law of any jurisdiction where it or any of its Affiliates conducts business or is registered, or (vi) if such Person or any of its Representatives is a Government Official or Governmental Authority, improperly using his, her or its position as a Government Official or Governmental Authority to influence the award of business or regulatory approvals to or for the benefit of such Person, its Representatives or any of their business operations, or failing to recuse

himself, herself or itself from any participation as a Government Official or Governmental Authority in decisions relating to such Person, its Representatives or any of their business operations.

Section 1.166 "Proposing Party" has the meaning set forth in Section 4.1.2 (Other Development Activities).

Section 1.167 "Quality Agreement" means any quality agreements between the Parties related to the Product supplied pursuant to this Agreement for clinical or commercial use. For clarity, "Quality Agreement" shall include any three-party quality agreements among Amgen, KKC, and a Third Party contract manufacturer or a Third Party test laboratory and any two-party quality agreements between Amgen and a Third-Party contract manufacturer or a Third Party test laboratory.

Section 1.168 "Quality and Compliance Standards" means the quality and compliance standards set forth by Amgen (including those contained in the Quality Agreement) from time to time, including manufacturing standards, such as international Good Clinical Practices (GCP), international Good Pharmacovigilance Practices (GVP), international Good Manufacturing Practices (GMP), quality standards, supply chain standards, such as PMDA, international Good Supply Practice (GSP), distribution standards, such as WHO Good Distribution Practice (GDP), safety and healthcare compliance standards and generally accepted national and international pharmaceutical industry codes of practice (including guidelines under the International Conference on Harmonization (ICH)).

Section 1.169 "Recoveries" means all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party in connection with the final judgment, award or settlement of any enforcement with respect to any Licensed KKC IP, Licensed Amgen IP or Joint Patents with respect to the Product in the Amgen Territory.

Section 1.170 "Regulatory Approval" means, with respect to any product, the productspecific approvals, licenses, permits, certifications, registrations or authorizations from Governmental Authorities necessary under Applicable Law for the clinical testing in humans, commercial distribution, manufacture, marketing and sale of such product in a country or some or all of an extra-national territory, including approvals of INDs and MAs.

Section 1.171 "Regulatory Authority(ies)" means any Governmental Authority or other authority responsible for granting INDs or Marketing Approvals, including the FDA, PMDA, the National Medical Products Administration, the European Commission/EMA and any corresponding national or regional regulatory authorities and any successor agencies thereto.

Section 1.172 "Regulatory Exclusivity" means, with respect to the Product or a Distracting Product, as applicable, in a country, any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority in such country with respect to the Product or a Distracting Product, as applicable, other than a Patent.

Section 1.173 "Regulatory Filing" means, with respect to any product, any filing with any regulatory authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of such product. For clarity, the term "Regulatory Filing" shall not mean, or apply to, any submission to any regulatory authority of adverse event reports, periodic safety reports, or other similar safety submissions with respect to the Product, which shall each be governed by the Pharmacovigilance Agreement.

Section 1.174 "Regulatory Lead" has the meaning set forth in Section 4.5(a).

Section 1.175 "Regulatory Support Information" has the meaning set forth in Section 4.6 (Transfer of Regulatory Documents; Regulatory Support Information).

Section 1.176 "Representatives" means, as to any Person, such Person's Affiliates and its and their successors, controlling Persons, directors, officers and employees.

Section 1.177 "Researching Party" has the meaning set forth in Section 10.2 (Allowed Activities).

Section 1.178 "Right of First Negotiation" has the meaning set forth in Section 3.4 (Right of First Negotiation.

Section 1.179 "ROFN Notice" has the meaning set forth in Section 3.4 (Right of First Negotiation.

Section 1.180 "ROFN Period" has the meaning set forth in Section 3.4 (Right of First Negotiation.

Section 1.181 "Royalty Term" has the meaning set forth in Section 8.17 (Royalty Term).

Section 1.182 "Safety Data" means, with respect to the Product, safety and toxicity information for the Product, in each case including information related to adverse drug reactions, adverse events, discontinuations due to adverse events and laboratory abnormalities.

Section 1.183 "Sales Force" or "Sales Force Representatives" means all sales force representatives that Detail the Product in a given territory in accordance with this Agreement.

Section 1.184 "Sales Force Costs" means the allocable share of each Party's or any of its Affiliates' or contractors' sales force costs for sales representatives that Detail the Product in the U.S. in accordance with this Agreement, calculated in accordance with Section 6.9 (Calculation of Sales Force Costs and Other Personnel Costs); *provided*, that a Party's contract sales force costs shall (i) be such Party's actual pass-through cost and (ii) in no event exceed amounts equal to the Sales Force FTE Costs calculated in accordance with Section 6.9 (Calculation of Sales Force Costs and Other Personnel Costs) (i.e., contract sales force costs shall in no event exceed the costs associated with a Party's internal sales force).

Section 1.185 "Sales Force FTE" means a full-time equivalent sales representative (i.e., one fully-dedicated or multiple partially-dedicated sales representatives aggregating to one full-

time sales representative employed or contracted by Amgen or KKC (or KKUS with respect to Detailing activities in the U.S.) based upon a total of [***]per Calendar Year and [***] Details per day undertaken in connection with the conduct of Details in accordance with the applicable Commercialization Plan. Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the Sales Force FTE contribution.

Section 1.186 "Sales Force FTE Rate" means the applicable rate agreed by the Parties in writing as of the Effective Date with respect to each Party's sales representatives, per Sales Force FTE per year (as of the Effective Date), increasing by [***] of the then-current Sales Force FTE Rate on January 1st of 2022 and each subsequent Calendar Year. The Sales Force FTE Rate includes costs associated with salaries, payroll taxes, bonuses, benefits, recruiting, relocation, employee stock option programs or stock grants, retirement programs, and applicable overhead (e.g., facilities, operating supplies, travel and training).

Section 1.187 "Sanctioned Country" means Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine, and any other country or region subject to comprehensive sanctions under U.S., or Japan law.

Section 1.188 "Sanctioned Person" means any natural or legal person (i) identified on the Specially Designated Nationals and Blocked Persons List administered by the U.S. Department of Treasury Office of Foreign Assets Control (OFAC), on the Entity List, the Unverified List, or the Denied Persons List administered by the U.S. Department of Commerce Bureau of Industry and Security (BIS), or on any equivalent lists maintained by the United Nations, (ii) fifty percent (50%) or greater owned, directly or indirectly, in the aggregate, or otherwise controlled by a person or persons described in clause (i), or (iii) that is organized, resident, or located in a Sanctioned Country.

Section 1.189 "Second Position Detail" means a Detail in which the 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 the Product).

Section 1.190 "Soliciting Party" has the meaning set forth in Section 3.4 (Right of First Negotiation.

Section 1.191 "Sublicense Income" means any and all payments or other consideration based on sales of the Product received by a Party or its Affiliates in consideration for granting to a Third Party a sublicense under the rights granted to such Party hereunder to Commercialize the Product, including upfront or advance royalty payments. For clarity, Sublicense Income shall not include [***].

Section 1.192 "Supply Agreement" means any supply agreement between the Parties regarding the clinical supply of the Product manufactured by KKC pursuant to this Agreement.

Section 1.193 "Taxes" means any direct or indirect tax, excise or duty and any surcharge thereon levied by any Governmental Authority in accordance with Applicable Law.

Section 1.194 "Term" means the period commencing on the Effective Date and continuing in perpetuity unless terminated by either Party pursuant to this Agreement.

Section 1.195 "Territory" means the Amgen Territory or the KKC Territory, as applicable.

Section 1.196 "Third Party" means any Person that is not a Party, or an Affiliate of a Party.

Section 1.197 "Third Party Claim" means any claim, action, lawsuit, or other proceeding brought by any Third Party.

Section 1.198 "Total FPDE Details" means, for a given period of time, the total number of Details on a First Position Detail Equivalent Basis estimated by Amgen as being appropriate in connection with the promotion of the Product in the Co-Promotion Territory.

Section 1.199 "United States" or "U.S." means the United States of America and its territories and possessions.

Section 1.200 "US$" means United States Dollars, the lawful currency of the United States.

Section 1.201 "U.S. Commercialization Cost Balancing Report" has the meaning set forth in Section 8.3.4 (Balancing Payment for Commercialization and Related Costs).

Section 1.202 "U.S. Commercialization Cost-Share Payments" has the meaning set forth in Section 8.3.3 (Commercialization and Related Cost Share).

Section 1.203 "Valid Claim" means (a) any claim of an issued and unexpired Patent owned or exclusively Controlled by a Party that has not been disclaimed, abandoned or dedicated to the public or held unenforceable, unpatentable, invalid or revoked by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal or (b) a pending claim of an unissued, pending patent application, which application has not been pending for more than [***] since its earliest claimed priority date.

Section 1.204 "Withholding Party" has the meaning set forth in Section 9.6.1 (Withholding).

Article II.

SCOPE AND GOVERNANCE

Section 2.1 Purpose of the Collaboration. The purpose of the collaboration is for the Parties to collaborate in the Development and Commercialization of the Product, all as described in more detail herein. Except as expressly set forth in this Agreement and subject to oversight of

the JSC, (i) Amgen will have sole responsibility for Development and Commercialization of the Product in the Amgen Territory and (ii) KKC will have sole responsibility for Development and Commercialization of the Product in the KKC Territory. With respect to all activities and expenses reported under this Agreement, each Party covenants and agrees to reasonably, fairly and accurately reflect the underlying substance of such activities and expenses.

Section 2.2 Committees and Teams.

2.2.1 Formation. Promptly but not later than [***] days following the Effective Date, the Parties will establish a cross-functional Joint Steering Committee ("JSC"), a cross-functional Joint Development Subcommittee ("JDS") and a cross-functional Joint Commercialization Subcommittee ("JCS"). The JSC, JDS and JCS shall establish such subcommittees and joint project teams as they may elect to establish pursuant to Section 2.2.9 (Additional Joint Project Teams).

2.2.2 Membership.

(a) The JSC will be comprised of six (6) members, three (3) appointed by each of the Parties or such other number of members as agreed by the Parties; *provided*, *however*, that there shall at all times be an equal number of members appointed by each of the Parties. The JSC will be led by two (2) co-chairs, one (1) appointed by each of the Parties. The initial members of the JSC will be identified by each Party promptly following the Effective Date.

(b) Each Party will ensure that the JSC, JDS and JCS 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, (ii) a range of expertise in the development, manufacture and Commercialization of therapeutic products, as applicable, to enable an efficient committee or team structure, and (iii) received compliance training with respect to Proper Conduct Practices and Anti-Corruption Laws. 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.

2.2.3 Meetings.

(a) The JSC will meet semi-annually, via teleconference or videoconference or otherwise, or as otherwise agreed by the Parties. Any in-person meetings of the JSC will be held at such location as agreed by the Parties. The JDS and JCS shall meet at a frequency established by the JDS and JCS, respectively. Each Party will be responsible for its own expenses relating to such JSC, JDS or JCS meetings and relating to any subcommittees or joint project teams. Either Party may also call for special meetings of the JSC as reasonably required to resolve a matter escalated to the JSC pursuant to Section 2.2.9 (Additional Joint Project Teams); *provided* that the requesting Party provides at least [***] Business Days' prior written notice to the co-chair of the JSC appointed by the other Party and such notice includes a proposed agenda for such meeting.

(b) As appropriate, other employee representatives of the Parties may attend meetings of the JSC as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties.

(c) All committee and team meetings must have at least one (1) member appointed by each Party in attendance. All documents for such committee and team meetings for the collaboration will be in English, unless otherwise agreed by the Parties. The co-chairs of the JSC shall ensure the preparation and issuance of written minutes of each meeting within [***] days thereafter accurately reflecting the discussions and decisions of such meeting.

2.2.4 Decision-Making. The decisions of the JSC and any subcommittees established hereunder (including the JDS and JCS) will be made by consensus of the members thereof, with each Party having one (1) vote, provided, that, subject to the terms of this Agreement (including Section 2.2.5(b) (JSC Deadlocks)), Amgen shall have final decision rights.

2.2.5 Joint Steering Committee.

(a) *Responsibilities*. Both Parties shall be entitled through the JSC to:

(i) coordinate the Parties' activities under this Agreement;

(ii) approve the Global Development Plan and related Global Development Budget, the Global Product Strategy, Global Pricing Policy, the Commercialization Plan and related Commercialization Budget, the Co-Detail and Field Medical Liaison Plan and any annual or material updates thereto, in each case, as may be prepared by Amgen and submitted by the applicable subcommittee including the JDS and JCS;

(iii) oversee and review the global overall strategy related to the Development of, Commercialization of, Manufacturing and government affairs, compliance, conduct of Medical Affairs Activities and regulatory matters related to, the Product in both the Amgen Territory and in the KKC Territory (regardless of which Party has tie-breaking decision-making rights), including the Parties' activities under the Global Product Strategy, and, as needed, attempt to resolve issues presented to it by, and disputes within, subcommittees and product teams created by the JSC and escalated to the JSC pursuant to Section 2.2.9 (Additional Joint Project Teams);

(iv) establish subcommittees or joint product teams in addition to the JDS and JCS, as appropriate, as described more fully in Section 2.2.9 (Additional Joint Project Teams) below;

(v) direct and oversee any operating subcommittee or team;f

(vi) address and resolve any disputes of any subcommittee escalated to the JSC pursuant to Section 2.2.9 (Additional Joint Project Teams); and

(vii) perform such other functions as appropriate to further the purposes of this Agreement as allocated to it in writing by the Parties or as otherwise specified in this Agreement.

(b) *JSC Deadlocks*.

(i) *Non-Critical Matters*. If the JSC is unable to reach consensus on a non-Critical Matter, the decision will be made by the members of the JSC:

(A) appointed by Amgen if such matter is primarily related to:

1. Commercialization of the Product in the Amgen Territory,

2. Manufacturing (including product quality) for the Amgen Territory, safety or compliance matters (including Quality and Compliance Standards and Applicable Law and compliance with any of the foregoing) in the Amgen Territory,

3. Development in the Amgen Territory (except with respect to [***]), and

4. All regulatory matters with respect to the Product in the Amgen Territory (including the timing and content of regulatory agency interactions, the timing and content of Regulatory Filings and listing of indications in Regulatory Filings); and

(B) appointed by KKC if such matter is primarily related to:

1. Commercialization of the Product in the KKC Territory,

2. Manufacturing (including product quality) for the KKC Territory, safety or compliance matters (including Quality and Compliance Standards and Applicable Law and compliance with any of the foregoing) in the KKC Territory,

3. Development in the KKC Territory (except with respect to [***]), and

4. all regulatory matters with respect to the Product in the KKC Territory (including the timing and content of regulatory agency interactions, the timing and content of Regulatory Filings and listing of indications in Regulatory Filings);

in each case contemplated in clauses (A) and (B) and all subclauses, so long as such decision is consistent with the Global Product Strategy, Global Pricing Policy, Global Development Plan, Global Development Budget, Commercialization Plan and Commercialization Budget.

(ii) *Critical Matters*. If the JSC is unable to reach consensus on any Critical Matter, the members of the JSC appointed by either Party will have the right to require that such issue be escalated to the Designated Officers for determination; *provided* that if, in the good faith determination of either Party, resolution of such Critical Matter requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on the Development or Commercialization of the Product or patients, (a) Amgen will have the right to make an interim decision for an exigent action within the Amgen Territory and (b) KKC will have the right to make an interim decision for an exigent action within the KKC Territory, in each case pending such determination by the Designated Officers; *provided further*, that prior to making any such exigent actions, each Party shall use reasonable efforts, if possible in a reasonable time-frame determined by the Party with the right to make such interim decision, to: (a) notify the other Party of the need for such exigent action; (b) solicit the other Party's feedback (and the other Party shall reasonably cooperate to provide such feedback within the time -frame required by the Party with the right to make such interim decision on an accelerated basis) and (c) subject to the other Party providing feedback within the required time -frame, consider such feedback in good faith when taking such exigent action.

2.2.6 Designated Officers.

(a) Either Party may call for a special meeting of the Designated Officers reasonably required in order to resolve a matter escalated to the Designated Officers pursuant to Section 2.2.5(b) (JSC Deadlocks) above; *provided* that the requesting Party provides at least [***] Business Days' prior written notice to the co-chair of the JSC appointed by the other Party and such notice includes a proposed agenda for such meeting.

(b) All decisions of the Designated Officers will be made by consensus, except (i) with respect to compliance, product safety or quality matters with respect to the Amgen Territory (which will be made by the Amgen Designated Officer), (ii) with respect to compliance, product safety or quality matters with respect to the KKC Territory (which will be made by the KKC Designated Officer) (iii) with respect to [***] and (iv) [***]. In the event that a Party makes a decision pursuant to this Section 2.2.6(b) without the consensus of the Designated Officers, then such Party shall provide timely notice to the other Party regarding the same.

2.2.7 Joint Development Subcommittee. Promptly but not later than [***] days following the Effective Date, the Parties will establish a Joint Development Subcommittee, which shall have equal representation from both Parties and shall establish a meeting frequency and meeting protocol necessary to coordinate and conduct the activities for which it is responsible, as agreed by the Parties. Decisions of the JDS will be made by consensus of the members thereof with each Party having one (1) vote. If the JDS is unable to reach consensus on a non-Critical Matter, the decision will be made by the member of the JDS with decision rights for such matter pursuant to Section 2.2.5(b)(i)(A) and (B), applied *mutatis mutandis* with respect to the JDS. If the JDS is unable to reach consensus on any Critical Matter after endeavoring in

good faith to do so, such matter shall be referred to the JSC for resolution. The JDS responsibilities shall include:

(a) Reviewing and discussing the Global Development Plan, and related Global Development Budget prepared by Amgen (or any updates or amendments to each of the foregoing), including [***] in each case consistent with the Global Product Strategy, and submitting the Global Development Plan and Global Development Budget to the JSC for approval in accordance with Section 2.2.5 (Joint Steering Committee);

(b) Reviewing, discussing and providing strategic oversight for proposed Development activities to the extent not included in the then-current Global Development Plan and proposed by a Party, including, without limitation, [***];

(c) Reviewing and discussing matters related to obtaining and maintaining Regulatory Approvals including Medical Affairs Activities for the Product and efforts directed to obtaining and maintaining Regulatory Approval for the Product in the respective jurisdictions;

(d) Reviewing and discussing Clinical Studies and non-clinical studies;

(e) Reviewing and discussing issues regarding supply of Product for Clinical Studies under the Global Development Plan;

(f) Reviewing and providing strategic oversight for pharmacovigilance and safety; and

(g) Serving as the principal means by which each Party shall keep the other Party reasonably informed regarding the progress and results of such Party's Development efforts for the Product, including regulatory matters and communications with any Regulatory Authority having jurisdiction regarding the Product, Medical Affairs Activities for the Product, and progress and results of Clinical Studies and non-clinical studies.

2.2.8 Joint Commercialization Subcommittee. The Parties shall establish a Joint Commercialization Subcommittee within [***]months before the anticipated First Commercial Sale in the Amgen Territory. The JCS shall have equal representation from both Parties and shall establish a meeting frequency and meeting protocol necessary to coordinate and conduct the activities for which it is responsible, as agreed by the Parties. Decisions of the JCS will be made by consensus of the members thereof with each Party having one (1) vote. If the JCS is unable to reach consensus on a non-Critical Matter, the decision will be made by the member of the JCS with decision rights for such matter pursuant to Section 2.2.5(b)(i)(A) and (B), applied *mutatis mutandis* with respect to the JCS. If the JCS is unable to reach consensus on any Critical Matter after endeavoring in good faith to do so, such matter shall be referred to the JSC for resolution. The JCS responsibilities shall include:

(a) Reviewing and discussing the overall strategy for Commercializing the Product in the Amgen Territory consistent with the Global Strategy Plan and Global Pricing Policy, and submitting to the JSC the Commercialization Plan prepared by Amgen, related

Commercialization Budget prepared by Amgen, Co-Detail and Field Medical Liaison Plan and any material updates or amendment thereto;

(b) Reviewing, discussing and providing strategic oversight for any proposed Commercialization activities to the extent not included in the then-current Commercialization Plan and proposed by a Party;

(c) Reviewing and discussing the target product profile to be Commercialized in the Amgen Territory, including [***];

(d) Serving as the principal means by which each Party shall keep the other Party reasonably informed regarding the progress and results of each Party's Commercialization efforts for the Product in the Amgen Territory, including efforts directed to pricing and reimbursement strategies and Medical Affairs Activities for the Product.

2.2.9 Additional Joint Project Teams. From time to time, in addition to the JDS and the JCS, the JSC or the Parties may establish other permanent or *ad hoc* cross-functional or function-specific subcommittees or joint project teams to oversee particular projects or activities, including Development, Manufacturing, regulatory affairs, supply chain, Medical Affairs Activities and Commercialization, within the scope of the JSC's authority hereunder, and such subcommittees or joint project teams will be constituted as the JSC approves. Without limitation to the foregoing, the Parties shall establish a joint project team under the JDS with functions, relating to the Party's Development activities hereunder, to be discussed and agreed upon by the JDS. If a Joint Operations Subcommittee is established hereunder by the Parties to provide strategic oversight of manufacturing matters, such JOS shall have governance and decision making terms equivalent to the JCS and JDS unless otherwise agreed by the Parties. Unless otherwise agreed by the Parties, each subcommittee or joint project team established pursuant to this Section 2.2.9 shall be subordinate to and governed by either the JCS or JDS (or, if applicable, the JOS, if established hereunder) and if such subcommittee or joint project team is unable to reach consensus on any matter after endeavoring in good faith to do so, such matter shall be referred to the JCS or JDS (or, if applicable, the JOS, if established hereunder), as applicable.

2.2.10 Information Sharing. Each Party will provide, through its participation in the JSC and any applicable subcommittees or project teams, information on the progress and results of its activities under the Initial Global Development Plan, Global Development Plan and Co-Detail and Field Medical Liaison Plan, including information such as [***]. In addition, each Party shall promptly make available to the other Party such information about its material activities under the Initial Global Development Plan and Co-Detail and Field Medical Liaison Plan as may be reasonably requested by the other Party.

Section 2.3 Reporting. Each Party will keep the applicable committee or team informed of key progress and key 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.

Section 2.4 No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, neither the JSC nor any other committee or team will have any authority to amend, modify or waive compliance with this Agreement or any other agreement between the Parties.

Section 2.5 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 Managers will have the right to attend all meetings of the JSC and any subcommittees and joint project 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.

Section 2.6 Global Product Strategy. Amgen shall prepare, and KKC shall provide comments and feedback on, an initial Global Product Strategy for the Product, not later than [***] prior to the anticipated launch of the Product in the Amgen Territory. Amgen and KKC shall submit the Global Product Strategy to the JSC for approval. Thereafter, the Global Product Strategy will be updated annually (or such other timeframe determined by the JSC) and submitted to the JSC for approval.

Article III.

GRANT OF LICENSE

Section 3.1 Licensed KKC Patents and Know-How. Subject to the terms and conditions of this Agreement, KKC hereby grants to Amgen, during the Term, effective as of the Effective Date (without any further action by either Party), subject to the terms and conditions hereof a sublicensable (solely in accordance with Section 3.3 (Sublicensing)) royalty-bearing right and license under the Licensed KKC Patents, Licensed KKC Know-How and KKC's interest in the Joint Patents, to:

(a) Research and Develop the Product in the Collaboration Territory, and take all actions necessary to accomplish the foregoing in accordance with the terms of this Agreement, including conducting Investigator Sponsored Studies as agreed upon by the parties pursuant to Section 4.3 (Investigator Sponsored Studies) and such license will be [***] (as between Amgen and KKC);

(b) Commercialize and conduct Medical Affairs Activities with respect to the Product in the Amgen Territory and take all actions necessary to accomplish the foregoing in accordance with the terms of this Agreement, and such license will be [***] (pursuant to KKC's governance rights pursuant to Article 2 (Scope and Governance), rights under Section 6.3 (Co-Marketing Right) and co-promotion rights under Section 6.4 (Co-Promotion Activities)); and

(c) Manufacture Product for use in connection with Development and Commercialization activities in the Collaboration Territory in accordance with the terms of this Agreement.

