

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, 2017

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

(State or other jurisdiction of incorporation or organization)

95-3540776

(I.R.S. Employer Identification No.)

**One Amgen Center Drive,
Thousand Oaks, California**

(Address of principal executive offices)

91320-1799

(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes No

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.

As of July 18, 2017, the registrant had 729,674,773 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.

INDEX

	<u>Page No.</u>
<u>PART I - FINANCIAL INFORMATION</u>	<u>1</u>
Item 1. <u>FINANCIAL STATEMENTS</u>	<u>1</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF INCOME</u>	<u>1</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u>	<u>2</u>
<u>CONDENSED CONSOLIDATED BALANCE SHEETS</u>	<u>3</u>
<u>CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	<u>4</u>
<u>NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS</u>	<u>5</u>
Item 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>26</u>
Item 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>35</u>
Item 4. <u>CONTROLS AND PROCEDURES</u>	<u>36</u>
<u>PART II - OTHER INFORMATION</u>	<u>36</u>
Item 1. <u>LEGAL PROCEEDINGS</u>	<u>36</u>
Item 1A. <u>RISK FACTORS</u>	<u>36</u>
Item 2. <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	<u>39</u>
Item 6. <u>EXHIBITS</u>	<u>39</u>
<u>SIGNATURES</u>	<u>40</u>
<u>INDEX TO EXHIBITS</u>	<u>41</u>

PART I — FINANCIAL INFORMATION

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,	
	2017	2016	2017	2016
Revenues:				
Product sales	\$ 5,574	\$ 5,474	\$ 10,773	\$ 10,713
Other revenues	236	214	501	502
Total revenues	5,810	5,688	11,274	11,215
Operating expenses:				
Cost of sales	1,024	1,050	2,020	2,068
Research and development	873	900	1,642	1,772
Selling, general and administrative	1,209	1,292	2,273	2,495
Other	6	66	50	98
Total operating expenses	3,112	3,308	5,985	6,433
Operating income	2,698	2,380	5,289	4,782
Interest expense, net	321	313	647	607
Interest and other income, net	165	137	360	287
Income before income taxes	2,542	2,204	5,002	4,462
Provision for income taxes	391	334	780	692
Net income	<u>\$ 2,151</u>	<u>\$ 1,870</u>	<u>\$ 4,222</u>	<u>\$ 3,770</u>
Earnings per share:				
Basic	\$ 2.93	\$ 2.49	\$ 5.74	\$ 5.01
Diluted	\$ 2.91	\$ 2.47	\$ 5.71	\$ 4.97
Shares used in calculation of earnings per share:				
Basic	734	751	736	753
Diluted	738	756	740	759
Dividends paid per share	\$ 1.15	\$ 1.00	\$ 2.30	\$ 2.00

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Net income	\$ 2,151	\$ 1,870	\$ 4,222	\$ 3,770
Other comprehensive (loss) income, net of reclassification adjustments and taxes:				
Foreign currency translation gains (losses)	35	(17)	59	16
Effective portion of cash flow hedges	(201)	(6)	(274)	(185)
Net unrealized gains on available-for-sale securities	80	184	238	542
Other	(1)	1	(1)	1
Other comprehensive (loss) income, net of taxes	(87)	162	22	374
Comprehensive income	\$ 2,064	\$ 2,032	\$ 4,244	\$ 4,144

See accompanying notes.

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

ASSETS	June 30, 2017	December 31, 2016
Current assets:		
Cash and cash equivalents	\$ 2,629	\$ 3,241
Marketable securities	36,598	34,844
Trade receivables, net	3,560	3,165
Inventories	2,961	2,745
Other current assets	2,694	2,015
Total current assets	48,442	46,010
Property, plant and equipment, net	4,980	4,961
Intangible assets, net	9,561	10,279
Goodwill	14,766	14,751
Other noncurrent assets	1,838	1,625
Total assets	\$ 79,587	\$ 77,626
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 883	\$ 917
Accrued liabilities	5,473	5,884
Short-term borrowings and current portion of long-term debt	1,459	4,403
Total current liabilities	7,815	11,204
Long-term debt	33,603	30,193
Long-term deferred tax liabilities	2,299	2,436
Long-term tax liabilities	2,605	2,419
Other noncurrent liabilities	1,543	1,499
Contingencies and commitments		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750.0 shares authorized; outstanding — 730.7 shares in 2017 and 738.2 shares in 2016	30,793	30,784
Retained earnings (accumulated deficit)	1,378	(438)
Accumulated other comprehensive loss	(449)	(471)
Total stockholders' equity	31,722	29,875
Total liabilities and stockholders' equity	\$ 79,587	\$ 77,626

See accompanying notes.

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

	Six months ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net income	\$ 4,222	\$ 3,770
Depreciation and amortization	1,042	1,043
Share-based compensation expense	156	139
Deferred income taxes	(180)	245
Other items, net	109	42
Changes in operating assets and liabilities:		
Trade receivables, net	(391)	(119)
Inventories	(90)	(156)
Other assets	(194)	(330)
Accounts payable	(43)	(100)
Accrued income taxes	(120)	(328)
Other liabilities	200	386
Net cash provided by operating activities	<u>4,711</u>	<u>4,592</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(353)	(344)
Purchases of intangible assets	—	(99)
Purchases of marketable securities	(19,244)	(14,969)
Proceeds from sales of marketable securities	14,425	9,063
Proceeds from maturities of marketable securities	3,284	1,339
Other	(82)	(37)
Net cash used in investing activities	<u>(1,970)</u>	<u>(5,047)</u>
Cash flows from financing activities:		
Net proceeds from issuance of debt	3,485	2,908
Repayment of debt	(4,405)	(1,000)
Net change in commercial paper	959	—
Repurchases of common stock	(1,562)	(1,218)
Dividends paid	(1,693)	(1,504)
Other	(137)	(245)
Net cash used in financing activities	<u>(3,353)</u>	<u>(1,059)</u>
Decrease in cash and cash equivalents	(612)	(1,514)
Cash and cash equivalents at beginning of period	3,241	4,144
Cash and cash equivalents at end of period	<u>\$ 2,629</u>	<u>\$ 2,630</u>

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2017
(Unaudited)

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and six months ended June 30, 2017 and 2016, 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, 2016, 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, 2017.

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 \$7.8 billion and \$7.5 billion as of June 30, 2017, and December 31, 2016, respectively.

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018. The new standards are required to be adopted using either a full retrospective or a modified-retrospective approach. We expect to adopt this standard by using the modified-retrospective approach beginning in 2018. We have substantially completed our impact assessment and do not currently anticipate a material impact on Total revenues in our Consolidated Statements of Income. We continue to review the impact that the new standard will have on our collaborations and license arrangements, as well as our financial statement disclosures. As we complete our assessment, we are also identifying and preparing to implement changes to our accounting policies, business processes, and internal controls to support the new accounting and disclosure requirements.

In January 2016, the FASB issued a new accounting standard that amends the accounting and disclosures of financial instruments, including a provision requiring that equity investments (except for investments accounted for under the equity method of accounting) be measured at fair value, with changes in fair value recognized in current earnings. The new standard is effective for interim and annual periods beginning on January 1, 2018. With the exception of equity investments currently being accounted for at cost, adjustments are applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. The new standard will be applied prospectively to those investments currently accounted for at cost. The impact that this new standard will have on our consolidated financial statements will depend on the fair value of available-for-sale securities in our portfolio in the future. See Note 6, Available-for-sale investments, for the fair value of equity securities as of June 30, 2017.

In February 2016, the FASB issued a new accounting standard that amends the guidance for the accounting and disclosure of leases. This new standard requires that lessees recognize the assets and liabilities that arise from leases on the balance sheet, including leases classified as operating leases under current GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019, but may be adopted earlier. We expect to adopt this standard beginning in 2019. We continue to evaluate the impact that this new standard will have on our consolidated financial statements, including related disclosures, as well as on our business processes and systems, accounting policies and internal controls. We do not expect that this standard will have a material impact on our Consolidated Statements of Income, but we do expect that upon adoption, this standard will have a material impact on our assets and liabilities on our Consolidated Balance Sheets. The primary effect of adoption will be the requirement to record right-of-use assets and corresponding lease obligations for current operating leases. In addition, the standard will require us to update our systems and processes used to track, record and account for our lease portfolio.

In June 2016, the FASB issued a new accounting standard that amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through Net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

In October 2016, the FASB issued a new accounting standard that amends the income tax accounting guidance for intra-entity transfers of assets other than inventory. The new standard requires entities to recognize the income tax consequences of an intercompany transfer of an asset, other than inventory, in the period the transfer occurs. The current exception to defer the recognition of any tax impact on intercompany transfers of inventory until it is sold to a third party remains unaffected. The new standard is effective for interim and annual periods beginning on January 1, 2018, but may be adopted earlier. We expect to adopt this standard beginning in 2018. The standard would be applied prospectively to any transaction occurring on or after the adoption date. We are currently evaluating the impact that this new standard will have on our consolidated financial statements.

In January 2017, the FASB issued a new accounting standard that changes the definition of a business to assist entities with the evaluation of when a set of assets acquired or disposed of should be considered a business. The new standard requires an entity to evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets; if so, the set would not be considered a business. The new standard also requires a business to include at least one substantive process and narrows the definition of outputs. The new standard will be applied prospectively and is effective for interim and annual periods beginning on January 1, 2018, but may be adopted earlier. We expect to adopt this standard beginning in 2018. Adoption of this new standard may result in more transactions being accounted for as asset acquisitions versus business combinations; however, the impact on our consolidated financial statements will depend on the facts and circumstances of any specific future transactions.

2. Restructuring

In 2014, we initiated a restructuring plan to both invest in continuing innovation and the launch of our new pipeline molecules while improving our cost structure. As part of the plan, we closed facilities in Washington State and Colorado and are reducing the number of buildings we occupy at our headquarters in Thousand Oaks, California, as well as at other locations.

We continue to estimate that we will incur \$800 million to \$900 million of pre-tax charges in connection with our restructuring, including (i) separation and other headcount-related costs of \$535 million to \$585 million with respect to staff reductions and (ii) asset-related charges of \$265 million to \$315 million that consist primarily of asset impairments, accelerated depreciation and other related costs resulting from the consolidation of our worldwide facilities. Through June 30, 2017, we incurred a total of \$517 million of separation and other headcount-related costs and \$243 million of net asset-related charges.

The amounts related to the restructuring recorded in the Condensed Consolidated Statements of Income during the three and six months ended June 30, 2017 and 2016, were not significant. As of June 30, 2017, the total restructuring liability was not significant.

3. Income taxes

The effective tax rates for the three and six months ended June 30, 2017, were 15.4% and 15.6%, respectively, compared with 15.2% and 15.5%, respectively, for the corresponding periods of the prior year. The effective rates differ from the federal statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States.

The increase in our effective tax rate for the three months ended June 30, 2017, was due primarily to a prior year benefit associated with tax incentives and lower tax benefits from share-based compensation payments, offset partially by discrete benefits associated with the effective settlement of certain state and federal tax matters.

The increase in our effective tax rate for the six months ended June 30, 2017, was due primarily to lower tax benefits from share-based compensation payments, offset partially by discrete benefits associated with the effective settlement of certain state and federal tax matters and favorable tax impacts of changes in the jurisdictional mix of income and expenses.

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 is 4% and 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 audited by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of 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 the interpretation of the relevant facts. As previously disclosed, on April 12, 2017, we received a Revenue Agent Report (RAR) from the Internal Revenue Service (IRS) for the years 2010, 2011, and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years. We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009. In addition, we are currently under examination by a number of other state and foreign tax jurisdictions.

During the three and six months ended June 30, 2017, the gross amount of our unrecognized tax benefits (UTBs) increased approximately \$110 million and \$225 million, respectively, as a result of tax positions taken during the current year. The UTB balance decreased approximately \$65 million during the second quarter of 2017 due to the effective settlement of certain state and federal tax matters. Substantially all of the UTBs as of June 30, 2017, if recognized, would affect our effective tax rate.

4. Earnings per share

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

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,	
	2017	2016	2017	2016
Income (Numerator):				
Net income for basic and diluted EPS	\$ 2,151	\$ 1,870	\$ 4,222	\$ 3,770
Shares (Denominator):				
Weighted-average shares for basic EPS	734	751	736	753
Effect of dilutive securities	4	5	4	6
Weighted-average shares for diluted EPS	738	756	740	759
Basic EPS	\$ 2.93	\$ 2.49	\$ 5.74	\$ 5.01
Diluted EPS	\$ 2.91	\$ 2.47	\$ 5.71	\$ 4.97

For the three and six months ended June 30, 2017 and 2016, the number of anti-dilutive employee share-based awards excluded from the computation of diluted EPS was not significant.

5. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two or more parties that are both: (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the research and development (R&D), manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for non-refundable up-front license fees, development and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success and each is unique in nature. Below is a significant arrangement that had a material change since the filing of our Annual Report on Form 10-K for the year ended December 31, 2016.

Novartis Pharma AG

In April 2017, we expanded our existing collaboration with Novartis Pharma AG (Novartis), a wholly owned subsidiary of Novartis AG, in the area of migraine. In the United States, Amgen and Novartis will jointly develop and collaborate on the commercialization of Aimovig™ (erenumab). Amgen, as the principal, will recognize product sales of Aimovig™ in the United States, and will share U.S. commercialization costs with Novartis and pay Novartis a significant royalty on net sales in the United States. Novartis holds global co-development rights and exclusive commercial rights outside the United States and Japan. Novartis will pay Amgen double-digit royalties on net sales of the products in the Novartis exclusive territories. Novartis will fund a portion of global R&D expenses. Novartis will also make payments to Amgen that could collectively exceed \$400 million if certain regulatory events occur and commercial thresholds are achieved. Amgen will manufacture and supply Aimovig™ worldwide.

The migraine collaboration will continue for the commercial life of the products unless terminated in accordance with its terms.

During the three months ended June 30, 2017 and 2016, costs recovered from Novartis for the migraine products were \$31 million and \$11 million, respectively. During the six months ended June 30, 2017 and 2016, costs recovered from Novartis for the migraine products were \$57 million and \$20 million, respectively. Costs recovered are included primarily in Research and development expense in the Condensed Consolidated Statements of Income.

6. Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and estimated fair values of available-for-sale investments by type of security were as follows (in millions):

Type of security as of June 30, 2017	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	\$ 7,664	\$ 9	\$ (12)	\$ 7,661
Other government-related debt securities:				
U.S.	226	1	(1)	226
Foreign and other	2,334	27	(8)	2,353
Corporate debt securities:				
Financial	9,591	56	(10)	9,637
Industrial	9,499	88	(18)	9,569
Other	1,229	8	(2)	1,235
Residential mortgage-backed securities	1,689	1	(8)	1,682
Other mortgage- and asset-backed securities	1,854	2	(3)	1,853
Money market mutual funds	2,165	—	—	2,165
Other short-term interest-bearing securities	2,382	—	—	2,382
Total interest-bearing securities	38,633	192	(62)	38,763
Equity securities	134	30	(5)	159
Total available-for-sale investments	\$ 38,767	\$ 222	\$ (67)	\$ 38,922

Type of security as of December 31, 2016	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
U.S. Treasury securities	\$ 6,681	\$ 1	\$ (68)	\$ 6,614
Other government-related debt securities:				
U.S.	302	—	(3)	299
Foreign and other	1,784	9	(34)	1,759
Corporate debt securities:				
Financial	8,476	21	(37)	8,460
Industrial	8,793	59	(63)	8,789
Other	1,079	5	(7)	1,077
Residential mortgage-backed securities	1,968	1	(29)	1,940
Other mortgage- and asset-backed securities	1,731	1	(13)	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	4,188	—	—	4,188
Total interest-bearing securities	37,784	97	(254)	37,627
Equity securities	127	31	(4)	154
Total available-for-sale investments	\$ 37,911	\$ 128	\$ (258)	\$ 37,781

The fair values of available-for-sale investments by classification in the Condensed Consolidated Balance Sheets were as follows (in millions):

Classification in the Condensed Consolidated Balance Sheets	June 30, 2017	December 31, 2016
Cash and cash equivalents	\$ 2,165	\$ 2,783
Marketable securities	36,598	34,844
Other noncurrent assets	159	154
Total available-for-sale investments	<u>\$ 38,922</u>	<u>\$ 37,781</u>

Cash and cash equivalents in the above table excludes bank account cash of \$464 million and \$458 million as of June 30, 2017 and December 31, 2016, respectively.

The fair values of available-for-sale interest-bearing security investments by contractual maturity, except for mortgage- and asset-backed securities that do not have a single maturity date, were as follows (in millions):

Contractual maturity	June 30, 2017	December 31, 2016
Maturing in one year or less	\$ 6,905	\$ 8,393
Maturing after one year through three years	11,629	10,404
Maturing after three years through five years	13,346	12,157
Maturing after five years through ten years	3,286	2,974
Maturing after ten years	62	40
Mortgage- and asset-backed securities	3,535	3,659
Total interest-bearing securities	<u>\$ 38,763</u>	<u>\$ 37,627</u>

For the three months ended June 30, 2017 and 2016, realized gains totaled \$40 million and \$31 million, respectively, and realized losses totaled \$87 million and \$54 million, respectively. For the six months ended June 30, 2017 and 2016, realized gains totaled \$75 million and \$68 million, respectively, and realized losses totaled \$171 million and \$121 million, respectively. The cost of securities sold is based on the specific identification method.

The unrealized losses on available-for-sale investments and their related fair values were as follows (in millions):

Type of security as of June 30, 2017	Less than 12 months		12 months or greater	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	\$ 5,784	\$ (12)	\$ —	\$ —
Other government-related debt securities:				
U.S.	132	(1)	—	—
Foreign and other	968	(8)	11	—
Corporate debt securities:				
Financial	2,231	(9)	22	(1)
Industrial	2,646	(18)	62	—
Other	370	(2)	5	—
Residential mortgage-backed securities	1,355	(6)	69	(2)
Other mortgage- and asset-backed securities	917	(3)	8	—
Equity securities	20	(5)	—	—
Total	<u>\$ 14,423</u>	<u>\$ (64)</u>	<u>\$ 177</u>	<u>\$ (3)</u>

Type of security as of December 31, 2016	Less than 12 months		12 months or greater	
	Fair value	Unrealized losses	Fair value	Unrealized losses
U.S. Treasury securities	\$ 5,774	\$ (68)	\$ —	\$ —
Other government-related debt securities:				
U.S.	201	(3)	—	—
Foreign and other	1,192	(34)	17	—
Corporate debt securities:				
Financial	3,975	(37)	44	—
Industrial	3,913	(61)	149	(2)
Other	486	(7)	7	—
Residential mortgage-backed securities	1,631	(26)	158	(3)
Other mortgage- and asset-backed securities	1,087	(10)	118	(3)
Equity securities	22	(4)	—	—
Total	\$ 18,281	\$ (250)	\$ 493	\$ (8)

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

We review our available-for-sale investments for other-than-temporary declines in fair value below our cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below our cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether we will more likely than not be required to sell, the security before recovery of its amortized cost basis. Our assessment of whether a security is other-than-temporarily impaired could change in the future based on new developments or changes in assumptions related to that particular security. As of June 30, 2017 and December 31, 2016, we believe the cost bases for our available-for-sale investments were recoverable in all material respects.

7. Inventories

Inventories consisted of the following (in millions):

	June 30, 2017	December 31, 2016
Raw materials	\$ 237	\$ 225
Work in process	1,618	1,608
Finished goods	1,106	912
Total inventories	\$ 2,961	\$ 2,745

8. Goodwill and other intangible assets

Goodwill

Changes in the carrying amounts of goodwill were as follows (in millions):

	Six months ended June 30,	
	2017	2016
Beginning balance	\$ 14,751	\$ 14,787
Goodwill related to acquisitions of businesses ⁽¹⁾	—	2
Currency translation adjustments	15	10
Ending balance	\$ 14,766	\$ 14,799

⁽¹⁾ Consists of goodwill recognized on the acquisition dates of business combinations and subsequent adjustments to these amounts resulting from changes to the acquisition date fair values of net assets acquired in the business combinations recorded during their respective measurement periods.

Identifiable intangible assets

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

	June 30, 2017			December 31, 2016		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
Finite-lived intangible assets:						
Developed product technology rights	\$ 12,562	\$ (6,436)	\$ 6,126	\$ 12,534	\$ (5,947)	\$ 6,587
Licensing rights	3,274	(1,450)	1,824	3,275	(1,300)	1,975
Marketing-related rights	1,326	(865)	461	1,333	(793)	540
Research and development technology rights	1,145	(755)	390	1,122	(704)	418
Total finite-lived intangible assets	18,307	(9,506)	8,801	18,264	(8,744)	9,520
Indefinite-lived intangible assets:						
In-process research and development	760	—	760	759	—	759
Total identifiable intangible assets	\$ 19,067	\$ (9,506)	\$ 9,561	\$ 19,023	\$ (8,744)	\$ 10,279

Developed product technology rights consist of rights related to marketed products acquired in business combinations. Licensing rights consist primarily of contractual rights acquired in business combinations to receive future milestones, royalties and profit sharing payments, capitalized payments to third parties for milestones related to regulatory approvals to commercialize products and up-front payments associated with royalty obligations for marketed products. Marketing-related intangible assets consist primarily of rights related to the sale and distribution of marketed products. R&D technology rights consist of technology used in R&D with alternative future uses.

In-process research and development (IPR&D) consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. As of June 30, 2017, the primary projects are AMG 899 (formerly TA-8995), acquired in the acquisition of Dezima Pharma B.V. (Dezima) in 2015, and oprozomib, acquired in the acquisition of Onyx Pharmaceuticals, Inc. in 2013. The valuation of AMG 899 reflects delayed development pending competitor clinical trials in the class. Detailed information from these trials is expected in the third quarter of 2017 and may have a material impact on the value of our related IPR&D.

All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require our completing clinical trials that demonstrate a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans, as well as competitive product launches, impact the revenues a product can generate. Consequently, the eventual realized value, if any, of the acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon the establishment of technological feasibility or regulatory approval.

During both of the three months ended June 30, 2017 and 2016, we recognized amortization charges associated with our finite-lived intangible assets of \$371 million. During the six months ended June 30, 2017 and 2016, we recognized amortization charges associated with our finite-lived intangible assets of \$744 million and \$740 million, respectively. The total estimated amortization charges for our finite-lived intangible assets for the remaining six months ending December 31, 2017, and the years ending December 31, 2018, 2019, 2020, 2021 and 2022, are \$0.6 billion, \$1.2 billion, \$1.1 billion, \$1.1 billion, \$0.9 billion and \$0.9 billion, respectively.

9. Financing arrangements

The carrying values and fixed contractual coupon rates of our borrowings were as follows (in millions):

	June 30, 2017	December 31, 2016
Commercial paper	\$ 960	\$ —
Short-term loan	—	605
2.125% notes due 2017 (2.125% 2017 Notes)	—	1,250
Floating Rate Notes due 2017	—	600
1.25% notes due 2017 (1.25% 2017 Notes)	—	850
5.85% notes due 2017 (5.85% 2017 Notes)	—	1,100
6.15% notes due 2018 (6.15% 2018 Notes)	500	500
4.375% €550 million notes due 2018 (4.375% 2018 euro Notes)	620	577
5.70% notes due 2019 (5.70% 2019 Notes)	1,000	1,000
1.90% notes due 2019 (1.90% 2019 Notes)	700	—
Floating Rate Notes due 2019	550	250
2.20% notes due 2019 (2.20% 2019 Notes)	1,400	1,400
2.125% €675 million notes due 2019 (2.125% 2019 euro Notes)	771	710
4.50% notes due 2020 (4.50% 2020 Notes)	300	300
2.125% notes due 2020 (2.125% 2020 Notes)	750	750
Floating Rate Notes due 2020	300	—
2.20% notes due 2020 (2.20% 2020 Notes)	700	—
3.45% notes due 2020 (3.45% 2020 Notes)	900	900
4.10% notes due 2021 (4.10% 2021 Notes)	1,000	1,000
1.85% notes due 2021 (1.85% 2021 Notes)	750	750
3.875% notes due 2021 (3.875% 2021 Notes)	1,750	1,750
1.25% €1,250 million notes due 2022 (1.25% 2022 euro Notes)	1,429	1,315
2.70% notes due 2022 (2.70% 2022 Notes)	500	500
2.65% notes due 2022 (2.65% 2022 Notes)	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)	731	687
2.25% notes due 2023 (2.25% 2023 Notes)	750	750
3.625% notes due 2024 (3.625% 2024 Notes)	1,400	1,400
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)	857	789
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)	619	586
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	912	864
6.375% notes due 2037 (6.375% 2037 Notes)	552	552
6.90% notes due 2038 (6.90% 2038 Notes)	291	291
6.40% notes due 2039 (6.40% 2039 Notes)	466	466
5.75% notes due 2040 (5.75% 2040 Notes)	412	412
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	974	974
5.65% notes due 2042 (5.65% 2042 Notes)	487	487
5.375% notes due 2043 (5.375% 2043 Notes)	261	261
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
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
Other notes due 2097	100	100
Unamortized bond discounts, premiums and issuance costs, net	(936)	(936)
Total carrying value of debt	\$ 35,062	\$ 34,596
Less current portion	(1,459)	(4,403)
Total noncurrent debt	\$ 33,603	\$ 30,193

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 and the 4.663% 2051 Notes, which have effective interest rates of approximately 6.3% and 5.6%, respectively.

Debt repayments

During the six months ended June 30, 2017, we repaid the \$605 million short-term loan, the \$1.25 billion aggregate principal amount of the 2.125% 2017 Notes, the \$600 million aggregate principal amount of the Floating Rate Notes due 2017, the \$850 million aggregate principal amount of the 1.25% 2017 Notes and the \$1.1 billion aggregate principal of the 5.85% 2017 Notes.

Debt issuances

In May 2017, we issued a \$3.5 billion principal amount of notes, consisting of the Floating Rate Notes due 2019, the 1.90% 2019 Notes, the Floating Rate Notes due 2020, the 2.20% 2020 Notes and the 2.65% 2022 Notes. In the event of a change-of-control triggering event, as defined in the terms of the notes, we may be required to purchase all or a portion of these debt securities at a price equal to 101% of the principal amount of the notes plus accrued and unpaid interest. All of the aforementioned fixed-rate notes may be redeemed at any time, in whole or in part, at the principal amount of the notes being redeemed plus accrued and unpaid interest and, except for the 2.65% 2022 Notes, a make-whole amount, which is defined by the terms of the notes. The 2.65% 2022 Notes may be redeemed without payment of the make-whole amount if redemption occurs on or after one month prior to maturity.

During the three months ended June 30, 2017, we issued commercial paper under our commercial paper program. As of June 30, 2017, the weighted-average effective borrowing rate on outstanding commercial paper was 1.3%.

10. Stockholders' equity

Stock repurchase program

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

	2017		2016	
	Shares	Dollars	Shares	Dollars
First quarter	3.4	\$ 555	4.7	\$ 690
Second quarter	6.2	1,006	3.9	591
	9.6	\$ 1,561	8.6	\$ 1,281

As of June 30, 2017, \$2.5 billion remained available under our stock repurchase program.

Dividends

In March 2017 and December 2016, the Board of Directors declared quarterly cash dividends of \$1.15 per share of common stock, which were paid in June 2017 and March 2017, respectively.

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, 2016	\$ (610)	\$ 282	\$ (138)	\$ (5)	\$ (471)
Foreign currency translation adjustments	21	—	—	—	21
Unrealized gains	—	17	116	—	133
Reclassification adjustments to income	—	(131)	49	—	(82)
Income taxes	3	41	(7)	—	37
Balance as of March 31, 2017	\$ (586)	\$ 209	\$ 20	\$ (5)	\$ (362)
Foreign currency translation adjustments	37	—	—	—	37
Unrealized gains	—	17	73	—	90
Reclassification adjustments to income	—	(330)	47	—	(283)
Other	—	—	—	(1)	(1)
Income taxes	(2)	112	(40)	—	70
Balance as of June 30, 2017	\$ (551)	\$ 8	\$ 100	\$ (6)	\$ (449)

The reclassifications out of AOCI and into earnings were as follows (in millions):

Components of AOCI	Amounts reclassified out of AOCI		Line item affected in the Condensed Consolidated Statements of Income
	Three months ended June 30, 2017	Three months ended June 30, 2016	
Cash flow hedges:			
Foreign currency contract gains	\$ 33	\$ 79	Product sales
Cross-currency swap contract gains (losses)	297	(212)	Interest and other income, net
	330	(133)	Income before income taxes
	(117)	49	Provision for income taxes
	\$ 213	\$ (84)	Net income
Available-for-sale securities:			
Net realized losses	\$ (47)	\$ (23)	Interest and other income, net
	(2)	8	Provision for income taxes
	\$ (49)	\$ (15)	Net income

Components of AOCI	Amounts reclassified out of AOCI		Line item affected in the Condensed Consolidated Statements of Income
	Six months ended June 30, 2017	Six months ended June 30, 2016	
Cash flow hedges:			
Foreign currency contract gains	\$ 90	\$ 175	Product sales
Cross-currency swap contract gains (losses)	371	(142)	Interest and other income, net
	461	33	Income before income taxes
	(164)	(12)	Provision for income taxes
	<u>\$ 297</u>	<u>\$ 21</u>	Net income
Available-for-sale securities:			
Net realized losses	\$ (96)	\$ (53)	Interest and other income, net
	(2)	8	Provision for income taxes
	<u>\$ (98)</u>	<u>\$ (45)</u>	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 ability to access
- Level 2 — Valuations for which all significant inputs are observable, either directly or indirectly, other than level 1 inputs
- Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

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

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

Fair value measurement as of June 30, 2017, 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 investments:				
U.S. Treasury securities	\$ 7,661	\$ —	\$ —	\$ 7,661
Other government-related debt securities:				
U.S.	—	226	—	226
Foreign and other	—	2,353	—	2,353
Corporate debt securities:				
Financial	—	9,637	—	9,637
Industrial	—	9,569	—	9,569
Other	—	1,235	—	1,235
Residential mortgage-backed securities	—	1,682	—	1,682
Other mortgage- and asset-backed securities	—	1,853	—	1,853
Money market mutual funds	2,165	—	—	2,165
Other short-term interest-bearing securities	—	2,382	—	2,382
Equity securities	159	—	—	159
Derivatives:				
Foreign currency contracts	—	18	—	18
Cross-currency swap contracts	—	153	—	153
Interest rate swap contracts	—	52	—	52
Total assets	<u>\$ 9,985</u>	<u>\$ 29,160</u>	<u>\$ —</u>	<u>\$ 39,145</u>
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 93	\$ —	\$ 93
Cross-currency swap contracts	—	398	—	398
Contingent consideration obligations in connection with business combinations	—	—	182	182
Total liabilities	<u>\$ —</u>	<u>\$ 491</u>	<u>\$ 182</u>	<u>\$ 673</u>

Fair value measurement as of December 31, 2016, 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 investments:				
U.S. Treasury securities	\$ 6,614	\$ —	\$ —	\$ 6,614
Other government-related debt securities:				
U.S.	—	299	—	299
Foreign and other	—	1,759	—	1,759
Corporate debt securities:				
Financial	—	8,460	—	8,460
Industrial	—	8,789	—	8,789
Other	—	1,077	—	1,077
Residential mortgage-backed securities	—	1,940	—	1,940
Other mortgage- and asset-backed securities	—	1,719	—	1,719
Money market mutual funds	2,782	—	—	2,782
Other short-term interest-bearing securities	—	4,188	—	4,188
Equity securities	154	—	—	154
Derivatives:				
Foreign currency contracts	—	203	—	203
Interest rate swap contracts	—	41	—	41
Total assets	<u>\$ 9,550</u>	<u>\$ 28,475</u>	<u>\$ —</u>	<u>\$ 38,025</u>
Liabilities:				
Derivatives:				
Foreign currency contracts	\$ —	\$ 4	\$ —	\$ 4
Cross-currency swap contracts	—	523	—	523
Interest rate swap contracts	—	7	—	7
Contingent consideration obligations in connection with business combinations	—	—	179	179
Total liabilities	<u>\$ —</u>	<u>\$ 534</u>	<u>\$ 179</u>	<u>\$ 713</u>

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.

Most of our other government-related and corporate debt securities are investment grade with maturity dates of five years or less from the balance sheet date. Our other government-related debt securities portfolio is composed of securities with weighted-average credit ratings of A- or equivalent by Moody's Investors Service, Inc. (Moody's), and BBB+ or equivalent by Standard & Poor's Financial Services LLC (S&P) or Fitch Ratings Inc. (Fitch); and our corporate debt securities portfolio has a weighted-average credit rating of A- or equivalent by Fitch, and BBB+ or equivalent by S&P or Moody's. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

Our residential mortgage-, other mortgage- and asset-backed securities portfolio is composed entirely of senior tranches, with credit ratings of AAA by S&P, Moody's or Fitch. We estimate the fair values of these securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. The inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

We value our other short-term interest-bearing securities at amortized cost, which approximates fair value given their near-term maturity dates.

All of our foreign currency forward and option derivatives contracts have maturities of three years or less, and all are with counterparties that have minimum credit ratings of A- or equivalent by S&P or Moody's. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. The inputs include foreign currency exchange rates, London Interbank Offered Rates (LIBOR), swap rates and obligor credit default swap rates. In addition, inputs for our foreign currency option contracts include implied volatility measures. The 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 or Moody's. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable either directly or indirectly. The 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 or Moody's. We estimate the fair values of these contracts by using an income-based industry standard valuation model for which all significant inputs were observable either directly or indirectly. The inputs included LIBOR, swap rates and obligor credit default swap rates.

Contingent consideration obligations

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

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Beginning balance	\$ 184	\$ 194	\$ 179	\$ 188
Net changes in valuation	(2)	(23)	3	(17)
Ending balance	\$ 182	\$ 171	\$ 182	\$ 171

As a result of our acquisition of Dezima in October 2015, we are obligated to pay its former shareholders up to \$1.25 billion of additional consideration contingent upon achieving certain development and sales-related milestones and low single-digit royalties on net product sales above a certain threshold. The estimated fair values of the contingent consideration obligations had an aggregate value of \$110 million at acquisition. The valuation of the contingent consideration reflects delayed development of AMG 899 pending competitor clinical trials. Detailed information from these trials is expected in the third quarter of 2017 and may have a material impact on the value of the Dezima contingent consideration.

As a result of our acquisition of BioVex Group, Inc. in 2011, we are obligated to pay its former shareholders up to \$325 million of additional consideration contingent upon the achievement of certain sales thresholds related to IMLYGIC[®] (talimogene laherparepvec) within specified periods of time.