Section 3.2 Licensed Amgen Know-How and Patents. Subject to the terms and conditions of this Agreement, Amgen hereby grants to KKC, during the Term, effective as of the Effective Date (without any further action by either Party), subject to the terms and conditions hereof a sublicensable (solely in accordance with Section 3.3 (Sublicensing)), non-exclusive, fully-paid, royalty-free, perpetual right and license under the Licensed Amgen Patents, Licensed Amgen Know-How and Amgen's interest in the Joint Patents, to:

(a) Research and Develop the Product in the KKC Territory, and take all actions necessary to accomplish the foregoing in accordance with the terms of this Agreement, including conducting Investigator Sponsored Studies as agreed upon by the parties pursuant to Section 4.3 (Investigator Sponsored Studies);

(b) Commercialize and conduct Medical Affairs Activities with respect to the Product in the KKC Territory and take all actions necessary to accomplish the foregoing in accordance with the terms of this Agreement;

(c) Conduct Detailing activities and Medical Affairs Activities with respect to the Product in the Co-Promotion Territory in accordance with Section 6.3 (Co-Marketing Right) and Section 6.4 (Co-Promotion Activities); and

(d) Manufacture Product for use in connection with the Development and Commercialization activities in the Collaboration Territory in accordance with the terms of this Agreement.

Section 3.3 Sublicensing. Each Party shall have the right to sublicense the rights granted to such Party hereunder, subject to the terms and conditions of this Section 3.3.

Section 3.4 Amgen shall have the right to sublicense the rights granted it hereunder (a) as mutually agreed by the Parties, (b) to [***], and (c) in connection with [***].

Section 3.5 KKC shall have the right to sublicense the rights granted it hereunder (a) as mutually agreed by the Parties, (b) to [***], (c) in connection with [***], and (d) to [***] in connection with [***].

The Party granting the sublicense hereunder will remain responsible for the full and complete performance of all of such Party's obligations and duties under this Agreement and compliance of any such Third Party and sublicense with the terms of this Agreement. Each Party shall promptly notify the other Party of the grant of each sublicense (other than a sublicense with a contractor). Any such sublicense agreement shall obligate the sublicensee to: (a) comply with all relevant restrictions, limitations and obligations in this Agreement including those relating to confidentiality of the other Party's Confidential Information and (b) assign or license to the sublicensing Party all of its rights and interest in and to the intellectual property that such sublicensee acquires, develops, creates, conceives of or obtains ownership of pursuant to the exercise of its rights under such sublicense arrangement. Any use by a Party of a Third Party (including contractors) to perform obligations under this Agreement shall be pursuant to a

written agreement that is materially as protective of the other Party and its intellectual property and proprietary rights as the terms of this Agreement.

Section 3.4 Right of First Negotiation. Without limitation to Section 3.3 (Sublicensing), in the event that either Party (as the "Soliciting Party") solicits proposals, begins discussions regarding, or proposes to enter into any arrangement to sublicense or to otherwise transfer any of its rights (in whole or in part) granted to it by the other Party hereunder in any country to a third party (excluding, [***]) for the purpose of enabling such third party to conduct [***] activities in such country), the Soliciting Party shall first provide timely notice to the other Party regarding the same (such notice, the "ROFN Notice"). Upon receipt of the ROFN Notice from the Soliciting Party, the other Party shall have the right, but not the obligation, to [***]. The other Party may exercise this right by providing the Soliciting Party with written notice within [***] of receiving the ROFN Notice. The Soliciting Party must not solicit proposals, begin discussions regarding, or enter into any arrangement with any third party until the other Party's Right of First Negotiation lapses. If the other Party exercises its right, the Soliciting Party will negotiate exclusively in good faith with the other Party during the ROFN Period (defined below) regarding the terms under which the other Party would assume the Development and/or Commercialization activities thereunder in such country(ies), including: [***]. If the other Party does not exercise its right or, if after negotiating in good faith for [***] Business Days (such period, the "ROFN Period"), the Parties have not agreed on terms under which the other Party would assume the [***] activities within such country(ies), then Soliciting Party may, thereafter, negotiate with and enter into an agreement with any third party for such activities.

Section 3.5 Provision of Know-How. Following the Effective Date, the Parties shall cooperate to establish procedures for the provision of Licensed KKC Know-How relating to the Product to Amgen and Licensed Amgen Know-How relating to the Product to KKC, in each case to the extent reasonably necessary for such Party to exercise its rights and perform its obligations in accordance with this Agreement. From and after the Effective Date, during the Term, KKC shall use reasonable efforts to provide all Licensed KKC Know-How related to the Product to Amgen, and Amgen shall use reasonable efforts to provide all Licensed Amgen Know-How related to the Product to KKC, in each case to the extent reasonably necessary to exercise its rights and perform its obligations in accordance with this Agreement. In any event, following the Effective Date, each of the Parties shall provide to the other any Licensed KKC Know-How or Licensed Amgen Know-How related to the Product (respectively) as the other Party shall reasonably request; provided, that a Party shall not be obligated to disclose any Licensed KKC Know-How or Licensed Amgen Know-How, as the case may be, that is (a) [***] and (b) [***].

Section 3.6 Trademark Grants.

3.6.1 Subject to the terms and conditions of this Agreement, KKC hereby grants to Amgen, effective as of the Effective Date (without any further action by either Party), a co-exclusive (except as otherwise expressly set forth herein) right and license during the Term, subject to the terms and conditions hereof, solely to research, Manufacture, Develop, conduct Medical Affairs Activities with respect to, use, make, sell, import and otherwise Commercialize the Product in the Amgen Territory, in each case under the same Licensed KKC Trademarks as

used by KKC, its Affiliates or permitted licensees or sublicensees for the Product in the corresponding indications in the KKC Territory. In the event that KKC has identified a Licensed KKC Trademark to be so used, and is developing plans to so use such Licensed KKC Trademark, the foregoing license shall permit Amgen to similarly conduct such planning activities in the Amgen Territory to the same extent of KKC's planning activities in the KKC Territory. Such license shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.6.2 Subject to the terms and conditions of this Agreement, Amgen hereby grants to KKC, effective as of the Effective Date (without any further action by either Party), a co-exclusive right and license during the Term, subject to the terms and conditions hereof, solely to research, Manufacture, Develop, conduct Medical Affairs Activities with respect to, use, make, sell, import and otherwise Commercialize the Product in the Amgen Territory (solely with respect to KKC's co-marketing activities pursuant to Section 6.3 (Co-Marketing Right) and co-promotion activities pursuant to Section 6.4 (Co-Promotion Activities)) and in the KKC Territory, in each case under the Licensed Amgen Trademarks as used by Amgen, its Affiliates or permitted licensees or sublicensees for the Product in the corresponding indications in the Amgen Territory. Such license shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.6.3 Should Amgen desire that a different trademark be used for the Product in the Amgen Territory, or if additional trademarks to those used in the KKC Territory are otherwise required, Amgen shall be entitled to do so after consulting with KKC and giving due consideration to KKC's reasonable comments regarding an additional or replacement trademark (or trademarks). Such replacement or additional trademark(s), including trademarks and translations of such trademarks in the KKC Territory, shall be registered and owned by Amgen. For clarity, if Amgen decides to use such different trademark, such trademark shall be included in the Licensed Amgen Trademarks and licensed to KKC in accordance with the terms set forth in Section 3.6.2. Each Party shall provide regular updates to the other Party regarding proposed Licensed KKC Trademarks and Licensed Amgen Trademarks, as the case may be.

Section 3.7 Trademark and Housemark Quality Standards. Each Party shall (a) maintain such reasonable quality standards for the KKC Housemarks and Licensed KKC Trademarks (with respect to Amgen) or the Amgen Housemarks and Licensed Amgen Trademarks (with respect to KKC) as it maintains for its own trademarks of a similar nature and shall comply with the other Party's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time), (b) not use any KKC Housemark or Licensed KKC Trademark (with respect to Amgen) or any Amgen Housemarks and Licensed Amgen Trademarks (with respect to KKC) in a manner that suggests any connection with any product or service, other than use associated with the Product or any service associated with the Product, and (c) not use or display the KKC Housemarks or Licensed KKC Trademarks (with respect to Amgen) or the Amgen Housemarks or Licensed Amgen Trademarks (with respect to KKC) in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any KKC Housemark or Licensed KKC Trademark (with respect to Amgen) or Amgen Housemark or Licensed Amgen Trademark (with respect to

KKC), the Parties shall agree upon a guideline for use of such trademarks, including the review procedure and timing. From time to time, upon request by a Party, the other Party shall provide copies of the usage of the KKC Housemarks and Licensed KKC Trademarks (with respect to Amgen) or Amgen Housemarks and Licensed Amgen Trademarks (with respect to KKC) used in the marketing or promotion of the Product in order to review such usage. KKC agrees that it shall not seek to register or obtain ownership rights in any Amgen Housemark or Licensed Amgen Trademark (or confusingly similar trademark) and Amgen agrees that it shall not seek to register or obtain ownership rights in any KKC Housemark or Licensed KKC Trademark or any trademark used by KKC in connection with the Product in the KKC Territory in any indication (or confusingly similar trademark to any of the foregoing).

Section 3.8 Domain Names.

3.8.1 KKC shall be exclusively entitled to register, own and use any Domain Names corresponding to or containing KKC Housemarks or KKC Licensed Trademarks in any generic Top Level Domains (gTLDs), including the new and to be introduced gTLDs. KKC shall own all goodwill associated with all Domain Names corresponding to or containing a KKC Housemark or KKC Licensed Trademark throughout the world. Amgen shall be exclusively entitled to register, own and use any Domain Names corresponding to or containing a Licensed KKC Trademark in any Country Code Top Level Domains (ccTLDs) corresponding to countries within the Amgen Territory.

3.8.2 Amgen shall be exclusively entitled to register, own and use any Domain Names corresponding to or containing Amgen Housemarks or Amgen Licensed Trademarks in any gTLDs, including the new and to be introduced gTLDs. Amgen shall own all goodwill associated with all Domain Names corresponding to or containing an Amgen Housemark or Amgen Licensed Trademark throughout the world. KKC shall be exclusively entitled to register, own and use any Domain Names corresponding to or containing a Licensed Amgen Trademark in any ccTLDs corresponding to countries within the KKC Territory.

Section 3.9 Retained Rights and Limitations.

No rights to either Party's patents, trademarks or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved. Notwithstanding the licenses granted in this Article III (and the [***] nature of the licenses granted in Section 3.1 (Licensed KKC Patents and Know-How)), each Party retains rights: (a) to perform (itself or through its Affiliates or contractors) its obligations under this Agreement and (b) to [***]; provided, that, [***]. Further, each Party covenants and agrees not to conduct any activity in connection with such research that could [***]. For the avoidance of doubt, KKC's retained or [***] rights pursuant to Section 3.1(b) to Commercialize and conduct Medical Affairs Activities with respect to the Product in the Amgen Territory are limited to KKC's governance rights pursuant to Article II (Scope and Governance) and KKC's rights under Section 6.3 (Co-Marketing Right) and co-promotion rights under Section 6.4(Co-Promotion Activities)).

Article IV.

DEVELOPMENT AND REGULATORY

Section 4.1 Development Matters.

4.1.1 Development Activities and Costs Generally. Amgen shall be the Development lead (the "Development Lead") for the Product subject to oversight of the JSC and subject to KKC's rights to conduct Development activities in the KKC Territory as set forth in Section 4.1.2. As Development Lead, Amgen shall be responsible for all Development activities for the Product in the Amgen Territory, including responsibility for conducting the Global Phase 3 Registrational Studies for the Product as more particularly set forth in the Global Development Plan. In the event that the JSC determines [***]: either (a) [***], in a manner consistent with the Global Development Strategy for the Product and with the Global Development Plan or (b) [***]. KKC must notify Amgen of their request to have [***] within [***] of the Effective Date, in the case of [***], or with reasonable advance notice for any other [***]. If Amgen elects to [***], the Parties shall discuss in good faith, through the JDS, the relevant terms for inclusion of [***]. From and after the Effective Date, the Parties shall collaborate to initiate the Global Phase 3 Registrational Studies of the Product in accordance with the Global Development Plan and the Global Development Budget. The Parties shall discuss in good faith through the JDS the overall Development strategy for the Products and opportunities for KKC to conduct Development activities with respect to the Products in the KKC Territory pursuant to the Global Development Plan. Without limitation to the foregoing, Amgen and KKC shall [***] as soon as reasonably practicable and in any event within [***].

4.1.2 Other Development Activities. Except as otherwise expressly provided in this Agreement or as otherwise may be agreed by the Parties in writing, (a) each Party may only conduct Development activities to the extent included in the Global Development Plan; provided, however, that subject to prior review by the JDS and, subject to the compliance with the process for any Critical Matters, each Party shall be entitled to [***] (provided, however, that [***]; provided, that the data from any such Development activities will be shared with the other Party, (b) Costs related to any Development activity in the Amgen Territory consistent with the Global Development Plan will be shared on a [***]basis between Amgen and KKUS, (c) except as set forth in the Global Development Plan and Global Development Budget, Costs related to any Development Activity in the KKC Territory will be the responsibility of KKC, and (d) each Party shall conduct Development activities in a manner consistent with [***]. In the event that a Party desires to [***], then such Party (the "Proposing Party") shall [***].

Section 4.2 Global Development Plan

The Parties shall Develop the Products pursuant to a Global Development Plan, as reviewed by the JDS and approved by the JSC from time to time, which sets forth (a) the objectives and activities of the Development for the Product, including indications (b) timelines for conduct of Clinical Studies, key Regulatory Authority meetings, filing of applications for Regulatory Approval, and the receipt of Regulatory Approvals, (c) the Global Development Budget for all such activities, (d) evaluation criteria of such Development activities, (e) a coordinated

Development and regulatory strategy, including the Parties' respective roles in the development of the registration dossier and Regulatory Materials for the Product and the countries in which Development of the Products will occur, and (f) the CMC development activities for the Product to be undertaken by the Parties, and related timelines and budgets therefor. The JDS shall regularly review the Global Development Plan and the progress of activities being conducted under the Global Development Plan. Any updated Global Development Plan, including the Global Development Budget, will be effective upon approval by the JSC. Any JSC-approved Global Development Plan and Global Development Budget supersede the previous Global Development Plan and Global Development Budget for the applicable period. In the event of any inconsistency between the Global Development Plan and Global Development Budget and this Agreement, the terms of this Agreement shall prevail.

Section 4.3 Investigator Sponsored Studies. In the event that a Party desires to facilitate an Investigator Sponsored Study in the Amgen Territory or in the KKC Territory, and such Investigator Sponsored Study is not already included in the then-current Global Development Plan, then such Party shall [***].

Section 4.4 Development Records. Each Party shall maintain complete, current, and accurate records (in the form of technical notebooks or electronic files) of all Development work conducted by it under the Global Development Plan and all information resulting from such work ("Development Records"). Each Party shall ensure that such records fully and properly reflect all work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party shall permit the other Party to review and copy such records at reasonable times during normal business hours and to obtain access to originals of such records if needed for patent or regulatory purposes or for other legal proceedings. Upon reasonable request, each Party shall provide the JDS with copies of such Development Records detailing its Development activities and the results of such activities.

4.4.1 Development Reports and Updates. Each Party shall promptly provide the other Party with any deliverables described in the Global Development Plan. At each regularly scheduled JDS meeting, each Party shall provide the JDS with regular reports detailing its Development activities for the Products, the results of such activities, and an update on the Global Development Budget and spend for such activities. The Parties shall discuss the status, progress, and results of each Party's Development activities under this Agreement at such JDS meetings. Each Party shall respond in a timely fashion to any reasonable requests of the other Party for additional information related to such reports provided to the JDS. In addition to Calendar Quarterly reports and meetings with the JDS, each Party shall promptly provide the other Party with any material updates on Development of the Products.

4.4.2 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 the Product for clinical or commercial use), the Parties will discuss in good faith and enter into an appropriate material transfer agreement related thereto as necessary, which agreement will be subject to this Agreement and will be interpreted consistent with the terms hereof.

Section 4.5 Regulatory Matters.

(a) Subject to the oversight of the JSC, Amgen shall be the regulatory lead for the Product in the Amgen Territory and KKC shall be the regulatory lead for the Product in the KKC Territory (each, in such capacity, the "Regulatory Lead"), responsible for establishing the regulatory strategy for the Products, and has full decision-making authority with respect thereto subject to the terms hereunder. Each of Amgen and KKC shall discuss such regulatory strategy with the other Party at the JDS (and any other subcommittees relating to regulatory affairs as may be established by the Parties) and shall consider in good faith the other Party's comments with respect thereto.

(b) Amgen shall be the IND holder and Marketing Authorization Holder for the Product in each jurisdiction in the Amgen Territory and KKC shall be the IND holder and Marketing Authorization Holder for the Product in each jurisdiction in the KKC Territory. The nature and objectives of each communication with Regulatory Authorities shall be consistent with [***]. Each Party will use Commercially Reasonable Efforts to conduct the activities assigned to it pursuant to the foregoing.

(c) The Parties will cooperate with each other with respect to any regulatory matters with respect to the Product in a manner sufficient to enable the Parties to satisfy any reporting obligations to Governmental Authorities. In furtherance of the foregoing, the Parties shall provide reasonable consulting support and advice in conjunction with Regulatory Filings and meetings with Regulatory Authorities related to the Product in the Collaboration Territory.

Section 4.6 Transfer of Regulatory Documents; Regulatory Support Information. Upon Amgen's written request, KKC, for itself and its Affiliates, shall assign and transfer to Amgen its entire right, title, and interest in and to any and all (i) INDs relating to the Product and (ii) any clinical trial applications related to the Product in the Amgen Territory and shall execute and deliver to the FDA (and any other Regulatory Authority in the Amgen Territory as requested by Amgen in writing) a letter in a form approved by Amgen transferring ownership to Amgen of any and all such INDs and clinical trial applications filed with the FDA (or such other Regulatory Authority) by or on behalf of KKC and its Affiliates. Any costs arising from the foregoing shall be [***], as applicable.

(a) In connection with such transfer and assignment, KKC shall provide Amgen with complete and accurate copies of all such assigned INDs and all related Regulatory Filings in the Amgen Territory and related documentation and data, including any such information controlled by KKC's Third Party contractors, including, without limitation, M3 modules (all such Regulatory Filings, documentation and data, the "Regulatory Support Information"), as soon as reasonably practicable after Amgen's written request therefor, but in any event within [***] of such request, or such longer period as the Parties may agree.

(b) In connection with Amgen's filing of any Regulatory Approval of the Product in the Amgen Territory, KKC shall reasonably cooperate in assisting Amgen to respond to any requests by Regulatory Authorities (including for clarity, [***]) and shall provide Amgen with complete and accurate copies of all Regulatory Support Information in KKC's or its Affiliate's

possession and which is reasonably useful or necessary to support or be included within any such Amgen Regulatory Filing. In connection with KKC's filing of any Regulatory Approval of the Product in the KKC Territory, Amgen shall reasonably cooperate in assisting KKC to respond to any requests by Regulatory Authorities (including for clarity, [***]) and provide KKC with complete and accurate copies of all Regulatory Support Information in Amgen's or its Affiliate's possession and which is reasonably useful or necessary to support or be included within any such KKC Regulatory Filing.

(c) Simultaneously with the delivery of any Regulatory Support Information by KKC, KKC shall certify to Amgen that (i) [***], (ii) all information contained in such Regulatory Support Information is true, complete and accurate as of the date delivered to Amgen, (iii) all data contained in such Regulatory Support Information were obtained in compliance with then-current Applicable Law, including data protection and privacy laws, and (iv) all required patient authorizations and consents under the United States Health Insurance Portability and Accountability Act of 1996, the EU Data Protection Directive or any other similar Applicable Law (to the extent applicable, if any) have been obtained in connection with the Clinical Studies associated with such Regulatory Support Documentation to permit the sharing of such Regulatory Support Information with Amgen.

Section 4.7 Regulatory Communications. With respect to regulatory activities, the following terms shall apply:

4.7.1 General. The Regulatory Lead will prepare, submit and maintain all Regulatory Filings and obtain all Regulatory Approvals in accordance with the Global Development Plan and Applicable Law, and so as to maintain consistency in the content of the registration dossiers and Regulatory Materials for the Product worldwide. The non-Regulatory Lead will cooperate with the Regulatory Lead with respect to any regulatory matters. Unless exigent action is required with respect to a Key Regulatory Filings and Material Communications, the Regulatory Lead shall provide the other Party with copies of Key Regulatory Filings and Material Communications (which, for clarity, shall not be required to include [***]) (and, if applicable, an English translation) prior to submission within [***]and reasonably consider comments of such other Party in good faith. The Regulatory Lead shall consult with the other Party regarding, and keep such other Party informed of, the status of the preparation of all Key Regulatory Filings and Material Communications (which, for clarity, shall not be required to include [***]) it submits, Governmental Authority review of any such Regulatory Filings, Regulatory Authority responses to such material communications, and all associated Regulatory Approvals that it obtains with respect to the Product. The Regulatory Lead shall provide to the other Party copies of all Key Regulatory Filings and Material Communications (and, if applicable, an English translation) with respect to the Product it submits promptly after the submission (but in no event later than [***] after submission) and copies of all material correspondence with or received from Regulatory Authorities. Notwithstanding anything in this Agreement to the contrary, each Party shall have the right to redact proprietary manufacturing information from any Key Regulatory Filings and Material Communications provided to the other Party

4.7.2 Regulatory Communications Received by a Party. Without limitation to the foregoing Section 4.7.1 (General), each Party shall promptly inform the other Party of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority (regardless of the territory) which [***]; [***] ; [***]; or relates to expedited and periodic reports of adverse events with respect to the Product regardless of the territory, or product complaints, and which may have an adverse impact on Regulatory Approval or the continued Development or Commercialization of the Product regardless of the territory.

4.7.3 Exigent Action. In the case of an exigent action, the Regulatory Lead shall use reasonable efforts to notify the other Party prior to making any Key Regulatory Filings and Material Communications for the Product and, thereafter, the Regulatory Lead shall use reasonable efforts to provide the other Party with a copy (and, if applicable, an English translation) of such Key Regulatory Filings and Material Communications within [***] after making such Key Regulatory Filings and Material Communications. For the purpose of this Section 4.7, "exigent action" shall mean an action that, in the good faith determination of the Regulatory Lead, requires attention on an expedited basis that does not allow for advance copies of Key Regulatory Filings and Material Communications required by this Section 4.7 and is not attributable to the fault of the Regulatory Lead.

4.7.4 Regulatory Meetings. The Regulatory Lead will consult with the other Party reasonably in advance of the date of any anticipated meeting regarding the Product with a Regulatory Authority and will consider any timely recommendations made by the other Party in preparation for such meeting. Upon the non-Regulatory Lead's request, at least [***] of the non-Regulatory Lead may attend such meetings between the Regulatory Lead and the applicable Regulatory Authority, to the extent permitted by such Regulatory Authority. Within [***] days of such meeting, the Regulatory Lead shall provide to the Non-Regulatory Lead a summary and, within [***] days of such meeting, written minutes of any such meetings with Regulatory Authorities.

Section 4.8 Pharmacovigilance Agreement. No later than [***] after the Effective Date, the Parties shall enter into a Pharmacovigilance Agreement (or modify an existing Pharmacovigilance Agreement between the Parties so as to govern this Agreement and the transactions contemplated hereunder) with respect to the Product. Such Pharmacovigilance Agreement shall define Amgen as the holder of the global safety database and define the safety governance process to be used by the Parties, the exchange of safety information (including adverse event and other safety information relating to the Product) between the Parties, and be on commercially reasonable terms and sufficient to enable the Parties to fulfill their respective regulatory reporting obligations under Applicable Law. KKC shall provide to Amgen relevant information from all Development conducted by KKC, Investigator Sponsored Studies proposed to be facilitated by KKC, and Commercialization of the Product by KKC reasonably necessary for inclusion in the global safety database in accordance with Amgen's legal and regulatory obligations. Amgen shall provide to KKC such information from the safety database as required to satisfy KKC's legal and regulatory obligations, or as otherwise provided under the terms of the Pharmacovigilance Agreement.

(a) Amgen shall be responsible for fulfilling all pharmacovigilance requirements in the Amgen Territory, including adverse event intake and reporting, post-marketing patient registries, and product complaint reporting, management of local labeling documents, unless, and only to the extent, otherwise required by Applicable Law, and KKC shall provide any reasonable assistance requested by Amgen in connection therewith, including incorporating safety monitoring and reporting for the Amgen Territory in the overall pharmacovigilance activities.

(b) KKC shall be responsible for fulfilling all pharmacovigilance requirements in the KKC Territory, including adverse event intake and reporting, post-marketing patient registries, and product complaint reporting, management of local labeling documents, unless, and only to the extent, otherwise required by Applicable Law, and Amgen shall provide any reasonable assistance requested by KKC in connection therewith, including incorporating safety monitoring and reporting for the KKC Territory in the overall pharmacovigilance activities.

Section 4.9 Ownership of Core Data Sheet and Global Safety Database. As between the Parties, Amgen shall own and control the global safety database, the Developmental core safety information ("DCSI"), and core data sheet for the Product throughout the Product's lifecycle, including Commercialization. Amgen shall provide to KKC copies of such DCSI and core data sheet and any updates thereto in a timely manner (such that KKC has a current version of such files), shall provide KKC the opportunity to review and provide comments on the core data sheet, and shall reasonably consider such comments of KKC in good faith. In the event that a Governmental Authority in the KKC Territory mandates a change to a regional or country-specific label for the Product that varies from the applicable core data sheet, KKC shall notify Amgen and Amgen shall [***]; *provided*, *however*, the Parties will cooperate to discuss and limit any such mandated changes, to the extent possible.

Section 4.10 Sharing of Data and Know-How; Rights of Reference.

4.10.1 Each Party shall (and shall cause its Affiliates to) reasonably cooperate with the other Party to promptly share and provide access to (i) all Development Records, Amgen Development Data, KKC Development Data and Investigator Sponsored Data (at such time as such Investigator Sponsored Data becomes available to such Party) and (ii) such other Know-How in each case as is reasonably necessary for the other Party to exercise its rights or fulfill its obligations under this Agreement (including, for clarity, as may be necessary for a Party to include in its Regulatory Filings); *provided*, *however*, that each Party shall be entitled to redact any of its proprietary CMC data. The JDS may establish reasonable policies to effectuate such exchange of data and Know-How between the Parties.

4.10.2 Amgen shall cause KKC to have a right of reference to any requested Regulatory Filings or Regulatory Approvals for the Product, in each case as reasonably necessary for KKC's Development, Manufacture (solely for the Amgen Territory for the Phase 3 Registrational Studies), Medical Affairs Activities or Commercialization of the Product as permitted under this Agreement; *provided*, *however*, that, Amgen shall be entitled to redact any of Amgen's proprietary CMC data. KKC shall cause Amgen to have a right of reference to any requested Regulatory Filings or Regulatory Approvals for the Product, in each case as reasonably necessary for Amgen's Development, Manufacture (solely for the Amgen Territory), Medical

Affairs Activities or Commercialization of the Product as permitted under this Agreement; *provided*, *however*, that, KKC shall be entitled to redact any of KKC's proprietary CMC data. Each Party shall transmit to the extent accessible to and Controlled by such Party all necessary and appropriate letters to applicable Regulatory Authorities advising such applicable Regulatory Authorities of such rights of reference and use. Each Party shall be entitled to sublicense the rights of reference under this Section 4.10.2 to any permitted licensee pursuant to Section 3.3 (Sublicensing).

Section 4.11 Medical Inquiries. Each Party shall be responsible for handling all medical questions or inquiries relating to the Product in its respective Territory, including all product complaints, with regard to any Product sold in such Territory, in each case in accordance with Applicable Laws and this Agreement. KKC shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of Amgen (or any of its Affiliates) in the Amgen Territory to Amgen in accordance with all Applicable Laws, and Amgen shall immediately forward to KKC any and all medical questions or inquiries that it receives with respect to Products sold by or on behalf of KKC (or any of its Affiliates) in the KKC Territory to KKC in accordance with all Applicable Laws.

Section 4.12 Cooperation with Audit and Inspection. Amgen and KKC shall each respond to any inspection of such Party conducted by a Regulatory Authority, and Amgen and KKC, as applicable, shall cooperate with the other Party in response thereto. The inspected Party shall notify the other Party promptly of any request received from any applicable Regulatory Authority to inspect or otherwise gain access to the information, data or materials pertaining to the other Party's activities hereunder. Each Party shall use reasonable efforts to make data and documents available for such inspection pertaining to the Product under this collaboration. For clarity, the foregoing obligations of cooperation are with respect to inspections by a Regulatory Authority related to the storage and distribution of the Product, and not with respect to an audit or inspection of the Manufacturing of the Product.

Article V.

MANUFACTURING AND SUPPLY

Section 5.1 Clinical and Commercial Supply.

5.1.1 Phase 3 Clinical Supply. KKC shall be the initial manufacturing lead for the Product (the "Manufacturing Lead"). As Manufacturing Lead, KKC shall use its Commercially Reasonable Efforts to supply mutually agreed clinical quantities (for the Global Phase 3 Registrational Studies and any additional phase 1 Clinical Studies initiated prior to the Manufacturing Transfer and included in the Global Development Plan) of the Product for the Development of the Product in accordance with the Global Development Plan and the Clinical Supply Agreement, including out of any inventory of the Product existing as of the Effective Date. Subject to Section 5.2 (Transfer of Manufacturing Technology), the parties will discuss the ability of Amgen to supply the Global Phase 3 Registrational Studies from and after the Manufacturing Transfer.

5.1.2 Commercial and Subsequent Clinical Supply. Amgen shall be the Manufacturing Lead for the supply in the Amgen Territory of the Product for Commercialization and any subsequent Clinical Study following the Global Phase 3 Registrational Study. As Manufacturing Lead, Amgen shall be solely responsible for all manufacture and supply in the Amgen Territory of Product for use in Commercialization and any subsequent Clinical Study included in the Global Development Plan, either itself or through a contract manufacturer, using the manufacturing process for the Product transferred from KKC to Amgen pursuant to Section 5.2 (Transfer of Manufacturing Technology). Amgen is responsible for and shall have the right (in its sole discretion) to make any updates and improvements to the manufacturing process for the Product and shall keep KKC reasonably informed with respect to any such updates and improvements in accordance with Section 4.10.1, including any such updates or improvements constituting Licensed Amgen Know-How or Licensed Amgen Patents, any notice regarding such updates or improvements to be provided at least [***] before the applicable regulatory submission or implementation thereof. Amgen will have the sole right to determine which manufacturing sites or contract manufacturers, if any, will be used to Manufacture the Product in the Amgen Territory. KKC shall be solely responsible for manufacture and supply of the Product in the KKC Territory for use in Commercialization in the KKC Territory and any subsequent Clinical Study included in the Global Development Plan.

5.1.3 Backup Manufacturing Rights.

(a) At the time of or reasonably prior to Regulatory Approval for the Product in the KKC Territory, Amgen will provide KKC with reasonable support (including the provision of necessary records, documents, data and other Know-How) to enable Amgen's manufacturing facilities or a contract manufacturer used by Amgen, in each case reasonably acceptable to KKC (such facility or contract manufacturer, a "Backup Manufacturer"), to be [***]. In the event that such Backup Manufacturer is not qualified to be registered as a backup site, Amgen shall provide reasonable cooperation to take steps as may be necessary to [***], and KKC shall reimburse reasonable and customary expenses actually incurred by Amgen in doing so.

(b) In the event that KKC wishes to have Amgen supply [***] following such registration and during the Term of this Agreement, the Parties shall discuss in good faith the terms and conditions for such backup manufacturing, and shall, as necessary, amend this Agreement or the Clinical Supply Agreement, and/or execute a separate supply agreement in connection with the foregoing.

Section 5.2 Transfer of Manufacturing Technology. In accordance with a transition plan and timeline agreed at the JSC (or a subcommittee thereof) within [***] following the Effective Date, or such longer period as the JSC may agree, KKC shall transfer (the "Manufacturing Transfer") to Amgen, or a contract manufacturer designated by Amgen reasonably acceptable to KKC, the tangible embodiments of Licensed KKC Know-How and materials (including [***]) Controlled by KKC that is reasonably required so that Amgen or such contract manufacturer (as appropriate) can replicate and validate the process employed by or on behalf of KKC to manufacture the Product. The reasonable and customary costs of the Parties

(including the costs of FTEs, starter materials and shipping), in carrying out such transfer will be [***].

Section 5.3 Clinical Supply Agreement and Clinical Product Quality Agreement. Promptly (but in any event, within [***], or such longer period as the JSC (or a subcommittee thereof) may agree) following the Effective Date, the Parties shall enter into (a) a Clinical Supply Agreement and (b) a Clinical Product Quality Agreement with respect to the supply of clinical product by KKC to Amgen for clinical use in with the initial Phase 3 Registrational Study and any other Clinical Study sponsored by Amgen, in each case prior to the Manufacturing Transfer.

Section 5.4 Manufacturing and Supply. From and after the Manufacturing Transfer, Amgen will be responsible to supply Product in the Amgen Territory. Amgen will have the sole right to determine which manufacturing sites will be used to Manufacture a Product and may transfer the Manufacturing of such Product from one site to another; *provided*, *however*, that any Costs relating to such transfer shall not be included as part of [***] nor [***], except to the extent [***].

Section 5.5 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. Practices primarily impacting the Amgen Territory with respect to brand security will comply with Amgen's then-current standards, where they define product security features, warehouse/cargo protection requirements, and response and communication process for brand security incidents, and, if applicable, practices primarily impacting the KKC Territory with respect to brand security will comply with KKC's then-current standards, where they define product security features, warehouse/cargo protection requirements, and response and communication process for brand security incidents.

Article VI.

COMMERCIALIZATION

Section 6.1 Commercialization Activities.

(a) Subject to the oversight of the JSC, Amgen shall be the commercial lead in the Amgen Territory, and, except as set forth in Section 6.3 (Co-Marketing Right) and Section 6.4 (Co-Promotion Activities), solely responsible for the Commercialization of the Product in the Amgen Territory, and KKC shall be the commercial lead (each, in such capacity, the "Commercial Lead") in the KKC Territory, and solely responsible for the Commercialization of the Product in the KKC Territory, in each case in a manner consistent with the Global Pricing Policy and the Global Product Strategy and Commercialization Plan and Commercialization Budget. Each Party shall use Commercially Reasonable Efforts (and, in the case of KKC for clarity, solely with respect to its governance activities pursuant to Article II (Scope and Governance), co-marketing activities pursuant to Section 6.3 (Co-Marketing Right) and co-promotion activities pursuant to Section 6.4 (Co-Promotion Activities)) to Commercialize the Product in the Amgen Territory in a manner consistent with the Global Pricing Policy and the Global Product Strategy and Commercialization Plan and Commercialization Budget; *provided*,

that, the Parties shall discuss Commercialization strategy of the Products at JCS meetings, including [***].

(b) Subject to the foregoing, Amgen's responsibilities in the Amgen Territory from and after the receipt of the initial Regulatory Approvals in the Amgen Territory shall include: (i) determination of commercial strategies (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch sequence, launch and post-launch marketing and promotion, pricing and reimbursement and field sales force optimization), (ii) determination of packaging and labeling, (iii) creation of promotional materials regarding the Product which are intended for distribution to Third Parties (including medical professionals) and to Amgen's and KKC's Sales Forces (subject to Section 3.7 (Trademark and Housemark Quality Standards) and Section 6.6 (Promotional Materials)), (iv) determining and conducting promotion activities, and (v) conducting sales and distribution activities, including pricing and liaising with the applicable Governmental Authority in connection with any applicable Pricing Approval, booking sales (i.e., recognizing all revenues), taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions, in each case in a manner consistent with the Global Pricing Policy, the Global Product Strategy, Commercialization Plan and Commercialization Budget. Except as otherwise expressly provided in this Agreement, including with respect to the cost sharing set forth in Section 8.3 (Commercialization and Related Cost Sharing in the U.S.), each Party shall be solely responsible for its costs incurred in its Commercialization of the Product.

Section 6.2 Global Pricing Policy. The Parties shall cooperate to prepare the Global Pricing Policy, incorporating the concepts in the Global Pricing Policy Considerations Schedule, not later than [***] prior to the anticipated launch of the Product in the U.S. Amgen and KKC shall submit the Global Pricing Policy to the JSC for approval. Thereafter, the Global Pricing Policy will be updated annually (or such other timeframe determined by the JSC) and submitted to the JSC for approval.

Section 6.3 Co-Marketing Right. Without limitation to the following Section 6.4 (Co-Promotion Activities), the Parties acknowledge and agree that, KKC shall retain the right, either itself or through its Affiliate, to co-market the Product with Amgen in South Korea as necessary to ensure that KKC retains the right to market the Product in South Korea and to Commercialize the Product with Amgen in South Korea. In the event that KKC exercises such retained right, the Parties shall discuss in good faith and agree upon the terms and conditions for such co-marketing activity (including the supply of Product in South Korea) consistent with the terms of this Agreement, at least [***] years prior to the anticipated launch of the Product in South Korea.

Section 6.4 Co-Promotion Activities

6.4.1 Co-Promotion in the U.S. Generally. KKC shall be entitled to conduct co-promotion activities, including Co-Detailing and Medical Affairs activities in the U.S. as set

forth in this Section 6.4. Amgen acknowledges and agrees that KKC shall conduct such co-promotion activities in the U.S. through its subsidiary, KKUS. The Parties further acknowledge and agree that any references to "KKC" in this Section 6.4 that may apply with respect to KKC's co-promotion rights and obligations in the U.S. (*i.e.*, to the extent any references to the "Co-Promotion Territory" below refer to the U.S.) shall therefore be considered references to "KKUS"; *provided, however*, that KKC shall remain responsible for the performance by KKUS of its co-promotion activities in the U.S. in accordance with the terms hereunder.

6.4.2 Co-Promotion Outside of U.S. Generally. KKC shall also have the right to opt in, at any time during Term at least [***] years prior to the anticipated launch of the Product or [***] with written notice to Amgen, to co-promote in Asia (comprised of China, Taiwan, Hong Kong, Singapore, Malaysia and Thailand), Australia, Switzerland, Canada, GCC Countries, the European Union Member States set forth on the European Member States Schedule and the United Kingdom. The Parties acknowledge and agree that in order to support co-promotion by the Parties in a given Co-Promotion Territory, there should be [***].

6.4.3 KKC Co-Promotion Right. From such time as Amgen's Sales Force Representatives Details the Product in the Co-Promotion Territory, KKC shall have the right to perform the Co-Detail Percentage of the Total FPDE Details with respect to the Product in accordance with the Co-Detail and Field Medical Liaison Plan and as otherwise specified by Amgen solely to ensure such activities are conducted in accordance with Applicable Law. The Parties shall negotiate in good faith to enter into a co-promotion agreement or addendum hereto pursuant to which KKC personnel would be allocated responsibility to co-promote the Products in the U.S. and such other Co-Promotion Territories that KKC opts into pursuant to this Section 6.4 either for territories or accounts under the direction of Amgen as Commercial Lead (such direction to be consistent with this Agreement and the terms of such co-promotion agreement or addendum as agreed upon by the Parties hereto). Starting at such time as Amgen plans to assign Sales Force Representatives to Detail the Product in a Co-Promotion Territory ([***] years prior to anticipated Product launch), Amgen shall provide KKC with written notice of Amgen's good faith estimate of the Total FPDE Details for such Co-Promotion Territory. For the U.S. and such Co-Promotion Territories that qualify for co-promotion pursuant to Section 6.4.2, KKC shall notify Amgen, within [***] days of receipt of such notice, of the Co-Detail Percentage that it elects for such Co-Promote Territory, such Co-Detail Percentage not to exceed [***] percent ([***]%) of Total FDPE Details. The Parties shall, with respect to the U.S., or with respect to the Ex-U.S. Amgen Territory following KKC's opt in to such Ex-U.S. Amgen Territory, discuss in good faith the co-promotion of the Products by KKC in such Co-Promotion Territory, with responsibility to be allocated in a manner that would [***], as well as [***], and such final determination of the allocation of FPDE Details shall be subject to discussion and escalation as a Critical Matter. Thereafter, the Parties shall discuss in good faith any change to the Co-Promotion Percentage during the term of the co-promotion in the Co-Promotion Territory. Not in limitation of the foregoing, KKC shall not reduce its Co-Detail Percentage by more than [***] percent ([***]%) in any given calendar year and, in connection with any reduction in Co-Detail Percentage, KKC shall notify Amgen at least [***] months prior to the effective date of any such reduction in Co-Detail Percentage. KKC shall bear any incremental costs, if any, of any such reduction in sales force including any incremental hiring, compensation

and benefit costs and other transition costs reasonably incurred by Amgen in connection with the replacement of Sales Force Representative Details required by such reduction. In connection with the JSC's annual review of the Commercialization Plan, the JSC will review and approve the Co-Detail Percentage.

6.4.4 Detailing. KKC shall perform any Details under this Section 6.4.4 only through Sales Force Representatives who are employees of KKC, and cause such employees to perform such Details in accordance with the Co-Detail and Field Medical Liaison Plan and as otherwise specified by Amgen solely to ensure such activities are conducted in accordance with Applicable Law, the terms of this Agreement and any applicable co-promotion agreement or addendum as agreed upon by the Parties, and solely in such geographic regions and to such target audiences assigned to KKC pursuant to the Co-Detail and Field Medical Liaison Plan. KKC shall ensure that its Sales Force Representatives conducting Details under this Section 6.4.4 (the "KKC Co-Detail Sales Force") perform (i) during the [***] years following Product launch, [***] percent ([***]%) of the Details conducted by such Sales Force Representative under this Section 6.4.4 in the First Position and (ii) during and after the [***] year following Product launch, at least [***] percent ([***]%) of the Details conducted by such Sales Force Representatives under this Section 6.4.4 in the First Position. In no event shall any member of the KKC Co-Detail Sales Force Detail the Product in the Co-Promotion Territory along with more than [***] other product without the consent of Amgen. Each member of the KKC Co-Detail Sales Force shall devote at least [***] percent ([***]%) of such Person's time (on an FTE basis) to performing Details pursuant to this Section 6.4.4. The KKC Co-Detail Sales Force shall perform its Details under this Section 6.4.4 using only Promotional Materials approved by Amgen in accordance with Section 6.6 (Promotional Materials) and in accordance with the Co-Detail and Field Medical Liaison Plan.

6.4.5 Co-Detail and Field Medical Liaison Plan. Amgen shall be responsible and have the sole authority for the creation and update of the Co-Detail and Field Medical Liaison Plan; *provided*, *however*, that Amgen shall use its Commercially Reasonable Efforts to reflect in good faith, in the assignment of geographic regions and target audiences within the Co-Promotion Territory to the KKC Co-Detail Sales Force, [***]. Further, Amgen and KKC agree that they will review and discuss the initial Co-Detail and Field Medical Liaison Plan and any material updates thereto prior to finalization thereof. For clarity, and without limiting the foregoing, the Parties acknowledge that the Co-Detail and Field Medical Liaison Plan is not intended to [***], to the extent the operations as conducted by or proposed to be conducted by such Party are otherwise or would otherwise be in compliance with the Co-Detail and Field Medical Liaison Plan.

6.4.6 Co-Detail Reports. For so long as KKC performs co-promotion activities as set forth hereunder, KKC shall provide Amgen with a report, in such form and manner as reasonably determined by Amgen, within [***] days after the end of each calendar quarter, setting forth the following information regarding the efforts of the KKC Co-Detail Sales Force in Detailing the Product in the Co-Promotion Territory during the preceding calendar quarter: (i) the total number of Details made by the KKC Co-Detail Sales Force in the Co-Promotion Territory, including a breakdown by First Position Details and Second Position Details by target, and

frequency of Detail by date and by individual representative; and (ii) such other information as may be reasonably specified by Amgen.

6.4.7 Medical Affairs Activities. KKC shall have the right to perform field Medical Affairs Activities with respect to the Product in each Co-Promotion Territory using up to the Medical Affairs Percentage (calculated on an FTE basis) of the total number of Medical Liaisons (calculated on an FTE basis) assigned by Amgen to perform field Medical Affairs Activities with respect to the Product in the Co-Promotion Territory. At such time as Amgen plans to assign Medical Liaisons to conduct field Medical Affairs Activities with respect to the Product in the Co-Promotion Territory ([***] years prior to anticipated Product launch), Amgen shall provide KKC with written notice (such notice, "Initial Medical Liaison Notice") of Amgen's reasonable estimate of the total number of Medical Liaisons (calculated on an FTE basis) to be assigned by Amgen to conduct field Medical Affairs Activities with respect to the Product in the Co-Promotion Territory (the "Amgen Co-Promote Medical Liaisons"). In connection with the JSC's annual review of the Commercialization Plan, the JSC will review and approve the number of Medical Liaisons to perform Medical Affairs Activities. Amgen shall provide KKC with at least [***] days' prior written notice (such notice, "Medical Liaison Change Notice") in the event of an anticipated material increase or decrease in the Amgen Co-Promote Medical Liaisons. KKC shall notify Amgen of the total number of Medical Liaisons that KKC elects to assign to conducting field Medical Affairs Activities under this Section 6.4.7 (the "KKC Co-Promote Medical Liaisons"), which shall not exceed the Medical Affairs Percentage (calculated on an FTE basis) of the Amgen Co-Promote Medical Liaisons (provided, that, unless otherwise agreed by the Parties, the Medical Affairs Percentage shall be consistent with KKC's Co-Detail Percentage for such Co-Promotion Territory), within [***] days of KKC's receipt of the Initial Medical Liaison Notice or Medical Liaison Change Notice, as applicable, and such KKC Co-Promote Medical Liaisons shall perform field Medical Affairs Activities in accordance with this Section 6.4.7; provided, however, that in the event of a material decrease in the number of Amgen Co-Promote Medical Liaisons that results in a decrease in the number of assignable KKC Co-Promote Medical Liaisons hereunder, KKC shall have a period of [***] days following Amgen's notice of such material decrease to continue the appointment of such KKC Co-Promote Medical Liaisons for the purposes of winding down and transitioning away the operations of any such KKC Co-Promote Medical Liaisons. KKC may, upon at least [***] days' prior written notice to Amgen, increase or decrease the KKC Co-Promote Medical Liaisons; *provided*, *however*, that in no event shall the KKC Co-Promote Medical Liaisons exceed the Medical Affairs Percentage (calculated on an FTE basis) of the Amgen Co-Promote Medical Liaisons. KKC shall perform Medical Affairs Activities under this Section 6.4.7 only through Medical Liaisons who are employed by KKC, and cause such employees to perform such Medical Affairs Activities in accordance with the Co-Detail and Field Medical Liaison Plan and as otherwise specified by Amgen solely to ensure such activities are conducted in accordance with Applicable Law, the terms of this Agreement and any applicable co-promotion agreement or addendum as agreed upon by the Parties, and solely in such geographic regions and to such target audiences assigned to KKC pursuant to the Co-Detail and Field Medical Liaison Plan. Each member of the KKC Co-Promote Medical Liaisons shall devote [***] percent ([***]%) of such member's time (calculated on an FTE basis) to the activities under this Section 6.4 unless otherwise agreed to by Amgen. KKC shall perform Medical Affairs Activities under this Section 6.4 using only

scientific literature and other materials approved by Amgen in accordance with Section 6.6 (Promotional Materials).