During the six months ended June 30, 2017 and 2016, there were no transfers of assets or liabilities between fair value measurement levels, and there were no material remeasurements of 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 estimated fair values of cash equivalents approximate their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimated the fair value of our borrowings (Level 2) by taking into consideration indicative prices obtained from a third-party financial institution that utilizes industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable either directly or indirectly. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; credit spreads; benchmark yields; foreign currency exchange rates, as applicable; and other observable inputs. As of June 30, 2017, and December 31, 2016, the aggregate fair values of our borrowings were \$37.9 billion and \$36.5 billion, respectively, and the carrying values were \$35.1 billion and \$34.6 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 these exposures, we utilize or have utilized certain derivative instruments, including foreign currency forward, foreign currency option, 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, associated primarily 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 offset partially 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 on our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales primarily over a three-year time horizon, with, at any given point in time, a higher percentage of nearer-term projected product sales being hedged than in successive periods.

As of June 30, 2017 and December 31, 2016, we had open foreign currency forward contracts with notional amounts of \$3.7 billion and \$3.4 billion, respectively, and open foreign currency option contracts with notional amounts of \$289 million and \$608 million, respectively. We have designated these foreign currency forward and foreign currency option contracts, which are primarily euro based, as cash flow hedges; and accordingly, we report the effective portions of the unrealized gains and losses on these contracts in AOCI in the Condensed Consolidated Balance Sheets, and we reclassify them to earnings 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, 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, and accordingly, the effective portions of the unrealized gains and losses on these contracts are reported in AOCI in the Condensed Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged debt affects earnings.

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

Hedged notes	Foreign currency			U.S. dollars		
		Notional amount	Interest rate		Notional amount	Interest rate
2.125% 2019 euro Notes	€	675	2.125%	\$	864	2.6%
1.25% 2022 euro Notes	€	1,250	1.25%	\$	1,388	3.2%
0.41% 2023 Swiss franc Bonds	CHF	700	0.41%	\$	704	3.4%
2.00% 2026 euro Notes	€	750	2.00%	\$	833	3.9%
5.50% 2026 pound sterling Notes	£	475	5.50%	\$	747	6.0%
4.00% 2029 pound sterling Notes	£	700	4.00%	\$	1,111	4.5%

In connection with anticipated issuances of long-term fixed-rate debt, we entered into forward interest rate contracts during the six months ended June 30, 2017. The forward interest rate contracts hedged the variability in cash flows due to changes in the applicable Treasury rate between the time we entered into these contracts and the time the related debt was issued in May 2017. Gains and losses realized on such contracts, which were designated as cash flow hedges, were recognized in AOCI and are being amortized into earnings over the lives of the associated debt issuances.

The effective portions of the unrealized gain/(loss) recognized in other comprehensive income for our derivative instruments designated as cash flow hedges were as follows (in millions):

Derivatives in cash flow hedging relationships	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Foreign currency contracts	\$ (203)	\$ 86	\$ (250)	\$ (62)
Cross-currency swap contracts	217	(226)	281	(195)
Forward interest rate contracts	3	(4)	3	(4)
Total	\$ 17	\$ (144)	\$ 34	\$ (261)

The locations in the Condensed Consolidated Statements of Income and the effective portions of the gain/(loss) reclassified out of AOCI and into earnings for our derivative instruments designated as cash flow hedges were as follows (in millions):

Derivatives in cash flow hedging relationships	Statements of Income location	Three months ended June 30,		Six months ended June 30,	
		2017	2016	2017	2016
Foreign currency contracts	Product sales	\$ 33	\$ 79	\$ 90	\$ 175
Cross-currency swap contracts	Interest and other income, net	297	(212)	371	(142)
Total		\$ 330	\$ (133)	\$ 461	\$ 33

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and the gains and losses of the ineffective portions of these hedging instruments were not material for the three and six months ended June 30, 2017 and 2016. As of June 30, 2017, the amounts expected to be reclassified out of AOCI and into earnings during the next 12 months are approximately \$114 million of net losses on our foreign currency and cross-currency swap contracts and approximately \$1 million of losses on forward interest rate contracts.

Fair value hedges

To achieve the desired mix of fixed and floating interest rates on our long-term debt, we entered into interest rate swap contracts that qualified and are designated as fair value hedges. The terms of these interest rate swap contracts correspond to the related hedged debt instruments and effectively convert a fixed interest rate coupon to a floating LIBOR-based coupon over the lives of the respective notes. As of March 31, 2017 and December 31, 2016, we had interest rate swap agreements with aggregate notional amounts of \$6.65 billion that hedge certain of our long-term debt issuances. The contracts have rates that range from three-month LIBOR plus 0.4% to three-month LIBOR plus 2.0%. During the three months ended June 30, 2017, we entered into interest rate swap contracts with an aggregate notional amount of \$3.65 billion with respect to our 3.625% 2024 Notes, 3.125% 2025 Notes and 2.60% 2026 Notes. The contracts have rates that range from three-month LIBOR plus 0.3% to three-month LIBOR plus 1.4%. In addition, during the three months ended June 30, 2017, interest rate swap contracts that had an aggregate notional amount of \$850 million matured. These contracts had rates of three-month LIBOR plus 0.4%.

For derivative instruments that qualify and are designated as fair value hedges, we recognize in current earnings the unrealized gain or loss on the derivative resulting from a change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from a change in fair value during the period attributable to the hedged risk. For the three and six months ended June 30, 2017, we included unrealized gains of \$37 million and \$18 million, respectively, on our interest rate swap agreements in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized losses of \$37 million and \$18 million, respectively, on the related hedged debt. For the three and six months ended June 30, 2016, we included unrealized gains of \$49 million and \$198 million, respectively, on our interest rate swap agreements in the same line item, Interest expense, net, in the Condensed Consolidated Statements of Income, as the offsetting unrealized losses of \$49 million and \$198 million, respectively, on the related hedged debt.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of June 30, 2017 and December 31, 2016, the total notional amounts of these foreign currency forward contracts were \$812 million and \$666 million, respectively.

The location in the Condensed Consolidated Statements of Income and the amounts of gain/(loss) recognized in earnings for our derivative instruments not designated as hedging instruments were as follows (in millions):

Derivatives not designated as hedging instruments	Statements of Income location	Three months ended June 30,		Six months ended June 30,	
		2017	2016	2017	2016
Foreign currency contracts	Interest and other income, net	\$ 13	\$ (24)	\$ 14	\$ (34)

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

June 30, 2017	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	\$ 18	Accrued liabilities/ Other noncurrent liabilities	\$ 93
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	153	Accrued liabilities/ Other noncurrent liabilities	398
Interest rate swap contracts	Other current assets/ Other noncurrent assets	52	Accrued liabilities/ Other noncurrent liabilities	—
Total derivatives designated as hedging instruments		223		491
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		\$ 223		\$ 491

December 31, 2016	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Foreign currency contracts	Other current assets/ Other noncurrent assets	\$ 203	Accrued liabilities/ Other noncurrent liabilities	\$ 4
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	523
Interest rate swap contracts	Other current assets/ Other noncurrent assets	41	Accrued liabilities/ Other noncurrent liabilities	7
Total derivatives designated as hedging instruments		244	534	
Derivatives not designated as hedging instruments:				
Foreign currency contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—	—	
Total derivatives		\$ 244	\$ 534	

Our derivative contracts that were in liability positions as of June 30, 2017, 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 the 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 to or from a counterparty under the contracts may be offset against other amounts due 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 for the six months ended June 30, 2017 and 2016, are included within Net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows.

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, 2016, 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 Note; in Note 18, Contingencies and commitments to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016; 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, 2017.

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 range from cases brought by a single plaintiff to a class action with thousands of putative class members. These legal proceedings, as well as other matters, involve various aspects of our business and a variety of claims—including but not limited to patent infringement, marketing, pricing and trade practices—some of which present novel factual allegations and/or unique legal theories. In each of the matters described in this filing, in Note 18, Contingencies and commitments to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016, 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, 2017, plaintiffs 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 faced by us often extend for several years). As a result, none of the matters pending against us described in this filing, in Note 18, Contingencies and commitments to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2016, 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, 2017, have progressed sufficiently through discovery and/or 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:

PCSK9 Antibody Patent Litigation

U.S. Patent Litigation—Sanofi/Regeneron

On June 6, 2017, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit Court) heard argument on the appeal by defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc., and Regeneron Pharmaceuticals, Inc. (Regeneron) of the judgment of the U.S. District Court for Delaware (the Delaware District Court), which had found that the patents in suit are valid and infringed by the defendants and the permanent injunction granted by the Delaware District Court prohibiting the infringing manufacture, use, sale, offer for sale or import of alirocumab in the United States.

Patent Disputes in the European Region

On May 2, 2017, Amgen filed its response to five oppositions seeking to invalidate European Patent No. 2,215,124 granted to Amgen by the European Patent Office and filed by each of Sanofi, Eli Lilly and Company, Regeneron, and Strawman Ltd., and a joint opposition filed by Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A.

Sensipar[®] (cinacalcet) Patent Litigation

On April 6, 2017, the Delaware District Court consolidated Amgen's lawsuit against Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. with 13 lawsuits previously consolidated that were filed by Amgen against defendants for infringement of our U.S. Patent No. 9,375,405 (the '405 Patent). These lawsuits are based on defendants' separate Abbreviated New Drug Applications (ANDAs) that seek approval to market generic versions of Sensipar[®] before expiration of the asserted patent. The Delaware District Court issued a claim construction ruling on July 19, 2017.

Amgen filed an additional four lawsuits that have not been consolidated in the Delaware District Court for infringement of the '405 Patent against: (1) Piramal Healthcare UK Limited (Piramal) on June 9, 2017; (2) Alkem Laboratories Ltd. on June 23, 2017; (3) Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin) on June 23, 2017; and (4) Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (MacLeods) on June 23, 2017. Responses seeking a declaration of non-infringement and invalidity of the '405 Patent were filed by Piramal on June 30, 2017, MacLeods on July 17, 2017, and Lupin on July 19, 2017. MacLeod's response included a counterclaim alleging sham litigation in violation of the Sherman Antitrust Act.

KYPROLIS[®] (carfilzomib) Patent Litigation

On April 18 and July 3, 2017, the Delaware District Court consolidated for purposes of discovery ten previously-disclosed lawsuits filed by Amgen against defendants for infringement of certain of our patents into a single case. These lawsuits are based on defendants' separate ANDAs that seek approval to market generic versions of KYPROLIS[®] before expiration of the asserted patent or patents. Responses to Amgen's complaints have been filed by defendants in all lawsuits alleging invalidity and, in certain instances, non-infringement of our patents. A claim construction hearing has been scheduled for March 26, 2018 and trial is scheduled to commence on March 11, 2019.

Other Biosimilars Patent Litigations

We have filed a number of lawsuits against manufacturers of products that purport to be biosimilars of certain of our products. In each case, our complaint alleges that the manufacturer's actions infringe certain patents we hold and may also allege that the manufacturer has failed to comply with certain provisions of the Biologics Price Competition and Innovation Act (BPCIA).

Sandoz Filgrastim Litigation

On June 12, 2017, the U.S. Supreme Court reversed the Federal Circuit Court ruling that a biosimilar applicant must wait to give the 180-day advance notice of first commercial marketing until after the U.S. Food and Drug Administration (FDA) has licensed the biosimilar product, holding that such notice can be given either before or after the FDA approval. On a second issue, the U.S. Supreme Court vacated the Federal Circuit Court's decision that the only remedy available when a biosimilar applicant refuses to provide its Biologics License Application is to bring a patent infringement claim. The U.S. Supreme Court agreed with the Federal Circuit Court that there is no remedy under federal law for failing to make the disclosure but remanded the case to the

Federal Circuit Court to determine whether California law would treat noncompliance with such requirement as unlawful and, if so, to determine whether the BPCIA pre-empts any additional remedy available under state law and whether Sandoz Inc. (Sandoz) forfeited any pre-emption defense. On June 29, 2017, Sandoz filed a request of the Federal Circuit Court to remand the case to the U.S. District Court for the Northern District of California to allow that court to address the questions of California law.

Apotex Pegfilgrastim/Filgrastim Litigation

On May 22, 2017, Amgen filed its response to the previously-disclosed *inter partes* review of our U.S. Patent Nos. 8,952,138 instituted by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office in response to Apotex's petition. Oral argument on the *inter partes* review, if requested, is scheduled for December 13, 2017.

Hospira Epoetin Alfa Litigation

On May 12, 2017, Hospira, Inc. (Hospira) filed a motion for summary judgment of non-infringement of the patents-in-suit and, on June 28, 2017, the Delaware District Court heard arguments on this motion. This lawsuit stems from the submission by Hospira under the BPCIA of an application for FDA licensure of an epoetin product as biosimilar to Amgen's EPOGEN[®] (epoetin alfa). Trial is scheduled to commence on September 18, 2017.

Coherus Pegfilgrastim Litigation

On May 10, 2017, Amgen filed a lawsuit in the District Court of Delaware against Coherus BioSciences, Inc. (Coherus) for infringement of our U.S. Patent No. 8,273,707 (the '707 Patent). This lawsuit stems from Coherus' submission of an application for FDA licensure of a pegfilgrastim product as biosimilar to Amgen's Neulasta[®] (pegfilgrastim) under the BPCIA. By its complaint, Amgen seeks, among other remedies, an injunction prohibiting Coherus from infringing the '707 Patent. On June 1, 2017, Coherus filed a motion to dismiss the complaint as purportedly failing to state a claim of patent infringement.

State Derivative Litigation

On June 2, 2017, plaintiffs in the consolidated state stockholder derivative cases (now captioned *Andersen v. Sharer, et. al*) filed a third amended complaint with the Ventura County Superior Court, adding Robert A. Bradway, François de Carbonnel, Vance D. Coffman, Robert A. Eckert, Rebecca M. Henderson, Tyler Jacks, and Ronald D. Sugar as defendants (together with the previously-disclosed defendants, the State Defendants) and removing Chris Larson as a plaintiff. The third amended complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp[®] (darbepoetin alfa) clinical studies, marketed both Aranesp[®] and EPOGEN[®] for off-label uses and that these actions or inactions caused stockholders to suffer damages. The complaint also alleges insider trading by the State Defendants and that Amgen engaged in improper marketing with respect to Enbrel[®] (eternacept), Vectibix[®] (panitumumab), Sensipar[®], and XGEVA[®] (denosumab). The plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation and legal costs.

ERISA Litigation

As previously disclosed, the U.S. District Court for the Central District of California entered a final order approving the settlement of this class action lawsuit on April 5, 2017. On May 4, 2017, plaintiff Don Hanks filed an appeal of the settlement with the U.S. Court of Appeals for the Ninth Circuit.

Pediatric Exclusivity Litigation

On May 25, 2017, Amgen filed a lawsuit in the U.S. District Court for the District of Columbia seeking effectively to reverse the FDA's May 22, 2017 rejection of Amgen's request for pediatric exclusivity for cinacalcet hydrochloride (Sensipar[®]/Mimpara[®]). On June 5, 2017, this litigation was stayed through early August 2017 pending additional review by the FDA of Amgen's request for pediatric exclusivity.

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, 2016, and our Quarterly Report on Form 10-Q for the period ended March 31, 2017. 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 U.S. 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 or written statements or in 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. 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 forecast 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 and restructuring plans. 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 committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. 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.

Currently, we market therapeutics for oncology/hematology, inflammation, nephrology, bone health and cardiovascular disease. Our principal products are ENBREL, Neulasta[®], Aranesp[®], Prolia[®] (denosumab), Sensipar[®]/Mimpara[®], XGEVA[®], and EPOGEN[®]. We market several other products as well, including KYPROLIS[®], Nplate[®] (romiplostim), Vectibix[®], NEUPOGEN[®] (filgrastim), Repatha[®] (evolocumab), BLINCYTO[®] (blinatumomab), IMLYGIC[®] and Corlanor[®] (ivabradine).

Significant developments

Following is a summary of selected significant developments affecting our business that have occurred since the filing of our Quarterly Report on Form 10-Q for the period ended March 31, 2017. 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, 2016, and our Quarterly Report on Form 10-Q for the period ended March 31, 2017.

Products/Pipeline

Bone Health

*EVENTITY™ (romosozumab)**

- In May 2017, we and UCB, our global collaboration partner in the development of *EVENTITY™*, announced that the *EVENTITY™ ARCH* (Active-controlled Fracture Study in Postmenopausal Women with Osteoporosis at High Risk of Fracture) study met both primary endpoints and the key secondary endpoint. An imbalance in positively adjudicated cardiovascular serious adverse events was observed as a new safety signal.
- In July 2017, we and UCB announced that the FDA issued a Complete Response Letter for the Biologics License Application (BLA) for *EVENTITY™* as a treatment for postmenopausal women with osteoporosis. The resubmission will include data from the Phase 3 *ARCH* study and the Phase 3 *BRIDGE* (placebo-controlled study evaluating the efficacy and safety of romosozumab in treating men with osteoporosis) study evaluating *EVENTITY™* in men with osteoporosis, in addition to the Phase 3 *FRAME* (Fracture study in postmenopausal women with osteoporosis) study. We do not expect approval of *EVENTITY™* in the United States to occur in 2017.

XGEVA®

- In June 2017, we announced that the FDA accepted the *XGEVA®* supplemental Biologics License Application (sBLA) that seeks to expand the current approved indication for the prevention of fractures and other skeletal-related events in patients with bone metastases from solid tumors to include patients with multiple myeloma. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of February 3, 2018.

Cardiovascular

Repatha®

- In June 2017, we announced the submission of a sBLA to the FDA and a variation to the marketing authorization to the European Medicines Agency (EMA) for *Repatha®*. The regulatory submissions are based on the *Repatha®* cardiovascular outcomes study (Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk).

Neuroscience

*Aimovig™**

- In July 2017, we announced that the FDA accepted for review the BLA for *Aimovig™* for the prevention of migraine in patients experiencing four or more migraine days per month. The FDA has set a PDUFA target action date of May 17, 2018. *Aimovig™* is being developed and commercialized jointly with Novartis.

Oncology/Hematology

BLINCYTO®

- In July 2017, we announced that the FDA approved the sBLA for *BLINCYTO®* to include overall survival data from the Phase 3 *TOWER* study. The approval converts *BLINCYTO®*'s accelerated approval to a full approval. The approval expands the indication of *BLINCYTO®* for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

KYPROLIS®

- In July 2017, we announced positive results from the final analysis of the Phase 3 *ASPIRE* (Carfilzomib, Lenalidomide, and Dexamethasone versus Lenalidomide and Dexamethasone for the treatment of Patients with Relapsed Multiple Myeloma) study. The study met the key secondary endpoint of overall survival, demonstrating that *KYPROLIS®*, lenalidomide and dexamethasone reduced the risk of death by 21% over lenalidomide and dexamethasone alone.
- In July 2017, we announced the submission of a supplemental New Drug Application to the FDA and a variation to the marketing application to the EMA to include overall survival data from the Phase 3 head-to-head *ENDEAVOR* (Randomized, Open Label, Phase 3 Study of Carfilzomib Plus Dexamethasone Vs Bortezomib Plus Dexamethasone in Patients With Relapsed Multiple Myeloma) study in the product label for *KYPROLIS®*.

Vectibix®

- In June 2017, we announced that the FDA approved a label update for Vectibix® to more precisely molecularly define patients with wild-type RAS metastatic colorectal cancer, as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Biosimilars

ABP 215

- In July 2017, the FDA's Oncologic Drugs Advisory Committee voted unanimously to recommend approval of ABP 215, a biosimilar candidate to Avastin® (bevacizumab). The FDA is not bound by the Committee's recommendation but does take its advice into consideration when considering the approval of a new therapeutic. The FDA has set a Biosimilar User Fee Act target action date of September 14, 2017. ABP 215 is being developed in collaboration with Allergan plc.

Next-Generation Biomanufacturing

- In May 2017, our Next-Generation Biomanufacturing plant in Singapore was approved by the FDA for commercial production of denosumab drug substance.

*FDA provisionally approved trade name

Selected financial information

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
Product sales:						
U.S.	\$ 4,386	\$ 4,317	2 %	\$ 8,481	\$ 8,436	1 %
Rest of the world (ROW)	1,188	1,157	3 %	2,292	2,277	1 %
Total product sales	5,574	5,474	2 %	10,773	10,713	1 %
Other revenues	236	214	10 %	501	502	— %
Total revenues	\$ 5,810	\$ 5,688	2 %	\$ 11,274	\$ 11,215	1 %
Operating expenses	\$ 3,112	\$ 3,308	(6)%	\$ 5,985	\$ 6,433	(7)%
Operating income	\$ 2,698	\$ 2,380	13 %	\$ 5,289	\$ 4,782	11 %
Net income	\$ 2,151	\$ 1,870	15 %	\$ 4,222	\$ 3,770	12 %
Diluted EPS	\$ 2.91	\$ 2.47	18 %	\$ 5.71	\$ 4.97	15 %
Diluted shares	738	756	(2)%	740	759	(3)%

The increases in global product sales for the three and six months ended June 30, 2017, were driven primarily by Prolia®, Sensipar®/Mimpara®, Repatha®, and KYPROLIS®.

The increase in other revenues for the three months ended June 30, 2017, was driven primarily by higher Ibrance® (palbociclib) royalty income. Other revenues for the six months ended June 30, 2017, were relatively flat, as lower milestone payments received were offset by higher Ibrance® royalty income.

Operating expenses decreased for the three and six months ended June 30, 2017. All expense categories benefited from our transformation and process improvement efforts. As in prior years, our operating expenses are expected to be higher in the second half of the year driven by the timing of expenses.

The increases in net income and diluted EPS for the three and six months ended June 30, 2017, were driven primarily by higher operating margins.

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 offset partially 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, 2017 and 2016.

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,		
	2017	2016	Change	2017	2016	Change
ENBREL	\$ 1,466	\$ 1,484	(1)%	\$ 2,647	\$ 2,869	(8)%
Neulasta®	1,087	1,149	(5)%	2,297	2,332	(2)%
Aranesp®	535	504	6 %	1,046	1,036	1 %
Prolia®	505	441	15 %	930	793	17 %
Sensipar®/Mimpara®	427	389	10 %	848	756	12 %
XGEVA®	395	381	4 %	797	759	5 %
EPOGEN®	292	331	(12)%	562	631	(11)%
Other products	867	795	9 %	1,646	1,537	7 %
Total product sales	\$ 5,574	\$ 5,474	2 %	\$ 10,773	\$ 10,713	1 %

Future sales of our products are influenced by a number of factors, some of which may impact sales of certain of our products more significantly than others. Such factors are discussed below and in the following sections of our Annual Report on Form 10-K for the year ended December 31, 2016: (i) Overview, Item 1. Business—Marketing, Distribution and Selected Marketed Products, (ii) Item 1A. Risk Factors and (iii) Item 7. Results of Operations—Product Sales; and in our Quarterly Report on Form 10-Q for the period ended March 31, 2017, 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,		
	2017	2016	Change	2017	2016	Change
ENBREL — U.S.	\$ 1,411	\$ 1,423	(1)%	\$ 2,529	\$ 2,749	(8)%
ENBREL — Canada	55	61	(10)%	118	120	(2)%
Total ENBREL	\$ 1,466	\$ 1,484	(1)%	\$ 2,647	\$ 2,869	(8)%

The decrease in ENBREL sales for the three months ended June 30, 2017, was driven primarily by the impact of competition, offset partially by favorable changes in inventory and net selling price.

The decrease in ENBREL sales for the six months ended June 30, 2017, was driven primarily by the impact of competition.

Neulasta®

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
Neulasta®— U.S.	\$ 937	\$ 962	(3)%	\$ 1,985	\$ 1,958	1 %
Neulasta®— ROW	150	187	(20)%	312	374	(17)%
Total Neulasta®	\$ 1,087	\$ 1,149	(5)%	\$ 2,297	\$ 2,332	(2)%

The decrease in global Neulasta® sales for the three months ended June 30, 2017, was driven primarily by a decline in unit demand.

The decrease in global Neulasta® sales for the six months ended June 30, 2017, was driven primarily by a decline in unit demand, offset partially by favorable changes in accounting estimates.

As of June 30, 2017, utilization of the Neulasta® Onpro® kit continued to grow in the United States.

We expect to face competition in the United States, which over time may have a material adverse impact on future sales of Neulasta®. Multiple companies have announced applications to the FDA for proposed biosimilar versions of Neulasta®. Two of these companies have received Complete Response Letters from the FDA regarding their applications.

Future Neulasta® sales will also depend in part on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

Aranesp®

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
Aranesp® — U.S.	\$ 288	\$ 260	11%	\$ 566	\$ 521	9 %
Aranesp® — ROW	247	244	1%	480	515	(7)%
Total Aranesp®	\$ 535	\$ 504	6%	\$ 1,046	\$ 1,036	1 %

The increase in global Aranesp® sales for the three months ended June 30, 2017, was driven primarily by higher unit demand.

The increase in global Aranesp® sales for the six months ended June 30, 2017, was driven primarily by higher unit demand, including a shift by some U.S. dialysis customers from EPOGEN® to Aranesp®, offset partially by unfavorable changes in foreign exchange rates.

Aranesp® may face short-acting competition from a proposed biosimilar in the United States.

Prolia®

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
Prolia® — U.S.	\$ 326	\$ 286	14%	\$ 605	\$ 507	19%
Prolia® — ROW	179	155	15%	325	286	14%
Total Prolia®	\$ 505	\$ 441	15%	\$ 930	\$ 793	17%

The increases in global Prolia® sales for the three and six months ended June 30, 2017, were driven primarily by higher unit demand.

Sensipar®/Mimpara®

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
Sensipar® — U.S.	\$ 342	\$ 303	13 %	\$ 679	\$ 581	17 %
Sensipar®/Mimpara® — ROW	85	86	(1)%	169	175	(3)%
Total Sensipar®/Mimpara®	\$ 427	\$ 389	10 %	\$ 848	\$ 756	12 %

The increases in global Sensipar®/Mimpara® sales for the three and six months ended June 30, 2017, were driven primarily by an increase in net selling price.

Our U.S. composition of matter patent relating to Sensipar®, a small molecule, expires in March 2018. We are also involved in a number of litigation matters related to Sensipar®. See Note 13, Contingencies and commitments, to the condensed consolidated financial statements.

XGEVA®

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

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
XGEVA® — U.S.	\$ 292	\$ 275	6 %	\$ 590	\$ 546	8 %
XGEVA® — ROW	103	106	(3)%	207	213	(3)%
Total XGEVA®	\$ 395	\$ 381	4 %	\$ 797	\$ 759	5 %

The increases in global XGEVA® sales for the three and six months ended June 30, 2017, were driven primarily by higher unit demand.

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Three months ended June 30,			Six months ended June 30,		
	2017	2016	Change	2017	2016	Change
EPOGEN® — U.S.	\$ 292	\$ 331	(12)%	\$ 562	\$ 631	(11)%

The decreases in EPOGEN® sales for the three and six months ended June 30, 2017, were driven primarily by a decrease in net selling price due to a negotiated contract with DaVita Inc.

We face competition in the United States, which has had, and will continue to have, a material adverse impact on sales of EPOGEN®. Multiple companies are developing proposed biosimilar versions of EPOGEN®. One company has received a Complete Response Letter from the FDA regarding its application.

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,		
	2017	2016	Change	2017	2016	Change
KYPROLIS® — U.S.	\$ 140	\$ 142	(1)%	\$ 277	\$ 271	2 %
KYPROLIS® — ROW	71	30	*	124	55	*
Nplate® — U.S.	99	84	18 %	196	170	15 %
Nplate® — ROW	65	58	12 %	122	113	8 %
Vectibix® — U.S.	62	52	19 %	123	108	14 %
Vectibix® — ROW	106	108	(2)%	192	196	(2)%
NEUPOGEN® — U.S.	90	141	(36)%	191	291	(34)%
NEUPOGEN® — ROW	47	55	(15)%	94	118	(20)%
Repatha® — U.S.	60	20	*	93	34	*
Repatha® — ROW	23	7	*	39	9	*
BLINCYTO®—U.S.	28	21	33 %	51	42	21 %
BLINCYTO®—ROW	15	9	67 %	26	15	73 %
Other — U.S.	19	17	12 %	34	27	26 %
Other — ROW	42	51	(18)%	84	88	(5)%
Total other products	\$ 867	\$ 795	9 %	\$ 1,646	\$ 1,537	7 %
Total U.S. — other products	\$ 498	\$ 477	4 %	\$ 965	\$ 943	2 %
Total ROW — other products	369	318	16 %	681	594	15 %
Total other products	\$ 867	\$ 795	9 %	\$ 1,646	\$ 1,537	7 %

* 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,		
	2017	2016	Change	2017	2016	Change
Cost of sales	\$ 1,024	\$ 1,050	(2)%	\$ 2,020	\$ 2,068	(2)%
% of product sales	18.4%	19.2%		18.8%	19.3%	
% of total revenues	17.6%	18.5%		17.9%	18.4%	
Research and development	\$ 873	\$ 900	(3)%	\$ 1,642	\$ 1,772	(7)%
% of product sales	15.7%	16.4%		15.2%	16.5%	
% of total revenues	15.0%	15.8%		14.6%	15.8%	
Selling, general and administrative	\$ 1,209	\$ 1,292	(6)%	\$ 2,273	\$ 2,495	(9)%
% of product sales	21.7%	23.6%		21.1%	23.3%	
% of total revenues	20.8%	22.7%		20.2%	22.2%	
Other	\$ 6	\$ 66	(91)%	\$ 50	\$ 98	(49)%

Transformation and process improvements

During 2014, we announced transformation and process improvement efforts that we continue to execute. As part of these efforts, we committed to a more agile and efficient operating model. Our transformation and process improvement efforts across the Company are enabling us to reallocate resources to fund many of our innovative pipeline and growth opportunities that deliver value to patients and stockholders.

The transformation includes a restructuring plan that will result in pre-tax accounting charges in the range of \$800 million to \$900 million. As of June 30, 2017, restructuring costs incurred to date were \$760 million. The charges that were recorded related to the restructuring during the three and six months ended June 30, 2017, were not significant. Since 2014, we have realized approximately \$1.3 billion of transformation and process improvement savings. Net savings have not been significant as savings were reinvested in product launches, clinical programs and external business development.

Cost of sales

Cost of sales decreased to 17.6% of total revenues for the three months ended June 30, 2017, driven primarily by lower royalties.

Cost of sales decreased to 17.9% of total revenues for the six months ended June 30, 2017, driven primarily by manufacturing efficiencies and lower royalties, offset partially by product mix.

The excise tax imposed by the U.S. territory of Puerto Rico on the gross intercompany purchase price of goods and services from our manufacturer in Puerto Rico (Puerto Rico excise tax) is recorded as a cost of sales expense. Excluding the impact of the Puerto Rico excise tax, cost of sales would have been 16.0% and 16.3% of total revenues for the three and six months ended June 30, 2017, respectively, compared with 16.7% and 16.8% for the corresponding periods of the prior year. See Note 3, Income taxes, to the condensed consolidated financial statements for further discussion of the Puerto Rico excise tax.

Research and development

The decrease in R&D expenses for the three months ended June 30, 2017, was driven primarily by lower spending required to support certain later-stage clinical programs. The costs associated with our later-stage clinical programs decreased by \$31 million. The costs associated with Discovery Research and Translational Sciences (DRTS) and marketed products were relatively unchanged.

The decrease in R&D expenses for the six months ended June 30, 2017, was driven primarily by lower spending required to support certain later-stage clinical programs and a payment related to a third-party collaboration agreement in the prior year period. The costs associated with later-stage clinical programs and marketed products decreased by \$71 million and \$58 million, respectively. DRTS spend was relatively unchanged.

Selling, general and administrative

The decrease in Selling, general and administrative (SG&A) expenses for the three months ended June 30, 2017, was driven primarily by the expiration of ENBREL residual royalty payments on October 31, 2016, offset partially by investments in product launches.

The decrease in SG&A expenses for the six months ended June 30, 2017, was driven primarily by the expiration of ENBREL residual royalty payments on October 31, 2016, as well as a charge related to an acquisition in the three months ended March 31, 2016, offset partially by investments in product launches.

Other

Other operating expenses for the three and six months ended June 30, 2017, included certain charges related to our restructuring plan.

Other operating expenses for the three and six months ended June 30, 2016, included legal proceeding charges of \$78 million and \$105 million, respectively.

Non-operating expenses/income and income taxes

Non-operating expenses/income and income taxes were as follows (dollar amounts in millions):

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Interest expense, net	\$ 321	\$ 313	\$ 647	\$ 607
Interest and other income, net	\$ 165	\$ 137	\$ 360	\$ 287
Provision for income taxes	\$ 391	\$ 334	\$ 780	\$ 692
Effective tax rate	15.4%	15.2%	15.6%	15.5%

Interest expense, net

The increase in Interest expense, net, for the three and six months ended June 30, 2017, was due primarily to a higher average amount of debt outstanding.

Interest and other income, net

The increase in Interest and other income, net, for the three and six months ended June 30, 2017, was due primarily to higher interest income that resulted from higher average investment balances.

Income taxes

The increase in our effective tax rate for the three months ended June 30, 2017, was due primarily to a prior year benefit associated with tax incentives and lower tax benefits from share-based compensation payments, offset partially by discrete benefits associated with the effective settlement of certain state and federal tax matters.

The increase in our effective tax rate for the six months ended June 30, 2017, was due primarily to lower tax benefits from share-based compensation payments, offset partially by discrete benefits associated with the effective settlement of certain state and federal tax matters and favorable tax impacts of changes in the jurisdictional mix of income and expenses.

Excluding the impact of the Puerto Rico excise tax, our effective tax rate for the three and six months ended June 30, 2017, would have been 18.1% and 18.3%, respectively, compared with 18.1% and 18.4%, respectively, for the corresponding period of the prior year.

As previously disclosed, on April 12, 2017, we received a RAR from the IRS for the years 2010, 2011, and 2012. The RAR proposes to make significant adjustments that relate primarily to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagree with the proposed adjustments and are pursuing resolution through the IRS administrative appeals process, which we believe will likely not be concluded within the next 12 months. Final resolution of the IRS audit could have a material impact on our results of operations and cash flows if not resolved favorably, however, we believe our income tax reserves are appropriately provided for all open tax years.

See Note 3, Income taxes, to the condensed consolidated financial statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data were as follows (in millions):

	June 30, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 39,227	\$ 38,085
Total assets	\$ 79,587	\$ 77,626
Short-term borrowings and current portion of long-term debt	\$ 1,459	\$ 4,403
Long-term debt	\$ 33,603	\$ 30,193
Stockholders' equity	\$ 31,722	\$ 29,875

We intend to continue to return capital to stockholders through the payment of cash dividends and stock repurchases reflecting our confidence in the future cash flows of our business. The timing and amounts of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, the 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 agreements of the Company. In addition, the timing and amounts of stock repurchases may also be affected by the stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include private block purchases, tender offers and market transactions.

In March 2017 and December 2016, the Board of Directors declared quarterly cash dividends of \$1.15 per share of common stock, which were paid on June 8 and March 8, 2017, respectively.

We have also returned capital to stockholders through our stock repurchase program. During the six months ended June 30, 2017, we repurchased and paid in cash \$1.6 billion of our stock during the period. During the six months ended June 30, 2016, we repurchased \$1.3 billion of our stock and paid \$1.2 billion in cash during the period. As of June 30, 2017, \$2.5 billion remained available under the Board of Directors-approved stock repurchase program.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, sales of marketable securities, borrowings through commercial paper and/or our syndicated credit facilities and access to other domestic and foreign debt markets and equity markets. During the three months ended June 30, 2017, we began borrowing under our \$2.5 billion commercial paper program and had \$960 million outstanding under this program as of the end of the period.

With respect to our U.S. operations, we believe that existing funds intended for use in the United States; cash generated from our U.S. operations, including intercompany payments and receipts; and existing sources of and access to financing (collectively, U.S. funds) are adequate to continue meeting our U.S. obligations, including our plans to pay dividends and repurchase stock with U.S. funds, for the foreseeable future. See our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1A. Risk Factors—Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Of our cash, cash equivalents and marketable securities balances totaling \$39.2 billion as of June 30, 2017, approximately \$37.4 billion was generated from operations in foreign tax jurisdictions and is intended to be invested indefinitely outside the United States. Under current tax laws, if these funds were repatriated for use in our U.S. operations, we would be required to pay additional income taxes at the tax rates then in effect.

Certain of our financing arrangements contain non-financial covenants. In addition, our revolving credit agreement includes a financial covenant with respect to the level of our borrowings in relation to our equity, as defined. We were in compliance with all applicable covenants under these arrangements as of June 30, 2017.

Cash flows

Our cash flow activities were as follows (in millions):

	Six months ended June 30,	
	2017	2016
Net cash provided by operating activities	\$ 4,711	\$ 4,592
Net cash used in investing activities	\$ (1,970)	\$ (5,047)
Net cash used in financing activities	\$ (3,353)	\$ (1,059)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the six months ended June 30, 2017, increased compared with the same period in the prior year due primarily to an increase in net income offset partially by the timing of payments to taxing authorities and receipts from customers.

Investing

Cash used in investing activities during the six months ended June 30, 2017, was due primarily to net activity related to marketable securities of \$1.5 billion and capital expenditures of \$353 million. Cash used in investing activities during the six months ended June 30, 2016, was due primarily to net activity related to marketable securities of \$4.6 billion and capital expenditures of \$344 million. Capital expenditures during the six months ended June 30, 2017 and 2016, were associated primarily with manufacturing capacity expansions in various locations, as well as other site developments. We currently estimate 2017 spending on capital projects and equipment to be approximately \$700 million.

Financing

Cash used in financing activities during the six months ended June 30, 2017, was due primarily to payment of dividends of \$1.7 billion, repurchases of our common stock of \$1.6 billion, and repayment of long-term debt, net of proceeds from issuances, of \$920 million, offset partially by proceeds from the issuance of commercial paper of \$959 million. Cash used in financing activities during the six months ended June 30, 2016, was due primarily to the payment of dividends of \$1.5 billion and repurchases of our common stock of \$1.2 billion, offset partially by proceeds from the issuance of long-term debt, net of repayments, of \$1.9 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, 2016. There were no material changes to our critical accounting policies during the six months ended June 30, 2017.

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, 2016, and is incorporated herein by reference. Except as discussed below, there have been no material changes during the six months ended June 30, 2017, 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, 2016.

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 \$3.65 billion during the three months ended June 30, 2017. In addition, we had interest rate swap contracts with an aggregate notional amount of \$850 million mature during the three months ended June 30, 2017. As of June 30, 2017, interest rate swap contracts with an aggregate notional amount of \$9.45 billion were 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 note. A hypothetical 100 basis point increase in interest rates relative to interest rates at June 30, 2017, would have resulted in reductions in fair values of approximately \$470 million on our interest rate swap contracts on this date and would not result in a material effect on the related income in the ensuing year. 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 values of debt that these interest rate sensitive interests were designed to offset.

Item 4. CONTROLS AND PROCEDURES

We maintain “disclosure controls and procedures,” as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen’s Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to Amgen’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and, in reaching a reasonable level of assurance, Amgen’s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen’s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2017.

Management determined that, as of June 30, 2017, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 13, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended June 30, 2017 and Note 12, Contingencies and commitments, to the condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2017, for discussions that are limited to certain recent developments concerning our legal proceedings. Those discussions should be read in conjunction with Note 18, 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, 2016.

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 facing our business. We have described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, the primary risks related to our business, and we periodically update those risks for material developments. Those risks are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

Below, we are providing, in supplemental form, the material changes to our risk factors that occurred during the past quarter. Our risk factors disclosed in Part I, Item 1A, Risk Factors, of our Annual Report, on Form 10-K for the year ended December 31, 2016, and in our Quarterly Report on Form 10-Q for the period ended March 31, 2017, provide additional disclosure for these supplemental risks and are incorporated herein by reference.

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

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in foreign countries to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and foreign regulatory agencies have substantial authority to require additional testing and

reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or foreign regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approval have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations, or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to regulations governing manufacturer communications concerning drug products and drug product candidates, and whether such changes could have a material adverse effect on our business and results of operations.

Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical endpoint. For example, a therapeutic oncology product candidate may be evaluated for its ability to extend the length of time during and after the treatment that a patient lives without the disease worsening progression-free survival (PFS). Demonstrating that the product candidate produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, our initial FDA application for Repatha[®] sought approval for a broader patient population based on data demonstrating that Repatha[®] reduced LDL-C levels. However, the FDA ultimately approved Repatha[®] only for a subset of those patients, citing among other things the absence of positive outcomes data showing that Repatha[®] prevents cardiovascular events. We subsequently announced that our phase 3 outcomes study evaluating the ability of Repatha[®] to prevent cardiovascular events met its primary composite endpoint and key secondary composite endpoint and that we submitted applications to the FDA and EMA to incorporate the results of the outcomes study into the respective Repatha[®] labels. See Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Significant Developments. However, we cannot predict the degree to which the results of this study will be incorporated into the Repatha[®] labels by regulators. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion or at all may delay our clinical development and regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current labels.

Some of our products have been approved by U.S. and foreign regulatory authorities on a conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, BLINCYTO[®] received conditional marketing authorization for the treatment of patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL from the European Commission in November 2015. Regulatory authorities are placing greater focus on monitoring products originally approved on an accelerated or conditional basis and on whether the sponsors of such products have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators re-evaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications or even withdraw the product from the market.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required to continuously collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In 2012, pharmacovigilance legislation became effective in the EU that enhanced the authority of European regulators to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the requirements on sponsor companies to analyze and evaluate the risk-benefit profiles of their products. Similarly, for our products with approved risk evaluation and mitigation strategy (REMS) (see our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1. Business—Government Regulation—Post-approval Phase), we are required to submit periodic assessment

reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to ensure that a drug's benefits outweigh the risks, and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety. As such, we are also required to collect and assess device and user complaints regarding our drug delivery devices. Additionally, regulatory agencies conduct routine monitoring and conduct inspections to identify and evaluate potential issues with our devices. For example, in July 2017 the FDA reported on its adverse event reporting system that it is evaluating our Neulasta[®] Onpro[®] kit. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours and that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that may result in our decision not to commercialize a product candidate;
- requirement of risk management activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- mandated post-marketing commitments or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- fewer treatments or product candidates being approved by regulatory bodies.

For example, since 2006, when adverse safety results involving erythropoiesis-stimulating agents (ESAs) were observed, ESAs continue to be the subject of ongoing review and scrutiny. Reviews by regulatory authorities of the risk-benefit profile of ESAs have resulted in, and may continue to result in, changes to ESA labeling and usage in both the oncology and nephrology clinical settings.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the Affordable Care Act (ACA) provided for such a pathway; while the FDA continues to implement it, questions remain as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products and what information can be included in biosimilar labeling. See our Annual Report on Form 10-K for the year ended December 31, 2016, Part I, Item 1A. Risk Factors—We currently face competition from biosimilars and expect to face increasing competition in the future. Delays or uncertainties in the development of such pathways could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict whether any repeal or reform of the ACA would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars. In addition, if we are unable to bring our biosimilar products to market on a timely basis, and secure “first-to-market” positions, our future biosimilar sales and results of operations could be materially and adversely affected.

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California; if significant disruptions or production failures occur at the Puerto Rico facility, we may not be able to supply these products or, at the Thousand Oaks facility, we may not be able to continue our clinical trials.

We currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and substantially all of our clinical manufacturing activities at our facility in Thousand Oaks, California. The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of these facilities. See our Annual Report on Form 10-K for the year ended December

The operation of our manufacturing facility in the U.S. territory of Puerto Rico is also subject to local economic challenges. Since June 2015, when the Governor of Puerto Rico announced that the government (including certain government entities) was unable to pay its roughly \$72 billion in debt, the government’s liquidity position has continued to deteriorate and public reports indicate that the Puerto Rico government is not making certain payments with respect to its obligations. On June 30, 2016, President Obama signed into law the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) to provide a mechanism for Puerto Rico to restructure its debt, achieve fiscal responsibility, and gain access to capital markets. PROMESA established a federal Financial Oversight and Management Board (Oversight Board) to provide fiscal oversight through the development and approval of fiscal plans and budgets for Puerto Rico and to assist in the debt restructuring. The Oversight Board approved the Puerto Rico government’s revised fiscal plan on March 13, 2017 and, on June 30, 2017, the government’s budget for fiscal year 2018. The establishment of the Oversight Board initially provided for an automatic stay of creditor actions against the Puerto Rico government until February 15, 2017, and subsequently extended the automatic stay until May 1, 2017, to pursue voluntary negotiations with the Puerto Rico government’s creditors. On May 3, 2017, after negotiations with creditors were unsuccessful and the automatic stay expired, the Oversight Board approved and certified the filing in the U.S. District Court for the District of Puerto Rico of a voluntary petition under Title III of PROMESA for the government of Puerto Rico, following thereafter with similar filings for certain Puerto Rico government entities. Title III of PROMESA provides Puerto Rico with a judicial process for restructuring its debt similar to, but not identical to, Chapter 9 of the U.S. Bankruptcy Code. Additionally, on January 29, 2017, the Puerto Rico government enacted the Puerto Rico Fiscal Emergency and Fiscal Responsibility Act, which, among other things, declared a state of financial emergency in Puerto Rico until May 1, 2017, and authorizes the Governor to designate certain services as essential services, and other services as non-essential in order to prioritize the use of available resources to satisfy Puerto Rico’s obligations. On July 19, 2017, the Puerto Rico government extended the emergency period through December 31, 2017, and authorized the Governor to further extend the emergency period for six-month terms under certain conditions. While PROMESA and the actions above continue to be important factors in moving Puerto Rico toward economic stability, there is still a risk that Puerto Rico’s economic situation could impact the territorial government’s provision of utilities or other services in Puerto Rico that we use in the operation of our business, create the potential for increased taxes or fees to operate in Puerto Rico, result in a migration of workers from Puerto Rico to the mainland United States, and/or make it more expensive or difficult for us to operate in Puerto Rico.

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

During the three months ended June 30, 2017, we had one outstanding stock repurchase program and the repurchase activity was as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program ⁽¹⁾
April 1 - 30	1,108,267	\$ 162.88	1,108,267	\$ 3,340,028,056
May 1 - 31	1,586,272	\$ 154.47	1,586,272	\$ 3,094,997,845
June 1 - 30	3,515,972	\$ 165.05	3,515,972	\$ 2,514,688,372
	<u>6,210,511</u>	<u>\$ 161.96</u>	<u>6,210,511</u>	

(1) In October 2016, our Board of Directors authorized an increase that resulted in a total of \$5.0 billion available under the stock repurchase program.

Item 6. EXHIBITS

Reference is made to the Index to Exhibits included herein.

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: July 26, 2017

By:

/s/ DAVID W. MELINE

David W. Meline
Executive Vice President and Chief Financial Officer

AMGEN INC.

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
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 13, 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 January 1, 1992, as supplemented by the First Supplemental Indenture, dated February 26, 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 forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 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 forms of the Company's 6.15% Senior Notes due 2018 and 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 forms of the Company's 5.70% Senior Notes due 2019 and 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 forms of the Company's 4.50% Senior Notes due 2020 and 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 forms of the Company's 3.45% Senior Notes due 2020 and 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 forms of the Company's 2.30% Senior Notes due 2016, 4.10% Senior Notes due 2021 and 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 forms of the Company's 1.875% Senior Notes due 2014, 2.50% Senior Notes due 2016, 3.875% Senior Notes due 2021 and 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 forms of the Company's 4.375% Senior Notes due 2018 and 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)

Exhibit No.	Description
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including forms of the Company's 2.125% Senior Notes due 2017, 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 forms of the Company's 2.125% Senior Notes due 2019 and 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 forms of the Company's Senior Floating Rate Notes due 2017, Senior Floating Rate Notes due 2019, 1.250% Senior Notes due 2017, 2.200% Senior Notes due 2019 and 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 2.125% Senior Notes due 2020, 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	Registration Rights Agreement, dated as of June 14, 2016, by and among Amgen Inc., Credit Suisse Securities (USA) LLC, J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Mizuho Securities USA Inc., as lead dealer managers, and Drexel Hamilton, LLC and The Williams Capital Group, L.P., as co-dealer managers. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 1.850% Senior Notes due 2021, 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.)
4.28	Officer's Certificate of Amgen Inc., dated as of May 11, 2017, including forms of the Company's Senior Floating Rate Notes due 2019, Senior Floating Rate Notes due 2020, 1.900% Senior Notes due 2019, 2.200% Senior Notes due 2020 and 2.650% Senior Notes due 2022. (Filed as an exhibit to Form 8-K on May 11, 2017 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 Stock Option Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 20, 2016.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.5+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 2009 Equity Incentive Plan. (As Amended on December 20, 2016.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)

Exhibit No.	Description
10.6+	Amgen Inc. 2009 Performance Award Program. (As Amended on 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.)
10.7+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended on December 20, 2016.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.8+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended on 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.)
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 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.)
10.11+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.12+	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.)
10.13+	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.)
10.14+	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.)
10.15+	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.)
10.16+	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.)
10.17+	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.)
10.18+	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.)
10.19+	Agreement between Amgen Inc. and David W. Meline, effective July 21, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2014 on October 29, 2014 and incorporated herein by reference.)
10.20+	Agreement between Amgen Inc. and Jonathan Graham, dated May 11, 2015. (Filed as an exhibit to Form 10-Q/A for the quarter ended June 30, 2015 on August 6, 2015 and incorporated herein by reference.)
10.21+	Agreement between Amgen Inc. and Lori Johnston, dated October 25, 2016. (Filed as an exhibit to Form 10-K for the year ended December 31, 2016 on February 14, 2017 and incorporated herein by reference.)
10.22	Shareholders' Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.23	Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders' Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)

Exhibit No.	Description
10.24	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.25	Amendment No. 12 to the Shareholders' Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
10.26	Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (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, 2007 on August 9, 2007 and incorporated herein by reference.)
10.27	Amendment No. 14 to the Shareholders' Agreement, dated March 26, 2014. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2014 on April 30, 2014 and incorporated herein by reference.)
10.28	Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986), between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.29	G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.30	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.31	Amended and Restated Credit Agreement, dated July 30, 2014, 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 July 30, 2014 and incorporated herein by reference.)
10.32	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.)
10.33	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.)
10.34	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.)
10.35	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.)
10.36	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.)
10.37	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.)

Exhibit No.	Description
10.38	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.)
10.39	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.)
10.40	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.)
10.41*	<u>Exclusive License and Collaboration Agreement, dated August 28, 2015, by and between Amgen Inc. and Novartis Pharma AG</u> (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
10.42*	<u>Amendment No. 1 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</u> (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
10.43*	<u>Amendment No. 2 to the Exclusive License and Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</u> (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
10.44*	<u>Collaboration Agreement, dated April 21, 2017, by and between Amgen Inc. and Novartis Pharma AG</u> (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
31*	<u>Rule 13a-14(a) Certifications.</u>
32**	<u>Section 1350 Certifications.</u>
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(* = 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)

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

BY AND BETWEEN

AMGEN INC.

AND

NOVARTIS PHARMA AG

DATED

AUGUST 28, 2015

Table of Contents

1.Definitions	1
2.Option	18
2.1.Option for Franchise Product 3.	18
2.2.Effect of Option Period Expiration.	19
2.3.Development Prior to Option Exercise Date	19
3.Collaboration Scope and Governance	19
3.1.Conduct of the Collaboration	19
3.2.Committees and Teams	20
3.3.Committee Co-Chairs	21
3.4.Committee Meetings	21
3.5.Decision Making	22
3.6.Interactions Between the Joint Management Committee, the Joint Steering Committee, and Joint Project Teams	23
3.7.Alliance Managers	24
3.8.Outside the Territory	24
4.Grant of License	24
4.1.Licensed Amgen Patents and Know-How	24
4.2.Licensed Novartis Know-How and Patents	25
4.3.Sublicensing	25
4.4.Provision of Know-How	26
4.5.Trademarks	26
4.6.Trademark and Housemark Quality Standards	27
4.7.Domain Names	27
4.8.Retained Rights and Limitations	28
5.Development and Regulatory	28
5.1.Responsibility for Development	28
5.2.Development Within and Outside Development Plan	28
5.3.Development Outside the Territory by Novartis or Inside the Territory by Amgen	29
5.4.Regulatory Matters	29
5.5.Safety Matters	32
5.6.Cooperation Generally	32
6.Commercialization	33

Table of Contents

6.1.Operational Control	33
6.2.Promotional Materials	33
6.3.Commercialization Outside the Territory	33
6.4.Reimportation	33
6.5.Cooperation Generally	34
6.6.[*]	34
7.Diligence; Activities Outside the Collaboration	34
7.1.Commercially Reasonable Efforts	34
7.2.Activities Outside the Collaboration	34
7.3.Post-Effective Date Affiliates	34
7.4. Termination or Divestiture	34
8.Manufacture and Supply	35
8.1.Manufacturing Rights	35
8.2.Supply	35
8.3.Quality Agreement	35
8.4.Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities	36
9.Payment	36
9.1.Royalty Payments	36
9.2.Royalty Reduction	37
9.3.[Reserved].	38
9.4.Appropriate Measure of Value	38
9.5.Reports	38
9.6.No Wrongful Reductions	39
9.7.Development Cost Sharing	39
9.8.Sublicense Payments	41
9.9.[Reserved]	41
9.10.Payment Method	42
9.11.Audits	42
9.12.Blocked Currency	43
9.13.Taxes	43
9.14.Withholding	43

Table of Contents

9.15.VAT	43
9.16.Late Payment	43
10.Intellectual Property	44
10.1.Ownership and Cooperation	44
10.2.Prosecution and Maintenance	44
10.3.Defense and Settlement of Third Party Claims	46
10.4.Enforcement	48
10.5.Cooperation	49
10.6.Allocation of Recoveries	50
10.7.Patent Term Extensions	50
10.8.Employee Agreements	50
11.Confidentiality and Publications	51
11.1.Confidentiality; Exceptions	51
11.2.Authorized Disclosure	51
11.3.Use of Confidential Information and Data with Distracting Programs	52
11.4.Terms and Conditions Confidential	52
11.5.Prior Agreement	53
11.6.Publications and Presentations	53
11.7.Scientific Papers, Abstracts and Posters	53
11.8.Deferral of Disclosures	55
11.9.Failure to Object to Disclosure	55
11.10.Attorney-Client Privilege	55
12.Representations, Warranties and Covenants	55
12.1.Mutual Representations and Warranties	55
12.2.Amgen Representations and Warranties	56
12.3.Disclaimer of Warranties	57
12.4.Covenants	57
13.Limitations of Liability; Insurance	59
13.1.Limitations of Liability	59
13.2.Insurance	59
14.Indemnification	59
14.1.Indemnity	59

Table of Contents

14.2.Claim for Indemnification	61
15.Term and Termination	61
15.1.Term	62
15.2.Termination	62
15.3.Effect of Termination	63
15.4.Additional Surviving Provisions	65
15.5.Transition Period	65
16.Miscellaneous	65
16.1.Affiliates	66
16.2.Assignment	66
16.3.Governing Law; Jurisdiction	66
16.4.Construction	66
16.5.Counterparts	67
16.6.[Reserved].	67
16.7.Entire Agreement	67
16.8.Force Majeure	67
16.9.Further Assurances	67
16.10.Headings	67
16.11.No Set-Off	67
16.12.Notices	67
16.13.Relationship of the Parties	68
16.14.Severability	68
16.15.Third Party Beneficiaries	68
16.16.Waivers and Modifications	69

SCHEDULES

Clinical Supply

Commercial Supply

Licensed Amgen Patents

Out-of-Pocket Development Expenses

Press Release

EXCLUSIVE LICENSE AND COLLABORATION AGREEMENT

PREAMBLE

This Exclusive License and Collaboration Agreement (this “*Agreement*”), effective as of August 28, 2015 (the “*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 is a global biopharmaceutical company that researches, develops, manufactures and commercializes novel therapeutics to treat grievous illness;

WHEREAS, Amgen is Developing its proprietary monoclonal antibody against calcitonin gene-related peptide (CGRP) receptor, known as AMG 334 (“*Franchise Product 1*”); its proprietary pituitary adenylate cyclase activating peptide (PACAP) receptor antibody, known as AMG 301 (“*Franchise Product 2*”); and [*] (“*Franchise Product 3*”);

WHEREAS, Novartis has existing development and commercialization capabilities in the Territory; and

WHEREAS, Amgen wishes to collaborate with Novartis, and Novartis wishes to collaborate with Amgen, in each case with respect to the Development and Commercialization of the Licensed Products in the Field in the Territory (each as defined below) in accordance with the terms and conditions hereof.

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

- 1.1. “*Accounting Standards*” means, with respect to Amgen, United States Generally Accepted Accounting Principles (“*U.S. GAAP*”), and means, with respect to Novartis, the International Financial Reporting Standards (“*IFRS*”), in each case, as generally and consistently applied throughout the applicable Party’s organization. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained; *provided, however*, that each Party may only use internationally recognized accounting principles (e.g. *IFRS*, *U.S. GAAP*, etc.).
- 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 and Section 1.139 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 50% or more (or if less than 50%, the maximum ownership interest permitted by applicable Law) of the securities entitled to be voted generally or in the election of directors of such Person, or by contract or otherwise. For purposes of this Agreement, [*] shall be deemed not to be an Affiliate of Novartis.
- 1.3. “*Agreement*” has the meaning set forth in the Preamble.
- 1.4. “*Alliance Managers*” has the meaning set forth in Section 3.7 (*Alliance Managers*).
- 1.5. “*Amgen*” has the meaning set forth in the Preamble.
- 1.6. “*Amgen Development Costs*” means the Development Costs incurred by Amgen and its Affiliates.
- 1.7. “*Amgen Development Data*” means, with respect to a given Licensed Product, the preclinical and clinical data generated by or on behalf or in possession of Amgen or its Affiliates (both within and outside the Territory) in the course of its preclinical and clinical Development of such Licensed Product, both before and after the Effective Date of this Agreement other than Amgen [*] Data. For the avoidance of doubt, Amgen Development Data excludes Novartis Development Data. All preclinical and clinical data generated pursuant to this Agreement by or on behalf of Amgen and its Affiliates to obtain, maintain and expand the Regulatory Approval for such Licensed Product outside of the Territory in accordance with the Development Plan shall be deemed Amgen Development Data.
- 1.8. “*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, Licensed Novartis 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.

- 1.9. “*Amgen [*] Data*” means, with respect to a given Licensed Product, the preclinical and clinical data generated by or on behalf of Amgen or its Affiliates in the course of its preclinical (if any) and clinical Development of such Licensed Product on or after the Effective Date of this Agreement, which Development is [*] and which [*].
- 1.10. “*Amgen Indemnites*” has the meaning set forth in Section 14.1 (Indemnity).
- 1.11. “*Annual Development Budget*” means, with respect to a given Calendar Year and a given Licensed Product, the amount apportioned for such Calendar Year and such Licensed Product in the Development Budget, as such budget may be revised from time to time by mutual agreement of the Parties.
- 1.12. “*Anti-Corruption Laws*” means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable laws, rules and regulations relating to or concerning public or commercial bribery or corruption.
- 1.13. “*Biosimilar Product*” means, with respect to a given Licensed Product in a given country in the Territory, after Regulatory Approval of such Licensed Product in such country, 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) such Licensed Product, (ii) has a purity, potency and safety profile that has no clinically meaningful difference from the purity, potency and safety profile of such Licensed Product, and (iii) is approved for use pursuant to a regulatory approval process in such country that is based on reliance, at least in part, 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 sold in such country by any Third Party.
- 1.14. “*BLA*” means a Biologic Licensing Application, including all supplements and amendments thereto, for the approval of a Licensed Product as a new drug by the FDA.
- 1.15. “*Business Day*” means a day that is not a Saturday, a Sunday or a day on which banking institutions in New York, New York, USA, or Basel, Switzerland, are authorized by applicable Law to remain closed.
- 1.16. “*Calendar Quarter*” means a three-month period beginning on January, April, July or October 1st.
- 1.17. “*Calendar Year*” means a one-year period beginning on January 1st and ending on December 31st.
- 1.18. “*Claims*” has the meaning set forth in Section 14.1 (Indemnity).
- 1.19. “*Clinical Trial*” means a Phase 1 Clinical Trial, a Phase 2 Clinical Trial, a Phase 3 Clinical Trial, a Phase 3b Clinical Trial or a Phase 4 Clinical Trial.
- 1.20. “*Co-Chair*” has the meaning set forth in Section 3.3 (Committee Co-Chairs).
- 1.21. “*Collaboration*” has the meaning set forth in Section 3.1 (Conduct of the Collaboration).

- 1.22. “*Commercialize*” means any and all processes and activities conducted to establish and maintain sales for a Licensed Product, including to market, advertise, promote, store, transport, distribute, import, export, offer to sell (including pricing and reimbursement activities), detail, and/or sell Licensed Products 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).
- 1.23. “[*]” has the meaning set forth in Section [*].
- 1.24. “*Commercially Reasonable Efforts*” means, with respect to the efforts to be expended by a Party 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, Development, conduct of Medical Affairs Activities with respect to, and Commercialization of a Licensed 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 Licensed Product, and at a similar stage in its Development or product life as the Licensed 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 a Licensed Product.
- 1.25. “*Committee*” has the meaning set forth in Section 3.2.3.
- 1.26. “*Confidential Information*” has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
- 1.27. “*Contract Interest Rate*” means [*] percent ([*]%) plus the [*] day U.S. Dollar LIBOR rate effective for the date that payment was due, as published by The Wall Street Journal, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Law.
- 1.28. “*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 such payments or it is subject to Section 9.8 (Sublicense Payments).

- 1.29. “Cover”, “Covered” or “Covering” means, with respect to a product and a Patent, that, in the absence of a (sub)license under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such product with respect to a given country would infringe a Valid Claim of such Patent.
- 1.30. “Critical Matter” means (i) all decisions made by the JSC or JMC that, in the reasonable opinion of either Party, are likely to have any of the following impacts: (a) a [*]; or (b) a [*] to a Development Plan or any change to a Development Plan that results in an increase, or decrease, of [*] percent ([*]%) or more to the then-current budgeted amount of Development Costs for any specific Calendar Year under the applicable Development Budget; (ii) agreement of the initial [*] for each Licensed Product; and (iii) [*] of a Licensed Product in the Territory [*] relating to a Licensed Product.
- 1.31. “Develop” or “Development” means those activities required and/or useful to obtain and maintain Regulatory Approval, including, without limitation, test method development and stability testing, assay development and audit development, pre-clinical/non-clinical studies (including toxicology studies), formulation, pharmacodynamics, quality assurance/quality control development, statistical analysis, clinical studies, packaging development, regulatory affairs, biomarker strategy and development, report writing and statistical analysis, the preparation, filing and prosecution of MAAs and activities to obtain international nonproprietary names and other nonproprietary names such as U.S. Adopted Name (USAN) for pharmaceutical substances; *provided, however*, that Development shall exclude Commercialization and Manufacturing activities. For clarity, Development shall include clinical trials that are required or requested in writing by a Governmental Authority as a condition of, or in connection with, obtaining or maintaining Regulatory Approval (whether the trial is commenced prior to or after receipt of such Regulatory Approval).
- 1.32. “Development Budget” means, (i) with respect to each of Franchise Product 1 and Franchise Product 2, the budget of Development Costs agreed by the Parties with respect to such product and (ii) with respect to Franchise Product 3, the budget of Development Costs agreed by the Parties pursuant to Section 2.3 (Development Prior to Option Exercise Date) or, if not agreed, proposed by Amgen in the Option Data Package for Franchise Product 3, in each case covering all activities contemplated by the applicable Development Plan, as such budget may be updated annually by the JSC in connection with updates to such Development Plan, as well as the amount of any Study Budgets as applicable for the applicable Licensed Product. The Development Budget shall include (with respect to Franchise Product 3, at the time of delivery of the Option Data Package) such aggregate budget of Development Costs and the estimated apportionment of such aggregate budget for each Calendar Year (or portion thereof) within the period covered by the Development Plan. The initial Development Budgets for each of Franchise Product 1 and Franchise Product 2 shall be agreed in writing by the Parties on the Effective Date. For the avoidance of doubt, the Development Budget shall cover all activities contemplated by the applicable Development Plan for the entire period thereof.
- 1.33. “Development Costs” means the direct costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement for the Development of a Licensed Product(s), calculated as the sum of (i) Out-of-Pocket Development Expenses, (ii) Development FTE

Costs and (iii) Other Development Expenses, each only to the extent incurred in accordance with the Development Plan and Development Budget after the Effective Date. For clarity, “Development Costs” does not include any costs associated with conducting any Phase 4 Clinical Trials unless the Parties otherwise agree to include a Phase 4 Clinical Trial in the Development Plan.

- 1.34. “*Development FTE Costs*” means the product of (i) the actual number of FTEs utilized in the Development of a Licensed Product(s) in accordance with the Development Plan and Development Budget after the Effective Date, as documented by the applicable Party using a reliable time tracking system and (ii) the FTE Rate.
- 1.35. “*Development Plan*” means, with respect to a given Licensed Product, the plan, including any Study Plan, for such Licensed Product in the Field (which plan will be updated annually by the JSC and will cover a period of at least [*] years) covering: (i) the research and Development of, and conduct of Medical Affairs Activities with respect to, such Licensed Product, including relating to biomarkers and including observational research and payer evidence generation including economic value; (ii) the then current target product profile of such Licensed Product; (iii) the preparation and submission of Regulatory Filings for such Licensed Product; and (iv) obtaining, maintenance and expansion of Regulatory Approvals for such Licensed Product in the Field. The initial Development Plans for each of Franchise Product 1 and Franchise Product 2 shall be agreed in writing by the Parties on the Effective Date.
- 1.36. “*Distracting Product*” means any [*] that [*] as a Licensed Product (i.e., [*] (excluding the Licensed Products and, in the case of Amgen only, Franchise Product 3, but including [*])).
- 1.37. “*Distracting Program*” means the clinical development, commercialization or manufacture of any Distracting Product.
- 1.38. “*Distracting Transaction*” means any transaction entered into by Novartis or its Affiliate or Amgen or its Affiliate after the Effective Date whereby a Third Party that is engaged in a Distracting Program becomes an Affiliate of such Party.
- 1.39. “*Distracting Transaction Affiliates*” means those entities that are or would become Affiliates of a Party by virtue of a Distracting Transaction.
- 1.40. “*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) in such Distracting Program by a Party or its Affiliates.
- 1.41. “*Dollars*” or “*\$*” means U.S. Dollars.
- 1.42. “*Domain Name(s)*” means a string of typographic characters used to describe the location of a specific location on the Internet.
- 1.43. “*Effective Date*” has the meaning set forth in the Preamble.
- 1.44. “*EMA*” means the European Medicines Agency, and any successor agency thereto.

- 1.45. “*European Union*” or “*EU*” means those countries, nations, states or other territories under the jurisdiction of the EMA, as such jurisdiction may change from time to time.
- 1.46. “*FDA*” means the U.S. Food and Drug Administration, and any successor agency thereto.
- 1.47. “*Field*” means any and all uses for the diagnosis, prevention or treatment of any disease or condition in all indications in humans.
- 1.48. “[*] *Royalty Floor Restriction*” has the meaning set forth in Section 9.2.2 (Third Party Payments).
- 1.49. “*First Commercial Sale*” means, with respect to a given Licensed Product, on a country-by-country basis, the first sale in such country in the Territory to a Third Party of such Licensed Product by or under the authority of Novartis or its Affiliate or sublicensee after receipt of the applicable Regulatory Approval. Sales for clinical study purposes or compassionate, named patient or similar use shall not constitute a First Commercial Sale.
- 1.50. “*Force Majeure*” has the meaning set forth in Section 16.8 (Force Majeure).
- 1.51. “*Franchise Product 1*” has the meaning set forth in the Recitals.
- 1.52. “*Franchise Product 2*” has the meaning set forth in the Recitals.
- 1.53. “*Franchise Product 2 Study*” means the Phase 2a Clinical Trial for Franchise Product 2 designed to evaluate the safety and efficacy of Franchise Product 2 in patients with [*].
- 1.54. “*Franchise Product 2 Study Readout*” means the Franchise Product 2 Study [*] data [*] following database lock of the Franchise Product 2 Study.
- 1.55. “*Franchise Product 3*” has the meaning set forth in the Recitals.
- 1.56. “*Franchise Product 3 Study*” means the Phase 1 Clinical Trial for Franchise Product 3 designed to evaluate the safety of Franchise Product 3 in healthy subjects and [*].
- 1.57. “*Franchise Product 3 Study Readout*” means the Franchise Product 3 Study [*] data [*] following database lock of the Franchise Product 3 Study.
- 1.58. “*Franchise Product 3 [*] Data Package*” means the data package presented to [*] for purposes of [*] with respect to [*], which shall include [*].
- 1.59. “*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 or Novartis based upon a total of [*] days or [*] hours per year undertaken in connection with the conduct of Development 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.
- 1.60. “*FTE Rate*” means \$[*] per FTE per year (as of the Effective Date), increasing by [*] percent ([*]%) of the then-current FTE Rate on January 1st of [*] and each subsequent Calendar Year. 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).