6.4.8 Medical Affairs Reports. For so long as KKC performs co-promotion activities as set forth hereunder, KKC shall provide Amgen with a report, in such form and manner as determined by Amgen, within [***] days after the end of each calendar quarter, setting forth the following information regarding the efforts of the KKC Co-Promote Medical Liaisons in performing field Medical Affairs Activities for the Product in the Co-Promotion Territory in accordance with this Section 6.4.8 during the preceding calendar quarter: (i) an overview of the field Medical Affairs Activities performed by the KKC Co-Promote Medical Liaisons, including a breakdown by date and by individual representative; and (ii) such other information as may be reasonably specified by Amgen.

6.4.9 Responsibility for KKC's Detailing and Medical Liaison Costs and Expenses. KKC's costs and expenses incurred by KKC or any of its Affiliates in connection with the activities under this Section 6.4 by the KKC Co-Detail Sales Force and KKC Co-Promote Medical Liaisons will be calculated in accordance with Section 6.9 (Calculation of Sales Force Costs and Other Personnel Costs) and included in (i) for the U.S., Commercialization and Related Costs or (ii) within the Amgen Territory but outside of the U.S. (the "Ex-U.S. Amgen Territory"), reimbursed by Amgen pursuant to Section 8.4 (KKC Ex-U.S. Amgen Territory Commercialization Costs). Except to the extent included in the foregoing, KKC shall otherwise be solely responsible for any and all costs and expenses incurred by KKC or any of its Affiliates in connection with the activities under this Section 6.4 by the KKC Co-Detail Sales Force and KKC Co-Promote Medical Liaisons, including, without limitation: [***].

6.4.10 Training and Compliance.

(a) Neither [***] or its Affiliates (including any Sales Force Representative or Medical Liaison) shall have authority to give any direction, either written or oral, relating to the making of any commitment by [***] or its agents to any Third Party in violation of terms of this Section 6.4 or any other provision of this Agreement.

(b) Amgen shall provide to the KKC Co-Detail Sales Force and the KKC Co-Promote Medical Liaisons, at such times as are mutually agreed by Amgen and KKC, training and training materials for the activities under this Section 6.4. Amgen shall provide such training at its own Costs, provided that KKC shall be solely responsible for all Costs associated with the attendance by the KKC Co-Detail Sales Force and the KKC Co-Promote Medical Liaisons at such trainings. The KKC Co-Detail Sales Force and the KKC Co-Promote Medical Liaisons shall not be entitled to participate in the activities under this Section 6.4 without first completing all trainings reasonably required by Amgen.

(c) If [***] becomes aware of a failure to comply with Applicable Law or the terms of this Agreement by any member of [***] Co-Detail Sales Force or Co-Promote Medical Liaisons, [***] shall promptly, but no later than [***] Business Days after it becomes aware, notify [***] of such violation and, as promptly as possible thereafter, notify [***] of the steps it has taken or intends to take to remediate such violation. If [***] has a reasonable basis for

believing any member of the other Party's Co-Detail Sales Force or Co-Promote Medical Liaisons has violated any Applicable Laws, or failed to comply with this Agreement, then [***] may notify [***] of the alleged violation and, if such alleged violation relates to a KKC Co-Detail Sales Force or Co-Promote Medical Liaison, Amgen shall promptly investigate the matter and, if the allegation turns out to be true, in the case of [***], such Party shall take the appropriate remedial action. Subject to the foregoing, each Party shall be solely responsible for taking any disciplinary actions in connection with the performance of such Party's Co-Detail Sales Force and Co-Promote Medical Liaisons. If, at any time, [***] has any other compliance-related concerns regarding the performance of any of the members of [***] Co-Detail Sales Force or Co-Promote Medical Liaisons, [***] shall notify [***] of such concerns in writing and Amgen and KKC shall discuss and resolve such matters.

(d) [***] shall instruct and cause its Co-Detail Sales Force and its Co-Promote Medical Liaisons to use only the materials, including Promotional Materials to be used by each Party's Co-Detail Sales Force, approved by Amgen and consistent with Applicable Law and the Co-Detail and Field Medical Liaison Plan. [***] shall instruct its Co-Detail Sales Force and its Co-Promote Medical Liaisons to limit their claims of efficacy and safety for the Product to such claims which are consistent with and do not exceed any labeling for the Product or the Promotional Materials.

(e) [***] acknowledges and agrees that [***] will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of [***] Co-Detail Sales Force or its Co-Promote Medical Liaisons, all of which shall be [***] sole responsibility.

(f) [***] acknowledges and agrees that all of the members of [***] Co-Detail Sales Force and its Co-Promote Medical Liaisons are employees of [***] or its Affiliates and are not, and are not intended to be treated as, employees of [***] or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans" (as such term is defined in section 3(3) of the Employee Retirement Income Security Act of 1974, as amended) that are sponsored by [***] or any of its Affiliates or that are offered from time to time by [***] or its Affiliates to their own employees. All matters of compensation, benefits and other terms of employment for any member of each Party's Co-Detail Sales Force and its Co-Promote Medical Liaisons shall be solely a matter between such Party and such individual. Neither Party shall be responsible to the other Party or to any member of the other Party's Co-Detail Sales Force or Co-Promote Medical Liaisons for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by the other Party or such individuals of this Agreement, all of which shall be the sole responsibility of the other Party, even if it is subsequently determined by any Governmental Authority that any such individual may be an employee or a common law employee of Amgen or any of its Affiliates or is otherwise entitled to such payments and benefits.

(g) [***] shall be solely responsible for the acts or omissions of its Co-Detail Sales Force or its Co-Promote Medical Liaisons that are not in compliance with Applicable Law and the terms of this Agreement while performing any of the activities under this Agreement, including this Section 6.4. [***] shall be solely responsible and liable for all probationary and termination actions taken by it, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its employees.

(h) At Amgen's discretion, Amgen will send a letter, either in hard copy or electronic form, to KKC that [***]. KKC shall respond to that notification and represent that [***]. To the extent that KKC does not maintain such a compliance program, KKC shall circulate [***] to all personnel engaged in activities under this Section 6.4.

6.4.11 Termination of Employment; Cessation of Co-Promotion Activities. If any member of the KKC Co-Detail Sales Force or the KKC Co-Promote Medical Liaisons leaves the employment of KKC or its Affiliates, or otherwise ceases to conduct the activities under this Section 6.4, KKC shall, ensure that such departing member shall cease providing services in accordance with KKC's internal policies and procedures.

Section 6.5 Medical Affairs Activities. Except as otherwise provided for in Section 6.3 (Co-Marketing Right) or Section 6.4 (Co-Promotion Activities), Amgen shall have the sole right and responsibility for all Medical Affairs Activities in the Amgen Territory. KKC shall have the sole right and responsibility for all Medical Affairs Activities in the KKC Territory.

Section 6.6 Promotional Materials.

(a) Amgen will prepare and approve all written sales, promotional and non-promotional and advertising materials relating to the Product, and other media and materials used to promote the Product or educate the public regarding an indication treated with the Product (collectively and including translations, "Promotional Materials"), in each case, for use in the Amgen Territory; provided, however, that Amgen shall reasonably consider in good faith any comments or concerns that KKC may raise with respect to such Promotional Materials. Amgen shall, at KKC's reasonable request, provide templates of such Promotional Materials for use by KKC in connection with its Commercialization of the Product in the KKC Territory or in connection with its co-promotion activities in the Co-promotion Territory. All costs of preparing Promotional Materials for the U.S. shall be included in Commercialization and Related Costs in the U.S. and shared by the Parties in accordance with Section 8.3 (Commercialization and Related Cost Sharing in the U.S.). All Promotional Materials used in the Collaboration Territory shall be consistent with the Global Product Strategy. If so instructed by Amgen (whether due to [***]), KKC will immediately cease use of any Promotional Materials in the Amgen Territory in connection with its co-promotion activities and will collect and destroy any such materials from its marketing representatives (and record and document such collection and destruction (and provide a copy of such documentation to Amgen upon request)). Amgen will own all right, title and interest in and to any and all Promotional Materials prepared by Amgen for use in the Amgen Territory. KKC will prepare and approve all Promotional Materials for use in the KKC

Territory. KKC will own all right, title and interest in and to any and all Promotional Materials prepared by KKC for use in the KKC Territory.

(b) Amgen agrees to grant, and hereby grants, to KKC a royalty-free right and license under its rights in and to the Promotional Materials contained therein, and any other copyrights, design rights or other registrations for the foregoing) for the purpose of using such Promotional Materials in connection with KKC's Commercialization of the Product in the KKC Territory and in connection with its co-promotion activities in the Co-Promotion Territory.

(c) KKC agrees to grant, and hereby grants, to Amgen a royalty-free right and license under its rights in and to the Promotional Materials contained therein, and any other copyrights, design rights or other registrations for the foregoing) for the purpose of using such Promotional Materials in connection with Amgen's Commercialization of the Product in the Amgen Territory.

Section 6.7 Distribution to the Other Party's Territory. Amgen shall not Commercialize the Product in the KKC Territory and shall not transfer or sell the Product to any Third Party whom Amgen knows or should reasonably know will Commercialize the Product in the KKC Territory. KKC shall not Commercialize the Product in the Amgen Territory (except as provided under Section 6.3 (Co-Marketing Right) or Section 6.4 (Co-Promotion Activities)), and KKC shall not sell the Product in the Amgen Territory or transfer or sell the Product to any Third Party whom KKC knows or should reasonably know will Commercialize the Product in the Amgen Territory. Each Party shall notify the other Party if it becomes aware of the exportation of the Product from inside the Amgen Territory to the KKC Territory (or vice versa).

Section 6.8 Payer Engagement. Except with Amgen's prior written consent, KKC shall not be permitted to engage in any discussions with any payer or customer with respect to [***] in the Amgen Territory or be permitted to enter into any agreements or arrangements for sale of the Product in the Amgen Territory. Except with KKC's prior written consent, Amgen shall not be permitted to engage in any discussions with any payer or customer with respect to [***] in the KKC Territory or be permitted to enter into any agreements or arrangements for sale of the Product in the KKC Territory

Section 6.9 Calculation of Sales Force Costs and Other Personnel Costs.

(a) Sales Force Costs and Other Personnel Costs incurred by Amgen or KKUS or any of its Affiliates from activities with respect to Commercialization and Detailing of the Product in the U.S. will be determined pursuant to the approved Commercialization Plan and Commercialization Budget and by allocation of the appropriate proportion of Sales Force and Other Personnel activities directed to Products as calculated on an FTE basis. Such Costs shall be included in KKUS's or Amgen's Commercialization and Related Costs in the U.S. (as applicable) and shared in accordance with Section 8.3 (Commercialization and Related Cost Sharing in the U.S.).

(b) Sales Force Costs and Other Personnel Costs incurred by Amgen or KKC or any of their Affiliates from activities with respect to Commercialization and Detailing of the Product within the Ex-U.S. Amgen Territory will be determined pursuant to the approved

Commercialization Plan and Commercialization Budget and by allocation of the appropriate proportion of Sales Force and Other Personnel activities directed to Products as calculated on an FTE basis (such costs, "Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs"). With respect to KKC, the Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs shall be subject to reimbursement pursuant to Section 8.4 (KKC Ex-U.S. Amgen Territory Commercialization Costs). With respect to Amgen, such Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs shall be solely borne by Amgen.

Section 6.10 Other KKC Ex-U.S. Amgen Territory Commercialization Costs. Any costs and expenses (of the type that would be included in the definition of "Commercialization and Related Costs" (if such definition were applicable to the Ex-U.S. Amgen Territory)) incurred by KKC in connection with the Commercialization of the Product in the Ex-U.S. Amgen Territory (that would not be included in the definition of Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs) pursuant to the approved Commercialization Plan and Commercialization Budget (such costs, "Ex-U.S. Amgen Territory Commercialization Costs – Other Costs") shall also be subject to reimbursement pursuant to Section 8.4 (KKC Ex-U.S. Amgen Territory Commercialization Costs). For the avoidance of doubt, unless otherwise agreed, Amgen shall bear and be solely responsible for its costs and expenses incurred for Commercialization of the Product in the Ex-U.S. Amgen Territory (including, for clarity, Amgen's (a) Ex-U.S. Amgen Territory Commercialization Costs – Sales Force Costs and Other Personnel Costs and (b) Ex-U.S. Amgen Territory Commercialization Costs – Other Costs).

Article VII.

PERFORMANCE STANDARDS

Section 7.1 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.

Section 7.2 Diligence Standards. The Parties shall use, and shall assure that each of its Affiliates and any Third Parties engaged by such Party uses, Commercially Reasonable Efforts to timely and diligently conduct the activities allocated to such Party under this Agreement in accordance with the Global Development Plan, Global Development Budget, Global Product Strategy, Commercialization Plan and Commercialization Budget and such reasonable directions as may be issued by the JSC from time to time, subject, at all times, to the terms of this Agreement.

Section 7.3 Fair Value Pricing. Amgen and KKC each shall not attempt to: (a) reduce compensation rightly due to the other Party hereunder by shifting compensation otherwise payable to such Party from a Third Party with respect to the Product to another product or service for which no compensation is payable to the other Party hereunder, (b) misallocate Costs incurred by such Party by wrongfully shifting or designating such Costs so as to cause such

Costs to be improperly shared by KKUS and Amgen under Section 8.2 (Global Development Cost Sharing) or Section 8.3 (Commercialization and Related Cost Sharing in the U.S.) or (c) include a single Cost in multiple types or categories of Costs and/or deductions from Net Revenues. In addition, Amgen and KKC each shall not divest, restructure, reorganize or reclassify its Affiliates, or conduct its activities hereunder through any Affiliates, with any intent in whole or in part to avoid, reduce or eliminate its or any of its Affiliates' obligations or commitments set forth in this Agreement. Without limitation of the foregoing, each Party agrees not to enter into any transaction that would result in the shifting of the benefits that would otherwise be due to the other Party hereunder and shall at all times contract in good faith for internally or externally provided services related to the Product.

Section 7.4 Proper Conduct Practices Standards. Each Party will conduct, and ensure that each of its Affiliates and Third Parties engaged by such Party conducts, all of its and their activities with respect to the development, registration, manufacture, distribution, promotion and Commercialization of the Product in accordance with this Agreement, the Initial Global Development Plan, the Global Development Plan, the Global Pricing Policy, the Quality and Compliance Standards, Proper Conduct Practices, and all Applicable Law. The Parties will provide each other with all reasonably requested cooperation to enable each of them to comply with Proper Conduct Practices, Applicable Law and the Quality and Compliance Standards, including permitting each Party to reasonably monitor activities conducted by a Party in connection with this Agreement in order to verify the other Party's compliance therewith with respect to such other Party's activities under this Agreement and market environment of the Amgen Territory. After the Effective Date, each Party shall review its own conduct practices from time to time to ensure continued compliance with the Proper Conduct Practices.

Section 7.5 Violation of Laws. Each Party will promptly notify the other Party of any formal or informal request for information, subpoena, investigation, litigation, penalty or claim from any Governmental Authority, or any Third Party, for violation or potential 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 JSC with respect thereto. The Parties will have the right to require that any personnel that materially violates Applicable Law or the Quality and Compliance Standards cease to perform activities under this Agreement.

Section 7.6 Use of Affiliates and Third Party Contractors. Each Party will perform its obligations under this Agreement itself or through any of its Affiliates, and keep the other Party reasonably informed of the use of any Third Parties to conduct such activities other than the engagement of Third Party contract manufacturers, contract research organizations and contract sales organizations in the ordinary course of business. Each Party will remain 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 or by the applicable Party.

Section 7.7 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, remuneration and employment taxes), disciplining, firing and otherwise controlling the personnel provided by such Party for performance of its obligations hereunder. In the event any remuneration is due to personnel provided by a Party to perform its obligations hereunder (whether pursuant to Applicable Law, contract or otherwise), such Party hereby agrees to pay, at its sole cost and expense, any such remuneration. Each Party will provide the day-to-day management of its representatives and other personnel, including furnishing administrative support, financial resources, equipment and supplies.

Section 7.8 Obligation to Notify. Each Party shall promptly notify the other Party upon becoming aware of any breach or violation by such Party (including through any Representative of such Party or Third Party engaged by such Party) of Sections 7.2 (Diligence Standards) and 7.3 (Fair Value Pricing) or the Anti-Corruption Laws and such Party shall take such steps as the Parties may reasonably agree to avoid a potential or continuing violation of the Anti-Corruption Laws or a breach of such Sections 7.2 (Diligence Standards) or 7.3 (Fair Value Pricing).

Article VIII.

FINANCIAL CONSIDERATION

Section 8.1 Upfront Payment. As partial consideration for the rights granted to Amgen hereunder, Amgen shall pay KKC a payment of four hundred million U.S. Dollars (US$400,000,000), due and payable within [***] days of the Effective Date and receipt of an invoice for such fee from KKC. Such payment shall not be refundable or returnable in any event, nor shall it be creditable against royalties or other payments

Section 8.2 Global Development Cost Sharing

8.2.1 KKUS Costs. Within [***] days after the end of each calendar quarter, KKUS will provide (or KKC will cause to be provided) to Amgen a final report of its Global Development Costs incurred by KKUS in accordance with this Agreement (collectively, "KKUS Development Costs") in such quarter in the Amgen Territory. KKUS will initially bear the Global Development Costs attributed to its activities hereunder in the Amgen Territory prior to any rebalancing payments therefor pursuant to Section 8.2.3 (Global Development Cost Share). In addition to the annual Global Development Budget approved hereunder, prior to the end of each calendar year, KKUS will provide (or KKC will cause to be provided) Amgen with a nonbinding good faith estimate of the anticipated Global Development Costs expected to be incurred by KKUS in the Amgen Territory for the [***]year period (detailed on a calendar year

basis) following the year covered by such approved budgets; *provided* that the Parties will review and discuss such estimated Costs at the JDS.

8.2.2 Amgen Costs. Within [***] days after the end of each calendar quarter, Amgen will provide to KKUS a final report of its Global Development Costs incurred by Amgen in accordance with this Agreement (collectively, "Amgen Development Costs") in such quarter in the Amgen Territory. Amgen will initially bear the Global Development Costs attributed to its activities hereunder prior to any rebalancing payments therefor pursuant to Section 8.2.3 (Global Development Cost Share) In addition to the annual Global Development Budget approved hereunder, prior to the end of each calendar year, Amgen will provide KKUS with a nonbinding good faith estimate of the anticipated Global Development Costs expected to be incurred by Amgen in the Amgen Territory for the [***]year period (detailed on a calendar year basis) following the year covered by such approved budgets; provided that the Parties will review and discuss such estimated Costs at the JDS.

8.2.3 Global Development Cost Share. Subject to Section 8.14 (Overruns), KKUS and Amgen will share Global Development Costs on a [***] basis in the Amgen Territory. KKUS and Amgen shall make payments to the other party as applicable so as to effectuate such cost sharing (such payment obligations, the "Global Development Cost-Share Payments"). The Global Development Costs shall be based on the applicable FTE Rate. The Global Development Cost-Share Payments shall be made each calendar quarter in the form of quarterly balancing payments as set forth in Section 8.2.4 (Balancing Payment for Global Development Costs).

8.2.4 Balancing Payment for Global Development Costs. Within [***] days after the end of each quarter, a balancing payment and report ("Global Development Cost Balancing Report") shall be provided by Amgen to KKUS to give effect to the Development Cost Share Payments for the Amgen Territory owed by Amgen to KKUS or vice versa, calculated pursuant to Section 8.2.3 (Global Development Cost Share) as the difference between the Development Cost-Share Payments owed Amgen and KKUS. The net paying party will make (or will cause to be made) a payment pursuant to this Section 8.2.4 within [***] days after delivery of the Global Development Cost Balancing Report. Payments pursuant to this Section 8.2.4 will be made in accordance with the provisions of Article IX (Payments).

Section VIII.3 Commercialization and Related Cost Sharing in the U.S.

8.3.1 KKUS Costs. Within [***] days after the end of each calendar quarter, KKUS or its Affiliates will provide to Amgen a final report of its Commercialization and Related Costs incurred by KKUS in accordance with this Agreement (collectively, "KKUS Commercialization Costs") in such quarter in connection with the Commercialization of Products in the U.S. KKUS will initially bear such Commercialization and Related Costs attributed to its and its Affiliates' activities hereunder prior to any balancing repayments therefor pursuant to Section 8.3.4 (Balancing Payment for Commercialization and Related Costs). In addition to the annual Commercialization Budget approved hereunder, prior to the end of each calendar year, KKUS will provide Amgen with a nonbinding estimate of its Commercialization and Related Costs for the [***]year period (detailed on a calendar year basis) following the year covered by such

approved budgets; *provided* that the Parties will review and discuss such estimated Costs at the JCS.

8.3.2 Amgen Costs. Within [***] days after the end of each calendar quarter, Amgen will provide to KKUS a final report of its Commercialization and Related Costs incurred by Amgen or its Affiliates in accordance with this Agreement (collectively, "Amgen Commercialization Costs") in such quarter in connection with the Commercialization of Products in the U.S. Amgen will initially bear such Commercialization and Related Costs attributed to its activities hereunder prior to any balancing repayments therefor pursuant to Section 8.3.4 (Balancing Payment for Commercialization and Related Costs). In addition to the annual Commercialization Budget approved hereunder, prior to the end of each calendar year, Amgen will provide KKUS with a nonbinding estimate of its Commercialization and Related Costs for the [***]year period (detailed on a calendar year basis) following the year covered by such approved budgets; *provided* that the Parties will review and discuss such estimated costs at the JCS.

8.3.3 Commercialization and Related Cost Share. Subject to Section 8.14 (Overruns), KKUS and Amgen will share Commercialization and Related Costs in connection with the Commercialization of Products in the U.S. on a [***], and each Party shall make (or cause to be made) payments to the other Party so as to effectuate such cost sharing (such payment obligations, the "U.S. Commercialization Cost-Share Payments"). The Commercialization and Related Costs shall be based on the applicable FTE Rate. The U.S. Commercialization Cost-Share Payments shall be made each calendar quarter in the form of quarterly balancing payments as set forth in Section 8.3.4 (Balancing Payment for Commercialization and Related Costs).

8.3.4 Balancing Payment for Commercialization and Related Costs. Within [***] days after the end of each quarter, a balancing payment and report ("U.S. Commercialization Cost Balancing Report") shall be provided by Amgen to KKUS to give effect to the U.S. Commercialization Cost Share Payments owed by each party to the other pursuant to Section 8.3.3 (Commercialization and Related Cost Share) and calculated as the difference between the U.S. Commercialization Cost-Share Payments owed by Amgen and KKUS. The net paying party will make a payment pursuant to this Section 8.3.4 within [***] days after delivery of the U.S. Commercialization Cost Balancing Report. Payments pursuant to this Section 8.3.4 will be made in accordance with the provisions of Article IX (Payments).

Section 8.4 KKC Ex-U.S. Amgen Territory Commercialization Costs. KKC shall, within [***] days after the end of each calendar quarter, provide a reasonably detailed and itemized cost report to Amgen specifying for such calendar quarter the amount of Ex-U.S. Amgen Territory Commercialization Costs incurred by KKC during such quarter. Amgen shall make a payment pursuant to this Section 8.4 within [***] days after delivery of such report. Payments pursuant to this Section 8.4 will be made in accordance with the provisions of Article IX (Payments). In connection with the Product or any Distracting Product included in the collaboration pursuant to Section 10.2 (Allowed Activities), if any such Product or Distracting Product is approved for use in any indication other than the Lead Indication pursuant to applicable Regulatory Approvals processes, the Parties agree to [***].

Section 8.5 Excluded Losses. The following losses shall not be included in the Global Development Costs or Commercialization and Related Costs of a Party: (i) losses of a Party to the extent attributable to a breach of this Agreement by such Party, (ii) losses subject to indemnification pursuant to Section 14.1 (Indemnity by KKC) or Section 14.2 (Indemnity by Amgen), (iii) any losses or Costs deducted from Net Revenue, (iv) any losses or Costs included in Commercialization and Related Costs of such Party (in the case of Global Development Costs) or (v) any losses or Costs included in Global Development Costs (in the case of Commercialization and Related Costs).

Section 8.6 FTE Rate. The FTE Rate used for calculation of Costs pursuant to this Article VIII with respect to any activity will be the relevant FTE Rate for the calendar year in which such activity was undertaken.

Section 8.7 Income Taxes. For the avoidance of doubt, income and withholding taxes or other Indirect Taxes imposed on either of the Parties hereunder will not be included in cost sharing hereunder.

Section 8.8 Exchange Rate. For purposes of calculating quarterly balancing payments as set forth in Section 8.2.4 (Balancing Payment for Global Development Costs) and Section 8.3.4 (Balancing Payment for Commercialization and Related Costs), Net Revenues, KKUS Development Costs, Amgen Development Costs, KKUS Commercialization Costs and Amgen Commercialization Costs will be converted from local currency (if different from $US) to $US in accordance with Section 9.3.3 (Conversions).

Section 8.9 Net Revenue Report. Within [***] days after the end of each calendar quarter, Amgen will provide KKC with a report of Net Revenues for such calendar quarter separately for each of the U.S. and Ex-U.S. Amgen Territory, which report will contain a calculation of Net Revenues for each Product during such calendar quarter and any other information relating to the Net Revenue as may be reasonably requested by KKC. Additionally, within [***] days after the end of each calendar quarter, each Party will provide the other Party with a report of any Recoveries for such calendar quarter in the Amgen Territory.

Section 8.10 Milestone Payments. As partial consideration for the rights granted to Amgen hereunder, Amgen shall pay KKC the following non-creditable, non-refundable payments (described in the table below under the column “Milestone Payment” and each such payment, a “Milestone Payment”) within [***] days following the date that each milestone (described in the table below under the column “Milestone”) is achieved by Amgen, its Affiliates or sublicensees:

	Milestone	**Milestone Payment**
1	[***]	[***]
2	[***]	[***]
	Commercial Milestones	
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]

Amgen will provide KKC with prompt written notice of the accomplishment of each such milestone and the corresponding Milestone Payment. Each Milestone Payment set forth in this Section 8.10 is payable only once upon the first achievement of the respective milestone and no Milestone Payment shall be payable for subsequent or repeated achievements of the same milestone.

Section 8.11 Calculation of Net Revenues. In calculating Net Revenues for the purposes of this Article VIII:

8.11.1 Free Product. Any disposal of a reasonable quantity of the Product for, or use of the Product in, clinical or preClinical Studies, given as free samples, or distributed at no charge to patients unable to purchase the Product shall [***].

8.11.2 Non-Monetary Compensation. Upon any sale or other disposal of the Product that should be included within Net Revenues for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, then for purposes of calculating the Net Revenues under this Agreement, such Product shall be deemed to be [***].

8.11.3 Multiple Product Offerings. In the event the Product is sold with one or more products or services for a single contracted price (together, a "Multiple Product Offering") in a given country, Net Revenues in such country for such Multiple Product Offering shall be calculated by multiplying actual Net Revenues of such Multiple Product Offering in such country by the fraction A/(A+B) where A is the ASP of the Product, if sold separately, and B is the sum of the ASPs for each of the other products in the Multiple Product Offering, if sold separately. If, on a country-by-country basis, the other products in the Multiple Product Offering are not sold separately in said country, Net Revenues for the purpose of determining royalties of the Multiple Product Offering in such country shall be calculated by multiplying actual Net Revenues of such Multiple Product Offering in such country by the fraction A/D, where A is the ASP of the Product, if sold separately, and D is the ASP of the Multiple Product Offering. If neither the Product nor the other products are sold separately in a given country, the Parties shall determine Net Revenues for such Multiple Product Offering in such country by mutual agreement based on the relative contribution of the Product (excluding other products) and each other product in the Multiple Product Offering.

Section 8.12 Clinical Supply Manufacturing Costs Calculation and True-Up. Manufacturing Standard Cost (in the case of Product manufactured in KKC's (or its designee's) clinical manufacturing facility) or Manufacturing Actual Costs (in the case of Product manufactured in KKC's (or its designee's) non clinical (i.e., commercial) manufacturing facility) for Product manufactured by KKUS or its Affiliates and used as part of Development will be included in KKUS's Global Development Costs at the time of manufacture of such Product. After the Manufacturing Transfer, Manufacturing Standard Cost (in the case of Product manufactured in Amgen's (or its designee's) clinical manufacturing facility) or Manufacturing Actual Costs (in the case of Product manufactured in Amgen's (or its designee's) non clinical (i.e., commercial) manufacturing facility) for Product manufactured by Amgen and intended for use in a Clinical Study will be included as part of Amgen's Global Development Costs at the time such Product is shipped to a site for use of such Product in a Clinical Study. 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 Global Development Costs for a particular calendar quarter, Amgen 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, Amgen will reconcile any estimated Manufacturing Actual Costs included in Global Development Costs in the prior calendar year with the final Manufacturing Actual Costs for such Product and provide such reconciliation to KKUS. If such reconciliation evidences an over or under payment by either Party, a balancing payment will be made between the Parties in order to maintain the intended cost sharing allocation set forth in this Agreement within [***] days after delivery of such reconciliation report by Amgen and agreement thereon by the Parties, and subject further to [***]. For clarity, in no event shall a Party's Manufacturing Actual Costs for a Product used as part of Commercialization in the U.S. be included in such Party's Commercialization and Related Costs hereunder or be subject to cost sharing pursuant to Section 8.3 (Commercialization and Related Cost Sharing in the U.S.).

Section 8.13 Development and Commercialization Budget Deadlocks. In the event that the JSC is unable to approve an annual Global Development Budget and/or Commercialization Budget prior to the expiration of any such budget, then, until approval of such budget by the Parties and resolution of such deadlock pursuant to Section 2.2.5(b) (JSC Deadlocks), each Party shall continue its designated activities in the Global Development Plan and/or Commercialization Plan, as applicable, for any calendar quarter not covered by an approved budget, until such time as the aggregate Global Development Costs and/or Commercialization and Related Costs of such Party for such calendar year is equal to [***]; and provided, further, that [***].

Section 8.14 Overruns. Each Party will promptly notify the other Party upon becoming aware that the anticipated Costs to be incurred by such Party for activities for a given calendar year will be in excess of the applicable Global Development Budget or Commercialization Budget. Unless otherwise agreed by the Parties in advance, in writing, Costs reported by a Party or its Affiliates pursuant to Section 8.2 (Global Development Cost Sharing) or Section 8.3 (Commercialization and Related Cost Sharing in the U.S.) incurred with respect to a Product: (a) attributable to [***]or (b) in excess of [***] percent ([***]%) of the aggregate amounts budgeted to be incurred by or on behalf of such Party or its Affiliates for its activities for such Product in such calendar year in the then-current applicable Global Development Budget or

Commercialization Budget, respectively, will not be included in the calculation of Global Development Cost-Share Payments pursuant to Section 8.2 (Global Development Cost Sharing) or in the calculation of U.S. Commercialization Cost-Share Payments pursuant to Section 8.3 (Commercialization and Related Cost Sharing in the U.S.); *provided* that each Party's Costs in excess of such amount will be included in the calculation of such cost-share payments to the extent such Costs were attributable to: [***]. In no event shall Costs reported by a Party or its Affiliates pursuant to Section 8.2 (Global Development Cost Sharing) or Section 8.3 (Commercialization and Related Cost Sharing in the U.S.) incurred due to gross negligence or willful misconduct with respect to its activities for a Product be included in the calculation of Global Development Cost-Share Payments pursuant to Section 8.2 (Global Development Cost Sharing) or in the calculation of U.S. Commercialization Cost-Share Payments pursuant to Section 8.3 (Commercialization and Related Cost Sharing in the U.S.).

Section 8.15 U.S. Royalties. Subject to the remainder of this Article VIII, during the Royalty Term, Amgen shall pay to KKC royalties on the annual Net Revenues for each Product sold in the U.S. as calculated by *multiplying* [***] percent ([***]%) by the annual Net Revenues for each Product sold in the U.S.

Section 8.16 Ex-U.S. Amgen Territory Royalties. Subject to the remainder of this Article VIII, during the Royalty Term, Amgen shall pay to KKC royalties on the annual Net Revenues for Product sold in the Ex-U.S. Amgen Territory, as calculated by *multiplying* the applicable royalty rates set forth below by the corresponding amount of incremental annual Net Revenues for Product sold in the Ex-U.S. Amgen Territory.

Aggregate Calendar Year Net Revenues in the Ex-U.S. Amgen Territory	Royalty Rate
For the portion of aggregate Net Revenue of the Product in the Ex-U.S. Amgen Territory during a calendar year less than or equal to [***] U.S. dollars (US$[***])	[***]%
For the portion of aggregate Net Revenue of the Product in the Ex-U.S. Amgen Territory during a calendar year in excess of [***] U.S. dollars (US$[***])	[***]%

Section 8.17 Royalty Term. Amgen shall pay KKC royalties as set forth in Section 8.15 (U.S. Royalties) and Section 8.16 (Ex-U.S. Amgen Territory Royalties) on a country-by-country basis on Net Revenues in the Amgen Territory during the period of time beginning on the First Commercial Sale of the Product in such country and expiring on the latest of (a) the date on which the Exploitation of the Product is no longer Covered by a Valid Claim of any Licensed KKC Patents in such country, (b) the expiration of Regulatory Exclusivity in such country, and (c) the earlier of (i) ten (10) years from the date of First Commercial Sale of the Product in such

country and (ii) twenty (20) years from the date of First Commercial Sale of the Product anywhere in the world (the "Royalty Term").

Section 8.18 Royalty Payments and Reports. Amgen shall (a) within [***] days after the end of each calendar quarter, provide royalty reports to KKC specifying for such calendar quarter (in confirmed figures, or reasonable estimates if firm figures are not available): the amount of Net Revenues, the royalty rate and the amount of royalty payable on such Net Revenues separately for each of the U.S. and the Ex-U.S. Amgen Territory; and (b) make the royalty payments owed to KKC hereunder in accordance with such royalty report in arrears, within [***] days from the end of the calendar quarter in which such payment accrues. KKC shall keep such reports confidential and shall not disclose them to any Third Party other than KKC's consultants and accountants that are obligated to keep such information confidential.

Section 8.19 Payments; Aggregation and Netting of Payments. Payments pursuant to this Article VIII will be made in accordance with the provisions of Article IX (Payments). If the Parties agree, the Parties may aggregate and net the quarterly payments between Amgen and KKUS pursuant to Section 8.2 (Global Development Cost Sharing) and Section 8.3 (Commercialization and Related Cost Sharing in the U.S.) and the net amount shall be paid by the net paying party in accordance with such sections.

Section 8.20 Third Party License Payments. The Parties shall share the Costs of any Third Party license payments, milestones and royalties owed with respect to the Product [***], on intellectual property that: (i) would (absent such Third Party license) be infringed by the use, research, Development or Commercialization or Manufacture of, or the conduct of Medical Affairs Activities with respect to the Product or (ii) would be reasonably necessary for the use, research, Development, Commercialization or Manufacture of, or the conduct of Medical Affairs Activities with respect to the Product (such license, a "Third Party License"). Such Costs shall be shared by the Parties on a [***] basis and each Party shall make (or cause to be made) payments to the other Party so as to effectuate such cost sharing. Payments pursuant to this Section 8.20 will be made in accordance with the provisions of Article IX (Payments).

Article IX.

PAYMENTS

Section 9.1 Appropriate Measure of Value. Each of the Parties acknowledges that (a) the value provided by the other Party 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 (b) the ratio of cost sharing payments and the royalties 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 Patent rights and allocation of operational responsibilities between the Parties, will not affect the amount of such payments, and the Parties agree that both the amount and duration of such payments are reasonable.

Section 9.2 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.

Section 9.3 Currency.

9.3.1 Payments. All payments made hereunder between the Parties will be made in United States Dollars (US$) or as otherwise agreed by the Parties. Each Party will pay all sums due hereunder by wire transfer, or electronic funds transfer (EFT) in immediately available funds. If the EFT option is chosen by Amgen or KKC, a completed electronic funds transfer form will be provided in a timeframe that facilitates timely payment. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. All amounts set forth in any budget established under this Agreement will be expressed in United States Dollars (US$). Notwithstanding anything in this Agreement to the contrary, United States Dollars (US$) shall be the controlling currency for all purposes under this Agreement, including budgeting and cost reimbursement, cost overruns and related calculations

9.3.2 Invoices. The Parties shall work to ensure that an appropriately detailed invoice is prepared and delivered in connection with any payments owed hereunder by one Party to the other. Except to the extent set forth otherwise hereunder, the party receiving the payment shall prepare and send the invoice to the paying party.

Any invoices sent to Amgen shall be addressed to:

Amgen Inc.
Accounts Payable
PO Box 667
Newbury Park, CA 92319-0667 USA
Attention Partnership Accounting

Any invoices sent to KKC shall be addressed to:

Kyowa Kirin Co., Ltd.
1-9-2 Otemachi, Chiyoda-ku, Tokyo, 100-0004
Japan
Attention: Business Development

Any invoices sent to KKUS shall be addressed to:

Kyowa Kirin, Inc.
135 Route 202/206, Suite 6, Bedminster, NJ 07921 USA
Attention: Finance Department

9.3.3 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. If a Party is not required to perform such a currency conversion for its GAAP 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.

Section 9.4 Audits.

9.4.1 Accounting. 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 the amount of payments and any Costs (including, for clarity, any Global Development Costs and Commercialization and Related Costs shared by the Parties pursuant to Section 8.2 (Global Development Cost Sharing) and Section 8.3 (Commercialization and Related Cost Sharing in the U.S.) due hereunder, and such records will be open (in such form as may be available or reasonably requested) to inspection during the Term of this Agreement and for an additional [***] years following the end of the last fiscal period to which they pertain, and such right shall survive termination or expiration of this Agreement. The Auditing Party will have the right, at its own expense to have an independent, certified public accountant, selected by it, perform a review (once annually unless a significant discrepancy is observed), of the records of the other Party (the "Audited Party") applicable to the accuracy of the amount of payments due or Costs hereunder (including any records kept in the ordinary course of the Audited Party's business) during regular business hours, with not less than [***] Business Days' advance written notice and under reasonable obligations of confidentiality, to ensure the accuracy of the amount of payments received hereunder (including the accuracy and calculation of any Net Revenues and royalties paid hereunder) and any Costs claimed by the Audited Party and shared between the Parties. 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 [***] years after the end of such year and the books and records for any particular calendar year will only be subject to [***]. Should an inspection pursuant to this Section 9.4.1 lead to the discovery of a discrepancy in the accuracy the amount of payments due or Costs hereunder, 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). The Auditing Party will pay for any audit under this Section 9.4.1; *provided* that if a payment discrepancy was greater than [***] percent ([***]%) 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. This Section 9.4.1 does not apply to or include pharmacovigilance audits, manufacturing audits or regulatory inspections.

9.4.2 Compliance. Each Party will also keep complete and accurate records pertaining to the activities (other than financial activities covered by Section 9.4.1(Accounting)) to be

conducted hereunder in sufficient detail to permit, and shall permit, the Auditing Party to confirm the other Party's compliance with its obligations under this Agreement and Applicable Law (including, for clarity, any Quality and Compliance Standards). Such records will be open (in such form as may be available or reasonably requested) to inspection for [***] years following the end of the period to which they pertain; provided that such records shall be subject to audit no more than once per calendar year except in the event that additional compliance issues are identified during such audit, in which case additional audits shall be permitted, and such right shall survive termination or expiration of this Agreement. The Auditing Party will have the right to use its own internal auditing team or, at its own expense, an external auditing team selected by it, to perform a review of the records of the Audited Party. The audits will occur during regular business hours, with not less than [***] Business Days' advance written notice and under reasonable obligations of confidentiality, unless the audits are requested by a Governmental Authority, in which case the Parties agree such notice period does not apply. The Audited Party will cooperate with the Auditing Party and, if applicable, the Governmental Authority, in these audits. Should an inspection pursuant to this Section 9.4.2 lead to the discovery of any material non-compliance by the Audited Party with this Agreement, then the Audited Party shall immediately take steps to remedy such material non-compliance. The Auditing Party will pay for any audit under this Section 9.4.2; *provided* that if material non-compliance was found as a result of such audit, then the Audited Party will pay the reasonable out-of-pocket cost of such inspection.

Section 9.5 Blocked Currency. Notwithstanding anything to the contrary in this Agreement, for any payment to a Party that is due and payable under this Agreement but is not successfully remitted to such Party upon the first application to the remitting bank in the Amgen Territory by the other Party or other payor (irrespective of whether the failure to remit payment is because of not passing the bank verification process, or because of ad hoc measures adopted by the Governmental Authorities in the Amgen Territory from time to time, or because approval is required from Governmental Authorities in the Amgen Territory, or for any other reason), the paying Party shall (i) as a guarantee and not as settlement, make payment of an equivalent amount in local currency to an account in a bank or depository in the Amgen Territory of the payee Party Affiliate designated by the payee Party in writing, (ii) immediately take all steps that are necessary or appropriate to rectify the inability to pay the payee Party, including initiating the proper approval process if applicable, and (iii) at such time as the inability to pay has been rectified, immediately pay to the payee Party the original amount that was due and payable at the time of deposit, notwithstanding any subsequent foreign exchange fluctuations.

Section 9.6 Taxes.

9.6.1 Withholding. If Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made pursuant to this Agreement (other than Indirect Taxes, which are governed by Section 9.6.2 (Indirect Taxes)), the paying Party will notify the other in writing of such payment or withholding requirements reasonably in advance of 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 receiving Party's efforts to claim any exemption from, reduction of, or credit or refund with respect to such Taxes

(including, for the avoidance of doubt, any reduction or exemption under an applicable Tax treaty). All such taxes withheld shall be timely paid to the applicable tax authority in accordance with Applicable Law.

9.6.2 Indirect Taxes. Unless otherwise mutually agreed by both Parties, all payments made pursuant to this Agreement are exclusive of Indirect Taxes. If Indirect Taxes are chargeable in respect of any payments made pursuant to this Agreement, 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 in accordance with Applicable Law issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Applicable Law with respect to Indirect Tax and irrespective of whether the sums may be netted for settlement purposes. The Parties shall cooperate and use all reasonable efforts to obtain any applicable reduction, exemption, zero-rating, credit or refund in respect of any Indirect Tax in accordance with Applicable Law. If any amount of Indirect Tax is 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 [***] days of receipt. [***]

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

9.6.4 Cooperation and Actions Requiring Consent.

(a) Each Party shall, with respect to any Taxes for which the other Party may be liable as a result of the transactions under this Agreement, (i) reasonably assist and cooperate with the other Party (at the cost and expense of the other Party) in preparing for or filing any Tax claim, Tax audit of, or dispute with any Governmental Authority regarding, and any judicial or administrative proceeding relating to, liability for such Taxes, and in the preparation of or conduct of litigation or investigation of claims in connection with the preparation of financial statements or other documents to be filed with any Governmental Authority in relation to such Taxes, (ii) make available to the other Party and to any Governmental Authority, as reasonably requested, all information, records and documents relating to Taxes relating to the Agreement, (iii) provide timely notice to the other Party of any pending or threatened Tax audits or assessments relating to the Agreement, and (iv) furnish the other Party hereto with copies of all correspondence received from any Governmental Authority in connection with a Tax audit or information request with respect to a Tax. For the avoidance of doubt, the cooperation noted in this Section 9.6.4 may include signing any Tax returns, amended Tax returns, claims or other documents with respect to any Taxes or Tax controversy or proceeding, the retention and (upon the other Party's request) the provision of records and information which are reasonably relevant to any such audit, litigation or other proceeding and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder.

(b) A Party (the "First Party") shall not, with respect to any Tax matter relating to this Agreement, (i) contest an involuntary tax assessment that may give rise to a Tax for which the other Party may be liable or incur a Loss, (ii) extend or waive, or cause to be extended or waived,

any statute of limitations or other period for the assessment of any Tax or deficiency with respect to which the other Party may be liable or incur a Loss, (iii) initiate any voluntary disclosure or other communication with any Governmental Authority in connection with any Taxes for which the other Party may be liable or incur a Loss, or (iv) settle any Tax matter or contest with respect to which the other Party may be liable or incur a Loss, in each case without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

Section 9.7 Late Payment. Any payments or portions thereof due hereunder which are not paid when due (other than amounts subject to a good faith dispute) will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days such payment is delinquent; *provided* that any amounts subject to such good faith dispute that are subsequently determined to be owed shall be subject to such interest calculated from the date such payment was initially due. This Section 9.7 will in no way limit any other remedies available to either Party.

Section 9.8 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.

Article X.

DISTRACTING PRODUCTS

Section10.1 General. During the Term, except as otherwise set forth in Section 10.2 (Allowed Activities), each Party shall not itself (and each Party shall ensure that its Affiliates do not), conduct or participate in, or advise, assist or enable any Third Party to conduct or participate in, any Distracting Program (the "Distracting Program Restriction") in the Amgen Territory or in the KKC Territory.

Section10.2 Allowed Activities. Notwithstanding anything in this Article X, each Party and its Affiliates will have the right to [***], subject to this Section 10.2 (Allowed Activities), and provided, for clarity, that no intellectual property or other rights of the other Party are granted hereunder to the Distracted Party with respect to a Distracting Product. 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 [***] 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 (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 Licensed KKC Patents, Licensed KKC Know-How, Licensed Amgen Patents, and Licensed Amgen Know-How, as applicable; (b) the Distracting Products included in the Distracting Program will be deemed Products hereunder; (c) the JDS will develop a Development Plan and Development Budget for each Distracting Product; and (d) the non-Researching Party will pay a one-time opt-in fee of [***], within [***] days following such election and, thereafter, all Global Development Costs and Commercialization and Related Costs with respect to each such Distracting Product will be shared [***] 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 (x) from and after the date of such election, the obligations of the Researching Party set forth in Section 10.1 (General) will no longer apply with respect to such Distracting Program, (y) the non-Researching Party shall destroy the confidential summary of the Distracting Program provided to it by the Researching Party (*provided*, that the non-Researching Party shall be entitled to retain one (1) copy of such information for its record-keeping purposes), and (z) for clarity, the Party's rights and obligations with respect to the Product shall remain unchanged and each Party shall continue to perform its obligations hereunder.

Section10.3 Distracting Transactions; Notice. Notwithstanding anything to the contrary herein, it shall not be deemed a breach of the Distracting Program Restriction by a Distracted Party if such Distracted Party enters into a Distracting Transaction and such Distracted Party complies with its obligations under this Section 10.3. If a Party enters into a Distracting Transaction (and thereby becomes a Distracted Party) then it will provide notice to the other Party (the "Affected Party"), within [***] Business Days after the first public announcement or disclosure of such Distracting Transaction and if no public announcement or disclosure occurs, within [***] Business Days after the closing of such transaction (the "Distracting Transaction Notice"), 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 either Section 10.3.1 (Divestiture of a Distracting Program) or Section 10.3.2 (Termination of a Distracting Program) are fully implemented, the Distracted Party will Segregate the Distracting Program from programs for the Product. Any notice provided pursuant to this Section 10.3 shall include a notification as to whether the Distracted Party intends to Divest or terminate the Distracted Program.