- 1.61. “*Global Brand Plan*” means, with respect to a given Licensed Product, the strategic and high-level tactical, cross-functional Commercialization plan jointly developed by Amgen and Novartis (including through the JSC) for such Licensed Product, including the Global Payer Plan and the Global Pricing Policy.
- 1.62. “*Global Payer Plan*” means, with respect to a given Licensed Product, the global plan for such Licensed 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 [*] for such Licensed Product.
- 1.63. “*Global Pricing Policy*” means, with respect to a given Licensed Product, the global plan for such Licensed Product jointly prepared by Amgen and Novartis (including through the JSC) that sets forth, globally and by region, the proposed [*] target population and [*] target.
- 1.64. “*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.
- 1.65. “*Government Official*” means (i) any Person employed by or acting on behalf of a Governmental Authority; (ii) any political party, party official or candidate; (iii) any Person who holds or performs the duties of an appointment, office or position created by custom or convention; and (iv) any Person who holds himself out to be the authorized intermediary of any of the foregoing.
- 1.66. “*Housemarks*” means the Novartis Housemarks or the Amgen Housemarks, as the case may be.
- 1.67. “*IND*” means, with respect to the United States, 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 or, with respect any jurisdiction other than the United States, an equivalent filing thereof.
- 1.68. “*Indemnified Party*” has the meaning set forth in Section 14.2 (Claim for Indemnification).
- 1.69. “*Indemnifying Party*” has the meaning set forth in Section 14.2 (Claim for Indemnification).
- 1.70. “*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, including biological compounds, chemical compounds, reagents, Trademarks and Housemarks.
- 1.71. “*Initiation*” of a clinical trial or to “*Initiate*” a clinical trial means the first dosing of the first human subject with a Licensed Product in such trial.
- 1.72. “*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 sixty (60) days 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 sixty (60) days; (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 sixty (60) days; (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; (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.

- 1.73. “[*]” means [*] or any of its Affiliates.
- 1.74. “*Joint Management Committee*” or “*JMC*” means the executive committee established pursuant to Article 3 (Collaboration Scope and Governance).
- 1.75. “*Joint Patents*” means any invention, patent or patent application jointly owned by the Parties pursuant to Section 10.1 (Ownership and Cooperation).
- 1.76. “*Joint Project Team*” or “*JPT*” has the meaning set forth in Section 3.2.5 (Joint Project Teams).
- 1.77. “*Joint Steering Committee*” or “*JSC*” means the steering committee established pursuant to Article 3 (Collaboration Scope and Governance).
- 1.78. “*Law*” means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.
- 1.79. “*Licensed Amgen Know-How*” means, with respect to a given Licensed Product, Information Controlled by Amgen or its Affiliates, as of the Effective Date or thereafter during the Term, that is [*] for Novartis to use, research, Develop, conduct Medical Affairs Activities with respect to or Commercialize such Licensed Product in the Field in the Territory. Licensed Amgen Know-How shall include Amgen Development Data that is [*] for Novartis to use, research, Develop, conduct Medical Affairs Activities with respect to or Commercialize such Licensed Product in the Field in the Territory.
- 1.80. “*Licensed Amgen Patents*” means, with respect to a given Licensed Product, those patents and patent applications set forth on the Licensed Amgen Patents 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 Territory Controlled by Amgen or its Affiliates on or after the Effective Date (including an interest in a patent or Joint Patent pursuant to Section 10.1 (Ownership and Cooperation))

that (i) would (absent the licenses granted herein) be infringed by the use, research, Development or Commercialization of, or the conduct of Medical Affairs Activities with respect to, such Licensed Product in the Field in the Territory or (ii) would be [*] for the use, research, Development or Commercialization of, or the conduct of Medical Affairs Activities with respect to, such Licensed Product in the Field in the Territory. 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.

- 1.81. *“Licensed Amgen Patent Schedule”* means the schedule of Licensed Amgen Patents attached hereto, which may be updated by Amgen from time to time upon reasonable notice to Novartis.
- 1.82. *“Licensed Amgen Trademarks”* means, with respect to a given Licensed Product, any Trademark rights Controlled by Amgen or its Affiliates in the Territory on or after the Effective Date and corresponding to any Trademarks adopted by Amgen for use with such Licensed Product in the Field outside the 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 Territory).
- 1.83. *“Licensed Novartis Know-How”* means, with respect to a given Licensed Product, Information Controlled, as of the Effective Date or thereafter during the Term, by Novartis or its Affiliates that is a Novartis Improvement or is [*] for Amgen to use, research, conduct Medical Affairs Activities with respect to, Develop, Commercialize or Manufacture such Licensed Product within or outside the Territory in the Field. Licensed Novartis Know-How shall include Novartis Development Data other than Novartis [*] Data that is [*] for Amgen to use, research, Develop, conduct Medical Affairs Activities with respect to, Commercialize or Manufacture such Licensed Product within or outside the Territory in the Field.
- 1.84. *“Licensed Novartis Patents”* means, with respect to a given Licensed Product, those Patents Controlled on or after the Effective Date by Novartis or its Affiliates (including an interest in a patent or Joint Patent pursuant to Section 10.1 (Ownership)) that Cover such Licensed Product or Novartis Improvement and (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, such Licensed Product within or outside the Territory in the Field or (ii) would be [*] for the use, research, Development, Commercialization or Manufacture of, or the conduct of Medical Affairs Activities with respect to, such Licensed Product within or outside the Territory 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.
- 1.85. *“Licensed Novartis Trademarks”* means, with respect to a given Licensed Product, any Trademarks Controlled and adopted by Novartis or its Affiliates on or after the Effective Date for use with such Licensed Product in the Field in the Territory (not including any Housemarks).

- 1.86. “*Licensed Product*” means (i) Franchise Product 1, (ii) Franchise Product 2, and (iii) from and after the Option Exercise Date only, Franchise Product 3.
- 1.87. “*Liens*” means, with respect to any property or asset, any mortgage, pledge, security interest, license or similar encumbrances (including any conditional sale or option).
- 1.88. “*Lifecycle Management*” means strategies and activities intended to optimize the full value of a drug product through its Development and Commercialization lifecycle.
- 1.89. “*Losses*” has the meaning set forth in Section 14.1 (Indemnity).
- 1.90. “*MAA*” means (i) in the United States, a BLA, and (ii) outside the United States, an application for the authorization to market a Licensed Product in any country or group of countries outside the United States, as defined in the applicable laws and regulations and filed with the Governmental Authority of such country or group of countries.
- 1.91. “*Manufacturing*” or “*Manufacture*” means any and all processes and activities directed to producing, manufacturing, processing, sourcing of materials, filling, finishing, packaging, labeling, inspecting, quality assurance testing and release, receiving, holding, shipping and/or storage of a Licensed Product or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing, including process and cost optimization, process qualification and validation, commercial manufacture, stability and release testing, and quality control.
- 1.92. “*Material Anti-Corruption Law Violation*” means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which would if [*] have a material adverse effect on [*].
- 1.93. “*Material Safety Issue*” means a Party’s good faith belief that [*] based upon (i) pre-clinical safety data [*] or (ii) [*].
- 1.94. “*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 research regarding, a Licensed Product, as established by the applicable Party’s internal policies and procedures, 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 publications in support of an approved indication for a Licensed 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.
- 1.95. “*Medical Journal*” has the meaning set forth in Section 11.6.2.
- 1.96. “*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 physicians regarding medical issues associated with a Licensed Product, and are not sales representatives or otherwise engaged in direct selling or promotion of such Licensed Product.
- 1.97. “*Net Sales*” means with respect to a given period and a given Licensed Product, the gross invoiced sales for such Licensed Product sold by or on behalf of Novartis or any of its

Affiliates or sublicensees hereunder to Third Parties other than sublicensees in bona fide, arms-length transactions, less the following charges or expenses recorded on an accrual basis, as determined in accordance with Novartis'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) following such deductions in (i) through (vii) above, less a deduction of [*] percent ([*]%) for direct expenses related to the sales of the Licensed 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 Novartis and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales; (b) if a Licensed 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 Novartis's Accounting Standards are met; and (c) in the event that the Licensed Product is sold in a given country together with one or more other therapeutically active ingredients or therapies not constituting a Licensed Product for a single price (regardless of their packaging) (a "*Combination Product*"), such Licensed Product shall be deemed to be sold in such country for an amount equal to the product of (i) the price at which the Combination Product was sold in such country and (ii) the fraction $A/(A+B)$, where A is the weighted (by sales volume) average sale price in such country during the applicable reporting period of the Licensed Product when sold alone, and B is the weighted average sale price (by sales volume) in such country 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 Licensed Product or other therapeutically active ingredients or therapies than those that are included in the Combination Product, then Novartis 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 Licensed 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 Licensed Product at no charge for, or use of such Licensed Product without charge in, clinical or preclinical trials shall not be included in Net Sales.

- 1.98. "Novartis" has the meaning set forth in the Preamble.
- 1.99. "Novartis Assumed Item" has the meaning set forth in Section 10.2.1.2 (Novartis Secondary Prosecution).
- 1.100. "Novartis Development Costs" means the Development Costs incurred by Novartis and its Affiliates.
- 1.101. "Novartis Development Data" means, with respect to a given Licensed Product, the preclinical and clinical data generated by or on behalf of Novartis or its Affiliates in the course of its preclinical (if any) and clinical Development of such Licensed Product, on or after the Effective Date of this Agreement, other than Novartis [*] Data. All preclinical and clinical data generated pursuant to this Agreement by or on behalf of Novartis and its Affiliates to obtain, maintain and expand the Regulatory Approval for such Licensed Product in the Territory in accordance with the Development Plan shall be deemed Novartis Development Data.
- 1.102. "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 Licensed Novartis Trademarks, Licensed Amgen 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.
- 1.103. "Novartis Improvement" means, with respect to a given Licensed Product, any improvement, modification, enhancement or novel use of such Licensed Product that either Covers or specifically relates to such Licensed Product and is Developed by or on behalf of, or Controlled by, Novartis or its Affiliates during the Term.
- 1.104. "Novartis Indemnitees" has the meaning set forth in Section 14.1 (Indemnity).
- 1.105. "Novartis Key Markets" means [*].
- 1.106. "Novartis [*] Data" means, with respect to a given Licensed Product, the preclinical and clinical data generated by or on behalf of Novartis or its Affiliates in the course of its preclinical (if any) and clinical Development of such Licensed Product on or after the Effective Date of this Agreement, which Development is [*] and which [*].
- 1.107. "Option" has the meaning set forth in Section 2.1 (Option for Franchise Product 3).
- 1.108. "Option Data Package 1" means (i) the Franchise Product 3 [*] Data Package; (ii) the then-current draft of the IND to be filed with FDA or EMA for Franchise Product 3 that includes the [*]; (iii) the then-current plan and budget for Development for Franchise Product 3; and (iv) the status of the prosecution of all Licensed Amgen Patents with respect to Franchise Product 3.

- 1.109. “*Option Data Package 2*” means (i) the Franchise Product 3 Study Readout; (ii) the Franchise Product 2 Study Readout; (iii) the then-current plan and budget for Development for Franchise Product 3; and (iv) the status of the prosecution of all Licensed Amgen Patents with respect to Franchise Product 3.
- 1.110. “*Option Exercise Date*” means the date on which Novartis has delivered to Amgen an Option Exercise Notice in accordance with Section 2.1 (Option for Franchise Product 3).
- 1.111. “*Option Exercise Notice*” has the meaning set forth in Section 2.1 (Option for Franchise Product 3).
- 1.112. “*Option Period*” means the period beginning on the date that Amgen provides Option Data Package 1 to Novartis, and expiring upon the expiration of Option Period 2.
- 1.113. “*Option Period 1*” means the period beginning on the date that Amgen provides Option Data Package 1 to Novartis, and expiring upon the earliest of (i) [*] days after [*] for Franchise Product 3, (ii) the Option Exercise Date and (iii) termination of this Agreement.
- 1.114. “*Option Period 2*” means the period beginning on the date that Amgen provides Option Data Package 2 to Novartis, and expiring upon the earliest of (i) [*] days after delivery of Option Data Package 2, (ii) the Option Exercise Date and (iii) termination of this Agreement.
- 1.115. “*Other Development Expenses*” means any other expenses incurred for clinical materials, analytical services or other items to the extent in the Development Plan and Development Budget.
- 1.116. “*Other Development Plan Opt-In Right*” has the meaning set forth in Section 5.2.2 (Development Outside the Current Development Plan).
- 1.117. “*Out-of-Pocket Development Expenses*” means direct expenses paid or payable to Third Parties which are specifically identifiable and incurred by a Party and its Affiliates for the Development of Licensed Product(s), including the expenses set forth on the Out-of-Pocket Development Expenses Schedule; *provided* that such expenses shall have been recorded as income statement items in accordance with such Party’s Accounting Standards and shall not include any pre-paid amounts, capital expenditures, or items intended to be covered by the FTE Rate.
- 1.118. “*Patent*” means any of the following, whether existing now or in the future, anywhere in the world: (i) any patents and patent applications (including provisional applications); (ii) any patent applications filed either from such patents or patent applications (including provisional applications) or from an application claiming priority from either of these, including continuations, continuations-in-part, divisionals, converted provisionals, continued prosecution applications, and substitute applications; (iii) any patents issued based on or claiming priority to any such patent applications in (i) and (ii); (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in (i), (ii) and (iii); and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent

or registration patent or patents of addition to any of such foregoing patents or patent applications.

- 1.119. “Party” or “Parties” has the meaning set forth in the Preamble.
- 1.120. “Patent and Trademark Matters” has the meaning set forth in Section 10.2.1.1 (Amgen Primary Prosecution).
- 1.121. “Pediatric Investigational Plan” means a required plan for the investigation of the drug/biologic compound in the pediatric population submitted to and approved by the EMA.
- 1.122. “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 U.S. Securities Exchange Act of 1934, as amended, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.
- 1.123. “Phase 1 Clinical Trial” means, with respect to the United States, a clinical trial of a product that meets the definition of a Phase 1 study as described under 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent clinical trial.
- 1.124. “Phase 2 Clinical Trial” means a Phase 2a Clinical Trial or a Phase 2b Clinical Trial.
- 1.125. “Phase 2a Clinical Trial” means, with respect to the United States, a clinical trial of a product that utilizes the pharmacokinetic and pharmacodynamic information obtained from one or more previously conducted Phase 1 Clinical Trial(s) and/or other Phase 2a Clinical Trial(s) in order to confirm the optimal manner of use of such product (dose and dose regimens) and to further evaluate safety and efficacy, as described under 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the United States, an equivalent clinical trial.
- 1.126. “Phase 2b Clinical Trial” means, with respect to the United States, a clinical trial of a product, designed to support and precede the Initiation of a Phase 3 Clinical Trial program, on sufficient numbers of patients that is designed to provide a preliminary determination of safety and efficacy of such product in the target patient population over a range of doses and dose regimens, as described under 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the United States, an equivalent clinical trial.
- 1.127. “Phase 3 Clinical Trial” means, with respect to the United States, a clinical trial of a product on sufficient numbers of patients that is designed to establish that such product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such product in the dosage range to be prescribed, and to support Regulatory Approval of such product or label expansion of such Licensed Product, as described under 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical trial. In the event that a human clinical trial that would otherwise meet the definition of a Phase 2 Clinical Trial would, if the defined end-points are met, be sufficient to obtain Regulatory Approval in the indication being studied then, for the purposes of this Agreement, such trial shall be considered a Phase 3 Clinical Trial.
- 1.128. “Phase 3b Clinical Trial” means, with respect to a Licensed Product for a given indication in a given country or jurisdiction, a clinical trial of such Licensed Product for such indication Initiated after submission of the MAA to the applicable Governmental Authority for the sale

of such product for such indication in such country or jurisdiction, but prior to receipt of Regulatory Approval for the sale of such product for such indication in such country or jurisdiction.

- 1.129. “*Phase 4 Clinical Trial*” means, with respect to a Licensed Product for a given indication in a given country or jurisdiction, a clinical trial of such Licensed Product for such indication Initiated after receipt of Regulatory Approval for the sale of such product for such indication in such country or jurisdiction. Phase 4 Clinical Trials may include epidemiological studies, modeling and pharmacoeconomic studies, and post-marketing surveillance studies, as well as any clinical study or research study sponsored and conducted by an individual not employed by or on behalf of either Party.
- 1.130. “*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).
- 1.131. “*Prior Agreement*” has the meaning set forth in Section 11.5 (Prior Agreement).
- 1.132. “*Quality Agreement*” has the meaning set forth in Section 8.3 (Quality Agreement).
- 1.133. “*RACI Documents*” means, with respect to a given Licensed Product, the document jointly developed and agreed in writing by the Parties on the Effective Date setting forth certain operational responsibilities of each Party with respect to Development, Manufacturing, Commercialization, Medical Affairs Activities and other Product-related activities.
- 1.134. “*Recall*” means a recall, market suspension or market withdrawal of a Licensed Product or any lots thereof.
- 1.135. “*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 Amgen Patent, Licensed Amgen Trademark, Licensed Amgen Know-How or Joint Patent, each of the foregoing with respect to any Licensed Product in the Field in the Territory.
- 1.136. “*Regulatory Approval*” means, with respect to a given Licensed Product, the product-specific approvals, licenses, permits, certifications, registrations or authorizations from Governmental Authorities necessary under applicable Law for the commercial distribution, Manufacture, marketing and sale of such Licensed Product in a country or some or all of an extra-national territory.
- 1.137. “*Regulatory Filing*” means, with respect to a given Licensed Product, any filing with any Governmental Authority with respect to the Development or Commercialization of such Licensed Product.
- 1.138. “*Royalty Term*” means, with respect to a given Licensed Product, on a country-by-country basis, that period from the First Commercial Sale of such Licensed Product following Regulatory Approval in such country until the later of: (i) the [*] anniversary of such First Commercial Sale; and (ii) the expiration of the last to expire Valid Claim of a Licensed Amgen Patent which, but for the licenses granted under this Agreement, would be infringed

by the Development, registration, Manufacture, use, Commercialization, sale, offer for sale or importation of such Licensed Product in such country.

- 1.139. “[*]” means, collectively, [*].
- 1.140. “*Scientific Meeting*” has the meaning set forth in Section 11.6.1.
- 1.141. “*Scientific Paper*” has the meaning set forth in Section 11.6.2.
- 1.142. “*Segregate*” means, with respect to two (2) programs: (i) to restrict and prevent all program-related contacts and communications between personnel (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Territory (for purposes of this Section 1.142, and Section 7.3 (Post-Effective Date Affiliates) and Section 7.4 ([*] Divestiture), “*Personnel*”)) working on or involved with the development or commercialization of the first program and Personnel working on or involved with the development or commercialization of the second program; (ii) to ensure that Personnel that are working on the first program will not simultaneously work on the second program and vice versa; (iii) to ensure that confidential information relating to the first program is not shared with or accessed by Personnel that are working on the second program and vice versa; and (iv) from time to time, upon the reasonable request of the other Party, to provide information requested relating to the foregoing items (i) through (iii), and to reasonably cooperate to enable the other Party to verify that such restrictions are in place and sufficient to achieve the foregoing. For clarity, the foregoing restrictions will not prevent employees or consultants of each Party or its Affiliates that are at or above the senior vice president level (or the equivalent) from providing high-level oversight of both Collaboration and non-Collaboration programs, *provided* that such employees do not have day-to-day responsibilities for either program and that such Party ensures that such employees understand and comply with their obligations of confidentiality and non-use as set forth herein.
- 1.143. “*Senior Officers*” means (i) for Development matters, the [*] for Novartis and the [*] for Amgen (ii) for Medical Affairs Activities matters, the [*] for Novartis and the [*] for Amgen; and (iii) for Commercialization matters, the [*] for Novartis and the [*] for Amgen.
- 1.144. “*SPC*” means any patent term extension or related extension of rights, including supplementary protection certificates and similar rights.
- 1.145. “*Specified Studies*” means, with respect to a Licensed Product, (i) all clinical trials currently underway in the Territory for such Licensed Product in the applicable Development Plan and (ii) all clinical trials in the applicable Development Plan to be Initiated after the Effective Date which are global in nature, including Phase 3b Clinical Trials.

- 1.146. “*Study Budget*” means, with respect to a Study Plan, the aggregate budget of Development Costs to conduct and complete the study contemplated by such Study Plan, which shall specify the apportionment by Calendar Year.
- 1.147. “*Study Plan*” means, with respect to a given Licensed Product, the plan for any study agreed by the Parties to be included in the Development Plan for such Licensed Product pursuant to Section 5.2.2 (Development Outside the Current Development Plan) or Section 5.3 (Development Outside the Territory).
- 1.148. “*Supply Agreement*” has the meaning set forth in Section 8.2 (Supply).
- 1.149. “*Taxes*” means any tax, excise or duty, other than taxes upon income.
- 1.150. “*Term*” means the period beginning on the Effective Date and ending upon the termination of this Agreement pursuant to Section 7.3 (Termination or Divestiture) or Article 15 (Term and Termination).
- 1.151. “*Territory*” means the entire world, excluding the United States, Canada and Japan.
- 1.152. “*Territory Brand Plan*” means, with respect to a given Licensed Product, the cross-functional Commercialization plan, including the go-to-market plan, as updated from time to time, for such Licensed Product in the Territory in accordance with the Global Brand Plan and approved by the JSC.
- 1.153. “*Territory Patents and Trademarks*” has the meaning set forth in Section 10.2.1.1 (Amgen Primary Prosecution).
- 1.154. “*Third Party*” means any entity other than a Party or an Affiliate of a Party.
- 1.155. “*Toxicology Report*” means the final toxicology report, audited by the [*], for Franchise Product 3.
- 1.156. “*Trademark*” means any and all trademarks of every kind and nature, however designated, whether arising by operation of law, contract, license or otherwise, whether or not registered or unregistered, including product names, trade names, service marks, logos, program names, taglines, slogans, trade dress, and any other indicia of origin, including all related rights thereto such as copyrights and design rights (including design patent rights) in pictures, logos, icons, drawings and the like, and any similar and analogous rights anywhere worldwide (excluding Housemarks).
- 1.157. “*Transition Period*” has the meaning set forth in Section 15.5 (Transition Period).
- 1.158. “*United States*” or “*U.S.*” means the United States of America, including its territories and possessions (including the District of Columbia and Puerto Rico).
- 1.159. “*Valid Claim*” means a claim of an issued and unexpired patent, which claim has not been revoked or held invalid or unenforceable by a court or other government agency of competent jurisdiction or has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise.
- 1.160. “*VAT*” means any value added tax.

2. **OPTION**

- 2.1. Option for Franchise Product 3. Novartis shall have [*] right, exercisable during the Option Period, to obtain the [*] licenses set forth in Section 4.1 (Licensed Amgen Patents and Know-How) and Section 4.5 (Trademarks), in each case with respect to Franchise Product 3 (the “*Option*”). Novartis may exercise the Option at any time during the Option Period by so notifying Amgen in writing (the “*Option Exercise Notice*”) prior to the expiration of the Option Period. In connection with the foregoing, as soon as reasonably practicable after the Effective Date, the Parties shall discuss the plan and budget for Development, in each case for Franchise Product 3, pursuant to Section 2.3 (Development Prior to Option Exercise Date). Amgen shall, [*], prepare and deliver to Novartis Option Data Package 1 (and thereafter during Option Period 1, [*] in Option Data Package 1, [*]). In the event that Option Period 1 expires without Novartis having exercised the Option in accordance with this Section 2.1 (Option for Franchise Product 3), Amgen shall, promptly (but in any event within [*] days) after [*], prepare and deliver to Novartis Option Data Package 2 (and thereafter during Option Period 2, [*] in Option Data Package 2, [*]). For purposes of clarity, (i) prior to the Option Exercise Date, Franchise Product 3 shall not be a “Licensed Product” hereunder and (ii) from and after the Option Exercise Date, Franchise Product 3 shall be included as a “Licensed Product” hereunder. Notwithstanding anything to the contrary herein, prior to the Option Exercise Date and, if the Option Period expires without Novartis having exercised the Option in accordance with this Section 2.1 (Option for Franchise Product 3), from and after such expiration of the Option Period, Novartis hereby covenants not to sue or assert any claim or liability against Amgen or its Affiliates or sublicensees under any Licensed Amgen Patent with respect to the Manufacture, Development or Commercialization of, or conduct of Medical Affairs Activities with respect to, Franchise Product 3 in or for the Territory. Promptly following the Option Exercise Date, Amgen shall update the Licensed Amgen Patent Schedule to include any Patents Controlled by Amgen or its Affiliates in the Territory relating to Franchise Product 3. In furtherance of the foregoing, Amgen hereby covenants and agrees that it shall not grant any licenses or rights (including, without limitation, any Development, Medical Affairs Activities or Commercialization rights) to any Third Party with respect to Franchise Product 3 during the Option Period.
- 2.2. Effect of Option Period Expiration. If the Option Period expires without Novartis having exercised the Option in accordance with Section 2.1 (Option for Franchise Product 3), then, effective immediately and automatically upon such expiration of the Option Period, and without any further action on the part of either Party, (i) the Option shall terminate and be of no further force or effect, (ii) the licenses granted in Article 4 (Grant of License) shall be deemed null and void ab initio with respect to Franchise Product 3; (iii) Amgen shall have no further obligation to Novartis with respect to Franchise Product 3 and Novartis shall have no further obligation to Amgen with respect to Franchise Product 3; and (iv) this Agreement shall terminate in accordance with Section 15.2.1 (Termination with Respect to Franchise Product 3 if Option not Exercised during Option Period) with respect to Franchise Product 3.
- 2.3. Development Prior to Option Exercise Date. Prior to the Option Exercise Date, subject to Section 7.3 (Post-Effective Date Affiliates), [*] for Development of Franchise Product 3 and the Parties shall meet [*] in person, via teleconference or videoconference or otherwise,

or as otherwise agreed by the Parties, to discuss Development of Franchise Product 3 globally and to develop an initial plan and budget for Development for Franchise Product 3. Any in-person meetings shall be held on an alternating basis between Novartis's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. Amgen shall consider [*] expressed by Novartis with respect to such Development, [*].

3. COLLABORATION SCOPE AND GOVERNANCE

3.1. Conduct of the Collaboration. The Parties shall cooperate to Develop the Licensed Products worldwide, conduct Medical Affairs Activities with respect to Licensed Products in the Field in the Territory, and Commercialize the Licensed Products in the Field in the Territory, in each case in accordance with the terms and conditions of this Agreement (the "Collaboration").

3.2. Committees and Teams.

3.2.1. Promptly but not later than sixty (60) days following the Effective Date, the Parties shall establish a cross-functional joint management committee (the "Joint Management Committee" or "JMC") to review the overall strategy of the Collaboration and, as needed, attempt to resolve issues presented to it by, and disputes within, the Joint Steering Committee, in accordance with Section 3.5 (Decision Making).

3.2.2. Promptly but not later than sixty (60) days following the Effective Date, the Parties shall establish a cross-functional joint steering committee (the "Joint Steering Committee" or "JSC") to upon such formation, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, (i) review strategies for Manufacture of such Licensed Product for and in the Territory and review and approve plans and strategies for, and the conduct and progress of, activities by each Party relating to the Development worldwide and Medical Affairs Activities and Commercialization in the Territory of such Licensed Product, including the applicable Development Plan, Global Brand Plan and Territory Brand Plan, (ii) monitor the Parties' activities under this Agreement pursuant to the applicable Development Plan, Territory Brand Plan and Global Brand Plan, (iii) review and annually approve the applicable Development Budget no later than [*] of each Calendar Year, (iv) direct and oversee any JPT established by the JSC, on all significant issues that fall within the responsibilities of such JPTs, (v) attempt to resolve issues presented to it by, and disputes within, the JPTs, in accordance with Section 3.5 (Decision Making), (vi) review and approve the RACI Documents and any updates thereto, as needed, and (vii) make such determinations as are expressly delegated to it under the terms of this Agreement. In accordance with Section 3.4.1, each Party shall keep the Joint Steering Committee informed of the progress and results of its activities under the Development Plan, Territory Brand Plan, Global Brand Plan and RACI Documents through its members on the Joint Steering Committee and as otherwise provided herein. Amgen shall

prepare the first draft of each Global Brand Plan, and Novartis shall prepare the first draft of each Territory Brand Plan, in each case for presentation to the JPT.

- 3.2.3. Each of the Joint Steering Committee and the Joint Management Committee (each, a “Committee”) will have solely the roles and responsibilities assigned to it in this Article 3 (Collaboration Scope and Governance) and as otherwise expressly set forth in this Agreement. Neither the Committees nor a Party exercising its final decision making pursuant to Section 3.5 (Decision Making) will have authority to amend, modify or waive compliance with this Agreement, to make decisions that conflict with the terms and conditions of this Agreement, or to create new financial or other obligations for a Party not specified in this Agreement.
- 3.2.4. Each Committee shall be comprised of an equal number of representatives from each of Amgen and Novartis. The number of such representatives shall be, with respect to the JSC, up to [*] for each of Amgen and Novartis, and with respect to the JMC, up to [*] for each of Amgen and Novartis, or for each Committee such other number as the Parties may agree in writing. The JSC and JMC shall be composed of members of relevant functional specialties and expertise. The members of each Committee shall have the appropriate level of seniority, decision-making authority and expertise commensurate with the responsibilities of the Committee to which they are appointed. The Alliance Managers appointed by Amgen and Novartis pursuant to Section 3.7 (Alliance Managers) are ex officio members of the JSC and JMC. Either Party may replace its respective committee representatives at any time upon prior written notice to the other Party. In the event a Committee member from either Party is unable to attend or participate in a Committee meeting, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion, the identity of whom shall be communicated in advance to the other Party, in which case no specific notice shall be required. In the event both the Committee member and its substitute representative are unable to attend or participate in a Committee meeting, the Party who designated such representatives may designate an *ad hoc* representative for the meeting in its sole discretion, with prior notice to the relevant Committee.
- 3.2.5. Joint Project Teams. From time to time, the Joint Steering Committee or the Parties may establish permanent or *ad hoc* cross-functional or function-specific joint project teams to oversee particular projects or activities, including Development, Manufacturing, Medical Affairs Activities and Commercialization, within the scope of the JSC’s authority hereunder, and such joint project teams will be constituted as the Joint Steering Committee 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 Joint Steering Committee for resolution as provided in Section 3.5 (Decision Making).
- 3.3. Committee Co-Chairs. Each Party shall appoint one of its members in each Committee to co-chair such Committee’s meetings (each, a “Co-Chair”). The Co-Chairs shall (i) ensure the orderly conduct of the Committee’s meetings, (ii) attend each Committee meeting (either in-person, by videoconference or telephonically), and (iii) ensure the preparation and

issuance of written minutes of each meeting within [*] days thereafter accurately reflecting the discussions and decisions of such meeting. Unless otherwise agreed, the Committee shall have at least one (1) representative with relevant decision-making authority from each Party such that the Committee is able to effectuate all of its decisions within the scope of its responsibilities. In the event the Co-Chair from either Party is unable to attend or participate in a Committee meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for the meeting in its sole discretion.

3.4. Committee Meetings.

3.4.1. The Joint Steering Committee shall meet [*], or more or less often as otherwise agreed by the Parties, but in no event less than [*] and such meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairs. As appropriate, and provided that not less than two (2) Business Days' prior written notice has been given to the other Party, other employees of the Parties may attend Joint Steering Committee meetings as observers, but a Party shall not bring a Third Party to a meeting without the other Party's prior consent. Either Party may also call for special meetings of the Joint Steering Committee (in person, by videoconference or teleconference) with reasonable prior written notice (it being agreed that at least [*] Business Days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making responsibility of the Joint Steering Committee. Each Co-Chair shall ensure that its Joint Steering Committee members receive adequate notice of such meetings.

3.4.2. The Joint Management Committee shall meet [*], or more or less often as otherwise agreed by the Parties, and such meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairs. As appropriate, provided that not less than two (2) Business Days' prior written notice has been given to the other Party, and subject to such other Party's approval (not to be unreasonably withheld, conditioned or delayed), other employees of the Parties may attend Joint Management Committee meetings as observers. Either Party may also call a special meeting of a Joint Management Committee (in person, by videoconference or teleconference) by at least [*] Business Days' prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the Joint Management Committee no later than [*] Business Days prior to the special meeting with materials reasonably adequate to enable an informed decision.

3.5. 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. If a dispute arises on a Critical Matter which

cannot be resolved within the Joint Steering Committee, the Co-Chair of either Party may cause such dispute to be referred to the Joint Management Committee for resolution; *provided* that if, in the good faith determination of the Co-Chair with the deciding vote at the JMC, resolution of such matter requires [*] pursuant to applicable Law or to prevent a material adverse effect on a Licensed Product or a Party, such Co-Chair will have the right to make an interim decision pending JMC determination. Within the Joint Steering Committee (for non-Critical Matters) and the Joint Management Committee (for Critical Matters):

3.5.1. *Development:*

3.5.1.1. Prior to [*], the Amgen Co-Chair shall have the deciding vote on all Development and Medical Affairs Activities matters for all Licensed Products whether within or outside the Territory.

3.5.1.2. Following [*], (i) the Amgen Co-Chair shall have the deciding vote on all Development and Medical Affairs Activities matters for all Licensed Products outside the Territory and (ii) the Novartis Co-Chair shall have the deciding vote on all Development and Medical Affairs Activities matters for all Licensed Products in the Territory unless, in either case, (a) [*] with respect to, any Licensed Product [*] or (b) [*] with respect to, any Licensed Product [*], in which case ((a) and (b)), [*].

3.5.2. *Regulatory:* The Amgen Co-Chair shall have the deciding vote on all regulatory matters for all Licensed Products outside the Territory and the Novartis Co-Chair shall have the deciding vote on all regulatory matters for all Licensed Products in the Territory unless, in either case, (a) [*] any Licensed Product [*] or (b) [*] any Licensed Product [*], in which case ((a) and (b)), [*].

3.5.3. *Commercialization.*

3.5.3.1. The Amgen Co-Chair shall have the deciding vote with respect to the Global Brand Plans and all Commercialization matters with respect to the Licensed Products outside the Territory.

3.5.3.2. The Novartis Co-Chair shall have the deciding vote with respect to the Territory Brand Plans and all Commercialization matters with respect to the Licensed Products within the Territory; *provided* that such activities must be consistent with the applicable Territory Brand Plan, and [*] must [*].

3.5.4. *Escalation of Critical Matters.* If either Party believes its comments as to any Critical Matter are not being given adequate consideration at the JMC, then such Party may request that such matter be reviewed and discussed by a Senior Officer of each Party who is not a JMC member prior to final decision by the JMC. Escalation of a matter to such Senior Officers shall suspend implementation of any decision of the JMC on such matter until completion of such escalation process or earlier resolution of the matter by the JMC; *provided* that if, in the good faith determination of the Co-Chair with the deciding vote at the JMC, resolution of such matter requires [*] pursuant to applicable Law or to prevent a material adverse effect on a Licensed

Product or a Party, such Co-Chair will have the right to make an interim decision pending JMC determination.