10.3.1 Divestiture of a Distracting Program. If the Distracted Party elects to Divest a Distracting Program arising from the Distracting Transaction, then it will Divest such Distracting

Program within [***]. If the Distracted Party fails to complete a Divestiture of the Distracting Program within [***], then the Distracted 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 10.3.2 (Termination of a Distracting Program); *provided* that if at the expiration of such [***]month period, the Distracted Party has agreed terms with a Third Party to Divest the Distracting Program arising from the Distracting Transaction then such [***]month period will be extended as required for the Distracted Party and such Third Party to consummate the transaction, but in no event will such extension exceed an additional [***] days.

10.3.2 Termination of a Distracting Program. If the Distracted Party elects to terminate a Distracting Program arising from a Distracting Transaction, it will terminate all activities of such Distracting Program within [***] [***] (other than any Clinical Studies or other activities which are being completed solely for ethical, regulatory, or legal obligations to complete the same and not for the purpose of obtaining Regulatory Approval). [***]

Section10.4 Reasonable Restrictions. The Distracted Party acknowledges the provisions of this Article X are reasonable and necessary to protect the legitimate interests of the Affected Party and to encourage the free sharing of information between the Parties with respect to the Product, and the Distracted Party agrees not to contest such limitations in any proceeding. The Distracted Party acknowledges that the Affected Party would not have entered into this Agreement absent the restrictions set forth in this Article X and that a breach or threatened breach of this Article X would be likely to result in irreparable harm to the Affected Party for which there is no adequate remedy at law. Therefore, the Affected Party 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. Nothing in this Section 10.4 (Reasonable Restrictions) is intended or will be construed to limit in any way either Party's rights to equitable relief or any other remedy for breach of this or any other provision of this Agreement.

Article XI.

INTELLECTUAL PROPERTY

Section11.1 Ownership and Cooperation.

11.1.1 Except to the extent expressly specified in Section 11.1.2(a) each Party shall retain and own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party, (b) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created jointly by the Parties pursuant to this Agreement and, subject to the provisions of this Agreement (including those licenses granted pursuant to Article III (Grant of License)), neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit, license or assign such intellectual property rights, and (iii) inventorship and authorship of any invention or work of authorship conceived or created by either Party or jointly by the

Parties pursuant to the Collaboration, shall follow the rules of the U.S. Patent and Trademark Office and the Applicable Law of the U.S. (without reference to any conflict of law principles).

11.1.2 Each Party shall cause any applicable employees, sublicensees, Subcontractors or consultants to assign to it, and hereby does assign to it, and agrees to assign to the other Party as appropriate, all rights, title and interest, without further consideration, in Patents to effectuate the ownership of intellectual property as set forth in Section 11.1.1. Upon a Party's request, the other Party will perform, or cause its or its Affiliates' applicable employees, sublicensees, Subcontractors or consultants to perform, any and all acts necessary to assist the requesting Party in perfecting its right, title and interest in and to intellectual property as set forth in Section 11.1.1. Such acts shall include, but not be limited to, executing all papers, including all documents associated with the filing and prosecution of patent applications, including invention assignments and inventor declarations, and providing affidavits or testimony in connection with prosecution of patent applications, patent interferences, patent derivation proceedings, post-grant reviews and oppositions, validity or infringement proceedings and participating in other legal proceedings as may be reasonably requested by the other Party.

11.1.3 Each Party shall promptly notify the other upon becoming aware (a) of any actual, suspected or threatened material infringement of any Licensed KKC Patents, Licensed KKC Trademarks or Licensed KKC Know-How, (b) of any claim that Amgen's, or its Affiliates' or sublicensees', exercise of the rights granted under the Licensed KKC Patents, Licensed KKC Trademarks, or Licensed KKC Know-How hereunder infringes any rights or patents of a Third Party, (c) of any claims of alleged patent or trademark infringement by KKC or Amgen with respect to the Manufacture, use, sale, offer for sale or importation of the Product, (d) of any actual, suspected or threatened material misappropriation of Licensed KKC Know-How, or (e) of any actual, suspected or threatened material infringement or dilution of the Licensed KKC Trademarks, KKC Housemarks related to the Product related to the Product, all of the foregoing, (a) through (e), anywhere in the world.

11.1.4 Each Party shall promptly notify the other upon becoming aware (a) of any actual, suspected or threatened material infringement of any Licensed Amgen Patents, Licensed Amgen Trademarks or Licensed Amgen Know-How, (b) of any claim that KKC's, or its Affiliates' or sublicensees', exercise of the rights granted under the Licensed Amgen Patents, Licensed Amgen Trademarks, or Licensed Amgen Know-How hereunder infringes any rights or patents of a Third Party, (c) of any claims of alleged patent or trademark infringement by Amgen or KKC with respect to the Manufacture, use, sale, offer for sale or importation of the Product, (d) of any actual, suspected or threatened material misappropriation of Licensed Amgen Know-How, or (e) of any actual, suspected or threatened material infringement or dilution of the Licensed Amgen Trademarks, Amgen Housemarks related to the Product, all of the foregoing, (a) through (e), anywhere in the world.

Section11.2 Prosecution and Maintenance.

(a) Licensed KKC Patents and Licensed KKC Trademarks.

(i) *KKC Primary Prosecution*. KKC shall control, itself or through outside counsel, the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent or trademark office communications, any office actions, oppositions, interferences and challenges (whether before a patent or trademark authority or judicial body) related thereto) (the foregoing collectively "Patent and Trademark Matters") with respect to Licensed KKC Patents and Licensed KKC Trademarks worldwide (collectively, the "Licensed KKC IP"), as well as preparation and filing for any patent term extensions or similar protections therefor (except with respect to the defense against certain invalidity challenges as set forth in Section 11.2(b)(i) (Amgen Primary Prosecution)). From and after the Effective Date, (i) KKC shall provide Amgen with copies of and an opportunity to review and comment upon the text of the applications relating to the Licensed KKC IP as soon as practicable (but in no event less than [***] days) before filing, (ii) KKC shall provide Amgen with a copy of each submission made to and document received from a patent or trademark authority, court or other tribunal regarding any Licensed KKC IP reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Licensed KKC IP as filed together with notice of its filing date and application number, (iii) KKC shall keep Amgen reasonably advised of the status of all material communications, actual and prospective filings or submissions regarding the Licensed KKC IP, and shall give Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent or trademark authority or judicial body, and (iv) KKC shall reasonably consider in good faith Amgen's comments on the communications, filings and submissions for the Licensed KKC IP. Without the prior written consent of Amgen, KKC shall not take any action (or fail to take any action) with respect to Licensed KKC Patents and Licensed KKC Trademarks in the KKC Territory that would reasonably be expected to have a material adverse effect on the Licensed KKC Patents and Licensed KKC Trademarks in the Amgen Territory.

(ii) *Amgen Secondary Prosecution*. From and after the Effective Date, if KKC proposes to abandon or fail to maintain any patent, trademark or application in the Amgen Territory within the Licensed KKC IP, it shall give Amgen reasonable notice thereof (with sufficient time for Amgen to assume control thereof and continue the prosecution or maintenance of such patent, trademark or application) and thereafter Amgen may, upon written notice to KKC and at Amgen's sole cost, control Patent and Trademark Matters with respect to such patent, trademark or application within the Licensed KKC IP thereafter in accordance with this Section 11.2(a)(ii) (any patent, trademark or application so assumed, an "Amgen Assumed Item"). Amgen shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Amgen, Patent and Trademark Matters with respect to Amgen Assumed Items in the Amgen Territory, at Amgen's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections therefor. Amgen shall provide KKC with a copy of each material submission made to and document received from a patent or trademark authority regarding any Amgen Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for

each item within the Amgen Assumed Items as filed together with notice of its filing date and application number.

(b) Licensed Amgen IP and Defense of Licensed KKC Patents Against Invalidity Challenges

(i) *Amgen Primary Prosecution*. Amgen shall control, itself or through outside counsel, Patent and Trademark Matters with respect to Licensed Amgen Patents and Licensed Amgen Trademarks worldwide (collectively, the "Licensed Amgen IP"), as well as preparation and filing for any patent term extensions or similar protections therefor and, notwithstanding Section 11.2(a)(i) (KKC Primary Prosecution), the defense of any Licensed KKC Patents against any invalidity challenges in the Amgen Territory brought by Third Parties for the purposes of introducing a Biosimilar Product in the Amgen Territory (any Licensed KKC Patents so challenged, "Challenged KKC Patents"). From and after the Effective Date, (i) Amgen shall provide KKC with copies of and an opportunity to review and comment upon the text of the applications relating to the Licensed Amgen IP developed for the collaboration as soon as practicable (but in no event less than [***] days) before filing, (ii) Amgen shall provide KKC with a copy of each submission made to and document received from a patent or trademark authority, court or other tribunal regarding any Licensed Amgen IP or Challenged KKC Patents [***] days after making such filing or receiving such document, including a copy of each application for each item within the Licensed Amgen IP as filed together with notice of its filing date and application number, (iii) Amgen shall keep KKC reasonably advised of the status of all material communications, actual and prospective filings or submissions regarding the Licensed Amgen IP or Challenged KKC Patents, and shall give KKC copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent or trademark authority or judicial body, and (iv) Amgen shall reasonably consider in good faith KKC's comments on the communications, filings and submissions for the Licensed Amgen IP or Challenged KKC Patents. Without the prior written consent of KKC, Amgen shall not take any action (or fail to take any action) with respect to Licensed Amgen IP in the Amgen Territory or with respect to Challenged KKC Patents anywhere in the world that would reasonably be expected to have a material adverse effect on Licensed Amgen IP in the KKC Territory or on the Challenged KKC Patents anywhere in the world.

(ii) *KKC Secondary Prosecution*. From and after the Effective Date, if Amgen proposes to abandon or fail to maintain any patent, trademark or application in the KKC Territory within the Licensed Amgen IP or proposes not to defend Challenged KKC Patents, it shall give KKC reasonable notice thereof (with sufficient time for KKC to assume control thereof and continue the prosecution, maintenance or defense of such patent, trademark or application) and thereafter KKC may, upon written notice to Amgen and at KKC's sole cost, control Patent and Trademark Matters with respect to such patent, trademark or application within the Licensed Amgen IP or with respect to the Challenged KKC Patents thereafter in accordance with this Section 11.2(b)(ii) (any items with respect to Licensed Amgen IP or Challenged KKC Patent so assumed, a "KKC

Assumed Item"). KKC shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by KKC, Patent and Trademark Matters with respect to KKC Assumed Items in the KKC Territory, at KKC's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections of the Licensed Amgen IP and defense of Challenged KKC Patents. KKC shall provide Amgen with a copy of each material submission made to and document received from a patent or trademark authority regarding any KKC Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the KKC Assumed Items as filed together with notice of its filing date and application number.

(c) Joint Patents.

(i) *KKC Primary Prosecution of Joint Patents in KKC Territory*. KKC shall control, through outside counsel reasonably acceptable to Amgen and directed by KKC, Patent and Trademark Matters with respect to Joint Patents in the KKC Territory, as well as preparation and filing for any patent term extensions or similar protections therefor at KKC's sole cost and expense. KKC shall provide Amgen with copies of and an opportunity to review and comment upon the text of the applications relating to the Joint Patents as soon as practicable (but in no event less than [***] days for new patent application filings and [***] days for all other filings or correspondence before submission thereof) before filing, (ii) KKC shall provide Amgen with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Joint Patents reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Joint Patents as filed together with notice of its filing date and application number, (iii) KKC shall keep Amgen advised of the status of all material communications, actual and prospective filings or submissions regarding the Joint Patents, and shall give Amgen 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) KKC shall reasonably consider in good faith Amgen's comments on the communications, filings and submissions for the Joint Patents.

(ii) *Amgen Secondary Prosecution of Joint Patents in the KKC Territory*. If KKC proposes to abandon or fail to maintain any patent, or application within the Joint Patents in the KKC Territory, it shall give Amgen reasonable notice thereof (with sufficient time for Amgen to assume control thereof and continue the prosecution or maintenance of such patent or application) and thereafter Amgen may, upon written notice to KKC and at Amgen's sole cost, control Patent and Trademark Matters with respect to such patent or application within the Joint Patents thereafter in accordance with this Section 11.2(a)(ii) (any patent or application so assumed, a "Amgen Assumed Joint Patent Item"). Amgen shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Amgen, Patent and Trademark Matters with respect to Amgen Assumed Joint Patent Items, at Amgen's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections therefor.

Amgen shall provide KKC with a copy of each material submission made to and document received from a patent authority regarding any Amgen Assumed Joint Patent Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Amgen Assumed Joint Patent Items as filed together with notice of its filing date and application number.

(iii) *Amgen Primary Prosecution of Joint Patents in the Amgen Territory*. Amgen shall control, through outside counsel reasonably acceptable to KKC and directed by Amgen, Patent and Trademark Matters with respect to Joint Patents in the Amgen Territory, as well as preparation and filing for any patent term extensions or similar protections therefor at Amgen's sole cost and expense. Amgen shall provide KKC with copies of and an opportunity to review and comment upon the text of the applications relating to the Joint Patents as soon as practicable (but in no event less than [***] days for new patent application filings and [***] days for all other filings or correspondence before submission thereof) before filing, (ii) Amgen shall provide KKC with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Joint Patents reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Joint Patents as filed together with notice of its filing date and application number, (iii) Amgen shall keep KKC advised of the status of all material communications, actual and prospective filings or submissions regarding the Joint Patents, and shall give KKC 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) Amgen shall reasonably consider in good faith KKC's comments on the communications, filings and submissions for the Joint Patents.

(iv) *KKC Secondary Prosecution of Joint Patents in the Amgen Territory*. If Amgen proposes to abandon or fail to maintain any patent, or application within the Joint Patents in the Amgen Territory, it shall give KKC reasonable notice thereof (with sufficient time for KKC to assume control thereof and continue the prosecution or maintenance of such patent or application) and thereafter KKC may, upon written notice to Amgen and at KKC's sole cost, control Patent and Trademark Matters with respect to such patent or application within the Joint Patents thereafter in accordance with this Section 11.2(a)(ii) (any patent or application so assumed, a "KKC Assumed Joint Patent Item"). KKC shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by KKC, Patent and Trademark Matters with respect to KKC Assumed Joint Patent Items, at KKC's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections therefor. KKC shall provide Amgen with a copy of each material submission made to and document received from a patent authority regarding any KKC Assumed Joint Patent Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the KKC Assumed Joint Patent Items as filed together with notice of its filing date and application number.

Section11.3 Defense and Settlement of Third Party Claims.

11.3.1 From and after the Effective Date, if a Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, offer for sale, sale or importation of the Product in the Amgen Territory by Amgen or in the KKC Territory by KKC, the Party receiving notice of such Third Party claim or assertion shall promptly notify the other Party and the Parties shall agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute, and, thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

11.3.2 Amgen, at its sole cost, shall be solely responsible for the defense of any such infringement claims in the Amgen Territory based on patents or any other proprietary right owned by such Third Party asserted to Cover the manufacture, use, offer for sale, sale or importation of the Product and which do not involve the defense (whether against an interference, opposition or other post-grant proceeding) of any Licensed KKC Patents, Licensed KKC Trademarks or Licensed KKC Know-How or any claim by the applicable Third Party regarding the invalidity of the same. KKC shall reasonably assist Amgen and cooperate in any such litigation at Amgen's request, and Amgen shall reimburse KKC any reasonable, documented, out-of-pocket costs incurred in connection therewith. Subject to such control, KKC may join any defense and settlement pursuant to this Section 11.3.2, with its own counsel at its sole cost. Amgen shall seek and reasonably consider KKC's comments before determining the strategy for such matter. Without limiting the foregoing, Amgen shall keep KKC advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide KKC copies of and an opportunity to review and comment on any such communications, filings and submissions. Amgen shall not settle or consent to the entry of any judgment in any such action without KKC's prior written consent, not to be unreasonably withheld or delayed. Amgen shall keep KKC fully informed of all claims and actions governed by this Section 11.3.2. In the event Amgen becomes engaged in settlement discussions with such Third Party, Amgen shall keep KKC reasonably informed of the status of such discussions, and Amgen shall consider in good faith any comments or suggestions of KKC.

11.3.3 KKC, at its sole cost, shall be solely responsible for the defense of: (i) any such infringement claims in the KKC Territory based on patents or any other proprietary right owned by such Third Party asserted to Cover the manufacture, use, offer for sale, sale or importation of the Product and (ii) any other infringement claim in the Amgen Territory for which Amgen does not have the primary responsibility to defend against pursuant to Section 11.3.2. Amgen shall reasonably assist KKC and cooperate in any such litigation at KKC's request, and KKC shall reimburse Amgen any reasonable, documented, out-of-pocket costs incurred in connection therewith. Subject to such control, Amgen may join any defense and settlement pursuant to this Section 11.3.3 with its own counsel at its sole cost. KKC shall seek and reasonably consider Amgen's comments before determining the strategy for such matter. Without limiting the foregoing, KKC shall keep Amgen advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Amgen copies of and an opportunity to review and comment on any such communications, filings and submissions. KKC shall not settle or consent to the entry of any judgment in any such action that would reasonably be expected to have a material adverse effect on the Licensed KKC Patents, the

Licensed KKC Trademarks or the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the Amgen Territory, without Amgen's prior written consent, not to be unreasonably withheld or delayed. KKC shall keep Amgen fully informed of all claims and actions governed by this Section 11.3.3. In the event KKC becomes engaged in: (i) settlement discussions with a Third Party that has specifically asserted that a patent right or trademark right of such Third Party would be infringed by the use, sale or importation of the Product, (ii) settlement discussions of an interference, opposition, or other post-grant proceeding involving a patent corresponding to a Licensed KKC Patent or a trademark corresponding to a Licensed KKC Trademark, or (iii) cross-license discussions with respect to a patent corresponding to a Licensed KKC Patent or a trademark corresponding to a Licensed KKC Trademark; and, in each such case, such Third-Party patent right or trademark right corresponds to a patent right or trademark right inside the Amgen Territory: (a) KKC shall keep Amgen reasonably informed of the status of such discussions, and (b) KKC shall consider in good faith any comments or suggestions of Amgen.

11.3.4 Mutual Provisions. Each Party shall have the right to redact any information disclosed to the other Party pursuant to this Section 11.3.4 relating to any product other than the Product.

Section11.4 Enforcement.

11.4.1 In Amgen Territory. Each Party shall promptly notify the other Party in writing if it reasonably believes that any Licensed KKC IP or Joint Patents are infringed or misappropriated by a Third Party in the Amgen Territory.

(a) *Amgen Primary Enforcement of Licensed KKC IP*. From and after the Effective Date, Amgen shall have the first right, but not the obligation, to enforce Licensed KKC IP against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Amgen Territory, at Amgen's sole cost, subject to Section 11.5 (Cooperation). In the event Amgen elects to bring and prosecute such an action, KKC shall reasonably assist Amgen and cooperate in any such action at Amgen's request (and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by KKC in connection therewith), and Amgen shall seek and reasonably consider KKC's comments in good faith before determining the strategy. Without limiting the foregoing, Amgen shall keep KKC advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide KKC copies of, and an opportunity to review and comment on, drafts of material communications, filings and submissions as reasonably practicable and shall reasonably consider in good faith KKC's comments. Upon KKC's request, Amgen will meet and confer in good faith with KKC to discuss such material communications, filings and submissions. Amgen shall not settle, or consent to any judgment in, any action under this Section 11.4.1(a) that would reasonably be expected to have a material adverse effect on the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the Collaboration Territory, without KKC's prior written consent, not to be unreasonably withheld or delayed.

(b) *KKC Secondary Enforcement of Licensed KKC IP.* From and after the Effective Date, in the event Amgen does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any Licensed KKC IP within [***] days after KKC requests Amgen to do so in writing (or, if later, within [***] days after such action can viably be brought by Applicable Law (as, for example, in the case of [***]), KKC shall be entitled to bring and prosecute such an action at KKC's sole cost and Amgen will cooperate with KKC. If KKC elects to bring and prosecute such an action, then KKC shall seek and reasonably consider Amgen's comments on strategy. Without limiting the foregoing, KKC shall keep Amgen advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions. KKC shall not settle, or consent to any judgment in, any action under this Section 11.4.1(b) that would reasonably be expected to have a material adverse effect on the Licensed KKC IP or the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the Collaboration Territory, without Amgen's prior written consent, not to be unreasonably withheld or delayed.

(c) *Amgen Primary Enforcement of Joint Patents*. From and after the Effective Date, Amgen shall have the first right, but not the obligation, to enforce Joint Patents against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Amgen Territory, at Amgen's sole cost, subject to Section 11.5 (Cooperation). In the event Amgen elects to bring and prosecute such an action, KKC shall reasonably assist Amgen and cooperate in any such action at Amgen's request (and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by KKC in connection therewith), and Amgen shall seek and reasonably consider KKC's comments before determining the strategy. Without limiting the foregoing, Amgen shall keep KKC advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide KKC copies of and an opportunity to review and comment on any such material communications, filings and submissions. Amgen shall not settle, or consent to any judgment in, any action under this Section 11.4.1(c) that would reasonably be expected to have a material adverse effect on the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the KKC Territory, without KKC's prior written consent, not to be unreasonably withheld or delayed.

(d) *KKC Secondary Enforcement of Joint Patents*. From and after the Effective Date, in the event KKC does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any Joint Patents within [***] days after KKC requests Amgen to do so in writing (or, if later, within [***] days after such action can viably be brought by Applicable Law (as, for example, in the case of [***]), KKC shall be entitled to bring and prosecute such an action at KKC's sole cost and Amgen will cooperate with KKC. If KKC elects to bring and prosecute such an action, then KKC shall seek and reasonably consider Amgen's comments on strategy. Without limiting the foregoing, KKC shall keep Amgen advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions. KKC shall not settle, or consent to

any judgment in, any action under this Section 11.4.1(d) that would reasonably be expected to have a material adverse effect on the Joint Patents or the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the Amgen Territory, without Amgen's prior written consent, not to be unreasonably withheld or delayed.

11.4.2 In KKC Territory. Each Party shall promptly notify the other Party in writing if it reasonably believes that any Licensed Amgen IP or Joint Patents are infringed or misappropriated by a Third Party in the KKC Territory. For clarity, Amgen shall have the sole right, but not the obligation, to enforce its patent rights, trademark rights and other intellectual properties, the Joint Patents, and Licensed Amgen IP in the KKC Territory against any actual, alleged or threatened infringement or misappropriation by Third Parties in the KKC Territory, at Amgen's sole cost, subject to Section 11.5 (Cooperation). In the event Amgen elects to bring and prosecute any such actions, KKC shall reasonably assist Amgen and cooperate in any such action at Amgen's request (and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith), and Amgen shall seek and reasonably consider KKC's comments before determining the strategy. Without limiting the foregoing, Amgen shall keep KKC advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide KKC copies of and an opportunity to review and comment on any such material communications, filings and submissions. Amgen shall not settle, or consent to any judgment in, any action under this Section 11.4.2 that would reasonably be expected to have a material adverse effect on the research, Manufacture, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of the Product in the KKC Territory, without KKC's prior written consent, not to be unreasonably withheld or delayed.