- 3.6. Interactions Between the Joint Management Committee, the Joint Steering Committee, and Joint Project Teams. The Parties recognize that while they will establish the Joint Management Committee, the Joint Steering Committee and Joint Project 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 Joint Management Committee, the Joint Steering Committee and Joint Project 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.
- 3.7. Alliance Managers. Promptly but not later than sixty (60) days following the Effective Date, each of Amgen and Novartis shall appoint one or more senior representatives who possess a general understanding of Development, regulatory, Medical Affairs Activities, Manufacturing and Commercialization matters to act as its respective alliance manager(s) for the 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 Committees. Consistent with the Development Plan, the Territory Brand Plan and Section 3.5 (Decision Making), each Alliance Manager, on behalf of the applicable Party's Co-Chair of the applicable Committee, will also be responsible for:
- 3.7.1. providing a single point of communication for seeking consensus both within the respective Party's organization and together regarding key strategy and plan issues;
 - 3.7.2. identifying and raising disputes to the JSC or JMC for discussion in a timely manner; and
 - 3.7.3. planning and coordinating internal and external communications in accordance with the terms of this Agreement.
- The Alliance Managers shall be entitled to attend all JSC and JMC meetings, and shall have the right to attend all JPT meetings. Consistent with Section 3.5 (Decision Making), each Alliance Manager may bring any matter to the attention of the JSC or JMC where such Alliance Manager reasonably believes that such matter requires attention of the JSC or JMC.
- 3.8. Outside the Territory. Unless expressly set forth in this Agreement otherwise, Amgen shall have sole decision-making authority with regard to Development, regulatory, Medical Affairs Activities, Manufacturing and Commercialization of Licensed Products outside the Territory. Novartis and its Affiliates shall not Commercialize or conduct Medical Affairs Activities with respect to Licensed Products in any country outside the Territory.

4. GRANT OF LICENSE

- 4.1. Licensed Amgen Patents and Know-How. Amgen hereby grants to Novartis, during the Term, effective as of the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and effective as of the Option Exercise Date, with respect to Franchise Product 3 (without any further action by either Party), subject to the terms and conditions hereof, (i) [*] ([*]), royalty-bearing right and license under the Licensed Amgen Patents, Licensed Amgen Know-How and Amgen's interest in the Joint Patents, solely to use, research, Develop, conduct Medical Affairs Activities with respect to, sell, import and otherwise Commercialize the Licensed Products in the Field in the Territory in accordance with this Agreement; and (ii) [*], royalty-bearing right and license under the Licensed Amgen Patents, Licensed Amgen Know-How and Amgen's interest in the Joint Patents, solely to Develop the Licensed Products outside of the Territory in support of the Development or Commercialization of Licensed Products in the Field in the Territory subject to Section 5.3 (Development Outside the Territory). Such license shall include the right to sublicense only as set forth in Section 4.3 (Sublicensing) and shall be subject to Amgen's right to conduct (itself or through its Affiliates or contractors) Development of Licensed Products in the Territory in accordance with this Agreement.
- 4.2. Licensed Novartis Know-How and Patents. Novartis hereby grants to Amgen, effective as of the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and effective as of the Option Exercise Date, with respect to Franchise Product 3 (without any further action by either Party), subject to the terms and conditions hereof (including Section 15.3.2 (Termination Effects)), [*], fully-paid, royalty-free, perpetual right and license, under the Licensed Novartis Know-How and Licensed Novartis Patents solely to Manufacture, research, Develop, conduct Medical Affairs Activities with respect to, use, sell, import and otherwise Commercialize, the Licensed Products in the Field outside the Territory (and worldwide after termination of this Agreement), and within and outside the Territory for Manufacturing and for performing its obligations hereunder, including any supply obligations with respect to the Licensed Products. Such license shall include the right to sublicense only as set forth in Section 4.3 (Sublicensing).
- 4.3. 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 4.3 (Sublicensing). Novartis shall have the right to sublicense the rights granted it hereunder (i) as mutually agreed by the Parties, (ii) to contractors (e.g., contract research organizations, distributors, wholesalers, contract sales forces) in the Territory provided that Novartis remains primarily responsible for the activities of any such contractors, (iii) in connection with country-specific (i.e., not international or multi-national) co-marketing arrangements and (iv) to country-specific (i.e., not international or multi-national) distributors; *provided* that any sublicense under the foregoing clause (iii) or (iv) shall be subject to Amgen's consent, not to be unreasonably withheld, solely in the event that the marketing authorization for the applicable Licensed Product in the applicable country will be transferred to such sublicensee. Amgen shall have the right to sublicense the rights granted it hereunder (i) as mutually agreed by the Parties and (ii) to those parties to which Amgen (or its Affiliate or licensee) is also granting licenses to Amgen patents or know-how relating to the applicable Licensed Product(s) or the use thereof (other than a global sublicense of all rights to Develop the applicable Licensed Product(s)). 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). Novartis shall provide Amgen a copy of the final executed sublicense agreement, redacted for information not pertinent to this Agreement (including financial terms). 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. 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.

4.4. Provision of Know-How. Following the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and following the Option Exercise Date, with respect to Franchise Product 3, the Parties shall cooperate to establish procedures for the provision of Licensed Amgen Know-How relating to the applicable Licensed Product to Novartis and Licensed Novartis Know-How relating to the applicable Licensed Product to Amgen, in each case to the extent [*] for such Party to exercise its rights and perform its obligations in accordance with this Agreement. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, during the Term, Amgen shall use [*] to provide all Licensed Amgen Know-How related to the applicable Licensed Product to Novartis, and Novartis shall use [*] to provide all Licensed Novartis Know-How related to the applicable Licensed Product to Amgen, in each case to the extent [*] to exercise its rights and perform its obligations in accordance with this Agreement. In any event, following the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and following the Option Exercise Date, with respect to Franchise Product 3, each of the Parties shall provide to the other any Licensed Amgen Know-How or Licensed Novartis Know-How related to the applicable Licensed Product (respectively) as the other Party shall reasonably request; *provided* that a Party shall not be obligated to disclose any Licensed Amgen Know-How or Licensed Novartis Know-How, as the case may be, that is (i) proprietary or trade secret with respect to such Party and (ii) not [*] for the other Party to exercise its rights and perform its obligations in accordance with this Agreement. Unless otherwise agreed by the Parties, information shared under this Section 4.4 (Provision of Know-How) shall be disclosed in the English language.

4.5. Trademarks.

4.5.1. *Grant to Novartis.* Amgen hereby grants to Novartis, effective as of the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and effective as of the Option Exercise Date, with respect to Franchise Product 3 (without any further action by either Party), [*] (except as otherwise expressly set forth herein (such exception to include the transition period described in Section 15.5 (Transition Period))) right and license during the Term, subject to the terms and conditions hereof, solely to research, Develop, conduct Medical Affairs Activities with respect to, use, sell, import and otherwise Commercialize the applicable Licensed Product in the Field in the Territory under the same Licensed Amgen Trademarks as used by Amgen, its Affiliates or permitted licensees or sublicensees for such Licensed

Product in the corresponding indications outside the Territory. In the event that Amgen has identified a Licensed Amgen Trademark to be so used, and is developing plans to so use such Licensed Amgen Trademark, the foregoing license shall permit Novartis to similarly conduct such planning activities in the Territory to the same extent of Amgen's planning activities outside the Territory. Each Party shall provide regular updates to the other Party regarding proposed Licensed Amgen Trademarks and Licensed Novartis Trademarks, as the case may be. Such license shall include the right to sublicense only as set forth in Section 4.3 (Sublicensing). Should Novartis desire that a different trademark be used for a given Licensed Product in the Field in the Territory, or if additional trademarks to those used outside the Territory are otherwise required, Novartis shall be entitled to do so after consulting with Amgen and giving due consideration to Amgen's reasonable comments regarding an additional or replacement trademark (or trademarks). Such replacement or additional trademark(s) shall be registered and owned by Novartis in the Territory. At Amgen's election and with the approval of the applicable Governmental Authority, the labeling, packaging and materials for any Licensed Product supplied by or on behalf of Amgen to Novartis hereunder shall include Amgen Housemarks in equal prominence with Novartis Housemarks, *provided* that Amgen shall inform Novartis sufficiently in advance of making such election.

- 4.6. Trademark and Housemark Quality Standards. Each Party shall (i) maintain such reasonable quality standards for the Amgen Housemarks and Licensed Amgen Trademarks (with respect to Novartis) or the Novartis Housemarks and Licensed Novartis Trademarks (with respect to Amgen) 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); (ii) not use any Amgen Housemark or Licensed Amgen Trademark (with respect to Novartis) or any Novartis Housemark or Licensed Novartis Trademark (with respect to Amgen) in a manner that suggests any connection with any product or service, other than use associated with the applicable Licensed Product or any service associated with such Licensed Product; and (iii) not use or display the Amgen Housemarks or Licensed Amgen Trademarks (with respect to Novartis) or the Novartis Housemarks or Licensed Novartis Trademarks (with respect to Amgen) in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any Amgen Housemark or Licensed Amgen Trademark (with respect to Novartis) or Novartis Housemark or Licensed Novartis Trademark (with respect to Amgen), 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 Amgen Housemarks and Licensed Amgen Trademarks (with respect to Novartis) or Novartis Housemarks and Licensed Novartis Trademarks (with respect to Amgen) used in the marketing or promotion of the applicable Licensed Product in order to review such usage. Amgen agrees that it shall not seek to register or obtain ownership rights in any Novartis Housemark or Licensed Novartis Trademark (or confusingly similar trademark) and Novartis agrees that it shall not seek to register or obtain ownership rights in any Amgen Housemark or Licensed Amgen Trademark

or any trademark used by Amgen in connection with the applicable Licensed Product outside the Territory in any indication (or confusingly similar trademark to any of the foregoing).

- 4.7. Domain Names. Amgen shall be [*] entitled to register, own and use any Domain Names corresponding to or containing Amgen Housemarks or Amgen Licensed Trademarks in any generic Top Level Domains (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. Novartis shall be [*] entitled to register, own and use any Domain Names corresponding to or containing a Licensed Amgen Trademark in any Country Code Top Level Domains (ccTLDs) corresponding to countries within the Territory.
- 4.8. 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. Subject to Section 2.3 (Development Prior to Option Exercise Date), Novartis shall not research, Develop, Manufacture, conduct Medical Affairs Activities with respect to or Commercialize Franchise Product 3 prior to the Option Exercise Date or any Licensed Product outside the Territory and Amgen shall not research, Develop, conduct Medical Affairs Activities with respect to or Commercialize any Licensed Product inside the Territory, in each case, other than as expressly set forth in this Agreement (including under a Development Plan). Notwithstanding the licenses granted in this Article 4 (Grant of License), each Party retains rights to perform (itself or through its Affiliates or contractors) its obligations under this Agreement.

5. **DEVELOPMENT AND REGULATORY**

- 5.1. Responsibility for Development. Except as otherwise set forth in this Section 5.1 (Responsibility for Development), from and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after Option Exercise Date, with respect to Franchise Product 3, the Parties will share responsibility for day-to-day Development activities for each Licensed Product worldwide in accordance with the applicable Development Plan and Development Budget, including generating protocols subject to the JSC's review and approval, conducting clinical trials, and data collection, verification and analysis. Solely with respect to Franchise Product 1 prior to receipt of the first Regulatory Approval therefor in the U.S., (i) Amgen shall be the Development lead and shall have primary responsibility for day-to-day Development activities relating thereto worldwide in accordance with the applicable Development Plan and Development Budget and (ii) Novartis shall provide both strategic input and operational support for such activities as agreed in the applicable Development Plan and Development Budget; *provided* that, notwithstanding the foregoing, Novartis shall have those responsibilities with respect to Franchise Product 1 and Franchise Product 2 as set forth in the RACI Documents, including with respect to [*]. In the event of a conflict between the terms of this Agreement, a Supply Agreement or a Quality Agreement, on the one hand, and the RACI Documents, on the other hand, the terms of this Agreement, such Supply Agreement or such Quality Agreement shall prevail. Additionally, [*] shall be [*] responsible for the development of any Clinical Trials or other activities directed to Lifecycle Management for the Licensed Products as agreed

by the JSC and approved by the JMC. [*] shall be responsible at its expense for determining and providing all Medical Affairs Activities relating to the Licensed Products in the Territory.

5.2. Development Within and Outside Development Plan.

5.2.1. *Development Plan.* From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, the Parties shall conduct Development of Licensed Products in accordance with the Development Plan and Development Budget. The JSC shall review the Development Plan and Development Budget, including the Study Plans and Study Budgets, at least annually and, if agreed, the Parties shall approve revisions to such plans and budgets.

5.2.2. *Development Outside the Current Development Plan.* In the event that either Party or any of its Affiliates or sublicensee(s) desires to conduct a clinical study with respect to Licensed Product(s) not included in the then-current Development Plan, then such Party shall provide written notice to the JSC of the proposed trial design (including the most current protocol draft), study size (estimated number of patients), study site and any identified investigators (including names, qualifications and professional positions), and the purpose of such study. If the other Party so agrees, such study will be included in the Development Plan and the Parties shall agree upon a Study Budget therefor. If the other Party does not wish to include such study in the Development Plan, [*], the Party proposing the study [*]. In any event, [*].

5.2.3. *Non-Clinical Studies.* Either Party may propose to the JSC additional non-clinical studies or other Development-related activities for Licensed Product(s) in the Territory not included in the then-current Development Plan, and the JSC shall consider appropriate participation and cost sharing between the Parties with respect to such activities.

5.3. Development Outside the Territory by Novartis or Inside the Territory by Amgen. In the event that in furtherance of the Development activities for Licensed Product(s) in the Territory (in the case of Novartis) or outside the Territory (in the case of Amgen), a Party or any of its sublicensee(s) believes it needs to conduct clinical studies outside the Territory (in the case of Novartis) or within the Territory to the extent not included in a Development Plan (in the case of Amgen) for such purpose, then such Party shall provide written notice to the JSC of the proposed trial design (including the most current protocol draft), study size (estimated number of patients), study site, investigators (including names, qualifications and professional positions) and the purpose of and need for such study. Such Party shall not conduct such studies outside the Territory (in the case of Novartis) or within the Territory (in the case of Amgen) without the other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed (it being understood that not providing consent shall be deemed reasonable in the event such other Party is in active enrollment for a clinical trial at such study site or if such proposed clinical study would reasonably be expected to adversely impact recruitment for any clinical trial of such other Party). If the other Party grants consent and so agrees, such studies will be included in the Development Plan and the Development Budget. If the other Party does not wish to include such studies in the Development Plan, the proposing Party shall [*].

5.4. Regulatory Matters.

- 5.4.1. *Regulatory Communications and Filings.* Amgen shall be the regulatory lead outside the Territory and shall have responsibility for regulatory activities relating to the Licensed Products outside the Territory, including preparing, submitting and maintaining all Regulatory Filings outside the Territory in accordance with the Development Plan, and Novartis shall provide strategic input for such activities therefor as set forth in the Development Plan. Subject to this Section 5.4.1 (Regulatory Communications and Filings), Novartis shall be the regulatory lead in the Territory and shall have primary responsibility for regulatory activities relating to the Licensed Products in the Territory, including preparing, submitting and maintaining all Regulatory Filings in the Territory in accordance with the Development Plan, and Amgen shall provide strategic input for such activities therefor as set forth in the Development Plan; [*]. Notwithstanding the foregoing or Section 3.5.2 (Regulatory), the Parties shall mutually agree on the timing of the filing strategy for marketing applications for each Licensed Product to be consistent with Amgen's drug Manufacturing plans applicable to Licensed Product to be supplied for the Territory. Unless [*] is required with respect to such Regulatory Filing or a material communication with a Governmental Authority with respect to any Licensed Product, the lead regulatory Party shall provide the other Party with copies of material Regulatory Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) prior to submission within a reasonable amount of time and reasonably consider 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 lead regulatory Party shall consult with the other Party regarding, and keep such 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, Governmental Authority review of any such Regulatory Filings, and all Regulatory Approvals that it obtains with respect to the Licensed Products. The lead regulatory Party shall provide to the other Party copies of all final Regulatory Filings it submits promptly after the submission (but in no event later than [*] days after submission). Through the JPT, the Parties shall agree to the point at which Novartis shall take the lead regulatory role in the Territory for purposes of performing Territory-specific clinical trials and supporting pricing and reimbursement in the Territory, with the intent of not interrupting Amgen's regulatory activities with respect to the Licensed Products, providing Novartis with sufficient lead-time to conduct interactions with Governmental Authorities in connection with any [*] for such Licensed Product in the Territory and to hold pre-MAA meetings with the EMA and file the MAAs for the Licensed Products in the Territory, and to effect a smooth and efficient transfer (which shall occur no later than promptly following [*] in the U.S. for the applicable Licensed Product).
- 5.4.2. *Regulatory Meetings.* The lead regulatory Party shall consult with the other Party reasonably in advance of the date of any anticipated meeting with a Governmental Authority in the Territory and shall consider any timely recommendations made by

such other Party in preparation for such meeting. A representative of Amgen [*] scheduled meetings between Novartis and the applicable Governmental Authority in the Territory with respect to any Licensed Product, to the extent permissible by such Governmental Authority. Novartis shall inform Amgen of any unscheduled teleconferences and meetings (other than teleconferences and meetings that are solely administrative in nature) with Governmental Authorities in the Territory with respect to the Licensed Product reasonably promptly after they occur. A representative of Novartis [*] scheduled meetings between Amgen and the applicable Governmental Authority outside the Territory with respect to any Licensed Product, to the extent permissible by such Governmental Authority. [*]

5.4.3. *Ownership of Regulatory Filings and Regulatory Approvals.* Consistent with the transfer of the lead regulatory role in the Territory described in Section 5.4.1 (Regulatory Communications and Filings), Amgen shall transfer to Novartis all prior Regulatory Filings in the Territory in Amgen's possession with respect to each Licensed Product. Novartis shall not transfer title in, fail to maintain or otherwise attempt in any manner to dispose of any Regulatory Filings or Regulatory Approvals or other governmental licenses, approvals or certificates for the Licensed Products in the Territory without the prior written approval of Amgen.

5.4.1. *Clinical Trial Data. Right of Reference.*

5.4.1.1. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, (i) Novartis shall maintain a database containing all clinical trial data accumulated from all clinical trials of the applicable Licensed Product conducted by, on behalf of, or with the support of Novartis in the Territory or outside the Territory if Amgen agrees ([*]), and (ii) Amgen shall maintain a database containing all clinical trial data accumulated from all clinical trials of the applicable Licensed Product conducted by, on behalf of, or with the support of Amgen outside the Territory or in the Territory ([*]). Each Party shall require that, with respect to any clinical trial conducted pursuant to the Development Plan, study investigators obtain patient authorizations and consents required under the United States Health Insurance Portability and Accountability Act of 1996, the EU Data Protection Directive or any other similar applicable Law in connection with such clinical trial to permit the sharing of clinical data from such clinical trial with the other Party.

5.4.1.2. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after Option Exercise Date, with respect to Franchise Product 3, upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings or Regulatory Approvals for each Licensed Product (*provided* that Novartis shall not grant a right of reference to Novartis [*] Data and any Regulatory Filings or Regulatory Approvals referring to Novartis [*] Data, and Amgen shall not grant a right of reference to Amgen [*] Data and any Regulatory Filings or

Regulatory Approvals referring to Amgen [*] Data), in each case as [*] for the requesting Party's Development, Manufacture (in the case of Amgen only), conduct of Medical Affairs Activities with respect to, or Commercialization of the applicable Licensed Product as permitted hereunder. Each Party shall be entitled to sublicense such right to any permitted licensee pursuant to Section 4.3 (Sublicensing).

5.5. Safety Matters.

5.5.1. *Safety Agreement.* Promptly following the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and promptly following the Option Exercise Date, with respect to Franchise Product 3, Amgen and Novartis shall develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the applicable Licensed Product sufficient to permit each Party, its Affiliates, permitted sublicensees and licensees to comply with Law, including, to the extent applicable, those obligations contained in FDA and EMA regulations. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed written pharmacovigilance agreement between the Parties which shall be entered into within ninety (90) days of the Effective Date (or any other longer period as may be agreed between the Parties).

5.5.2. *Adverse Event Reporting.* From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, each Party shall (i) be responsible for reporting to the relevant Governmental Authorities all adverse events with respect to the Licensed Products (whether within or outside the Territory), to the extent required by and in accordance with Law; (ii) ensure that its Affiliates, permitted sublicensees and licensees, as applicable, comply with all such reporting obligations; and (iii) designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events with respect to the Licensed Products.

5.5.3. *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 each Licensed Product throughout each Licensed Product's lifecycle, including Commercialization. Amgen shall provide to Novartis copies of such DCSI and core data sheet and any updates thereto in a timely manner (such that Novartis has a current version of such files), shall provide Novartis the opportunity to review and provide comments on the core data sheet, and shall reasonably consider such comments of Novartis in good faith. In the event that a Governmental Authority in the Territory mandates a change to a regional or country-specific label for a Licensed Product that varies from the applicable core data sheet, Novartis shall notify Amgen and Amgen shall permit such mandated variance from such core data sheet.

5.6. Cooperation Generally. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to

Franchise Product 3, 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 Development of and Regulatory Approval for the Licensed Products.

6. COMMERCIALIZATION

- 6.1. Operational Control. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, Novartis shall have sole responsibility for Commercialization of the Licensed Products in the Field in the Territory. Such Commercialization shall be conducted in accordance with the then-current Territory Brand Plan consistent with the Global Brand Plan and approved by the JSC. Subject to the foregoing, Novartis's responsibilities from and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, 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 Licensed Products which are intended for distribution to Third Parties (including medical professionals) and to Novartis's sales force (subject to Section 4.6 (Trademark Quality Standards) and Section 6.2 (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. Novartis shall be solely responsible for its costs incurred in its Commercialization of the Licensed Products.
- 6.2. Promotional Materials. Each Party shall only prepare and use promotional materials that are compliant with applicable Law and are consistent with, in respect of Novartis, the Global Brand Plan and the Territory Brand Plan, and in respect of Amgen, the Global Brand Plan. Upon reasonable request, each Party shall provide to the other Party copies of the key promotional materials used by such providing Party in the Territory (in respect of Novartis) or outside the Territory (in respect of Amgen) with respect to Licensed Products.
- 6.3. Commercialization Outside the Territory. Except as expressly set forth in this Agreement, Amgen shall be solely responsible for the Commercialization of the Licensed Products outside the Territory and the costs thereof. Novartis shall have no rights with respect thereto.
- 6.4. Reimportation. To the extent permitted by applicable Law, each Party shall use Commercially Reasonable Efforts to prevent Licensed Products provided to or made for or on behalf of such Party for use or sale inside the Territory with respect to Novartis or outside of the Territory with respect to Amgen from being distributed or sold in the other Party's territory, except where Amgen and Novartis agree that the exporting person or entity is in possession of all regulatory authorizations and intellectual property licenses necessary for

such export, import and sale. Each Party shall notify the other Party if it becomes aware of the exportation of Licensed Products from its territory and discuss with the other Party the same.

6.5. Cooperation Generally. Subject to the oversight of the JSC, the Parties shall cooperate generally with respect to the Commercialization of the Licensed Products in the Field in the Territory.

6.6. [*].[*]

7. **DILIGENCE; ACTIVITIES OUTSIDE THE COLLABORATION**

7.1. Commercially Reasonable Efforts. From and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Franchise Product 3, Novartis shall use Commercially Reasonable Efforts to (i) Develop the Licensed Products in the Field as contemplated under the applicable Development Plan; (ii) conduct Medical Affairs Activities for each Licensed Product in the Field in the Territory as contemplated by this Agreement; and (iii) Commercialize each Licensed Product in the Field in the Territory following the issuance of Regulatory Approval for such Licensed Product in the Field in the Territory; *provided* that the Parties acknowledge that such Commercialization activities shall be subject to the Territory Brand Plan and in accordance with the Global Brand Plan.

7.2. Activities Outside the Collaboration. Except as set forth in Sections 7.3 (Post-Effective Date Affiliates) and 7.4 ([*] Divestiture), during the Term, neither Party shall, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist or enable a Third Party to conduct or participate in, any Distracting Program.

7.3. Post-Effective Date Affiliates. In the event that a Party enters into a Distracting Transaction with a Third Party, then such Party shall provide prompt written notice to the other Party. Until the provisions of Section 7.4 ([*] Divestiture) are effectuated, each Party shall ensure that information and materials relating to the Collaboration are not shared with or used for the benefit of, and are Segregated from, such Distracting Transaction Affiliate(s).

7.4. [*] Divestiture. The notice provided pursuant to Section 7.3 (Post-Effective Date Affiliates) shall include a notification as to whether such Party intends to: (i) Divest the Distracting Program, in which case such Party shall hold separate such Distracting Program (including Segregating such Distracting Program from the Collaboration) and use its commercially reasonable, good-faith efforts to Divest such Distracting Program; (ii) terminate such Distracting Program, in which case such Party shall terminate all activities of such program within [*] days after the closing of the Distracting Transaction, during which period such Party shall hold separate such Distracting Program (including Segregating such Distracting Program from the Collaboration); or (iii) in the case of Amgen only, [*] or, in the case of Novartis, [*], in each case within [*] days after the closing of the Distracting Transaction. In the event such Party selects to Divest the Distracting Program under subsection (i) and fails to complete such Divestiture within [*] of the closing of the Distracting Transaction, then such Party shall be deemed to have chosen to terminate such Distracting Program and

shall promptly, and no later than within [*] days, comply with the requirements of subsection (ii), above.

8. MANUFACTURE AND SUPPLY

- 8.1. Manufacturing Rights. Except in the case of failure to supply as provided in the applicable Supply Agreement, Novartis shall not Manufacture any Licensed Product or obtain any Licensed Product from any entity other than Amgen or its designee.
- 8.2. Supply. Except in the case of failure to supply as may be provided in the applicable Supply Agreement, Novartis shall obtain its requirements of each Licensed Product in [*] for use in clinical Development or for commercial sale solely from Amgen (or Amgen's designee as permitted under the applicable Supply Agreement) at Amgen's cost. Amgen shall have the right to transition [*] to Novartis on a region-by-region basis and subject to a mutually agreed upon (i) notice and transfer period, (ii) transfer plan and (iii) transfer costs. Amgen may consider and grant requests from Novartis to transition [*] to Novartis on a region-by-region basis. Promptly (but in any event, within [*] days) following the Effective Date, the Parties shall negotiate in good faith a supply agreement for commercial supply of Franchise Product 1 in [*] to Novartis for use in the Territory and supply agreements for clinical supply of Franchise Product 1 and Franchise Product 2. Promptly (but in any event, within [*] days) following the Option Exercise Date, the Parties shall negotiate in good faith a supply agreement for clinical supply of Licensed Product 3. Promptly (but in any event, at least [*] prior to anticipated launch of a Licensed Product (other than Franchise Product 1), the Parties shall negotiate in good faith a supply agreement for commercial supply of such Licensed Product. Each of the foregoing supply agreements shall be referred to herein as a "*Supply Agreement*". Each Supply Agreement shall include provisions relating to (i) forecasts and orders, and (ii) representations that the Licensed Product will be Manufactured according to specifications and in accordance with cGMP. The terms for providing clinical and commercial supply for Franchise Product 1 shall be materially consistent with the Clinical Supply Schedule and the Commercial Supply Schedule, respectively. The terms for providing clinical and commercial supply for Franchise Product 2 and Franchise Product 3, if applicable, shall be substantially similar to the terms of the Clinical Supply Schedule and the Commercial Supply Schedule, respectively, except for example with respect to the actual amount of the manufacturing cost cap.
- 8.3. Quality Agreement. Promptly (but in any event, within [*] days) following the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and promptly (but in any event, within [*] days) following the Option Exercise Date, with respect to Franchise Product 3, Amgen and Novartis shall develop and agree upon a quality agreement governing the quality and specifications of clinical and commercial Licensed Products to be supplied hereunder (each, a "*Quality Agreement*"). Each Quality Agreement shall include provisions relating to (i) the handling of Recalls and product complaints relating to such Licensed Product in the Territory, (ii) Manufacturer release of Licensed Product, (iii) facility inspections by Governmental Authorities and Novartis and (iv) change management with respect to Manufacture of such Licensed Product. Without limitation of the foregoing, the Quality Agreement shall also include provisions to [*]. Each Quality Agreement shall be documented in writing, and routinely updated by mutual written agreement of the Parties.

8.4. Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities. Amgen shall develop [*] a [*] Marketing Application Core Dossier (the “*CMC Core Dossier*”) for the purpose of [*]. [*] shall [*] the table of contents for the CMC Core Dossier and, with respect to [*], the [*] strategic plan for the CMC Core Dossier for such jurisdictions, including developing key messages planned in the CMC Core Dossier, determining data planned to support such key messages, and identifying risks within such key messages and data in such jurisdictions, consistent with Amgen’s standard procedures. Based on such table of contents and strategic plan, Amgen shall prepare the draft of the CMC Core Dossier and provide such draft to Novartis for review and comment. Novartis shall participate in the authoring process for the CMC Core Dossier by providing its comments to Amgen reasonably promptly, which Amgen shall consider in good faith. Following provision of the [*] CMC Core Dossier to Novartis, [*]. As between the Parties, Novartis shall have responsibility for the assessment by Governmental Authorities of [*] with respect to Licensed Products in the Territory and Amgen shall have responsibility for the [*] with respect to Licensed Products outside the Territory. Novartis shall have no right to participate in inspections by any Governmental Authority of any facility where any Licensed Product is Manufactured, whether prior to or after Regulatory Approval of such Licensed Product. For avoidance of doubt, all information disclosed by Amgen under this Section 8.4 (Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities) shall be subject to the restrictions set forth in Section 11.2 (Authorized Disclosure).

9. PAYMENT

9.1. Royalty Payments. As partial consideration for the rights granted to Novartis hereunder, subject to Section 9.2 (Royalty Reduction), Novartis shall pay Amgen a royalty on annual Net Sales of each Licensed Product for each Calendar Year (or portion thereof) during the applicable Royalty Term at the following rates:

Net Sales in the Territory of the Applicable Licensed Product	Royalty Rate for Franchise Product 1	Royalty Rate for Franchise Product 2	Royalty Rate for Franchise Product 3
For that portion of annual Net Sales of the Licensed Product in the Territory less than [*]	[*]%	[*]%	[*]%
For that portion of annual Net Sales of the Licensed Product in the Territory equal to or greater than [*] but less than [*]	[*]%	[*]%	[*]%
For that portion of annual Net Sales of the Licensed Product in the Territory equal to or greater than [*] but less than [*]	[*]%	[*]%	[*]%
For that portion of annual Net Sales of the Licensed Product in the Territory equal to or greater than [*]	[*]%	[*]%	[*]%

9.2. Royalty Reduction.

9.2.1. Biosimilar Competition. Notwithstanding the foregoing, if, following the first commercial sale of a Biosimilar Product of a given Licensed Product in a given

country, Net Sales of such Licensed Product in that country in any Calendar Year are less than [*] percent ([*]%) as compared with Net Sales of such Licensed Product in the [*] month period in that country immediately preceding the marketing or sale of a Biosimilar Product of such Licensed Product in such country, the applicable Net Sales from such country based upon which royalties are calculated shall be reduced by [*] percent ([*]%) for purposes of the calculation of such royalties. Notwithstanding the foregoing, [*].

9.2.2. *Third Party Payments.* If Novartis or any of its Affiliates or sublicensees determines in its good faith judgment with advice from legal counsel that it is necessary or advisable to obtain a license from any Third Party in order to use, sell, offer for sale or import any Licensed Product in the Field in the Territory, then Novartis shall promptly notify Amgen and shall use commercially reasonable efforts to negotiate a favorable economic license to minimize payments by Novartis (and deductions from amounts otherwise payable to Amgen), and if Novartis obtains such a license, Novartis will be entitled to deduct up to [*] percent ([*]%) of any payments (including fees, milestones, royalties, settlements, payments or other payments) under such license for a given Calendar Quarter, to the extent such payments and license relate to such Licensed Product, from the royalties otherwise payable under Section 9.1 (Royalty Payments) with respect to such Licensed Product for such same Calendar Quarter; *provided, however*, that in no event shall the aggregate royalties payable to Amgen for a given Licensed Product for a given Calendar Quarter be reduced pursuant to this Section 9.2.2 (Third Party Payments) to less than [*] percent ([*]%) of the amounts otherwise payable under Section 9.1 (Royalty Payments) with respect to such Licensed Product for such Calendar Quarter (the “[*] Royalty Floor Restriction”); *provided further* that in no event shall the royalties payable to Amgen for Franchise Product 1 be reduced to less than [*] percent ([*]%) and for each of Franchise Product 2 and Franchise Product 3 be reduced to less than [*] percent ([*]%); and *provided further* that any excess amounts that are not deducted and would have been deductible from the royalty payments in a given Calendar Quarter but for the application of the [*] Royalty Floor Restriction or the foregoing [*] percent ([*]%) or [*] percent ([*]%) floors, may be deducted by Novartis in succeeding Calendar Quarter(s), as necessary, until such excess amounts are reimbursed to Novartis in full. The foregoing shall be without prejudice to Section 9.8 (Sublicense Payments), *provided* that, in the event Novartis proposes to enter into a license with respect to any intellectual property described in clause (ii) of Section 9.8 (Sublicense Payments), to the extent Amgen has notified Novartis of the license or acquisition relating to such intellectual property, Novartis shall obtain Amgen’s written consent (not to be unreasonably withheld or delayed) prior to entering into any such license.

9.2.3. *Maximum Reduction.* Notwithstanding the foregoing, in no event shall the operation of Sections 9.2.1 (Biosimilar Competition) and 9.2.2 (Third Party Payments) together operate to reduce the royalties otherwise payable to Amgen hereunder by more than [*] percent ([*]%) other than as and to the extent set forth in the last sentence of Section 9.2.1 (Biosimilar Competition).

9.3. [Reserved].

- 9.4. 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 commercial expertise, clinical data and other financial and non-financial consideration and that the royalties set forth in Section 9.1 (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 royalties set forth in this Article 9 (Payment) are reasonable.
- 9.5. Reports.
- 9.5.1. Beginning with the Calendar Quarter in which the First Commercial Sale of a given Licensed Product in the Territory occurs and thereafter for each Calendar Quarter until the expiration of Novartis's obligation to pay royalties with respect to such Licensed Product hereunder, reports of the sale of such Licensed Product for each Calendar Quarter will be delivered by Novartis to Amgen under this Agreement within [*] days after the end of each such Calendar Quarter. Such report shall state: (i) Net Sales of such Licensed Product by or on behalf of Novartis, its Affiliates or sublicensees during the applicable Calendar Quarter (detailed country-by-country); and (ii) a calculation of the royalty payment due from Novartis hereunder for such Calendar Quarter.
- 9.5.2. Based on the report received by Amgen from Novartis pursuant to Section 9.5.1 and without prejudice to Section 9.11 (Audits), Amgen shall issue an invoice to Novartis for the amount of the royalty payments indicated in the report. Following receipt of such invoice, to the extent that Novartis does not dispute, in good faith, the amount set forth on such invoice, Novartis shall pay the amount of the royalty payments indicated on such invoice within [*] days to an account designated by Amgen.
- 9.5.3. 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.
- 9.6. No Wrongful Reductions. Novartis shall not attempt to reduce compensation rightly due to Amgen hereunder by shifting compensation otherwise payable to Novartis from a Third Party with respect to any Licensed Product to another product or service for which no royalties are payable by it hereunder.
- 9.7. Development Cost Sharing.
- 9.7.1. *General.* In addition to the other payments referenced herein, with respect to each Licensed Product, Novartis shall bear the percentage of Amgen Development Costs set forth in the "Novartis Share" column of the applicable chart below and Amgen shall bear the percentage of Novartis Development Costs set forth in the "Amgen

Share” column of the chart below, in each case, that are included in the applicable Development Budget.

Franchise Product 1 Development Costs	Novartis Share	Amgen Share
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%

Franchise Product 2 Development Costs	Novartis Share	Amgen Share
[*]	[*]%	[*]%
[*]	[*]%	[*]%

Franchise Product 3 Development Costs*	Novartis Share	Amgen Share
[*]	[*]%	[*]%
[*]	[*]%	[*]%

*The percentages listed above with respect to Franchise Product 3 shall only apply if the Option Exercise Date occurs prior to the expiration of Option Period 1.

In the event that the Option Exercise Date occurs after the expiration of Option Period 1, Novartis shall bear the percentage of Amgen Development Costs set forth in the “Novartis Share” column of the applicable chart below and Amgen shall bear the percentage of Novartis Development Costs set forth in the “Amgen Share” column of the chart below, in each case, that are included in the applicable Development Budget.

Franchise Product 3 Development Costs	Novartis Share	Amgen Share
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%
[*]	[*]%	[*]%

9.7.2. *Annual Development Budget Overruns.* With respect to each Licensed Product, each Party shall promptly notify the other Party upon becoming aware that its Development Costs to be incurred in performing the applicable Development Plan for a Calendar Year will be in excess of the amounts budgeted to be incurred by or on behalf of such Party for its activities in the applicable Annual Development Budget. If the aggregate Development Costs incurred by a Party for performing the applicable Development Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of such Party for its activities in the applicable Annual Development Budget, the other Party shall reimburse the performing Party for the applicable percentage set forth above of such excess; *provided* that (i) in no event shall Novartis be responsible for reimbursement for such excesses to the extent the Amgen Development Costs in performing the Development Plan (a) for [*], exceed the amounts budgeted to be incurred by or on behalf of Amgen for its activities in the applicable Annual Development Budget for such Calendar Year, and (b) for [*], exceed the amounts budgeted to be incurred by or on behalf of Amgen for its activities in the applicable Annual Development Budget for such Calendar Year by more than [*] percent ([*]%) and (ii) in no event shall Amgen be responsible for reimbursement for such excesses to the extent the Novartis Development Costs in performing the Development Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of Novartis for its activities in the applicable Annual Development Budget for such Calendar Year by more than [*] percent ([*]%); *provided* that a Party shall be responsible for reimbursement for such excesses to the extent that the Amgen Development Costs or Novartis Development Costs, as the case may be, are attributable to (a) a change in applicable Law, (b) a Force Majeure event, (c) [*], (d) [*] or (e) a mutually agreed amendment to the applicable Development Plan.

9.7.3. *Reports.* Within [*] days after the end of each Calendar Quarter, each Party shall provide the other Party with a report specifying in reasonable detail (which shall include system-generated time-tracking data) the Development Costs (including Development Costs in respect of any clinical study undertaken by the providing Party that have been approved by the other Party or the regulatory materials and data from any clinical study such other Party wishes to cross reference, file or incorporate by reference in a Regulatory Filing as described in Section 5.2.2 (Development Outside the Current Development Plan) or Section 5.3 (Development Outside the Territory)) for such Party in such Calendar Quarter, as well as any other costs for

which such Party is entitled to reimbursement hereunder. Such Development Costs may be attributed by such Party to either the Calendar Quarter in which they are expensed.

- 9.7.4. *Payments.* Based on the report received from the other Party pursuant to Section 9.7.3 (Reports), the Party which has borne more than its share of Development Costs as determined pursuant to Section 9.7.1 (General) shall issue an invoice to the owing Party for such excess amount in accordance with Section 9.10 (Payment Method) within [*] days after receiving the other Party's report pursuant to Section 9.7.3 (Reports).
- 9.7.5. *Budget Deadlocks.* In the event that the JSC is unable to approve an Annual Development Budget for a Calendar Year prior to the start of such Calendar Year, then, until approval of such budget by the JSC, (i) the Annual Development Budget most recently approved by the JSC for such Calendar Year (or if not JSC approved, the initial apportioned amount for such Calendar Year in the applicable initial Development Budget agreed in writing by the Parties on or after the Effective Date) shall apply and (ii) if not approved by the JSC and no apportioned amount for such Calendar Year is included in such Development Budget, then the apportionment for the prior Calendar Year shall apply. In the event that the JSC is unable to approve an annual apportionment of a Study Budget for a Calendar Year prior to the start of such Calendar Year, then, until approval of such annual budget by the JSC, (a) the amount apportioned for such Calendar Year in the most recent Study Budget approved by the JSC for such Study Plan (or if not JSC approved, the initial apportioned amount for such Calendar Year in such Study Budget) shall apply; and (b) if not approved by the JSC and no apportioned amount for such Calendar Year is included in such Study Budget, then the apportionment for the prior Calendar Year shall apply.
- 9.8. Sublicense Payments. Amgen shall be responsible for any Third Party license fees, milestones, royalties or other payments owed with respect to any Licensed Product, on intellectual property that: (i) is licensed by Amgen prior to or as of the Effective Date or (ii) is licensed or acquired by Amgen after the Effective Date [*]. For the avoidance of doubt, such Third Party payments shall not be included in any calculation of Development Costs.
- 9.9. [Reserved.]
- 9.10. 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 9.12 (Blocked Currency). Any sales incurred in a currency other than U.S. Dollars shall be converted to the U.S. Dollar equivalent using Novartis' 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 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 9.14 (Withholding) and Section 9.15 (VAT)).

- 9.11. Audits. Novartis shall keep complete and accurate records pertaining to Novartis Development Costs and to the underlying revenue and expenses data relating to the calculation of Net Sales for the Licensed Products in the Territory in sufficient detail to permit Amgen to confirm the accuracy of all payments due hereunder, including Amgen's obligation to reimburse Novartis for Amgen's share of Novartis Development Costs pursuant to Section 9.7 (Development Cost Sharing). Amgen shall keep complete and accurate records pertaining to Amgen Development Costs of Licensed Products in sufficient detail to permit Novartis to reasonably confirm the accuracy of all payments due hereunder with respect to Novartis's obligation to reimburse Amgen for Novartis's share of Amgen Development Costs pursuant to Section 9.7 (Development Cost Sharing). Such records of Novartis and Amgen 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 9.11 (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 and under reasonable obligations of 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.
- 9.12. Blocked Currency. If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, Novartis shall have the right and option to make such payments by depositing the amount thereof in local currency to Amgen's account in a bank or depository designated by Amgen in the Territory.
- 9.13. Taxes. All Taxes levied on account of a payment made by Novartis to Amgen pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 9.14 (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.

- 9.14. **Withholding.** In the event that Law requires Novartis to pay or withhold Taxes with respect to any payment to be made by Novartis pursuant to this Agreement, Novartis shall notify Amgen in writing of such payment or withholding requirements prior to making the payment to Amgen and provide such assistance to Amgen, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in Amgen's efforts to claim an exemption from or reduction of such Taxes. Novartis will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish Amgen 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, Novartis shall provide such assistance to Amgen 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 Novartis unilaterally restructures the payment of any royalty or any other monies payable to Amgen under this Agreement such that Novartis or any of its Affiliates makes the payment of such royalty or any other monies payable to Amgen under this Agreement and solely as a result of such unilateral restructuring said amount is subject to withholding and further, Amgen is not able to recover or credit all or part of such withheld amount(s), Novartis agrees to compensate, without interest, Amgen 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 Amgen. For the avoidance of doubt, the preceding sentence shall apply only in respect of a unilateral restructuring of payments by Novartis and shall not apply (x) in the event of a change in applicable Law or circumstance, (y) as the result of Amgen's inability to recover or credit such withholding on a current or future basis due to Amgen's taxable income (loss) position or other tax attributes in a given year, or (z) for any other reason beyond the exclusive control of Novartis.
- 9.15. **VAT.** All payments due Amgen from Novartis pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by Novartis upon receipt of a valid VAT invoice).
- 9.16. **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 9.16 (Late Payment) shall in no way limit any other remedies available to either Party.

10. INTELLECTUAL PROPERTY

10.1. Ownership and Cooperation.

10.1.1. 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 Collaboration and, subject to the provisions of this Agreement (including those licenses granted pursuant

to Article 4 (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 Laws of the U.S. (without reference to any conflict of law principles).

10.1.2. Each Party shall promptly notify the other upon becoming aware (i) of any actual, suspected or threatened material infringement of any Licensed Amgen Patents, Licensed Amgen Trademarks or Licensed Amgen Know-How, (ii) of any claim that Novartis'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, (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 the Licensed Product, (iv) of any actual, suspected or threatened material misappropriation of Licensed Amgen Know-How, and/or (v) of any actual, suspected or threatened material infringement or dilution of the Licensed Amgen Trademarks, Amgen Housemarks related to the Licensed Products or Novartis Housemarks related to the Licensed Products, all of the foregoing, (i) through (v), anywhere in the world.

10.2. Prosecution and Maintenance.

10.2.1. *In Territory.*

10.2.1.1. *Amgen Primary Prosecution.* Amgen shall control, itself or through outside counsel reasonably acceptable to Novartis and directed by Amgen, 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 Amgen Patents, Licensed Amgen Trademarks and Joint Patents (in which case the prosecution will be in the name of both Parties), in each case solely in the Territory (collectively, the "*Territory Patents and Trademarks*"), as well as preparation and filing for any patent term extensions or similar protections therefor. Novartis shall be responsible for reasonable, documented costs incurred by or on behalf of Amgen in connection with such activities with respect to the Territory Patents and Trademarks (other than the costs associated with the creative development of Trademarks and related availability searches). Within [*] days following each Calendar Quarter, Amgen shall provide Novartis an invoice setting forth such costs in reasonable detail, and Novartis shall pay such invoice within [*] days of receipt thereof. From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect

to Territory Patents and Trademarks related to Franchise Product 3, (i) Amgen shall provide Novartis with copies of and an opportunity to review and comment upon the text of the applications relating to the Territory Patents and Trademarks 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 Novartis with a copy of each submission made to and document received from a patent or trademark authority, court or other tribunal regarding any Territory Patents and Trademarks reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Territory 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 the Territory 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's comments on the communications, filings and submissions for the Territory Patents and Trademarks.

10.2.1.2. *Patent and Trademark Prosecution Strategy*. No later than [*] days after the date of this Agreement, [*].

10.2.1.3. *Novartis Secondary Prosecution*. From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks related to Franchise Product 3, if Amgen proposes to abandon or fail to maintain any patent, trademark or application within the Territory Patents and Trademarks, it shall give Novartis reasonable notice thereof (with sufficient time for Novartis to assume control thereof and continue the prosecution or maintenance of such patent, trademark or application) and thereafter Novartis may, upon written notice to Amgen and at Novartis's sole cost, control Patent and Trademark Matters with respect to such patent, trademark or application within the Territory Patents and Trademarks thereafter in accordance with this Section 10.2.1.3 (Novartis Secondary Prosecution) (any patent, trademark or application so assumed, a "*Novartis Assumed Item*"). Novartis shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Novartis, Patent and Trademark Matters with respect to Novartis Assumed Items in the Territory, at Novartis's sole cost and expense, as well as preparation and filing for any patent term extensions or similar protections therefor. Novartis shall provide Amgen with a copy of each material submission made to and document received from a patent or trademark authority regarding any Novartis Assumed Items reasonably promptly after making such filing or

receiving such document, including a copy of each application for each item within the Novartis Assumed Items as filed together with notice of its filing date and application number.

10.2.2. *Outside Territory.* Amgen shall control and be solely responsible for all Patent and Trademark Matters with respect to its patent rights, trademark rights and other intellectual property outside the Territory, at its sole cost and expense. Amgen shall control and be solely responsible for Patent and Trademark Matters with respect to Joint Patents outside the Territory, at its sole cost and expense. Notwithstanding the other provisions of this Section 10.2.2 (Outside 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 [*] the Licensed Amgen Patents or the research, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of Licensed Products [*].

10.3. Defense and Settlement of Third Party Claims.

10.3.1. *Territory Patents and Trademarks.* From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks related to Franchise Product 3, 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 Licensed Product in the Territory by Novartis, Novartis shall have the sole right to defend against any such assertions at its sole cost. Amgen shall reasonably assist Novartis and cooperate in any such litigation at Novartis's request, and Novartis 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 10.3 (Defense and Settlement of Third Party Claims), with its own counsel at its sole cost. Novartis shall seek and reasonably consider Amgen's comments before determining the strategy for such matter. 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 communications, filings and submissions. Novartis shall not settle or consent to the entry of any judgment in any such action [*]. Novartis shall keep Amgen fully informed of all claims and actions governed by this Section 10.3 (Defense and Settlement of Third Party Claims). In the event Novartis 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, offer for sale, sale or importation of the Licensed Product; (ii) settlement discussions of an interference involving a patent corresponding to a Licensed Amgen Patent or a trademark corresponding to a Licensed Amgen Trademark; or (iii) cross-license discussions with respect to a patent corresponding to a Licensed Amgen Patent or a trademark corresponding to a Licensed Amgen Trademark; and, in each such case, such Third-Party patent right or trademark right corresponds to a patent right or trademark right outside the

Territory: (a) Novartis shall keep Amgen reasonably informed of the status of such discussions; and (b) Novartis shall consider in good faith any comments or suggestions of Amgen.

10.3.2. *Ex-Territory Patents and Trademarks.* From and after the Effective Date, with respect to Licensed Amgen Patents, Licensed Amgen Trademarks and Joint Patents, in each case outside the Territory (collectively, the “*Ex-Territory Patents and Trademarks*”) related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Ex-Territory Patents and Trademarks related to Franchise Product 3, 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 Licensed Product outside the Territory by Amgen, 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 incurred in connection therewith. Subject to such control, Novartis may join any defense and settlement pursuant to this Section 10.3 (Defense and Settlement of Third Party Claims), with its own counsel at its sole cost. Amgen shall seek and reasonably consider Novartis’s 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 Licensed Amgen Patents, the Licensed Amgen Trademarks or the research, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of Licensed Products [*]. Amgen shall keep Novartis fully informed of all claims and actions governed by this Section 10.3 (Defense and Settlement of Third Party Claims). In the event Amgen 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 Licensed Product; (ii) settlement discussions of an interference involving a patent corresponding to a Licensed Amgen Patent or a trademark corresponding to a Licensed Amgen Trademark; or (iii) cross-license discussions with respect to a patent corresponding to a Licensed Amgen Patent or a trademark corresponding to a Licensed Amgen Trademark; and, in each such case, such Third-Party patent right or trademark right corresponds to a patent right or trademark right inside the Territory: (a) Amgen shall keep Novartis reasonably informed of the status of such discussions; and (b) Amgen shall consider in good faith any comments or suggestions of Novartis.

10.3.3. *Mutual Provisions.* Each Party shall have the right to redact any information disclosed to the other Party pursuant to this Section 10.3 (Defense and Settlement of Third Party Claims) relating to any product other than the applicable Licensed Product.

10.4. Enforcement.

10.4.1. *In Territory*. Each Party shall promptly notify the other Party in writing if it reasonably believes that any Territory Patents and Trademarks are infringed or misappropriated by a Third Party in the Territory.

10.4.1.1. *Prior to Option Exercise Date with Respect to Franchise Product 3*. Prior to the Option Exercise Date, Amgen shall have the sole right, but not the obligation, to enforce Territory Patents and Trademarks relating to Franchise Product 3 against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Territory, at Amgen's sole cost.

10.4.1.2. *Novartis Primary Enforcement*. From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks related to Franchise Product 3, Novartis shall have the first right, but not the obligation, to enforce Territory Patents and Trademarks against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Territory, at Novartis's sole cost, 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's request (and Novartis shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith), 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. Novartis shall not settle, or consent to any judgment in, any action under this Section 10.4.1.2 (Novartis Primary Enforcement), without Amgen's prior written consent, not to be unreasonably withheld or delayed.

10.4.1.3. *Amgen Secondary Enforcement*. From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks related to Franchise Product 3, in the event Novartis does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any Territory Patents and Trademarks within [*] days after Amgen requests Novartis to do so in writing (or, if later, within [*] days 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 at Amgen's sole cost and Novartis will cooperate with Amgen. If Amgen elects to bring and prosecute such an action, then Amgen shall seek and reasonably consider Novartis's 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 Amgen Manufacturing information and any information relating to any product other than the Licensed Product from any such materials). Amgen shall not settle, or consent to any judgment in, any action under this Section 10.4.1.3 (Amgen Secondary Enforcement) that would reasonably be expected to [*] the Licensed Amgen Patents, the Licensed Amgen Trademarks or the research, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of Licensed Products [*].

10.4.2. *Outside Territory*. 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 outside the Territory against any actual, alleged or threatened infringement or misappropriation by Third Parties outside the Territory, and to settle any such matters in its sole discretion subject to Section 10.3 (Defense and Settlement of Third Party Claims). Novartis shall have no right to enforce such rights outside the Territory.

10.5. Cooperation. When either Party is bringing or defending an action of the type described in Sections 10.3 (Defense and Settlement of Third Party Claims) or 10.4.1 (In 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.

10.6. 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 Novartis or Amgen from and after the Effective Date during the Term, with respect to Franchise Product 1 or Franchise Product 2, or from and after the Option Exercise Date, with respect to Franchise Product 3, that are left over after such reimbursement shall be allocated between the Parties [*] percent ([*]%) to the Party initiating the action and [*] percent ([*]%) to the other Party. Amgen shall have the sole right to retain (i) any and all Recoveries from actions brought by Amgen with respect to Territory Patents and Trademarks related to Franchise Product 3 prior to the Option Exercise Date, (ii) any and all recoveries with respect to the enforcement of any Amgen intellectual property or proprietary right or Joint Patents outside the Territory and (iii) any and all Recoveries from actions brought by Amgen after termination of this Agreement.

10.7. Patent Term Extensions. From and after the Effective Date, with respect to Territory Patents and Trademarks related to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks related to Franchise Product 3, each Party shall provide reasonable assistance to the other Party in connection with obtaining SPCs for Licensed Amgen Patents in the Territory consistent with the rights of the other Party to control such matters as specified in Section 10.2 (Prosecution

and Maintenance). To the extent reasonably and legally required in order to obtain any such 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 SPC in such country.

- 10.8. Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement or being given access to Licensed Amgen Know-How or Licensed Novartis Know-How or 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: (a) promptly reporting any Information, as appropriate; (b) 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; (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 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.

11. CONFIDENTIALITY AND PUBLICATIONS

- 11.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] years thereafter, the receiving Party 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 for activities outside the Territory except as required under the applicable Development Plan. Amgen shall have no right to and shall not utilize any Confidential Information of Novartis for activities in the Territory except as required under the applicable Development Plan or for purposes of Manufacturing the Licensed Products. 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:

- 11.1.1. 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;
 - 11.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
 - 11.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
 - 11.1.4. 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
 - 11.1.5. 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.
- 11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) 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 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 Licensed 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 information and materials relating to the Collaboration are not shared with or used for the benefit of, and are Segregated from, [*].

- 11.3. 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 Licensed Products or, in the case of Amgen prior to the Option Exercise Date, Franchise Product 3.
- 11.4. 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 regards to this Agreement or any Licensed 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, the Parties shall agree upon and each Party shall release a press release to announce the execution of this Agreement in the applicable form attached hereto as the Press Release Schedule; thereafter, Novartis and Amgen may each disclose to Third Parties the information contained in such press release without the need for further approval by the other Party.
- 11.5. Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated [*] and amended on [*], including any written requests thereunder, (the "*Prior Agreement*") with respect to information disclosed thereunder relating to the Licensed Products 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.
- 11.6. Publications and Presentations. Amgen and Novartis shall be free to (provided that, with respect to Franchise Product 3, Novartis shall only have such rights after the Option Exercise Date):
- 11.6.1. present findings with respect to any Licensed Product at symposia and other meetings of healthcare professionals, and international, national or regional 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 Section 11.6 (Publications and Presentations) and Section 11.7 (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;

11.6.2. publish in medical and scientific journals and similar publications ("*Medical Journals*") articles and papers, including primary reports of clinical data, secondary or pooled analyses, and review papers concerning any Licensed Product which have been prepared by or on behalf of such Party, for publication outside or in the Territory and related to studies conducted after the Effective Date outside or in the Territory concerning such Licensed Product (each a "*Scientific Paper*"); *provided, however*, that the Party proposing to publish such Scientific Paper shall have complied with the provisions of Section 11.7 (Scientific Papers, Abstracts and Posters) with respect to such Scientific Paper; and

11.6.3. disclose any clinical data generated by such Party concerning any Licensed 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.

11.7. Scientific Papers, Abstracts and Posters.

11.7.1. *Scientific Papers.* Each Party through a JPT 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. 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 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' need to comply with any healthcare compliance guidelines). To enable free exchange of copyrighted material between the Parties, each Party agrees that it has or shall (i) obtain and maintain, at its own expense, an Annual Copyright License or equivalent license from the Copyright Clearance Center and (ii) list the other Party as a collaborator in an agreement with the Copyright Clearance Center.

11.7.2. *Abstracts and Posters.* Each Party shall provide to the other, prior to submission or presentation, as the case may be, copies of (i) all abstracts that will be submitted for publication in connection with any international or major national Scientific Meeting

in the Territory or outside of the Territory, and (ii) all posters and other materials (such as slides) that will be presented at such Scientific Meeting, in each case, concerning a Licensed Product which have been prepared by or on behalf of one of the Parties, for submission or presentation outside or in the Territory. 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. 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 accepted for publication and all final posters to be presented [*] Business Days or as soon as practicable prior to the planned publication or presentation thereof and oral presentations and accompanying written materials at least [*] Business Days prior to presentation (upon availability and distribution of such information assuming that providing such information is acceptable taking into consideration the publishers' need to comply with any healthcare compliance guidelines).

Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for (i) extensions of the above timelines (in Sections 11.6 (Publications and Presentations) and 11.7 (Scientific Papers, Abstracts and Posters)) in the event that material late-breaking clinical data becomes available or (ii) shortening of the above timelines (in Sections 11.6 (Publications and Presentations) and 11.7 (Scientific Papers, Abstracts and Posters)) if the requesting Party has a good faith belief that circumstances warrant such acceleration. The Parties acknowledge and agree that all publications and presentations pursuant to Sections 11.6 (Publications and Presentations) and 11.7 (Scientific Papers, Abstracts and Posters) shall comply with the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

- 11.8. 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 11.9 (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 for 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.
- 11.9. 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.

- 11.10. 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.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

- 12.1.1. As of the 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;
- 12.1.2. As of the 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 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;
- 12.1.3. To its knowledge, as of the 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 EMA 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;

- 12.1.4. As of the Effective Date, it has not been debarred or excluded or the subject of debarment or exclusion proceedings by any Governmental Authority;
- 12.1.5. To its knowledge, as of the Effective Date it and its Affiliates have not committed any Material Anti-Corruption Law Violation other than, 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 Department of Health and Human Services in December 2012; and
- 12.1.6. As of the Effective Date, it has not knowingly used in connection with the research, Development, 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.

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

- 12.2.1. 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;
- 12.2.2. As of the Effective Date, it has sufficient legal and/or beneficial title and ownership under the Licensed Amgen Patents, Licensed Amgen Trademarks and Licensed Amgen Know-How (with respect to Amgen) to grant the licenses to the other Party as purported to be granted pursuant to this Agreement;
- 12.2.3. Amgen Controls the Licensed Amgen Patents listed on the Licensed Amgen Patents Schedule, free of any Liens. The Licensed Amgen Patents in the Territory listed on the Licensed Amgen Patents Schedule constitute a true and complete list of all Patents Controlled by Amgen in the Territory relating to the Franchise Product 1 and Franchise Product 2 in the Territory;
- 12.2.4. Amgen has not received any written notice from any Third Party asserting or alleging that the Development, Manufacture, use or sale of any Licensed Product infringes rights of such Third Party in the Territory;
- 12.2.5. Amgen has not received any written notice of any opposition or challenge against any Licensed Amgen Patent in the Territory;
- 12.2.6. All data and information relating to Franchise Product 1 and Franchise Product 2 filed by Amgen with the EMA are true and accurate in all material respects;
- 12.2.7. Amgen has filed with the EMA all [*] relating to Franchise Product 1 and Franchise Product 2 in Amgen's possession that are required to be filed, and has made available to Novartis, all such [*]; and
- 12.2.8. 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 Development, Manufacture or Commercialization of Franchise Product 1 or Franchise Product 2, [*].

12.3. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES AND COVENANTS), NOVARTIS AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, THE LICENSED PRODUCTS, THE LICENSED AMGEN PATENTS, LICENSED AMGEN TRADEMARKS, LICENSED AMGEN KNOW-HOW, LICENSED NOVARTIS PATENTS, LICENSED NOVARTIS TRADEMARKS, LICENSED NOVARTIS KNOW-HOW, 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 12 (Representations, Warranties and Covenants), all licenses by Novartis to Amgen under the Licensed Novartis Know-How and Licensed Novartis Patents shall be granted “as-is” and all licenses by Amgen to Novartis under the Licensed Amgen Know-How, Licensed Amgen Trademarks and Licensed Amgen Patents shall be granted “as-is”.

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

12.4.1. It shall not knowingly use in connection with the research, Development, 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;

12.4.2. 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 research, Development, conduct of Medical Affairs Activities, Manufacture or Commercialization to take place pursuant to this Agreement:

12.4.2.1. 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.

12.4.2.2. 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.

12.4.2.3. 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 12.4.2.1 and 12.4.2.2 above.

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

- (a) Upon becoming aware of any breach or violation by a Party or its Party Representative of any representation, warranty or undertaking set forth in Sections 12.4.2.1 and 12.4.2.2.
- (b) Upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Party Representatives connected with this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

12.4.3. If either Party requests that the other Party complete a compliance certification certifying compliance with Section 12.4.2.1, 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;

12.4.4. If either Party requests, in connection with a Corporate Integrity Agreement or similar arrangement with a Governmental Authority, 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;

12.4.5. 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 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); and

12.4.6. It shall not grant any right to any Third Party that conflicts with the rights granted to the other Party hereunder.

13. LIMITATIONS OF LIABILITY; INSURANCE

13.1. 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 13.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 14 (Indemnification), (ii) 11.1 (Confidentiality; Exceptions) or 11.2 (Authorized Disclosure) or (iii) the gross negligence or willful misconduct of a Party.

13.2. 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.

14. INDEMNIFICATION

14.1. Indemnity.

14.1.1. *By Novartis*. Subject to the remainder of this Article 14 (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's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (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) (collectively, "*Losses*") 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, (ii) a breach by Novartis of this Agreement, including any failure of Novartis's representations or warranties in Section 12.1 (Mutual Representations and Warranties) to be true, or (iii) Novartis's, its Affiliate's or its licensee's (other than Amgen, its Affiliates or its licensees) Development or Commercialization of, or conduct of Medical Affairs Activities with respect to, the Licensed Products other than clinical studies conducted by Amgen in the Territory but, in each case, excluding such Losses to the extent they arise from (x), (y) or (z) of Section 14.1.2 (By Amgen) below.

14.1.2. *By Amgen*. Subject to the remainder of this Article 14 (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 (x) the gross negligence or willful misconduct of Amgen, or its Affiliates or agents in performing under this Agreement, (y) a breach by Amgen of this Agreement, including any failure of Amgen's representations or warranties in Section 12.1 (Mutual Representations and Warranties) and 12.2 (Amgen Representations and Warranties) to be true, or (z) Amgen's, its Affiliate's or its licensee's (other than Novartis, its Affiliates or its licensees) Development or Manufacture of the Licensed Products prior to the Effective Date, or thereafter, Development, Manufacture or Commercialization of, or conduct of Medical Affairs Activities with respect to, the Licensed Product for use or sale outside the Territory or performance of clinical studies with the Licensed Product in the Territory, but, in each case, excluding such Losses to the extent they arise from (i), (ii), or (iii) of Section 14.1.1 (By Novartis) above.

14.1.3. *Supply Agreement*. Notwithstanding any other provision of this Agreement, with respect to any Claim for which a Party would be entitled to be indemnified in accordance with the terms of this Section 14 (Indemnification) relating to Manufacturing for which such Party is also entitled to be indemnified in accordance with a given Supply Agreement, such Party shall only be entitled to be indemnified pursuant to such Supply Agreement in accordance with the terms thereof (including any applicable limitations of liability) and this Section 14.1 (Indemnity) shall not apply to such Claim.

14.2. 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 14 (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 14.2 (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 14.2 (Claim for Indemnification), 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 11 (Confidentiality and Publications). 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.

15. TERM AND TERMINATION

15.1. Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect during the Term. For the avoidance of doubt, after the expiry of the Royalty Term with respect to a given Licensed Product in a given country, the licenses granted by Amgen to Novartis pursuant to this Agreement with respect to such Licensed Product and Licensed Amgen Trademarks for such Licensed Product in such country shall become fully paid up, and royalty free and Novartis shall no longer have any obligations pursuant to this Agreement with respect to such Licensed Product other than as set forth in Section 15.4 (Additional Surviving Provisions).

15.2. Termination. This Agreement may be terminated as follows:

15.2.1. *Termination with respect to Franchise Product 3 if Option not Exercised during Option Period*. This Agreement shall immediately and automatically terminate solely with respect to Franchise Product 3 upon expiration of the Option Period in the event Novartis has not exercised the Option in accordance with Section 2.1 (Option for Franchise Product 3) prior to such expiration. For purposes of clarity, upon such termination, Amgen shall be free to conduct research, Development, Medical Affairs Activities, Manufacturing and Commercialization activities with respect to Franchise Product 3 within or outside the Territory at its sole discretion, and this Agreement shall survive and continue in full force and effect with respect to Franchise Product 1 and Franchise Product 2.

15.2.2. *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 16.3 (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.

15.2.3. *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.

15.2.4. *Termination for Challenge.* Amgen shall have the right to terminate this Agreement should Novartis, its Affiliate or its or their licensee under the Licensed Amgen Patents or Licensed Amgen Trademarks bring or join any challenge to the validity or enforceability of any Licensed Amgen Patent or Licensed Amgen 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.

15.2.5. *Novartis Termination for Convenience.* Novartis shall have the right to terminate this Agreement, in whole or with respect to a given Licensed Product:

15.2.5.1. from and after [*] until [*], upon [*] months' prior written notice to Amgen, and in the event of such termination, (i) for purposes of clarity, Novartis's obligations to fund its share of Development Costs pursuant to Section 9.7 (Development Cost Sharing) and to use Commercially Reasonable Efforts to Commercialize Licensed Products pursuant to Section 7.1 (Commercially Reasonable Efforts) shall continue during such [*] notice period, and (ii) Novartis shall additionally pay to Amgen an amount equal to (a) the amount of Development Costs borne (whether or not actually paid as of such termination) by Novartis pursuant to Section 9.7 (Development Cost Sharing) from the Effective Date through the effective date of such termination, multiplied by (b) [*]; and

15.2.5.2. from and after [*] months after [*], upon [*] prior written notice to Amgen, and in the event of such termination, for purposes of clarity Novartis's obligations to fund its share of Development Costs pursuant to Section 9.7 (Development Cost Sharing) and to use Commercially Reasonable Efforts to Commercialize Licensed Products pursuant to Section 7.1 (Commercially Reasonable Efforts) shall continue during such [*] month notice period.

For purposes of clarity, from [*] until [*] thereafter, Novartis shall not have any right to terminate this Agreement under this Section 15.2.5 (Novartis Termination for Convenience).

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

15.3.1. *General*. In the event of any termination of this Agreement, with respect to the terminated Licensed Products, unless otherwise expressly provided, any liabilities previously accrued (including the obligation of Novartis to pay royalties pursuant to Section 9.1 (Royalty Payments) with respect to sales made prior to the effective date of such termination or, if later, prior to completion of the transition by Novartis pursuant to Section 15.5 (Transition Period)) 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).

15.3.2. *Termination Effects*. In the event of any termination of this Agreement (other than by Amgen pursuant to Section 7.4 ([*] Divestiture)), with respect to the applicable terminated Licensed Product(s) (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 Licensed Products in the Territory 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) the Parties shall transition responsibility for Commercialization, Development, Medical Affairs Activities and any other activities as requested by Amgen with respect to the Licensed Products to Amgen in accordance with Section 15.5 (Transition Period); (iii) the Parties shall cooperate to promptly transition sole responsibility for the prosecution, maintenance and enforcement in the Territory of Territory Patents and Trademarks to Amgen; (iv) Amgen shall have the right to reacquire some or all of the inventory of the Licensed Products, as requested by Amgen, in possession of Novartis and its Affiliates and, if Amgen so reacquires inventory, shall [*]; (v) the Parties shall cooperate to promptly transfer ownership of all Regulatory Filings and Regulatory Approvals and responsibility for regulatory communication held by Novartis in the Territory to Amgen, or to terminate or withdraw such Regulatory Filings and Regulatory Approvals in lieu of transfer (if so requested by Amgen); (vi) all sublicenses granted by Novartis shall terminate; (vii) Amgen shall have the right to control all Recalls of the Licensed Products in the Territory, and in each case Novartis shall provide any reasonable assistance requested by Amgen in connection therewith; (viii) Section 4.2 (Licensed Novartis 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 Licensed Products as of the date of termination) shall survive; (ix) Amgen shall have a fully paid, royalty-free [*] right and license to use the Licensed Novartis Trademarks (and

the associated goodwill) in connection with Licensed Products in all indications within the Territory; (x) the Parties shall cooperate to promptly transfer ownership of all Domain Names and Domain Name registrations related to the Licensed Products held by Novartis to Amgen; and (xi) at Amgen's request, the Parties will discuss in good faith the wind-down or transfer to Amgen of any ongoing clinical trials for the Licensed Products conducted by or on behalf of Novartis or its Affiliates; *provided* that [*] shall bear any expenses incurred in connection with any such transfer except in the event of termination by [*] pursuant to [*] or by [*] pursuant to [*]. In the event that the Parties are not permitted to transfer Regulatory Filings or Regulatory Approvals under clause (v) above pursuant to Law, the Parties shall cooperate to establish a right of access and reference to such filings and approvals for Amgen, and Novartis shall maintain such filings and approvals, and take any actions reasonably requested by Amgen with respect thereto, and thereafter Novartis shall transfer ownership of all such Regulatory Filings and Regulatory Approvals to Amgen or its designee as and when it becomes permissible to do so. [*] In the event of any termination of this Agreement by Amgen pursuant to Section 7.4 ([*] Divestiture), (a) the licenses granted to Novartis under Section 4.1 (Licensed Amgen Patents and Know-How) and under Section 4.5.1 (Grant to Novartis) (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 Licensed Products as of the date of termination) shall survive, (b) Amgen shall continue to Manufacture and supply Licensed Product for a period of up to [*] months in accordance with the Supply Agreement, (c) the Royalty Rates shall [*] *provided* that in no event shall the royalties payable to Amgen for Franchise Product 1 [*] and for each of Franchise Product 2 and Franchise Product 3 [*], and (d) the Parties shall negotiate in good faith a process for the transition of ongoing activities necessary to allow Novartis to exercise its rights under such license and allow Novartis to continue to Develop, Manufacture and Commercialize the Licensed Product in the Territory, including assistance from Amgen for the transfer of Manufacturing to a contract manufacturing organization mutually agreed by the Parties.