Section11.5 Cooperation. When either Party is bringing or defending an action of the type described in Section 11.3 (Defense and Settlement of Third Party Claims) or Section 11.4.1 (In Amgen Territory) or Section 11.4.2 (In KKC Territory), then upon reasonable request by such a Party, the other Party will reasonably assist in the defense against or enforcement of such action at the requesting Party's costs, including if required or desirable to bring, maintain or prove damages in such action, furnishing a power of attorney, furnishing documents and information, providing employee witnesses and executing all necessary documents as such Party may reasonably request.

Section11.6 Allocation of Recoveries. All Recoveries shall first be applied to reimbursement of the unreimbursed legal fees and expenses reasonably incurred by the Parties in the action from which such Recovery was received on a pro rata basis. Any Recoveries from actions brought by either Party during the Term within the Amgen Territory, that are left over after such reimbursement, shall be [***]. KKC shall be fully entitled to any Recoveries from actions within the KKC Territory during the Term that are left over after such reimbursement.

Section11.7 Patent Term Extensions. From and after the Effective Date, each Party shall provide reasonable assistance to the other Party in connection with obtaining patent term extensions or supplementary protection certificates (SPCs) for Licensed KKC Patents in the

Collaboration Territory consistent with the rights of the other Party to control such matters as specified in Section 11.2 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such patent term extension or SPC in a particular country, each Party shall make available to the other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the patent term extension or SPC in such country.

Section11.8 Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement or being given access to Licensed KKC Know-How or Licensed Amgen Know-How or Confidential Information of the other Party, each employee, consultant or agent of Amgen or KKC, respectively, shall have either signed or shall be bound by a non-disclosure and invention assignment agreement or similar obligation pursuant to which each such person shall agree to comply with all of the obligations of Amgen or KKC, as appropriate, substantially including: (a) promptly reporting any Information, as appropriate, (b) assigning to Amgen or KKC, as appropriate, all of his or her right, title and interest in and to any such Information or be bound by Applicable Law to assign to Amgen or KKC, as appropriate, all of his or her right, title and interest in and to any such Information, (c) cooperating in the preparation, filing, prosecution, maintenance, enforcement and defense of any intellectual property rights, (d) performing all acts and signing, executing, acknowledging and delivering any and all papers, documents and instruments required for effecting the obligations and purposes of this Agreement, and (e) abiding by the obligations of confidentiality and non-use set forth in this Agreement. It is understood and agreed that any such non-disclosure and invention assignment agreement or similar obligation need not be specific to this Agreement, and that the operation of a collective employment policy sufficient to achieve the intent of the foregoing shall be sufficient to satisfy such obligation. Each Party shall be responsible for any compensation and any other payments due to its own inventors of any patent right.

Article XII.

CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

Section12.1 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 or on behalf of 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 any purpose other than (i) as provided for in this Agreement or (i) otherwise in connection with exploiting its rights to the Product in a manner consistent with the terms of this Agreement. 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:

12.1.1 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;

12.1.2 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;

12.1.3 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

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

Section12.2 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) to the extent such disclosure is to such Party's personnel, solely on a need-to-know basis to the extent such personnel requires such information for the performance of such Party's activities hereunder and under appropriate confidentiality provisions substantially equivalent to those in this Agreement; (ii) 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 arbitration or 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 regulatory obligations for the Product, or otherwise required by Applicable Law, including regulations of the Securities and Exchange Commission, Securities and Exchange Surveillance Commission (SESC) or similar regulatory authority, 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 (ii), will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed, (iii) 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, (iv) to such Party's [***]; provided further, that, prior to any such disclosure, each such disclosee is bound by written obligations of confidentiality, non-disclosure, and non-use at least as restrictive as the obligations set forth in this Article XII to maintain the confidentiality thereof and not to use or disclose such Confidential Information except as expressly permitted by this Agreement, (v) to Third Party licensors (including, for clarity, sharing a redacted copy of this Agreement) on a need to know basis in connection with any reporting, auditing or other similar obligations as may be set forth in

any Third Party Licenses, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, and (vi) to the extent mutually agreed to by the Parties.

Section12.3 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 terms and conditions will not be disclosed, except (i) as otherwise permitted under Section 12.2 (Authorized Disclosure) and (ii) if required by Applicable Law (including disclosure of a redacted version of this Agreement in a filing required by the Securities and Exchange Commission, the Securities and Exchange Surveillance Commission (SESC) or similar regulatory authority. 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.

Section12.4 Press Releases and Disclosures. Notwithstanding Section 12.3 (Confidential Treatment of Terms and Conditions), the Parties will each issue a press release to announce the execution of this Agreement, each of which is attached hereto as the Press Releases Schedule and is for use in responding to inquiries about this Agreement. Thereafter, KKC 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 regarding the terms of this Agreement only with the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed (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 or by Applicable Law but not less than [***] Business Days. The disclosing Party shall provide the finalized press release or material to be disclosed to the other Party prior to such publication of the press release or such disclosure.

Section12.5 Confidential Information Exchanged Prior to the Effective Date. All confidential information exchanged between the Parties and their respective Affiliates prior to the Effective Date (including all confidential information exchanged under the Confidentiality Agreement between Amgen and Kyowa Kirin Co., Ltd., dated [***] (including that certain Request for Restricted Information dated [***], as amended), will be deemed Confidential Information of the disclosing Party disclosed hereunder and will be subject to the terms of this Agreement.

Section12.6 Publications and Presentations. Each of Amgen and KKC shall be free to:

12.6.1 present findings with respect to the Product at symposia and other meetings of healthcare professionals, and congresses, conferences or meetings organized by a professional

society or organization (any such occasion, a "Scientific Meeting"); *provided*, *however*, unless otherwise agreed by the Parties, that (i) the Party presenting at any such Scientific Meeting shall have complied with the provisions of this Section 12.6 and Section 12.7 (Scientific Papers, Abstracts and Posters) with respect to such presentation, and, with respect to any such Scientific Meeting at which a Party is presenting, such presenting Party shall inform the other Party of such Scientific Meeting and where invitation is required, invite the other Party to attend such Scientific Meeting; and (ii) a Party shall not organize or sponsor any satellite symposia in a country outside its territory without the other Party's prior written consent, not to be unreasonably withheld;

12.6.2 publish in medical or scientific journals ("Medical Journals") articles and papers, including primary reports of clinical data, data obtained from Investigator Sponsored Studies, secondary or pooled analyses, and review papers concerning the Product which have been prepared by or on behalf of such Party, for publication in the Amgen Territory or in the KKC Territory and related to studies conducted after the Effective Date outside or in the Territory concerning the Product (each a "Scientific Paper"); *provided, however*, that the Party proposing to publish such Scientific Paper shall have complied with the provisions of Section 12.7 (Scientific Papers, Abstracts and Posters) with respect to such Scientific Paper; and

12.6.3 disclose any clinical data generated by such Party concerning the Product in clinical trial registries; *provided, however*, that, the Party proposing to make such disclosure shall have provided the other Party at least [***] Business Days prior to such disclosure (to the extent practicable), a detailed description of the proposed disclosure and shall have, in good faith, considered the comments made by the other Party.

Section12.7 Scientific Papers, Abstracts and Posters.

12.7.1 Scientific Papers. The JSC will establish a subcommittee to review Scientific Papers and establish an annual publication plan which will be presented for review and approval by the JSC. Each Party, through such subcommittee, if applicable, shall provide to the other, prior to submission of any Scientific Paper to a Medical Journal, a draft of such Scientific Paper. Commencing with the receipt of such draft Scientific Paper, the receiving Party shall have [***] Business Days to notify the sending Party of its observations and suggestions with respect thereto; it being understood that, during such [***] Business Day period, no submission for publication thereof shall take place and the Parties shall discuss these suggestions if requested by either Party. The Party proposing to publish such Scientific Paper shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not publish or present any Confidential Information of the other Party (whether in a Scientific Paper or otherwise) without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of any final Scientific Paper accepted by a Medical Journal, not less than [***] Business Days or as soon as practicable prior to the planned publication thereof (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' requirements). To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (a) obtain and maintain, at its

own expense, an annual copyright license or equivalent license from the Copyright Clearance Center and (b) list the other Party as a collaborator in an agreement with the Copyright Clearance Center.

12.7.2 Abstracts and Posters. Each Party shall provide to the other, prior to submission or presentation, as the case may be, copies of (a) all abstracts that will be submitted to any Scientific Meeting in the Amgen Territory or in the KKC Territory, and (b) all posters and other materials (such as slides) that will be presented at such Scientific Meeting, in each case, concerning the Product, which have been prepared by or on behalf of one of the Parties, for submission or presentation. Commencing with the receipt of any such abstract or poster or oral presentation materials the receiving Party shall have [***] Business Days to inform the sending Party of its observations and suggestions with respect thereto; it being understood that, during such [***] Business Day period, no submission or presentation thereof shall take place and the Parties shall discuss these suggestions, if requested by either Party. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not submit in any abstract or present in any poster, other written materials or oral presentation any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of all final abstracts as submitted and all final posters to be presented no later than [***] after submission or presentation.

12.7.3 Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for (a) extensions of the above timelines (in Section 12.6 (Publications and Presentations) and this Section 12.7) in the event that material late-breaking clinical data becomes available or (b) shortening of the above timelines (in Section 12.6 (Publications and Presentations) and this Section 12.7) if the requesting Party has a good faith belief that circumstances warrant such acceleration. The Parties acknowledge and agree that all publications pursuant to Section 12.6 (Publications and Presentations) shall comply with the authorship guidelines of the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Without limitation to the foregoing, each Party shall acknowledge the contributions of the other Party as appropriate and consistent with the applicable Medical Journal or Scientific Meeting guidelines, and shall properly credit and name the other Party in any Scientific Papers and presentations in Scientific Meetings so as to reflect the good name, goodwill and reputation of the Parties.

12.7.4 In addition to the requirements set forth in Sections 12.7.1 (Scientific Papers) through 12.7.3, Amgen will document when a publication is to be led by Amgen. For those publications led by Amgen, the Parties agree to comply with Amgen's publications policies and processes (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). Among other things, all such publications will undergo Amgen's internal review process and publication documentation will be kept in Amgen's publication system where required under Amgen's

policies and processes. Publications led by KKC will be developed in accordance with KKC's publications policies and processes.

Section12.8 Deferral of Disclosures. If either Party believes that any proposed press release or other public statement, or any publication, presentation, or other disclosure would be prejudicial to its opportunity to obtain any patent rights, then the affected Party shall notify the publishing Party within the timeframe provided for in Section 12.9 (Failure to Object to Disclosure) as applicable, or if not applicable, as soon as practicable after receipt of the proposed press release or other public statement, publication, presentation, or other disclosure, and the publishing Party shall refrain from making such press release, other public statement, publication, presentation or other disclosure an additional [***] days from the last day of the period otherwise provided for herein to enable the preparation and filing of any necessary patent applications.

Section12.9 Failure to Object to Disclosure. If the Party proposing any press release or other public statement, or any publication, presentation, or other disclosure receives no objection from the other Party within the timeframes set forth in the corresponding Section, then the Party proposing such press release, other public statement, publication, presentation, or other disclosure shall be free to proceed with the same without further reference to or agreement from other Party.

Section12.10 Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (i) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections, (ii) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates, (iii) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates, and (iv) intend that after the Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

Article XIII.

REPRESENTATIONS, WARRANTIES AND COVENANTS

Section13.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants, as of the Execution Date and the Effective Date to the other Party as follows:

13.1.1 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 (and, each Party shall have

obtained all necessary approvals to execute and perform this Agreement on or before the Effective Date);

13.1.2 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 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;

13.1.3 neither it nor any of its directors, officers, nor any of its employees has been debarred, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;

13.1.4 neither it, nor its officers or directors are Sanctioned Persons, nor are they owned 50% or more individually or in the aggregate by, or controlled by, any Sanctioned Person or Persons;

13.1.5 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;

13.1.6 no claim or demand of any Third Party has been asserted in writing to it arising out of such Party's Development, Manufacture, or Commercialization activities with respect to any other product, and no investigations are pending or, to the knowledge of such Party, threatened related to such activities, that in each case could reasonably be expected to impact such Party's ability to perform any of its obligations under this Agreement;

13.1.7 to its knowledge, it and each of its Representatives have at all times complied with Proper Conduct Practices in connection with the Product; and

13.1.8 it has established and maintains reasonable internal policies and controls, including codes of conduct and ethics and reasonable reporting requirements, intended to ensure compliance with Anti-Corruption Laws, International Trade Laws, and other Applicable Law, to the extent applicable to such Party, including healthcare compliance, privacy laws and data protection laws.

Section13.2 KKC Representations and Warranties. In addition to the representations and warranties set forth in Section 13.1 (Mutual Representations and Warranties), KKC hereby represents and warrants to Amgen that, as of the Execution Date and the Effective Date:

13.2.1 KKC has (or, with respect to the Effective Date, shall have) obtained all necessary consents, approvals and authorizations of all Third Parties required to be obtained by it as of the

Execution Date and Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;

13.2.2 to KKC's knowledge, all issued Patents within Licensed KKC Patents covering the composition of matter of the active ingredient of the Product in the Amgen Territory have been filed and maintained properly and correctly and KKC has not failed to pay any applicable fees on or before the expiration of the applicable grace period for such payment;

13.2.3 it has the full right, power and authority to grant the licenses granted by KKC under Article III (Grant of License) and neither KKC nor its Affiliates have granted any right or license to any Third Party relating to any of the Licensed KKC Patents, Licensed KKC Trademarks or Licensed KKC Know-How that would conflict with or limit the scope of any of the rights or licenses granted to Amgen hereunder;

13.2.4 as of the Effective Date, KKC has sufficient legal and/or beneficial title and ownership, or a license or other right under the Licensed KKC Patents, Licensed KKC Trademarks and Licensed KKC Know-How to grant the licenses to Amgen as purported to be granted pursuant to this Agreement;

13.2.5 KKC Controls the Licensed KKC Patents listed on the Licensed KKC Patents Schedule, free of any Liens. To KKC's knowledge, the Licensed KKC Patents in the Amgen Territory listed on the Licensed KKC Patents Schedule constitute a true and complete list of all Patents Controlled by KKC in the Amgen Territory Covering the Product in the Amgen Territory;

13.2.6 Except with respect to the patents set forth on the Licensed KKC Patents Schedule, none of the Licensed KKC Patents is in-licensed by KKC from a Third Party;

13.2.7 no claim has been issued and served against KKC or any of its Affiliates that alleges that any Licensed KKC Patent in the Amgen Territory is invalid or unenforceable;

13.2.8 KKC has not received any written notice of any opposition or challenge against any Licensed KKC Patent in the Amgen Territory except with respect to the Licensed KKC Patent Opposition;

13.2.9 neither KKC nor its Affiliates have received any written notice of any claim that any Patent or Information (including any trade secret right) owned or controlled by a Third Party would be infringed or misappropriated by the development, manufacture, or Commercialization of the Product in the Amgen Territory;

13.2.10 to KKC's knowledge, there is no issued Patent of any Third Party, other than Patents of Third Parties included within the Licensed KKC Patents, that would be required to develop, manufacture or commercialize the Product in or for the Amgen Territory as currently contemplated by this Agreement;

13.2.11 to KKC's Knowledge, there are no activities by Third Parties that would constitute significant infringement or misappropriation of the Licensed KKC Patents or Licensed KKC Know-How, which would have a material adverse effect on the rights granted to Amgen for the Territory;

13.2.12 to KKC's knowledge, the development of the Product by or on behalf of KKC has been conducted in compliance in all material respects with all Applicable Law;

13.2.13 to KKC's knowledge, all data and information relating to the Product filed by KKC with the any Regulatory Authority are true and accurate in all material respects;

13.2.14 KKC has filed with the Regulatory Authorities in the United States, Europe and in Japan all safety and efficacy data and information relating to the Product in KKC's possession that are required to be filed, and has made available to Amgen, all such material safety and efficacy data; and

13.2.15 KKC has not received any written notice that any Governmental Authority has commenced any investigation or any action to withdraw any Regulatory Filing with respect to the Development, Manufacture or Commercialization of Product, which may have a material adverse effect on the development, Manufacture or Commercialization of the Product in the Amgen Territory.

Section13.3 Mutual Covenants. Each Party hereby covenants to the other Party that, during the Term:

13.3.1 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;

13.3.2 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, excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;

13.3.3 it shall comply with all Applicable Law (including Applicable Law relating to healthcare compliance, data protection and privacy), International Trade Laws, Proper Conduct Practices, Anti-Corruption Laws and the Quality and Compliance Standards in connection with the performance of its rights, duties and obligations under this Agreement;

13.3.4 it shall provide the other Party with any information required for that Party or the Parties to comply with International Trade Laws;

13.3.5 it shall for the Term of this Agreement and [***] years thereafter maintain complete and accurate books, accounts, invoices and reasonably detailed records related to this Agreement or any work conducted for or on behalf of such Party under this Agreement including

all records required to establish compliance with Section 13.3.3 above and in accordance with Section 9.4 (Audits);

13.3.6 it 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 of any representation, warranty or undertaking set forth in Section 13.3.3 above or Section 13.3.11 below and in such case it shall cooperate with the other Party in any resulting formal or informal investigation related thereto;

(b) upon receiving a formal or informal notification that it is the target of a formal or informal request for information, subpoena, investigation, litigation, penalty or claim from any Governmental Authority for violation or potential violation of any Anti-Corruption Law, Proper Conduct Practices, or International Trade Laws;

13.3.7 if either Party requests that the other Party complete a compliance certification certifying compliance with Section 13.3.3 above, which request shall occur no more than once per calendar year, such other Party shall promptly complete and deliver such compliance certification truthfully and accurately in the form set forth in the Compliance Certification Exhibit;

13.3.8 if either Party requests that the other Party provide additional information as may be reasonably necessary to verify compliance with the obligations set forth in Section 13.3.3 above, such other Party shall promptly provide such additional information;

13.3.9 prior to beginning any development or Commercialization of the Product under this Agreement, each employee, agent or independent contractor of Amgen or KKC or of either Party's respective Affiliates involved in the development or Commercialization of the Product shall be required to undergo compliance training with respect to Proper Conduct Practices and Anti-Corruption Laws;

13.3.10 it shall use only legitimate and ethical business practices (including Proper Conduct Practices) in connection with activities conducted in connection with this Agreement whether directly, through the use of Representatives or otherwise, and shall not take any action that would subject any other Party to penalties under any Applicable Law;

13.3.11 it shall comply with all applicable International Trade Laws and their respective regulations and obtain all import, export, re-export approvals and licenses required for any goods, services and technical data exchanged or delivered by it and shall retain documentation to support compliance with those laws and regulations, in each case, in connection with activities conducted in connection with this Agreement;

13.3.12 it will not export, directly or indirectly, any technical information acquired from any other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental

approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authorities in accordance with International Trade Laws or other Applicable Law;

13.3.13 it shall cause its Affiliates and its and their officers, directors, employees and agents to comply with this Agreement, including the covenants in this Section 13.3; and

13.3.14 neither it nor its Representatives will knowingly make any untrue statement of a material fact to any Regulatory Authority with respect to the Product (whether in any submission to such Regulatory Authority or otherwise) in the Collaboration Territory, and neither will knowingly fail to disclose a material fact required to be disclosed to any Regulatory Authority in the Collaboration Territory with respect to the Product.

Section13.4 Privacy and Data Protection. Without limiting each Party's respective obligations elsewhere in the Agreement, each Party, as applicable, agrees that where a Party determines the purpose and means of processing Personal Information, such Party is: (a) acting as a "controller" (as defined under applicable law) of such information, and (b) shall comply with all applicable data privacy and protection laws applicable to a controller, which shall include employing and maintaining appropriate Security (as defined below) to protect such information. "Security" means technological, physical and administrative controls, including policies, procedures, organizational structures, hardware and software functions, as well as physical security measures, the purpose of which is, in whole or part, to ensure the confidentiality, integrity or availability of Personal Information.

13.4.1 Without limiting the generality of each Party's respective obligations set forth in Section 13.4, and to the extent either Party is required to disclose or otherwise transfer Personal Information (inclusive of Amgen Development Data or KKC Development Data, as the case may be or Safety Data) (each a "Disclosing Party") to the other Party (each, a "Receiving Party"), the Parties agree as follows:

(a) In the event of an actual or reasonably suspected breach or violation of Security concerning the Personal Information ("Privacy Incident"), each Party shall notify the other of such incident without undue delay (but in no event later than [***] after discovery). In such event, each Party shall be responsible for fulfilling any reporting and notification obligations required under GDPR and other Applicable Law with regard to the data processing operations it carries out.

(b) The Parties hereby incorporate the EU Standard Contractual Clauses necessary to effectuate the compliant onward transfer of EU Personal Information outside of EU/EEA to third countries attached hereto as the Standard Contractual Clauses Schedule. In addition, the Parties agree to cooperate with each other to effectuate the compliant transfer of Personal Information applicable to other jurisdictions, which may include executing additional data transfer agreements.

(c) The Parties shall notify each other without delay (but in no event later [***] business days after receipt) in the event a data subject asserts one of his/her rights under GDPR

and other applicable data privacy and protection laws. With respect to patient data, any such notifications shall be made in a pseudonymous form using the subject's trial-specific identification number only. If necessary and appropriate, the Parties shall reasonably cooperate with each other by providing the necessary information to ensure full and effective implementation of the rights of the data subject. Notification required under this Section shall be made as follows: [***]

(d) To the extent required under GDPR and Applicable Law, each receiving Party shall (i) make available to the other Party such information as is reasonably necessary to demonstrate the receiving Party's compliance with its obligations under GDPR and Applicable Law and this Agreement and (ii) allow for and contribute to audits and inspections conducted by the disclosing Party in accordance with the terms of this provision to demonstrate compliance with the receiving Party's obligations set out in this Agreement, GDPR and Applicable Law. Should a disclosing Party choose to exercise the right to conduct an audit or inspection as described in (ii) above, the disclosing Party shall designate an independent, qualified third-party that is reasonably acceptable to and approved by the receiving Party to perform such audit or inspection, at the disclosing Party's cost and expense. The timing of such audit or inspection shall be agreed to by the Parties. The receiving Party shall document the results of such audits and inspections and present them to the disclosing Party for approval. If the receiving Party objects to the disclosing Party's request for audit or inspection, it shall advise the disclosing Party of its objections, the reasons for objecting, and reasonably work with the disclosing Party to tailor the audit to address such objections, to the extent commercially reasonable.

Without limiting the foregoing, where each Party is acting as "processor" (as defined under Applicable Law) of the other Party, such processor Party shall comply with the terms of the Privacy and Data Protection Schedule attached hereto.

Section13.5 Information Security. The Parties agree to comply with the Information Security Schedule attached hereto (the "Information Security Schedule") and the following:

(i) a mechanism to determine and promptly report suspected Security Breaches in accordance with the Information Security Schedule;

(ii) controls to ensure the return or destruction, at the other Party's direction, of data as required under this Agreement;

(iii) a process for maintaining the confidentiality, integrity, security and availability of data; and

(iv) methods for controlling access to data, which shall include (a) permitted access methods, (b) an authorization process for users' access and privileges, and (c) maintenance of a list of authorized users, in accordance with the data.

Section13.6 Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE XIII, KKC AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL

REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT, LICENSED AMGEN PATENTS, LICENSED AMGEN KNOW-HOW, LICENSED KKC PATENTS, LICENSED KKC KNOW-HOW, AMGEN HOUSEMARKS, KKC HOUSEMARKS, LICENSED AMGEN TRADEMARKS, LICENSED KKC 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.

Section13.7 Limitation of Liability. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, OTHER THAN TO THE EXTENT RESULTING FROM EITHER PARTY'S BREACH OF ARTICLE X (DISTRACTING PRODUCTS) OR ARTICLE XII (CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES) OR EITHER PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT WILL KKC 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 14.1 (INDEMNITY BY KKC) OR SECTION 14.2 (INDEMNITY BY AMGEN).