15.4. Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.3 (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: Articles 11 (Confidentiality and Publications) (except with respect to Section 11.6 (Publications and Presentations), 11.7 (Scientific Papers; Abstracts and Posters), 11.8 (Deferral of Disclosures) and 11.9 (Failure to Object to Disclosure)); 13 (Limitations of Liability; Insurance); 14 (Indemnification); 15 (Term and Termination) and 16 (Miscellaneous); 9.1 (Royalty Payments) through 9.6 (No Wrongful Reductions) (inclusive) (with respect to sales made prior to such termination or, if later, prior to completion of the transition by Novartis pursuant to Section 15.5 (Transition Period)); 9.7 (Development Cost Sharing) (with respect to Development Costs reasonably incurred prior to such termination); 9.8 (Sublicense Payments) (with respect to amounts incurred prior to such termination); 9.10 (Payment Method) through 9.16 (Late Payment) (inclusive); 10.1 (Ownership and

Cooperation); 10.6 (Allocation of Recoveries) (with respect to periods prior to termination); and 12.3 (Disclaimer of Warranties).

15.5. Transition Period. In the event of any termination of this Agreement by Novartis pursuant to Section [*] or by Amgen pursuant to Section [*], then upon Amgen's reasonable request, during the [*] month period following provision of notice of termination (or, in each case, for such shorter period as Amgen shall reasonably request) (the "*Transition Period*"), the Parties shall cooperate to transition the Development (including any ongoing trials, to the extent permitted by Law) and Commercialization of, regulatory responsibility for, and conduct of Medical Affairs Activities with respect to, the Licensed Products in the Field in the Territory from Novartis to Amgen. Novartis shall take all 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 Development and Commercialization of, and Medical Affairs Activities with respect to, the Licensed Products in the Territory. Subject to Section 15.3.2 (Termination Effects), the Parties shall each be responsible for their own costs incurred in accordance with this Section 15.5 (Transition Period).

16. MISCELLANEOUS

16.1. 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.

16.2. 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 [*]. 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.

16.3. 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.

- 16.4. 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.
- 16.5. 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.
- 16.6. [Reserved].
- 16.7. Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits 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.
- 16.8. 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.

- 16.9. 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.
- 16.10. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.
- 16.11. 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).
- 16.12. 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: [*]
Telephone: [*]
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 16.12 (Notices).

- 16.13. 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.
- 16.14. 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.
- 16.15. Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or Novartis Indemnities in Article 14 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.
- 16.16. 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 Exclusive License and Collaboration Agreement as of the Effective Date.

NOVARTIS PHARMA AG

By: /s/ Corinne Savill
Name: Corinne Savill
Novartis Pharma AG Head Business
Development & Licensing
Forum 2-6.04
Title: 4002 Basel

AMGEN INC.

By: /s/ Robert A. Bradway
Name: Robert A. Bradway
Chairman and Chief Executive
Title: Officer

By: /s/ Barbara Levi Mager
Name: Barbara Levi Mager
Title: Global Legal Head, GPS&C

Schedule
Clinical Supply

•Terms and descriptions outlined below, together with any terms contained or described in the Agreement, will serve as the basis for a definitive Supply Agreement and Quality Agreement between the Parties.

<u>Term</u>	<u>Description</u>
Stage Supplied	Amgen will supply Novartis with Franchise Product 1 in [*] form in accordance with the provisions of the Supply Agreement. The Parties shall determine whether to supply Franchise Product 1 in [*] form based on whether [*]. Additionally, Amgen will supply Novartis with placebo of Franchise Product 1.
Specifications	Amgen will Manufacture and supply one distinct Franchise Product 1 fulfilling one set of specifications. However, the Franchise Product 1 specifications may need to be revised in accordance with requests from the local health authorities (including with respect to testing methods) on a country-by-country basis. Novartis will not agree to commitments with a local health authority with respect thereto without the prior written consent of Amgen.
Remaining Shelf Life	The minimum shelf life remaining upon delivery for use in a particular country shall be equal to [*]% of the then current approved shelf life of the Franchise Product 1 in such country (provided that the then current approved shelf life in such country is a minimum of [*] months). If the then current approved shelf life of the Franchise Product 1 in such country is less than [*] months, the Parties shall, through a governance body established under the Supply Agreement, negotiate in good faith a new minimum shelf life taking into account Governmental Authority requirements and existing tender constraints.
IncoTerm	Franchise Product 1 will be supplied to Novartis [*] (Incoterms 2010 ICC). Risk and title to the Franchise Product 1 shall transfer at [*].
Cost	Franchise Product 1 will be supplied to Novartis at [*] (such terms to be defined in the Supply Agreement in a manner substantially similar as defined in that certain [*] effective as of [*]. In addition thereto, Amgen will be entitled to charge Novartis certain support costs directly related to the Manufacture or supply of Franchise Product 1 for the Territory that are not included in [*] (“Support Costs”) ([*]). The mechanism for discussing, tracking and charging for Support Costs to be more fully detailed in the Supply Agreement. The Supply Agreement shall [*] to be defined in the Supply Agreement.
Site of Manufacture	Amgen has sole discretion to determine which Amgen site will be utilized for Manufacturing drug substance and drug product for the Franchise Product 1, [*]. [*]. [*]. At any time, Amgen can use a Third Party CMO, [*], provided that [*].
Audit Right	Novartis will have the right to inspect Amgen’s sites utilized for Manufacturing, [*] storage, testing, shipping or receiving of the Franchise Product 1 [*] per twelve (12) month period, as well as more often in case of quality issue.

<u>Term</u>	<u>Description</u>
Official Inspection	<p>Amgen will permit, and cause its Third Party CMO to permit, officials of any Regulatory Authority to inspect the Manufacturing facility utilized for Manufacturing drug substance and drug product for the Franchise Product 1, and will inform Novartis promptly of any planned or anticipated inspection.</p> <p>Amgen will permit, and cause its Third Party CMO to permit, Novartis to accompany such official inspection. Amgen will provide Novartis with copies of all reports and communications with the Regulatory Authority in connection therewith, will take into account Novartis's comments before responding to such communications and will remedy any deficiencies at its own expense (provided, however, that Amgen shall be permitted to include certain of such expenses in its [*] cost of Manufacturing of Franchise Product 1).</p>
Orders and Quantities	The Supply Agreement will include provisions relating to forecasting, including frequency and length of forecasting, minimum order quantities, binding periods, variances, and long-range planning.
Variation Management	The Supply Agreement will include provisions relating to variation management, including notification requirements, whether or not such variation is required by Governmental Authorities, or requires Governmental Authority approval.
Indemnification	Each Party (the "Indemnifying Party") will indemnify the other Party for losses for any claim brought by a Third Party against the other Party to the extent such losses result from (i) the gross negligence or willful misconduct of the Indemnifying Party in performing under the Supply Agreement or the Quality Agreement or (ii) the breach by the Indemnifying Party of its obligations under the Supply Agreement. Amgen will indemnify Novartis for losses for any claim brought by a Third Party against Novartis to the extent such losses result from any manufacturing defect at the time of delivery of Franchise Product 1 to Novartis (including failure of product to be manufactured in accordance with cGMP), except in the case that the Amgen reasonably requests Novartis to take prompt mitigating actions (including conducting a recall) with respect to such Franchise Product 1, in which case (1) Amgen shall be responsible for the costs related to such mitigation actions and (2) Novartis shall be responsible for losses with respect to such Franchise Product 1 for which Novartis declines to take such requested actions to the extent that such losses result from Novartis' refusal to implement such requested actions.
Miscellaneous	The Supply Agreement would contain other customary provisions including, without limitation, provisions regarding financial audit rights, shelf life extension process, confidentiality, warranties, and termination.
Franchise Product 2 and Franchise Product 3	<p>The terms and conditions set out in this Clinical Supply Schedule shall only serve as a basis for the Supply Agreement for the Franchise Product 1.</p> <p>The Supply Agreements for the Franchise Product 2 and the Franchise Product 3, if any, shall include terms and conditions substantially similar to those set out in this Clinical Supply Schedule.</p>

Schedule

Commercial Supply

- Terms and descriptions outlined below, together with any terms contained or described in the Agreement, will serve as the basis for a definitive Supply Agreement and Quality Agreement between the Parties.

<u>Term</u>	<u>Description</u>
Stage Supplied	Amgen will supply Novartis with Franchise Product 1 in accordance with an available SKU schedule in [*] in accordance with the provisions of the Supply Agreement. Amgen will have the right to transition the [*] to Novartis on a region-by-region basis and subject to a mutually agreed upon (i) notice and transfer period, (ii) transfer plan and (iii) transfer costs. Amgen shall consider in good faith requests from Novartis to transition [*] on a region-by-region basis.
Remaining Shelf Life	The minimum shelf life remaining upon delivery for use in a particular country shall be equal to [*]% of the then current approved shelf life of the Franchise Product 1 in such country (provided that the then current approved shelf life in such country is a minimum of [*] months). If the then current approved shelf life of the Franchise Product 1 in such country is less than [*] months, the Parties shall, through a governance body established under the Supply Agreement, negotiate in good faith a new minimum shelf life taking into account Governmental Authority requirements and existing tender constraints.
IncoTerm	Franchise Product 1 will be supplied to Novartis [*] (Incoterms 2010 ICC). Risk and title to the Franchise Product 1 shall transfer at [*].
Cost	Subject to [*], Franchise Product 1 will be supplied to Novartis at [*] (the "Supply Price"). In addition thereto, Amgen will be entitled to charge Novartis certain support costs directly related to the Manufacture or supply of Franchise Product 1 for the Territory that are not included in [*] ("Support Costs") ([*]). The mechanism for discussing, tracking and charging for Support Costs to be more fully detailed in the Supply Agreement. The Supply Agreement shall [*] to be defined in the Supply Agreement.

<u>Term</u>	<u>Description</u>																																				
[*]	<p>Notwithstanding anything to be contained in the Supply Agreement to the contrary, [*].</p> <p style="text-align: center;">[*]</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; text-align: center;">[*]</td> <td style="width: 33%; text-align: center;">[*]</td> <td style="width: 33%; text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> <td style="text-align: center;">[*]</td> </tr> <tr> <td colspan="3" style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td colspan="2" style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td colspan="2" style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td colspan="2" style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td colspan="2" style="text-align: center;">[*]</td> </tr> <tr> <td style="text-align: center;">[*]</td> <td colspan="2" style="text-align: center;">[*]</td> </tr> </table> <p>[*]</p>	[*]	[*]	[*]	[*]			[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]			[*]	[*]		[*]	[*]		[*]	[*]		[*]	[*]		[*]	[*]	
[*]	[*]	[*]																																			
[*]																																					
[*]	[*]	[*]																																			
[*]	[*]	[*]																																			
[*]	[*]	[*]																																			
[*]	[*]	[*]																																			
[*]																																					
[*]	[*]																																				
[*]	[*]																																				
[*]	[*]																																				
[*]	[*]																																				
[*]	[*]																																				
Site of Manufacture	Amgen has sole discretion to determine which Amgen site will be utilized for Manufacturing drug substance and drug product for the Franchise Product 1, [*]. [*]. [*]. At any time, Amgen can use a Third Party CMO, [*] provided that [*].																																				
Audit Right	Novartis will have the right to inspect Amgen’s sites utilized for Manufacturing, [*] storage, testing, shipping or receiving of the Franchise Product 1 [*] per twelve (12) month period, as well as more often in case of quality issue. No such audit of any commercial Manufacturing facility shall occur until after [*] at such facility for the applicable Franchise Product 1.																																				
Official Inspection	Amgen will permit, and cause its Third Party CMO to permit, officials of any Regulatory Authority to inspect the Manufacturing facility utilized for Manufacturing drug substance and drug product for the Franchise Product 1, and will inform Novartis promptly of any planned or anticipated inspection. Amgen will permit, and cause its Third Party CMO to permit, Novartis to accompany such official inspection. Amgen will provide Novartis with copies of all reports and communications with the Regulatory Authority in connection therewith, will take into account Novartis’s comments before responding to such communications and will remedy any deficiencies at its own expense (provided, however, that Amgen shall be permitted to include certain of such expenses in [*] of Franchise Product 1).																																				
Orders and Quantities	The Supply Agreement will include provisions relating to forecasting, including frequency and length of forecasting, minimum order quantities, binding periods, variances, and long-range planning.																																				

<u>Term</u>	<u>Description</u>
Variation Management	The Supply Agreement will include provisions relating to variation management, including notification requirements, whether or not such variation is required by Governmental Authorities, or requires Governmental Authority approval.
Indemnification	Each Party (the “Indemnifying Party”) will indemnify the other Party for losses for any claim brought by a Third Party against the other Party to the extent such losses result from (i) the gross negligence or willful misconduct of the Indemnifying Party in performing under the Supply Agreement or the Quality Agreement or (ii) the breach by the Indemnifying Party of its obligations under the Supply Agreement. Amgen will indemnify Novartis for losses for any claim brought by a Third Party against Novartis to the extent such losses result from any manufacturing defect at the time of delivery of Franchise Product 1 to Novartis (including failure of product to be manufactured in accordance with cGMP), except in the case that the Amgen reasonably requests Novartis to take prompt mitigating actions (including conducting a recall) with respect to such Franchise Product 1, in which case (1) Amgen shall be responsible for the costs related to such mitigation actions and (2) Novartis shall be responsible for losses with respect to such Franchise Product 1 for which Novartis declines to take such requested actions to the extent that such losses result from Novartis’ refusal to implement such requested actions.
Distribution	Novartis will require its distributors to have appropriate controls in place to manage the Franchise Product 1 in accordance with product labeled conditions.
Miscellaneous	The Supply Agreement would contain other customary provisions including, without limitation, provisions regarding financial audit rights, confidentiality, warranties, and termination.
Franchise Product 2 and Franchise Product 3	<p>The terms and conditions set out in this Commercial Supply Schedule shall only serve as a basis for the Supply Agreement for the Franchise Product 1.</p> <p>The Supply Agreements for the Franchise Product 2 and the Franchise Product 3, if any, shall include terms and conditions substantially similar to those set out in this Commercial Supply Schedule.</p>

[*]

[*]

[*]

[*]

Amgen Ref. No. 2015641252

SCHEDULE

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Country	Application No.	Filing Date	Title
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

Schedule

Out-of-Pocket Development Expenses

Out-of-Pocket Development Expenses, with respect to a Licensed Product, include direct out-of-pocket costs that are attributable to the Development of the Licensed Product including:

1. Toxicology and pharmacokinetics studies;
2. Clinical studies, including all activities associated with starting, maintaining, and closing studies;
3. Clinical materials [*];
4. Consultants and temporaries used to obtain, maintain, or expand the Development of the Licensed Products for market approval;
5. Regulatory fees;
6. Costs associated with [*] Development activities relating to the Licensed Products, including [*];
7. [*] Development, [*] and ongoing [*] activities;
8. Costs to prepare, submit, or Develop data or information for submission to a Governmental Authority to obtain, maintain, or expand marketing approval of the Licensed Products (pre- or post-launch);
9. Costs associated with any [*] in support of [*] activities such as [*];
10. Payments to Third Parties for the performance of any Development activities with respect to the Development of the Licensed Products; and
11. [*] costs associated with Regulatory Filings. These costs include [*].

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Schedule
Press Release

Amgen Ref. No. 2015641252 SCHEDULE



News Release

AMGEN ENTERS INTO NEUROSCIENCE COLLABORATION WITH NOVARTIS FOR ALZHEIMER'S DISEASE AND MIGRAINE PROGRAMS

**Global Co-Development and Co-Commercialization Agreement in Alzheimer's Disease With Novartis'
Phase 1/2a BACE Inhibitor as the Lead**

**Preventative Treatment Approach Directed at Genetically Predisposed Individuals at Risk of Developing
Alzheimer's Disease; Builds on Amgen's Genetic Validation Strategy**

**Global Co-Development Agreement More Rapidly Advances Amgen's Migraine Programs, Including
AMG 334 in Phase 3**

**Amgen Retains Migraine Commercialization Rights in the U.S., Japan and Canada; Provides Novartis
With Rights to Commercialize Migraine Programs in Europe and Rest of World; Leverages Novartis'
Strong Commercial Neuroscience Presence**

THOUSAND OAKS, Calif., Sept. 1, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced a neuroscience collaboration with Novartis in the areas of Alzheimer's disease and migraine. The collaboration accelerates Amgen's potential entry into Alzheimer's disease by teaming up with Novartis on a differentiated and genetically validated Alzheimer's disease program directed at genetically predisposed individuals at risk of developing Alzheimer's disease. The collaboration also enables Amgen to focus on the commercialization of its migraine programs in the U.S., Canada and Japan, while leveraging Novartis' strong commercial capabilities in neuroscience throughout Europe and other markets worldwide.

The agreement combines each company's BACE (beta-site APP-cleaving enzyme-1) programs targeting Alzheimer's disease into a global co-commercialization and co-development arrangement. Novartis' Phase 1/2a BACE inhibitor (CNP520) will be the lead molecule and each company's pre-clinical BACE inhibitor programs will be potential follow-ons. Amgen will make upfront and milestone payments, and will be responsible for

disproportional research and development (R&D) costs for an agreed-upon period followed by a 50/50 cost and profit share arrangement. CNP520 is planned to be included in a pioneering prevention study, in collaboration with the Banner Alzheimer's Institute. Amgen was the first company to clone the BACE gene and subsequent genetic validation of the BACE target has been confirmed by Amgen subsidiary deCODE Genetics.

As part of the collaboration, Novartis receives global co-development rights and commercial rights outside of the U.S., Canada and Japan to the investigative molecules in Amgen's migraine portfolio program. This includes AMG 334 in Phase 3 and AMG 301 in Phase 1, as well as an option to commercialize an additional early-stage Amgen molecule in these territories. In exchange for territory rights, Novartis will fund disproportional amounts of global R&D expenses for an agreed-upon period on the migraine programs and pay Amgen double-digit royalties on sales.

"We are very pleased to be joining forces with Novartis on two important neuroscience programs where there remains high unmet medical need," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Our collaboration on BACE inhibition reflects Amgen's strategic focus on genetically validated drug candidates while our collaboration in migraine creates an opportunity to more rapidly advance AMG 334 on a global scale."

About CNP520

Novartis' CNP520 is an oral drug designed to prevent the production of different forms of amyloid and has the potential to prevent, slow or delay the symptoms associated with Alzheimer's disease. It is currently in Phase 1/2a trials.

About Amgen's BACE Research

BACE (beta-site APP-cleaving enzyme-1) initiates the production of beta amyloid (Ab), the primary constituent of amyloid plaques that are believed to play a key role in the etiology of Alzheimer's disease. It is hypothesized that inhibiting BACE could reduce the production of amyloid plaques. Amgen was the first to clone and characterize BACE in a 1999 *Science* publication.¹ Amgen subsidiary deCODE Genetics subsequently added corroborating human genetic evidence of its link to Alzheimer's disease in a 2012 *Nature* publication.² Amgen has a number of preclinical candidates targeting BACE inhibition.

About Novartis' Collaboration with the Banner Alzheimer's Institute

In collaboration with the Banner Alzheimer's Institute (BAI), Novartis is conducting a pioneering prevention study. The study with BAI is part of a ground-breaking research program known as the Alzheimer's Prevention Initiative and will involve more than 1,300 cognitively healthy adults, ages 60 to 75, with a genetic risk of developing symptoms of Alzheimer's disease because they inherited two genetic copies of the apolipoprotein E epsilon 4 (APOE4) allele – one from each parent. About 2 percent of the world's population has this genetic profile, which is strongly linked to late-onset Alzheimer's disease. One in four people carries one copy of the APOE4 gene. Participants in the study will be given either CNP520, CAD106 (not included in the collaboration with Amgen), or placebo. Pending regulatory approval, the study is planned to start in late 2015/early 2016 in sites in North America and Europe.

About Alzheimer's Disease

Alzheimer's disease, the most common type of dementia, is a progressive neurodegenerative disease that begins with microscopic changes in the brain. Alzheimer's disease causes problems with memory, thinking and behavior. Symptoms of the disease develop slowly and worsen over time. Two important components

of Alzheimer's disease are amyloid plaques and inflammation, the combination of which is believed to lead to a loss of synapses and neuronal death. The disease continuum can span decades with the initial amyloid accumulation occurring many years before the first signs of memory loss appear. It is estimated that approximately 44 million people globally have Alzheimer's disease or a related dementia.³ The global direct costs of Alzheimer's disease are estimated to be more than \$600 billion.⁴

About AMG 334

AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 targets the calcitonin gene-related peptide (CGRP) receptor, which is believed to transmit signals that can cause incapacitating pain. AMG 334 is currently under evaluation in several large global, randomized, double-blind, placebo-controlled studies to evaluate its safety and efficacy in migraine prevention.

About AMG 301

AMG 301 is a monoclonal antibody being investigated for the treatment of migraine.

About Migraine

Migraine has been declared one of the top 10 most disabling conditions in the world, with more than 10 percent of the worldwide population suffering from the condition.⁵ More complex than just a headache, migraines involve incapacitating head pain and physical impairment, frequently accompanied by nausea, vomiting, and aura-related sound or other sensory disturbances.⁶ Migraine also has a tremendous impact on patients' everyday lives, including work productivity and social interactions.^{7,8} More than half of people living with migraine will go undiagnosed.⁹

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. 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.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this

information as of Sept. 1, 2015, and expressly disclaims any duty to update information contained in this news release.

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

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

operations. Amgen's efforts to integrate the operations of companies it has acquired may not be successful. Amgen may experience difficulties, delays or unexpected costs and not achieve anticipated cost savings from its ongoing restructuring plan. Amgen's business performance could affect or limit the ability of Amgen's Board of Directors to declare a dividend or their ability to pay a dividend or repurchase Amgen common stock.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (media)
Kristen Neese, 805-313-8267 (media)
Arvind Sood, 805-447-1060 (investors)

References

- ¹ Vassar, R. et al. " β -Secretase cleavage of Alzheimer's amyloid precursor protein by the transmembrane aspartic protease BACE." *Science* 286.5440 (1999): 735-741.
- ² Supporting deCODE genetic evidence: Jonsson, T. et al. "A mutation in APP protects against Alzheimer's disease and age-related cognitive decline." *Nature* 488.7409 (2012): 96-99.
- ³ Policy Brief for Heads of Government: The Global Impact of Dementia 2013-2015, Alzheimer's Disease International (ADI), December 2013.
- ⁴ New Report Reveals Global Cost of Alzheimer's and Related Dementias is More Than \$600 Billion, Alzheimer's Association, 2010.
- ⁵ Vos et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *The Lancet*. 2012 Dec-2013 Jan;30(9859):2163-2196.
- ⁶ National Institute for Neurological Disorders and Stroke. Headache: Hope Through Research. http://www.ninds.nih.gov/disorders/headache/detail_headache.htm. Accessed June 4, 2015.
- ⁷ Migraine Research Foundation. Migraine Fact Sheet. 2015. Available: <http://www.migraineresearchfoundation.org/fact-sheet.html>. Accessed June 4, 2015.
- ⁸ Scher AI, Stewart WF, Ricci JA, Lipton RB. Factors associated with the onset and remission of chronic daily headache in a population-based study. *Pain*. 2003 Nov; 106(102:81-9).
- ⁹ National Headache Foundation. *Migraine*. Oct 2007. Available: <http://www.headaches.org/2007/10/25/migraine/>. Accessed June 4, 2015.



Novartis announces global partnership with Amgen to develop and commercialize pioneering neuroscience treatments

- The companies plan to co-develop and co-commercialize a BACE inhibitor program in Alzheimer's Disease (AD); Novartis' oral therapy CNP520 will be the lead molecule
- Novartis and Amgen also plan to co-develop and co-commercialize Amgen's migraine portfolio, including fully human monoclonal antibody AMG 334 with first phase III data expected in 2017
- Partnership reinforces Novartis' continued commitment to developing and bringing innovative neuroscience treatment options to patients

Basel, September 1, 2015 - Novartis announced today that it has entered into a global collaboration with Amgen to commercialize and develop pioneering neuroscience treatments. The companies will partner in the development and commercialization of a BACE inhibitor program in Alzheimer's Disease (AD). Novartis' oral therapy CNP520 will be the lead molecule and further compounds from both company's pre-clinical BACE inhibitor programs may be considered as follow-on molecules. The collaboration will also focus on new Amgen drugs in the migraine field, including phase III AMG 334 and phase I AMG 301. For the migraine program, Novartis will have global co-development rights and commercial rights outside the U.S., Canada, and Japan.

"This Novartis collaboration with Amgen highlights our clear commitment to neuroscience and to bring multiple, new targeted therapies to patients living with Alzheimer's disease and migraine, where the unmet medical need remains high." said David Epstein, Head of Novartis Pharmaceuticals.

Alzheimer's Disease is an irreversible, progressive brain disease characterized by loss of memory and other cognitive abilities. Amyloid build-up is considered a key driver of the progressive damage of the nervous system in AD. CNP520 is an oral drug designed to prevent the production of different forms of amyloid and has the potential to prevent, slow or delay the symptoms associated with AD. It is currently in phase I/IIa trials. CNP520 is

planned to be included in a pioneering prevention study in people with a genetic risk of developing AD, in collaboration with the Banner Alzheimer's Institute.

Migraine is a severe headache condition affecting more than 10% of the population[1] worldwide and a leading cause of disability. AMG 334 is a fully human monoclonal antibody under investigation for the prevention of migraine. AMG 334 inhibits the activity of Calcitonin-Gene-Related-Peptide (CGRP) by targeting its receptor. CGRP is believed to play a key role in the development of migraine. AMG 334 is currently under evaluation in several large global, randomized, double-blind, placebo-controlled phase III trials to assess its safety and efficacy in migraine prevention. In addition to AMG 334, the migraine portfolio will include the development of AMG 301 and potentially another investigational compound of Amgen. AMG 301 is a monoclonal antibody being investigated in phase I trials for the prevention of migraine.

The partnership with Amgen follows two recent developments in the Novartis neuroscience portfolio aimed at complementing Novartis' neuroscience presence and pipeline in, among others, multiple sclerosis, AD and neuromuscular diseases. In July 2015 Novartis acquired Spinifex Pharmaceuticals adding phase II compound EMA401 for the treatment of neuropathic pain to the portfolio. In August 2015 Novartis announced that it has entered into an agreement to acquire all remaining rights to Ofatumumab from GlaxoSmithKline plc (GSK) for relapsing-remitting multiple sclerosis (RRMS) and certain other autoimmune indications; closing of this transaction is subject to expiry of any waiting period under the US Hart-Scott-Rodino Act and other customary closing conditions.

Under the terms of the arrangement, Novartis and Amgen will share responsibilities for development and commercialization of the BACE inhibitor program. Amgen will pay an upfront payment and milestone payments as well as disproportional research and development costs for an agreed upon period followed by a 50/50 cost and profit share arrangement. For the compounds in the migraine field, Novartis receives global co-development rights and commercial rights outside the U.S., Canada and Japan to the investigative molecules in Amgen's migraine portfolio. This includes AMG 334 in phase III and AMG 301 in phase I as well as an option to commercialize an additional early-stage Amgen molecule in these territories. Novartis will fund disproportional global R&D expenses for an agreed period on the migraine programs and will pay Amgen double-digit royalties on sales.

About Alzheimer's

It is estimated that around 44 million people globally have Alzheimer's or a related dementia[2]. Alzheimer's Disease is an irreversible, progressive brain disease that slowly destroys memory and thinking skills and, eventually even the ability to carry out the simplest tasks of daily living. In most people with Alzheimer's, symptoms first appear after age 60. Alzheimer's Disease is the most common cause of dementia among older people. Although treatment can help manage symptoms in some people, currently there is no cure for this devastating disease.

About Migraine

Migraine is a type of headache disorder that involves recurrent attacks of moderate to severe pain that is typically pulsating, often unilateral and often associated with nausea, vomiting and sensitivity to light, sound and odors.[1] Headache disorders are underestimated, under-recognized and under-treated throughout the world and are associated with personal and societal burdens of pain, disability, damaged quality of life and financial cost.[3] There is a significant need for tolerable and efficacious preventive medications for migraine as discontinuation rates for existing oral preventive medications are high.[4]

About Novartis in Alzheimer's Disease

Novartis has a strong commitment to the treatment and prevention of Alzheimer's Dementia.

Exelon® Patch (rivastigmine transdermal system) is approved for the treatment of mild-to-moderate Alzheimer's Disease (AD) dementia in more than 90 countries, including more than 20 countries where it is also approved for Parkinson's disease dementia. Exelon Patch is also indicated for the treatment of patients with severe AD in 14 countries, including the US.

Novartis AD pipeline includes CNP520, an oral drug designed to prevent the production of different forms of amyloid that has the potential to prevent, slow or delay the symptoms associated with AD. It is currently in phase I/IIa trials. The pipeline also includes investigational compound CAD106. This is an anti-amyloid active immunotherapy which has completed phase IIa trials.

About collaboration with Banner Alzheimer's Institute (BAI)

In collaboration with the Banner Alzheimer's Institute (BAI), Novartis is conducting a pioneering prevention study. The study with Banner is part of a ground-breaking research program known as the Alzheimer's Prevention Initiative and will involve more than 1,300 cognitively healthy adults, ages 60 to 75, with a genetic risk of developing symptoms of AD because they inherited two genetic copies of the apolipoprotein E epsilon 4 (APOE4) allele - one from each parent. About 2 percent of the world's population has this genetic profile, which is strongly linked to late-onset AD. One in four people carries one copy of the APOE4 gene. Participants in the study will be given either CAD106 (not included in the collaboration with Amgen), CNP520, or placebo. Pending regulatory approval, the study is planned to start in late 2015/early 2016 in sites in North America and Europe.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "plan," "will," "expected," "commitment," "may," "under investigation," "under evaluation," "potentially," "investigational," "being investigated," "aimed," "subject to," "investigative," "pipeline," "pending," "planned," or similar terms, or by express or implied discussions regarding potential marketing approvals for CNP520, AMG 334, AMG 301, CAD106, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the partnership and collaboration, new indications or labeling for Exelon Patch, or regarding potential future revenues from such investigational compounds and products, and potential future revenues from the partnership

and collaboration with Amgen. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that CNP520, AMG 334, AMG 301, CAD106, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the partnership and collaboration will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that Exelon Patch will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that the partnership and collaboration with Amgen will achieve any or all of its intended goals and objectives, or be commercially successful. Nor can there be any guarantee that Exelon Patch or any of the investigational compounds subject to the partnership and collaboration with Amgen will be commercially successful in the future. In particular, management's expectations regarding such investigational compounds and products, and the partnership and collaboration with Amgen could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety issues; unexpected manufacturing or quality issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>(link is external).

References

[1.] National Institute for Neurological Disorders and Stroke. Headache: Hope

ThroughResearch. http://www.ninds.nih.gov/disorders/headache/detail_headache.htm(link is external). Accessed August 2015.

[2.] Policy Brief for Heads of Government: The Global Impact of Dementia 2013-2015. Published by Alzheimer's Disease International (ADI), London. December 2013.

[3.] World Health Organization. Headache disorders. Fact sheet N°277. <http://www.who.int/mediacentre/factsheets/fs277/en/>(link is external). 2012.

[4.] Blumenfeld et al; Headache 2013; 53:644-655

###

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Angela Fiorin
Novartis Global Pharma Communications
+41 61 324 8631 (direct)
+41 79 752 6955 (mobile)
angela.fiorin@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis(link is external)

For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: 41 61 324 7944

Samir Shah 41 61 324 7944

North America:

Pierre-Michel Bringer 41 61 324 1065

Richard Pulik 1 212 830 2448

Thomas Hungerbuehler 41 61 324 8425

Sloan Pavsner 1 212 830 2417

Isabella Zinck 41 61 324 7188

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

AMENDMENT No. 1
to the Exclusive License and Collaboration AGREEMENT
between Novartis Pharma AG and Amgen Inc.

This Amendment No. 1 (“**Amendment**”) is entered into as of April 21, 2017 (“**Amendment Effective Date**”) by and between Novartis Pharma AG, a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland (“**Novartis**”), and Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, USA (“**Amgen**”). Novartis and Amgen are each referred to individually as a “**Party**” and together as the “**Parties**”.

WHEREAS, Novartis and Amgen are parties to an Exclusive License and Collaboration Agreement dated as of August 28, 2015 (the “**Agreement**”), and amended as of April 21, 2017, concerning the development and commercialization of the Licensed Products;

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement regarding the payment of certain Third Party royalties;

WHEREAS, [*] (the “**Specified Third Party**”) owns certain intellectual property rights that may be relevant for [*] Franchise Product 1, related to [*] (the “**Third Party Patent**”);

WHEREAS, the Parties agree that in accordance with Section 9.8(ii) of the Agreement, [*] would be [*] any Third Party license fees, royalties or other payments payable with respect to Franchise Product 1 in relation to the Third Party Patent (the “**Third Party Patent Royalty**”) to the extent Amgen were to obtain a license to or acquire the Third Party Patent after the Effective Date without Novartis’s prior written consent; and

WHEREAS, the Parties agree that in accordance with the Agreement, Information or intellectual property is not “Controlled” by a Party unless such 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 in the Agreement without violating the terms of any agreement with any Third Party as of the time such Party would first be required under the Agreement 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 such payments or it is subject to Section 9.8 (Sublicense Payments) of the Agreement (i.e., such intellectual property is (i) licensed by Amgen prior to or as of the Effective Date or (ii) licensed or acquired by Amgen after the Effective Date without Novartis’s prior written consent and related to a Licensed Product or uses or methods of Manufacture thereof (or of its components));

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

1. DEFINITIONS

Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Agreement.

2. AMENDMENTS

The Parties agree that, as of the Amendment Effective Date, the Agreement is amended as set forth in this Section 2.