Section13.8 Disclosure Laws. Notwithstanding anything to the contrary in this Agreement, KKC acknowledges and agrees that (i) Amgen is permitted to publicly disclose information regarding this Agreement to comply with Applicable Laws (including without limitation the Physician Payment Sunshine Act and related requirements (collectively, "Disclosure Laws")), and (ii) this information may include without limitation payments, or other transfers of value, made on behalf or at the request of Amgen to physicians, teaching hospitals, and other persons or entities that are the subject of the Disclosure Laws. KKC agrees to promptly respond to, and cooperate with, the reasonable requests of Amgen regarding collection of information regarding and compliance with Disclosure Laws.

Section13.9 Filings, Consents and Approvals.

13.9.1 To the extent permitted by Applicable Law, each of Amgen and KKC shall consult and cooperate with one another, and consider in good faith the views of one another, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party hereto in connection with proceedings under or relating to the HSR Act or any applicable foreign antitrust or competition-related legal requirement. Amgen and KKC shall cooperate fully with each other in connection with the making of all such filings or responses.

13.9.2 Each of Amgen and KKC shall notify the other promptly upon the receipt of: (i) any communication from any official of any Governmental Authority in connection with any filing made pursuant to this Agreement; (ii) knowledge of the commencement or threat of commencement of any legal proceeding or before any Governmental Authority with respect to the transactions under this Agreement (and shall keep the other Party informed as to the status of any such legal proceeding or threat); and (iii) any request by any official of any Governmental Authority for any amendment or supplement to any filing made pursuant to this Agreement or any information required to comply with any legal requirement applicable to the transactions under this Agreement. In addition, except as may be prohibited by any Governmental Authority or by any Applicable Law each Party hereto will permit authorized representatives of the other Parties to be present at each meeting or telephone call and to have access to and be consulted in connection with any document, opinion or proposal made or submitted to any Governmental Authority in connection with such communication, request or proceeding.

13.9.3 Subject to the terms and conditions of this Agreement, each of Amgen and KKC shall use its Commercially Reasonable Efforts to take, or cause to be taken, all other actions and do, or cause to be done, all other things necessary, proper or advisable under Applicable Law to consummate the transactions contemplated by this Agreement, including (i) making all filings and submissions under the HSR Act, to the extent required, as promptly as practicable after the date hereof and (ii) obtaining as promptly as practicable the termination of any waiting period under the HSR Act, if applicable.

13.9.4 Notwithstanding anything in this Agreement to the contrary, it is expressly understood and agreed that: (i) neither Amgen nor KKC shall have any obligation to litigate or contest any administrative or judicial action or proceeding or any decree, judgment, injunction or other order, whether temporary, preliminary or permanent; and (ii) neither Amgen nor KKC shall be under any obligation to make proposals, execute or carry out agreements, enter into consent decrees or submit to orders providing for (A) the sale, divestiture, license or other disposition or holding separate (through the establishment of a trust or otherwise) of any assets or categories of assets of Amgen or KKC or any of their subsidiaries, or (B) the imposition of any limitation or regulation on the ability of Amgen or KKC to freely conduct their business or own such assets.

Article XIV.

INDEMNIFICATION AND INSURANCE

Section14.1 Indemnity by KKC. KKC will defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "Amgen Indemnitees"), at KKC'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: (i) the negligence or willful misconduct of KKC or its Affiliates (or any employees, agents or representatives of any of them) in performing under this Agreement, (ii) a breach by KKC of Applicable Law or this Agreement, including the failure of KKC's representations or warranties in Article XIII

(Representations, Warranties and Covenants) to be true in any material respect, (iii) the negligence or willful misconduct of KKC's Sales Representatives or Medical Liaisons in connection with the activities under Section 6.4 (Co-Promotion Activities), (iv) prior to the Manufacturing Transfer, any product liability claims to the extent arising from the failure by KKC, its Affiliates or contractors in connection with the Manufacture of the Product, or (v) KKC's or its Affiliates' Development, Commercialization or Manufacture of the Product prior to or after the Effective Date. The indemnification obligations under this Section 14.1 exclude Losses to the extent they arise from (i), (ii) or (iii) below in Section 14.2 (Indemnity by Amgen) or are subject to a right of indemnification under the Supply Agreement.

Section14.2 Indemnity by Amgen. Amgen will defend, indemnify, and hold harmless KKC, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "KKC Indemnitees"), at Amgen's cost and expense, from and against any and all Losses arising out of any Third Party Claims brought against any KKC Indemnitee to the extent such Losses result from: (i) the negligence or willful misconduct of Amgen or its Affiliates (or any employees, agents or representatives of any of them) in performing under this Agreement, (ii) a breach by Amgen of Applicable Law or this Agreement, including the failure of Amgen's representations or warranties in Article XIII (Representations, Warranties and Covenants) to be true in any material respect or (iii) Amgen's or its Affiliates' Development, Manufacture or Commercialization of, or conduct of Medical Affairs Activities with respect to, the Product. The indemnification obligations under this Section 14.2 exclude Losses to the extent they arise from (i) through (v)) above in Section 14.1 (Indemnity by KKC) or are subject to a right of indemnification under the Supply Agreement.

Section14.3 Claim for Indemnification. Whenever any Third Party Claim or Loss arises for which a KKC Indemnitee or an Amgen Indemnitee (the "Indemnified Party") may seek indemnification under this Article XIV, 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 such Third Party Claim without the prior written consent of the Indemnified Party, unless such settlement: (i) includes a complete release of the Indemnified Party from liability with respect to the Third Party Claim (including any cost sharing under this Agreement), and (ii) does not include any admission of wrongdoing by the Indemnified Party or a stipulation that any intellectual property or proprietary right of the Indemnified Party is invalid or unenforceable; *provided* that in the event consent is required by the Indemnifying Party for a settlement such consent shall not unreasonably withheld, conditioned or delayed. In the event of a disagreement regarding such settlement, such matter shall be escalated to the JSC. Notwithstanding the foregoing, the Indemnifying Party shall not be prohibited from entering into a settlement that involves one or more countries in addition to Amgen Territory so long as such settlement does not result in any liability or admission of wrongdoing by the Indemnified Party or a stipulation 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. For the avoidance of doubt, any Third Party Claims or Losses, to the extent indemnifiable pursuant to this Section 14.3, shall be excluded from the definition of "Commercialization and Related Costs."

Section14.4 Defense of Third Party Claims. Except as otherwise provided in Section 11.3 (Defense and Settlement of Third Party Claims) and Section 14.3 (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. 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. 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 and 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 the Product or relating to a device used in connection with, or the manufacture of, the Product. The Defending Party will control the defense and settlement of Third Party Claims, at the Defending Party's expense. The Defending Party will not settle such Third Party Claim without the prior written consent of the other Party, unless such settlement: (i) includes a complete release of the Assisting Party from liability with respect to the Third Party Claim (including any cost sharing under this Agreement), and (ii) does not include any admission of wrongdoing by the Assisting Party; *provided* that in the event consent is required by the other Party for a settlement such consent shall not be unreasonably withheld, conditioned or delayed. In the event of a disagreement regarding such settlement, such matter shall be escalated to the JSC. 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. This Section 14.4 will not apply to employment or similar personnel-related claims.

Section14.5 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.

Article XV.
TERM AND TERMINATION

Section15.1 Term. Except for the terms and conditions of Article XII (Confidentiality, Publications and Press Releases) and Article XIII (Representations, Warranties and Covenants), which shall become effective on the Execution Date, this Agreement shall become effective on the latest of (i) the date on which the Parties have obtained all necessary consents and approvals for the closing of this Agreement, including any regulatory consents and approvals, (ii) if the Parties determine that an HSR Filing is required, the date on which any applicable waiting period under the HSR Act with respect to the transactions contemplated by this Agreement expires or is terminated, and (iii) June 3, 2021 (or such later date agreed by the Parties) (such date, the "Effective Date"). This Agreement will become effective on the Effective Date and will continue until the expiration of the Term for the Product, unless terminated earlier in accordance with this Article XV.

Section15.2 Termination by Amgen. Subject to any termination obligations set forth in 15.4.2 (Termination Effects), Amgen may terminate this Agreement in its entirety upon [***] months prior written notice (or, after First Commercial Sale of a Product, [***] months' prior written notice) to KKC.

Section15.3 Mutual Termination Rights for the Agreement. Either Party may terminate this Agreement in its entirety upon prior written notice to the other Party:

15.3.1 Material Breach. If the other Party is in material breach of this Agreement, then the non-breaching Party may terminate this Agreement in its entirety by providing written notice to the breaching Party of such material breach (specifying the nature of the breach in reasonable detail) and termination; *provided* that the breaching Party (or its Affiliate) shall have an opportunity to cure (if such breach is capable of cure or remedy and provided that a similar breach has not previously occurred two or more times in the prior [***]month period) such material breach within [***] days after the receipt of such notice. During any such [***]day cure period, either Party may require that the Designated Officers meet and confer in good faith to resolve such breach condition. So long as the breaching Party is demonstrating Commercially Reasonable Efforts to cure such material breach, the breaching Party (or its Affiliate) shall have an additional [***] days to cure such material breach. If KKC is in material breach of its obligations under Section 6.4 (Co-Promotion Activities), Amgen may, subject to the foregoing opportunity and procedure to cure such material breach, terminate this Agreement solely with respect to such Section 6.4 (Co-Promotion Activities) and any grants of licenses and other rights to KKC in connection with such Section 6.4 (Co-Promotion Activities), effective upon written notice of such termination by Amgen to KKC.

15.3.2 Insolvency. If the other Party, or an Affiliate which controls such Party (as the term "control" is defined in Article I (Definitions) ("Affiliate")), suffers an Insolvency Event,

then the non-affected Party may terminate this Agreement in its entirety upon written notice to the other Party.

15.3.3 Breach of Proper Conduct Practices. If either Party reasonably determines that the other Party (including through any Representative or Third Party engaged by the other Party) has failed to comply with the Proper Conduct Practices in any material respect, such Party shall promptly notify the non-compliant Party in writing, and the non-compliant Party shall take such actions as are reasonably necessary or as reasonably requested by the notifying Party in order to mitigate the effects of such failure to comply, and to avoid the continuation or reoccurrence of such failure or similar failures to comply with such Proper Conduct Practices. If the non-compliant Party fails to complete such remedial or mitigating actions within a reasonable period of time and to the reasonable satisfaction of the notifying Party, or if the failure to comply amounts to a violation of Anti-Corruption Laws, the notifying Party may terminate this Agreement in its entirety by providing written notice to the non-compliant Party.

Section15.4 Effect of Termination. Termination of this Agreement shall have the following effects with regard to the Product:

15.4.1 General. In the event of any termination of this Agreement, unless otherwise expressly provided, any liabilities previously accrued (including the obligation of Amgen to pay royalties pursuant to Section 8.15 (U.S. Royalties) and Section 8.16 (Ex-U.S. Amgen Territory Royalties) with respect to sales made prior to the effective date of such termination shall survive. In addition, in the event of termination of this Agreement, each Party shall return to the other Party or destroy (and certify such destruction to such other Party) all Confidential Information of the other Party (provided that each Party shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by Applicable Law or regulatory requirement).

15.4.2 Termination Effects. In the event of any termination of this Agreement (i) Amgen shall use reasonable efforts to, to the extent permitted by Applicable Law and requested by KKC, assign any contracts solely to the extent related to the Product in the Amgen Territory to KKC or its designee (including by requesting and using good-faith efforts to obtain any required consents, provided that Amgen shall be under no obligation to make any payments or incur any liabilities in order to obtain such consent), (ii) the Parties shall cooperate to promptly transition responsibility for Commercialization, Development and Medical Affairs Activities with respect to the Product to KKC, (iii) KKC shall have the right to reacquire some or all of the inventory of the Product, as requested by KKC in its sole discretion, in possession of Amgen and its Affiliates and, if KKC so reacquires inventory, shall reimburse Amgen for [***], (iv) the Parties shall reasonably cooperate and discuss in good faith the terms and conditions pursuant to which Amgen could continue to manufacture and supply KKC with Product for a transitionary period following the termination of this Agreement, (v) the Parties shall cooperate to promptly transfer ownership of all Regulatory Filings and Regulatory Approvals and responsibility for regulatory communication held by Amgen in the Amgen Territory to KKC, (vi) Amgen shall promptly transfer all Promotional Materials in its possession to KKC, [***], (vii) Amgen shall promptly transfer all material books, records, files and documents Controlled by Amgen solely to the extent related to the Product, (viii) at KKC’s option, all sublicenses granted by Amgen with

respect to the Product shall terminate or all rights thereunder shall be assigned to KKC, (ix) KKC shall have the right to control all Recalls of the Product in the Amgen Territory, (x) Section 3.2 (Licensed Amgen Know-How and Patents) (solely to the extent such intellectual property has been or is incorporated into or used in the Development, Manufacture, Medical Affairs Activities, regulatory activities or Commercialization of the Product (as such intellectual property exists as of the date of termination)) shall survive and shall become perpetual, fully paid-up and irrevocable, (xi) KKC shall have a fully paid, perpetual, irrevocable, royalty-free non-exclusive right and license to use the Licensed Amgen Trademarks (and the associated goodwill) in connection with the Product in all indications, (xii) the Parties shall cooperate to promptly transfer ownership of all Domain Names and Domain Name registrations related to the Product held by Amgen to KKC, (xiii) at KKC's request, the Parties will discuss in good faith the wind-down or transfer to KKC of any ongoing Clinical Studies for the Product conducted by or on behalf of Amgen or its Affiliates; provided that the Parties will share any expenses incurred in connection with any such transfer except in the event of termination by (A) [***] or (B) [***] in which case [***] shall bear such cost. In the event that the Parties are not permitted to transfer Regulatory Filings or Regulatory Approvals under clause (iv) above pursuant to Applicable Law, the Parties shall cooperate to establish a right of access and reference to such filings and approvals for KKC, and Amgen shall maintain such filings and approvals, and take any actions reasonably requested by KKC with respect thereto, and thereafter Amgen shall transfer ownership of all such Regulatory Filings and Regulatory Approvals to KKC or its designee as and when it becomes permissible to do so. KKC shall reimburse Amgen its reasonable, documented, out-of-pocket costs incurred as necessary for such maintenance and to perform such requested actions.

Section15.5 Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.4 (Effect of Termination), in the event of any expiration or termination of this Agreement the following provisions shall survive: Article I (Definitions), Article VIII (Financial Consideration) (with respect to amounts incurred or earned prior to any such expiration or termination), Article IX (Payments) (with respect to amounts incurred or earned prior to any such expiration or termination and any audit rights set forth in Section 9.4), Article XI (Intellectual Property)(solely with respect to ownership of intellectual property and any enforcement, infringement or defense action initiated in good faith prior to such expiration or termination), Article XII (Confidentiality, Publications and Press Releases), Article XIV (Indemnification and Insurance) and Article XVI (Miscellaneous) and Section 4.8 (Pharmacovigilance Agreement), Section 4.10 (Sharing of Data and Know-How; Rights of Reference), Section 13.4 (Privacy and Data Protection), Section 13.6 (Disclaimer of Warranties), Section 13.7 (Limitation of Liability) and Section 15.4 (Effects of Termination) and this Section 15.5.

Article XVI.

MISCELLANEOUS

Section16.1 Assignment; Change of Control. 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 (i) either Party may assign this Agreement, and its rights and obligations hereunder, to an Affiliate only with the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), (ii) Amgen may (subject to Section 3.4 (Right of First Negotiation))) assign this Agreement and its rights and obligations hereunder in its entirety in connection with the transfer or sale of all or substantially all of the rights to the Product to which this Agreement relates, and (iii) either Party may assign this Agreement, and its rights and obligations hereunder in connection with a Change of Control. Notwithstanding anything to the contrary in this Agreement, KKC shall not be entitled to assign or otherwise transfer (whether by operation of Applicable Law, general succession or otherwise) its rights under Section 6.4 (Co-Promotion Activities) without the consent of Amgen and a Change of Control of KKC shall be deemed an assignment under this sentence. Any assignment not in accordance with this Agreement will be null and 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. Additionally, if this Agreement is assigned, in whole or in part, in accordance with its terms, then: (1) any Pharmacovigilance Agreement or Quality Agreement may be assigned, in whole or in part, by the assignor to the permitted assignee of this Agreement, and (2) the assignor's ongoing and future obligations to the other Party under the Pharmacovigilance Agreement or Quality Agreement will be deemed terminated to the extent commensurate with the assignment of the corresponding obligations under this Agreement.

Section16.2 Non-Solicitation of Employees. After the Effective Date, during the Term and for a period of [***] year after the Term, each Party agrees that neither it nor any of its divisions, operating groups or Affiliates shall recruit, solicit or induce any employee of the other Party or its Affiliates directly or indirectly involved in the activities conducted pursuant to this Agreement to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean: (a) circumstances where an employee of a Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

Section16.3 Compliance with Laws. The Parties enter into this Agreement with the intent of conducting their relationship in full compliance with Applicable Law. Notwithstanding any unanticipated effect of any of the provisions herein, neither Party will intentionally conduct itself under the terms of this Agreement in a manner that does or would constitute a violation of Applicable Law. In the event that any Governmental Authority of competent jurisdiction determines that this Agreement or any material provision of this Agreement violates any Applicable Law, the Parties shall negotiate in good faith to amend this Agreement or the relevant provision thereof to remedy such violation in a manner that will not be inconsistent with the intent of the Parties or such provision. If the Parties are unable to so negotiate a modification

within [***] days of delivery of the notice regarding such violation, then either Party may elect to terminate this Agreement upon written notice to the other.

Section16.4 Change in Applicable Law. If any change in Applicable Law enacted after the Execution Date could reasonably be expected to have a material adverse effect on the ability of either Party to carry out its obligations, or receive the benefits under, this Agreement, such Party, upon written notice to the other Party (which notice may be given within [***] following enactment of such change in Applicable Law, whether or not such change is effective on the date of such enactment or is effective at a later date), may request renegotiation of this Agreement. Such renegotiation will be undertaken in good faith.

Section16.5 Governing Law; Dispute Resolution.

16.5.1 This Agreement 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., without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued.

16.5.2 Subject to Section 16.5.3 below, any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any question regarding the existence, validity or termination of this Agreement (and including the applicability of this Section 16.5 to any such dispute, controversy or claim), but excluding any dispute, controversy or claim subject to Section 2.2.5(b) (JSC Deadlocks) or Section 8.13 (Development and Commercialization Budget Deadlocks) (each a "Dispute"), shall be referred to and finally settled under the Rules of Arbitration of the International Chamber of Commerce in effect at the time of submitting for arbitration, which rules are deemed to be incorporated by reference in this clause:

(a) The arbitration tribunal (the "Tribunal") shall consist of three (3) arbitrators who are experienced in the biopharmaceutical industry. Each Party shall designate one arbitrator and the third arbitrator, who shall serve as chair of the Tribunal, shall be designated by the two party-appointed arbitrators in consultation with the Parties.

(b) The seat of arbitration shall be New York, New York, and the arbitration proceedings shall be held in English.

(c) The award of the Tribunal shall be final and judgment upon such an award may be entered in any competent court or application may be made to any competent court for juridical acceptance of such an award and order of enforcement.

(d) The costs of the Tribunal shall be paid by the non-prevailing Party.

(e) Neither Party or its Affiliates nor any arbitrator may disclose the existence, content, or results of any arbitration under this Agreement without the prior written consent of the applicable parties, unless and only to the extent such disclosure is necessary to confirm, vacate or enforce the award or is otherwise required by Applicable Law.

(f) The Tribunal shall not have the power to grant any award or remedy other than such awards or remedies that are available under the governing law set forth in Section 16.5.1.

Notwithstanding anything contained in this Section 16.5 a Party or its Affiliate may seek interim or provisional relief or measures in any applicable courts and tribunals that may be necessary to protect the rights of a Party or its Affiliate pending the establishment of the Tribunal or pending the Tribunal's determination of the merits of the controversy.

16.5.3 Any Dispute shall first be referred to the Alliance Managers for each of the Parties to facilitate and assist resolution of such Dispute, including scheduling an initial meeting between their respective Designated Officers for attempted resolution within [***] Business Days after such referral if such matter had not previously been reviewed by the Designated Officers under Section 2.2.5(b) (JSC Deadlocks). If such Dispute is not resolved within [***] days after such referral to the Alliance Managers and, if applicable, the meeting between the Designated Officers, then either Amgen or KKC may commence arbitration under Section 16.5 (Governing Law; Dispute Resolution).

Section16.6 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 word "will" shall be construed to have the same meaning and effect as the word "shall". 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. Unless otherwise agreed by the Parties, information shared under this Agreement shall be disclosed in the English language.

Section16.7 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.

Section16.8 Entire Agreement. This Agreement, including the attached Exhibits and 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.

Section16.9 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, earthquakes, labor strikes, hostilities, acts of war, terrorism, civil unrest, national emergencies, pandemics or epidemics (each, a "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.

Section16.10 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.

Section16.11 Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

Section16.12 No Set-Off. Except as expressly set forth in Section 9.6.1 (Withholding) or Section 9.6.2 (Indirect Taxes), neither 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.

Section16.13 Notices. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand, overnight courier with tracking capabilities, mailed postage prepaid by registered or certified mail, or confirmed facsimile 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
United States
Attention: Corporate Secretary
Facsimile: [***]

If to KKC: Kyowa Kirin Co., Ltd.
1-9-2 Otemachi, Chiyoda-ku, Tokyo, 100-0004
Japan
Facsimile No. [***]
Attn: Global Business Development Head,
Director, Business Development Department

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 16.12.

Section16.14 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed, for the purpose of any Applicable Law, 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. Neither Party shall make any filing or initiate any communication with a Governmental Authority that is inconsistent with this Section 16.14 and each Party shall notify the other Party within [***] days of receiving any written communication from a Governmental Authority that asserts a position that is inconsistent with this Section 16.14.

Section16.15 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.

Section16.16 Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or KKC Indemnities in Article XIV (Indemnification and Insurance), there are no Third Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.

Section16.17 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.

****

(Signature page follows)

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

KYOWA KIRIN CO., LTD.		AMGEN INC.	
By:	/s/ Masashi Miyamoto, Ph.D.	By:	/s/ Robert A. Bradway
Name:	Masashi Miyamoto, Ph.D.	Name:	Robert A. Bradway
Title:	Executive Director of the Board President and Chief Executive Officer	Title:	Chairman of the Board, President & CEO

List of Exhibits and Schedules Omitted from the License and Collaboration Agreement
Referenced in Exhibit 10.49 Above

Pursuant to Regulation S-K, Item 601(b)(2), the Exhibits and Schedules to the License and Collaboration Agreement referenced in Exhibit 10.49 above, as listed below, have not been filed. The Registrant agrees to furnish supplementally a copy of any omitted Exhibit or Schedule to the Securities and Exchange Commission (the "Commission") upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

Schedules
Excluded Patents
European Union Member States
Global Pricing Policy Considerations
Standard Contractual Clauses
Information Security Requirements
Licensed KKC Patents
Press Releases
Privacy and Data Protection

Exhibit
Form of Compliance Certification

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2021

/s/ ROBERT A. BRADWAY
Robert A. Bradway
Chairman of the Board,
Chief Executive Officer and President

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2021

/s/ PETER H. GRIFFITH

Peter H. Griffith

Executive Vice President and Chief Financial Officer

Exhibit 32

Certification of Chief Executive Officer

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 3, 2021

/s/ ROBERT A. BRADWAY
Robert A. Bradway
Chairman of the Board,
Chief Executive Officer and President

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

Certification of Chief Financial Officer

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 3, 2021

/s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer

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