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

2.1 Section 9.8 of the Agreement is amended by the addition of the following sections immediately after Section 9.8 of the Agreement:

9.8.1 In the event that Amgen obtains license rights to the Third Party Patent with respect to Franchise Product 1, Novartis agrees to partially reimburse Amgen for the Third Party Patent Royalty in accordance with the following terms and conditions:

- a. Novartis shall reimburse Amgen [*] percent ([*]%) of the Third Party Patent Royalty payable by Amgen to Specified Third Party, however, such reimbursement shall not exceed [*] of Franchise Product 1 in the Territory; and
- b. The foregoing obligation shall apply to sales of Franchise Product 1 in the Territory from the First Commercial Sale of Franchise Product 1 in the Territory until the earlier of (i) the date of expiry of the Third Party Patent [*] or (ii) such date upon which any federal court of competent jurisdiction or any other Patent court of competent jurisdiction, in each case without any possibility of appeal, [*]; and
- c. For clarity, in the event that the First Commercial Sale of Franchise Product 1 in the Territory does not occur prior to (i) the date of expiry of the Third Party Patent, or (ii) such date upon which [*] by the relevant court of competent jurisdiction without any possibility of appeal, whichever occurs earlier, then Novartis shall not be obligated to reimburse Amgen for any Third Party Patent Royalty; and
- d. Amgen shall issue an invoice substantially in the form attached hereto as Annex 1 to Novartis with respect to the foregoing payments. Novartis will pay such invoice to Amgen within [*] days from the date of its receipt by Novartis; and
- e. Novartis shall reasonably cooperate with Amgen, including without limitation by providing information reasonably necessary to enable Amgen to meet its obligations to the Specified Third Party with respect to the Third Party Patent Royalty for Franchise Product 1 in the Territory.

9.8.2 For the avoidance of doubt, any payments of such Third Party Patent Royalty made by Amgen shall exclusively be reimbursed to Amgen under the present Amendment and Amgen will not include any payments or costs related to Third Party Patent Royalty in the calculation of Development Costs or in any costs related to Manufacturing/Manufacture and/or Supply of Franchise Product 1 according to the Clinical Supply Agreement or the Commercial Supply Agreement (being both ancillary agreements to the Agreement); for the avoidance of doubt, Amgen shall not invoice, and Novartis shall not make any duplicate payments in relation to, the Third Party Patent Royalty under the Commercial Supply Agreement.

9.8.3 Subject to Section 9.8.1, Novartis hereby consents to Amgen obtaining a license from Specified Third Party with respect to the Third Party Patent solely in relation to Franchise Product 1.

9.8.4 Subject to Section 9.8.1, Novartis will be deemed to have met its payment requirements under the definition of "Control" with respect to the Specified Third Party and the Third Party Patent solely in relation to Franchise Product 1 in the Territory.

3. INTEGRATION

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

4. APPLICABLE LAW & JURISDICTION

This Amendment shall be governed by, and construed in accordance with, the laws which govern the Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Agreement.

5. COUNTERPARTS

This Amendment 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 Amendment may be exchanged by facsimile or other electronic means without affecting the validity thereof.

[Remainder of Page Intentionally Left Blank – Signature Page to Follow]

EXECUTION COPY

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives.

NOVARTIS PHARMA AG

AMGEN INC.

By: /s/ Nigel Sheail

By: /s/ Somnath Chattopadhyay

Name: Nigel Sheail

Name: Somnath Chattopadhyay

Title: Novartis Pharma AG Head Business Development & Licensing
Forum 2-6.04
4002 Basel

Title: VP Global Supply Chain

Date: April 7, 2017

Date: April 21, 2017

By: /s/ Gregor von Arx/

Name: Gregor von Arx

Title: Head Legal, Neurosciences Franchise a.i.

Date: April 10, 2017

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

ANNEX 1

Sample Invoice to Novartis Pharma AG

[Amgen Letterhead]

[Date]
NOVARTIS PHARMA AG
Zentraler Faktureneingang
Postfach
4002 Basel
Switzerland

Attn: [Please insert]

Dear _____

Re: Third Party Patent Royalty – Letter Amendment Agreement [EFFECTIVE DATE]

This is an invoice requesting payment in connection with the above-captioned agreement between Amgen Inc. and Novartis Pharma AG.

Project Contact Person in Novartis: [_____]

SPECIFICATION: [describe in reasonable detail the event for which payment is due]

Amount and Currency: [_____]

Amount of VAT (if applicable): [_____]

Total Amount (including VAT): [_____]

VAT number (if applicable) [_____]

Bank Address and Account No.: [insert the name and address of the bank to which the payment should be sent and the account number to which it should be credited]

Sincerely yours,

[Amgen]

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

AMENDMENT No. 2
to the Exclusive License and Collaboration Agreement
between Novartis Pharma AG and Amgen Inc.

This Amendment No. 2 (“**Amendment**”) is entered into as of April 21, 2017 (“**Amendment No. 2 Effective Date**”) by and between Novartis Pharma AG a Swiss corporation having its principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland (“**Novartis**”) and Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, USA (“**Amgen**”). Novartis and Amgen are each referred to individually as a “**Party**” and together as the “**Parties**”.

WHEREAS, Novartis and Amgen are parties to an Exclusive License and Collaboration Agreement dated August 28, 2015 and amended as of April 21, 2017 (the “**Agreement**”) concerning the development and commercialization of the Licensed Products.

WHEREAS, simultaneously herewith, the Parties are entering into that certain US Collaboration Agreement (as defined below).

WHEREAS, the Parties mutually desire to expand the Territory to include Canada.

WHEREAS, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement in connection with the US Collaboration Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants herein contained, it is mutually agreed as follows:

1. DEFINITIONS

Unless otherwise defined herein, capitalized words in this Amendment shall have the meaning attributed to them in the Agreement.

2. AMENDMENTS

The Parties agree that, as of the Amendment No. 2 Effective Date, the Agreement is amended as set forth in this Section 2.

- 2.1 Solely with respect to those provisions of the Agreement not hereby amended in this Amendment, Novartis’ and Amgen’s rights and obligations under the Agreement with respect to Franchise Product 1 in the United States are subject to the terms and conditions set forth in the US Collaboration Agreement (for clarity, including the obligations of the Parties under Article 14 of the Agreement, which are subject to the obligations of the Parties under Article 13 of the US Collaboration Agreement with respect to Franchise Product 1 in the United States); *provided*, for clarity, nothing in the US Collaboration Agreement shall be deemed to alter, modify or limit in any manner the rights and licenses of the Parties set forth in Article 4 of the Agreement or the

defined terms utilized in such Article or the rights and obligations of the Parties set forth in Sections 11.6.2 or 11.7.2 of the Agreement.

2.2 The Licensed Amgen Patent Schedule is hereby updated to include the Patents Controlled by Amgen or its Affiliates in Canada relating to the Licensed Products as of the Amendment No. 2 Effective Date, as set forth on the schedule of Licensed Amgen Patents for the Licensed Products for Canada attached hereto.

2.3 The following sentence shall be added to the Recitals:

“WHEREAS, Amgen and Novartis are parties to that certain Collaboration Agreement, dated April 21, 2017, with respect to the Commercialization of, and Medical Affairs Activities for, Franchise Product 1 in the United States (the “*US Collaboration Agreement*”).”

2.4 The second Recital of the Agreement is hereby deleted in its entirety and replaced with the following:

“WHEREAS, Amgen is Developing its proprietary monoclonal antibody against calcitonin gene-related peptide (CGRP) receptor, known as AMG 334 (“*Franchise Product 1*”); its proprietary pituitary adenylate cyclase activating peptide (PACAP) receptor antibody, known as AMG 301, and [*] (“*Franchise Product 2*”); and [*] (“*Franchise Product 3*”).”

2.5 The following definitions shall be added to Article 1 in appropriate alphabetical order:

“*Amgen Proprietary Manufacturing Know-How*” has the meaning set forth in Section 5.4.7.1.

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

“*Canadian Territory Transition Plan*” has the meaning set forth in Section 5.4.6.2.

“*Confidential Regulatory Process*” has the meaning set forth in Section 5.4.7.1.1.

“*Designated Personnel*” has the meaning set forth in Section 5.4.7.1.2.

“*Drug Master File*”, and its abbreviation “*DMF*” mean with respect to the United States, the drug master file or any supplement thereto, in respect of the active pharmaceutical or therapeutic ingredient(s) for a Licensed Product, filed by Amgen or its Affiliates or a Third Party with the FDA, which shall include the specifications for such Licensed Product or, with respect to any jurisdiction other than the United States, an equivalent filing thereof.

“*Franchise Product 1 Distracting Product*” means any compound or product, [*], that [*] (i.e., [*]).

“*Franchise Product 1 Distracting Program*” means the clinical development, commercialization or manufacture of any Franchise Product 1 Distracting Product.

“*IND Reference Letter*” has the meaning set forth in Section 5.4.6.1.

“*Termination Date*” has the meaning set forth in Section 15.3.3.

“*US Collaboration Agreement*” has the meaning set forth in the Recitals.

2.6 The last sentence of Section 1.2 of the Agreement is hereby deleted in its entirety.

2.7 Section 1.13 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.13 “*Biosimilar Product*” means, with respect to a given Licensed Product in a given country in the Territory, after Regulatory Approval of such Licensed Product in such country, 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) such Licensed Product, (ii) has a purity, potency and safety profile that has no clinically meaningful difference from the purity, potency and safety profile of such Licensed Product, (iii) is approved for use pursuant to a regulatory approval process in such country that is based on reliance, at least in part, on such Licensed Product, whether or not such regulatory approval was based upon data generated by either Party filed with the applicable Governmental Authority in such country or was obtained using an abbreviated, expedited or other process, and (iv) is sold in such country by any Third Party.”

2.8 Section 1.31 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.31 “*Develop*” or “*Development*” means those activities required and/or useful to obtain and maintain Regulatory Approval, including, without limitation, test method development and stability testing, assay development and audit development, pre-clinical/non-clinical studies (including toxicology studies), formulation, pharmacodynamics, quality assurance/quality control development, statistical analysis, clinical studies, packaging development, regulatory affairs, biomarker strategy and development, device strategy and development, report writing and statistical analysis, the preparation, filing and prosecution of MAAs and activities to obtain international nonproprietary names and other nonproprietary names such as U.S. Adopted Name (USAN) for pharmaceutical substances; *provided, however*, that Development shall exclude Commercialization and Manufacturing activities. For clarity, Development shall include clinical trials that are required or requested in writing by a Governmental Authority as a condition of, or in connection with, obtaining or maintaining Regulatory Approval (whether the trial is commenced prior to or after receipt of such Regulatory Approval). Further, Development shall include Phase 4 Clinical Trials and lifecycle management activities that relate specifically to the United States.”

2.9 Section 1.33 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.33 “*Development Costs*” means the direct costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement for the Development of and Medical Affairs Activities with

respect to a Licensed Product(s), calculated as the sum of (i) Out-of-Pocket Development Expenses, (ii) Development FTE Costs and (iii) Other Development Expenses, each only to the extent incurred in accordance with the Development Plan and Development Budget after the Effective Date. For clarity, “Development Costs” does not include any costs associated with conducting any Phase 4 Clinical Trials or lifecycle management activities unless the Parties otherwise agree to include a Phase 4 Clinical Trial or lifecycle management activities in the Development Plan or the Parties otherwise agree pursuant to the US Collaboration Agreement with respect to Phase 4 Clinical Trials and lifecycle management activities that relate specifically to the United States.”

2.10 Section 1.34 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.34 “*Development FTE Costs*” means the product of (i) the actual number of FTEs utilized in the Development of and Medical Affairs Activities with respect to a Licensed Product(s) in accordance with the Development Plan and Development Budget after the Effective Date, as documented by the applicable Party using a reliable time tracking system, if available, or other internal process for FTE allocations, and (ii) the FTE Rate.”

2.11 Section 1.93 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.93 “*Material Safety Issue*” means, with respect to a given Licensed Product, a Party’s good faith belief that, after reviewing applicable safety data and other relevant safety factors, such Licensed Product should not [*].”

2.12 Section 1.94 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.94 “*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, a Licensed Product, as established by the applicable Party’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 a Licensed 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.”

2.13 Section 1.97 of the Agreement is hereby deleted in its entirety and replaced with the following:

“1.97 “*Net Sales*” means with respect to a given period and a given Licensed Product, the gross invoiced sales for such Licensed Product sold by or on behalf of Novartis or any of its Affiliates or sublicensees hereunder 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 Novartis’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 any [*] imposed upon the sale of the Licensed Product to Third Parties; and
- (ix) following such deductions in (i) through (viii) above, less a deduction of [*] percent ([*]%) for direct expenses related to the sales of the Licensed 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 Novartis and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales; (b) if a Licensed 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 Novartis's Accounting Standards are met; and (c) in the event that the Licensed Product is sold in a given country together with one or more other therapeutically active ingredients or therapies not constituting a Licensed Product for a single price (regardless of their packaging) (a "*Combination Product*"), such Licensed Product shall be deemed to be sold in such country for an amount equal to the product of (i) the price at which the Combination Product was sold in such country and (ii) the fraction $A/(A+B)$, where A is the weighted (by sales volume) average sale price in such country during the applicable reporting period of the Licensed Product when sold alone, and B is the weighted average sale price (by sales volume) in such country 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 Licensed Product or other therapeutically active ingredients or therapies than those that are included in the Combination Product, then Novartis 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 Licensed 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 Licensed Product at no charge for, or use of such Licensed Product without charge in, clinical or preclinical trials shall not be included in Net Sales."

2.14 Section 1.117 of the Agreement is hereby deleted in its entirety and replaced with the following:

"1.117 *"Out-of-Pocket Development Expenses"* means direct expenses paid or payable to Third Parties which are specifically identifiable and incurred by a Party and its Affiliates for the Development of and Medical Affairs Activities with respect to Licensed Product(s), including the expenses set forth on the Out-of-Pocket Development Expenses Schedule; *provided* that such expenses shall have been recorded as income statement items in accordance with such Party's Accounting Standards and shall not include any pre-paid amounts, capital expenditures, or items intended to be covered by the FTE Rate."

2.15 Section 1.139 of the Agreement is hereby deleted in its entirety.

2.16 Section 1.151 of the Agreement is hereby deleted in its entirety and replaced with the following:

"1.151 *"Territory"* means the entire world, excluding the United States and Japan."

2.17 The following sentence shall be added to the end of Section 3.2.5 of the Agreement (which, for clarity, shall be renumbered to Section 3.2.6 pursuant to Section 2.18 below):

"The Parties agree that the JSC shall establish a Joint Project Team to oversee Development activities, Medical Affairs Activities and publications, in each case to the extent relating solely to Franchise Product 1 in the United States, during the term of the US Collaboration Agreement."

2.18 The following language shall be added as a new Section 3.2.5 of the Agreement (and the remainder of Section 3.2 to be renumbered accordingly):

"3.2.5 *Committees in the United States.* During the term of the US Collaboration Agreement, the Joint US Leadership Team and US Collaboration Team (each as defined in the US Collaboration Agreement) shall oversee matters relating to Commercialization of, and facilitate coordination of such activities with Medical Affairs Activities for, Franchise Product 1 in the United States pursuant to the terms of the US Collaboration Agreement; *provided, however* that, pursuant to the terms of the US Collaboration Agreement, certain matters relating to Medical Affairs Activities for, and the Commercialization of, Franchise Product 1 in the United States may be escalated to the JSC."

2.19 Section 3.5.3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

"3.5.3.1 Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1 in the United States, the Amgen Co-Chair shall have the deciding vote with respect to the Global Brand Plans and all Commercialization matters with respect to the Licensed Products outside the Territory."

2.20 Section 3.7 of the Agreement is hereby deleted in its entirety and replaced with the following:

“3.7 Alliance Managers. Promptly but not later than sixty (60) days following the Effective Date, each of Amgen and Novartis shall appoint one or more senior representatives who possess a general understanding of Development, regulatory, Medical Affairs Activities, Manufacturing and Commercialization matters to act as its respective alliance manager(s) for the 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 Committees. Consistent with the Development Plan, the Territory Brand Plan and Section 3.5 (Decision Making), each Alliance Manager, on behalf of the applicable Party’s Co-Chair of the applicable Committee, will also be responsible for:

- 3.7.1 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
- 3.7.2 identifying and raising disputes to the JSC or JMC for discussion in a timely manner.

The Alliance Managers shall be entitled to attend all JSC and JMC meetings, and shall have the right to attend all JPT meetings. Consistent with Section 3.5 (Decision Making), each Alliance Manager may bring any matter to the attention of the JSC or JMC where such Alliance Manager reasonably believes that such matter requires attention of the JSC or JMC. During the term of the US Collaboration Agreement, the Alliance Managers appointed under this Agreement shall also serve as the Alliance Managers under the US Collaboration Agreement pursuant to Section 2.7 of the US Collaboration Agreement.”

2.21 Section 3.8 of the Agreement is hereby deleted in its entirety and replaced with the following:

“3.8 Outside the Territory. Except as expressly set forth in this Agreement or, with respect to Franchise Product 1, the US Collaboration Agreement, Amgen shall have sole decision-making authority with regard to Development, regulatory, Medical Affairs Activities, Manufacturing and Commercialization of Licensed Products outside the Territory. Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, Novartis and its Affiliates shall not Commercialize or conduct Medical Affairs Activities with respect to Licensed Products outside the Territory.”

2.22 The last sentence of Section 4.6 of the Agreement is hereby deleted in its entirety and replaced with the following:

“Except as expressly set forth in the US Collaboration Agreement with respect to Trademarks for Franchise Product 1, Amgen agrees that it shall not seek to register or obtain ownership rights in any Novartis Housemark or Licensed Novartis Trademark (or confusingly similar trademark) and Novartis agrees that it shall not seek to register or obtain ownership rights in any Amgen Housemark or Licensed Amgen Trademark or any trademark used by Amgen in connection with the applicable Licensed Product outside the Territory in any indication (or confusingly similar trademark to any of the foregoing).”

2.23 Section 4.8 of the Agreement is hereby deleted in its entirety and replaced with the following:

“4.8 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. Subject to Section 2.3 (Development Prior to Option Exercise Date), (i) Novartis shall not research, Develop, Manufacture, conduct Medical Affairs Activities with respect to or Commercialize Franchise Product 3 prior to the Option Exercise Date or any Licensed Product outside the Territory other than as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1 and (ii) Amgen shall not research, Develop, conduct Medical Affairs Activities with respect to or Commercialize any Licensed Product inside the Territory, in each case ((i) and (ii)), other than as expressly set forth in this Agreement (including under a Development Plan). Notwithstanding the licenses granted in this Article 4 (Grant of License), each Party retains rights to perform (itself or through its Affiliates or contractors) its obligations under this Agreement.”

2.24 Section 5.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“5.1 Responsibility for Development. Except as otherwise set forth in this Section 5.1 (Responsibility for Development), from and after the Effective Date, with respect to Franchise Product 1 and Franchise Product 2, and from and after Option Exercise Date, with respect to Franchise Product 3, the Parties will share responsibility for day-to-day Development activities for each Licensed Product worldwide in accordance with the applicable Development Plan and Development Budget, including generating protocols subject to the JSC’s review and approval, conducting clinical trials, and data collection, verification and analysis. Solely with respect to Franchise Product 1 prior to receipt of the first Regulatory Approval therefor in the U.S., (i) Amgen shall be the Development lead and shall have primary responsibility for day-to-day Development activities relating thereto worldwide in accordance with the applicable Development Plan and Development Budget and (ii) Novartis shall provide both strategic input and operational support for such activities as agreed in the applicable Development Plan and Development Budget; *provided* that, notwithstanding the foregoing, Novartis shall have those responsibilities with respect to Franchise Product 1 and Franchise Product 2 as set forth in the RACI Documents, including with respect to [*]. In the event of a conflict between the terms of this Agreement, a Supply Agreement or a Quality Agreement, on the one hand, and the RACI Documents, on the other hand, the terms of this Agreement, such Supply Agreement or such Quality Agreement shall prevail. Additionally, [*] shall be [*] responsible for the development of any Clinical Trials or other activities directed to Lifecycle Management for the Licensed Products as agreed by the JSC and approved by the JMC; *provided, however*, with respect to such activities conducted in the

United States for Franchise Product 1, in the event of a conflict between the terms of this Agreement and the US Collaboration Agreement, the terms of the US Collaboration Agreement shall prevail during the term of the US Collaboration Agreement. For clarity, as between the Parties, Amgen shall have the sole right to perform Development activities solely relating to Development of the Licensed Products for Regulatory Approval in Japan to the extent such activities are not allocated to Novartis in the Development Plan as of the Amendment No. 2 Effective Date. Notwithstanding anything to the contrary contained herein, [*] shall be responsible at its expense for determining and providing all Medical Affairs Activities relating to the Licensed Products in the Territory.”

2.25 The following sentence shall be added to the end of Section 5.2.1 of the Agreement:

“For clarity, with respect to Franchise Product 2, the Parties may elect in the Development Plan to [*].”

2.26 The following language shall be added as a new Section 5.4.5 of the Agreement:

“5.4.5 *United States*. During the term of the US Collaboration Agreement, all regulatory matters with respect to Franchise Product 1 in the United States shall be governed by Section 4.2 of the US Collaboration Agreement and Section 3.5 (Decision Making) of this Agreement.”

2.27 The following language shall be added as a new Section 5.4.6 of the Agreement:

“5.4.6 *Regulatory Filings and Support in Canada.* Notwithstanding anything to the contrary in Section 5.4 (Regulatory Matters) or Section 8.4 (Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities):

5.4.6.1 *DMF for Franchise Product 1 in Canada.* Amgen shall prepare a DMF for Franchise Product 1 and submit such DMF to the relevant Governmental Authority in Canada at least [*] days prior to the date on which the Parties anticipate, [*]. Amgen shall [*], such DMF during [*] for Novartis to maintain Regulatory Approval for Franchise Product 1. Amgen shall grant to Novartis the right of cross-reference, as of the Amendment No. 2 Effective Date, to the IND for Franchise Product 1 in Canada until it is transferred to Novartis or withdrawn, and thereafter, to the DMF for Franchise Product 1, in connection with the Development and Regulatory Approval of Franchise Product 1 in the Field within the Territory. Amgen shall promptly deliver to the relevant Governmental Authority in Canada any instruments, including the appropriate letters of the right to cross-reference, necessary to grant Novartis the right to cross-reference (i) as of the Amendment No. 2 Effective Date, the IND for Franchise Product 1 in Canada (“*IND Reference Letter*”) and (ii) as of the date of Regulatory Approval of Franchise Product 1 in Canada, the DMF for Franchise Product 1, in accordance with this Agreement. For clarity, except as may be redacted to protect the confidential and proprietary rights in its Information related to Manufacturing, Amgen shall provide to Novartis electronic copies (in substantially the same layout and format as submitted to the relevant Governmental Authority) of the IND for Franchise Product 1 in Canada and any IND equivalent filings for Franchise Product 1 submitted to the relevant Governmental Authorities outside Canada in the Territory, as of the Amendment No. 2 Effective Date, together with all material communications and correspondence with the relevant Governmental Authorities in connection with the submission or approval of such Regulatory Filing.

5.4.6.2 *Transition of Canadian Territory to Novartis for Franchise Product 1.* Promptly following the Amendment No. 2 Effective Date, the Parties will meet to coordinate the transition of development and regulatory activities from Amgen to Novartis with respect to Franchise Product 1 in Canada. Within [*] after the Amendment No. 2 Effective Date or such other timeframe as may be mutually agreed by the Parties in writing, the Parties will develop a written plan for transfer of the ongoing Development and regulatory activities for Franchise Product 1 in Canada (the “*Canadian Territory Transition Plan*”). Unless otherwise agreed by the Parties in writing in the Canadian Territory Transition Plan, (i) such plan shall provide that Amgen will file the MAA for Franchise Product 1 in Canada with the relevant Governmental Authority and transfer such MAA to Novartis at a mutually agreed time prior to receipt of Regulatory Approval for Franchise Product 1 in Canada, (ii) prior to the transfer of the MAA for Franchise Product 1 in Canada to Novartis the provisions set forth in Sections 5.4.6.2.1 and 5.4.6.2.2 shall apply with respect to regulatory matters in Canada in respect of Franchise Product 1 and (iii) after the transfer of the MAA for Franchise Product 1 in Canada to Novartis, the provisions set forth in Sections 5.4.1 and 5.4.2 shall apply with respect to regulatory matters in Canada for Franchise Product 1 (at which time, for clarity, Novartis shall be the regulatory lead in Canada).

5.4.6.2.1 Prior to the transfer of the MAA for Franchise Product 1 in Canada to Novartis, Amgen shall be the regulatory lead in Canada and shall have primary responsibility for regulatory activities relating to Franchise Product 1 in Canada, including preparing, submitting and maintaining all Regulatory Filings in Canada 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 with respect to Franchise Product 1, Amgen shall provide Novartis with draft copies of material Regulatory Filings (which, for clarity, shall not be required to include communications that are solely administrative in nature) with respect to Franchise Product 1 in Canada prior to submission within a reasonable amount of time and reasonably consider comments of Novartis (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). Amgen shall consult with Novartis regarding, and keep Novartis 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 with respect to Franchise Product 1 in Canada, and Governmental Authority review of any such Regulatory Filings. Amgen shall provide to Novartis copies of all final Regulatory Filings it submits with respect to Franchise Product 1 in Canada promptly after the submission. Notwithstanding the foregoing, Amgen shall have no obligation to share with Novartis the contents of the CMC Core Dossier for Franchise Product 1.

5.4.6.2.2 Prior to the transfer of the MAA for Franchise Product 1 in Canada to Novartis, Amgen shall consult with Novartis reasonably in advance of the date of any anticipated meeting with a Governmental Authority in Canada with respect to Franchise Product 1 and shall consider any timely recommendations made by Novartis in preparation for such meeting. Based on the discussions between Amgen and Novartis, Amgen shall create an agenda for such meeting and use good faith judgment to assign roles to each of Amgen and Novartis, as appropriate based on the expertise of such participants. One or more (up to [*]) representatives of Novartis with appropriate subject matter expertise may attend scheduled meetings between Amgen and the applicable Governmental Authority in Canada with respect to Franchise Product 1, and shall participate in such meetings consistent with the agenda for the meeting created by Amgen and the role(s) assigned to Novartis by Amgen thereunder, in each case to the extent permissible by such Governmental Authority. Amgen shall inform Novartis of any unscheduled teleconferences and meetings (other than teleconferences and meetings that are solely administrative in nature) with Governmental Authorities in Canada with respect to Franchise Product 1 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 Canada with respect to Franchise Product 1 manufacturing or CMC information (or any such meetings solely with respect to Franchise Product 1 manufacturing or CMC information).

5.4.6.3 *Licensed Products other than Franchise Product 1:*

5.4.6.3.1 Amgen shall have the option, exercisable at its sole discretion, to prepare a DMF for Franchise Product 2 and Franchise Product 3 and submit any such DMF to the relevant Governmental Authority in Canada on a timeline mutually agreed by the Parties. Amgen shall [*], any such DMF during the Term until such time [*] for Novartis to maintain Regulatory Approval for Franchise Product 2 or Franchise Product 3, as the case may be. Amgen shall grant to Novartis a right of cross-reference to any DMF for Franchise Product 2 or Franchise Product 3 in connection with the Development and Regulatory Approval of the applicable Licensed Product in the Field within the Territory. Amgen shall promptly deliver to the relevant Governmental Authority in Canada any instruments, including the appropriate letters of the right to cross-reference, necessary to grant Novartis such right of cross-reference in accordance with this Agreement.

5.4.6.3.2 For clarity, (i) the provisions of this Section 5.4.6, other than Section 5.4.6.3.1, apply only to Franchise Product 1 and not Franchise Product 2 or Franchise Product 3 and (ii) the provisions set forth in Section 5.4 (Regulatory Matters) other than this Section 5.4.6, but including Section 5.4.6.3.1, shall apply with respect to regulatory matters in Canada for Franchise Product 2 and Franchise Product 3 as of the Amendment No. 2 Effective Date (i.e., Novartis shall be the regulatory lead in Canada for Franchise Product 2 and Franchise Product 3 as of the Amendment No. 2 Effective Date).”

2.28 The following language shall be added as a new Section 5.4.7 of the Agreement:

“5.4.7 *Regulatory Filings and Support related to Manufacturing.* Notwithstanding anything to the contrary in Section 5.4 (Regulatory Matters) or Section 8.4 (Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities):

5.4.7.1 In the event that Novartis requires additional Information from Amgen related to Manufacturing in order to respond to the relevant Governmental Authority in the Territory in connection with the Development and Regulatory Approval of a Licensed Product in the Field in the Territory (including any required information to prepare its Regulatory Filings for such Licensed Product), then Amgen shall [*] provide [*] such additional Information (to the extent such Information is in existence and available) to Novartis in order to meet any applicable time period required or otherwise specified by the relevant Governmental Authority in the Territory; *provided, however*, Novartis shall promptly provide any relevant questions or inquiries from such Governmental Authority to Amgen to allow Amgen to meet any applicable time period. In the event any such additional Information is proprietary to and maintained as confidential by Amgen at the time such response is to be made (“*Amgen Proprietary Manufacturing Know-How*”) (for clarity, and without limiting the foregoing, any Information previously redacted by Amgen prior to delivery to Novartis shall constitute Amgen Proprietary Manufacturing Know-How), Amgen shall [*] such Amgen Proprietary Manufacturing Know-How as follows:

5.4.7.1.1 If a process has been agreed to with the relevant Governmental Authority in the Territory to allow Amgen to respond to such Governmental Authority without having to disclose Amgen Proprietary Manufacturing Know-How to Novartis (“*Confidential Regulatory Process*”), then Amgen shall provide to such Governmental Authority such Amgen Proprietary Manufacturing Know-How through such Confidential Regulatory Process and provide to Novartis a redacted copy (to protect the confidential and proprietary rights in such Amgen Proprietary Manufacturing Know-How) of the relevant document submitted to such Governmental Authority within [*] days of its submission to be retained by the regulatory department of Novartis in its repository as an archival copy. Novartis shall not intentionally seek to access or obtain any such Amgen Proprietary Manufacturing Know-How submitted through such Confidential Regulatory Process from the relevant Governmental Authority, and Novartis shall [*] to obtain consent with the relevant Governmental Authority to establish a Confidential Regulatory Process, including, by way of example, a process to allow Amgen to respond directly to such Governmental Authority on Novartis’s behalf or a process to allow Amgen to provide Amgen Proprietary Manufacturing Know-How in an encrypted format to Novartis to submit to such Governmental Authority and to provide the Governmental Authority with the password or key to unencrypt such Amgen Proprietary Manufacturing Know-How.

5.4.7.1.2 [*].”

2.29 Section 6.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

“6.3 Commercialization Outside the Territory. Except as expressly set forth in this Agreement or, with respect to Franchise Product 1, the US Collaboration Agreement, Amgen shall be solely responsible for the Commercialization of the Licensed Products outside the Territory and the costs thereof. Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, Novartis shall not Commercialize the Licensed Products outside the Territory.”

2.30 Section 7.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

“7.4 [*] Divestiture. The notice provided pursuant to Section 7.3 (Post-Effective Date Affiliates) shall include a notification as to whether such Party intends to: (i) Divest the Distracting Program, in which case such Party shall hold separate such Distracting Program (including Segregating such Distracting Program from the Collaboration) and use its commercially reasonable, good-faith efforts to Divest such Distracting Program; (ii) [*] such Distracting Program, in which case such Party shall [*] all activities of such program within [*] days after the closing of the Distracting Transaction, during which period such Party shall hold separate such Distracting Program (including Segregating such Distracting Program from the Collaboration); or (iii) in the case of Amgen only, [*] and, under Section [*] ([*] Distracting Program) of the US Collaboration Agreement, [*] or, in the case of Novartis, [*], in each case within [*] days after the closing of the Distracting Transaction. In the event such Party selects to Divest the Distracting Program under subsection (i) and fails to complete such Divestiture within [*] of the closing of the Distracting Transaction, then such Party shall be deemed to have chosen to terminate such Distracting Program and shall promptly, and no later than within [*] days, comply with the requirements of subsection (ii) above.”

2.31 The first sentence of Section 9.7.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“In addition to the other payments referenced herein, and subject to Novartis’ obligations set forth in the last sentence of Section 5.1 (Responsibility for Development) with respect to Medical Affairs Activities Costs, and without limitation to Novartis’ obligations set forth in Article 8 (Payment) of the US Collaboration Agreement, with respect to each Licensed Product, Novartis shall bear the percentage of Amgen Development Costs set forth in the “Novartis Share” column of the applicable chart below and Amgen shall bear the percentage of Novartis Development Costs set forth in the “Amgen Share” column of the chart below, in each case, that are included in the applicable Development Budget.”

2.32 Section 9.7.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

Annual Development Budget Overruns. With respect to each Licensed Product, each Party shall promptly notify the other Party upon becoming aware that its Development Costs to be incurred in performing the applicable Development Plan for a Calendar Year will be in excess of the amounts budgeted to be incurred by or on behalf of such Party for its activities in the applicable Annual Development Budget. If the aggregate Development Costs incurred by a Party for performing the applicable Development Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of such Party for its activities in the applicable Annual Development Budget, the other Party shall reimburse the performing Party for (i) the applicable percentage set forth above of such excess, and (ii) in the case of Franchise Product 1 during the term of the US Collaboration Agreement, the applicable percentage set forth in Section 8.6.1.3 of the US Collaboration Agreement of such excess; *provided* that (a) in no event shall Novartis be responsible for reimbursement for such excesses to the extent the Amgen Development Costs in performing the Development Plan (I) for [*], exceed the amounts budgeted to be incurred by or on behalf of Amgen for its activities in the applicable Annual Development Budget for [*], and (II) for [*],

exceed the amounts budgeted to be incurred by or on behalf of Amgen for its activities in the applicable Annual Development Budget for such Calendar Year by more than [*] percent ([*]%) and (b) in no event shall Amgen be responsible for reimbursement for such excesses to the extent the Novartis Development Costs in performing the Development Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of Novartis for its activities in the applicable Annual Development Budget for such Calendar Year by more than [*] percent ([*]%); *provided* that a Party shall be responsible for reimbursement for such excesses to the extent that the Amgen Development Costs or Novartis Development Costs, as the case may be, are attributable to (I) a change in applicable Law, (II) a Force Majeure event, (III) [*], (IV) [*], or (V) a mutually agreed amendment to the applicable Development Plan.

2.33 Section 9.7.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

“9.7.4 *Payments*. Based on the report received from the other Party pursuant to Section 9.7.3 (Reports), the Party which has borne more than its share of Development Costs as determined pursuant to Section 9.7.1 (General) of this Agreement and, solely with respect to Development Costs with respect to Franchise Product 1, Section 8.6.1.3 of the US Collaboration Agreement shall issue an invoice to the owing Party for such excess amount in accordance with Section 9.10 (Payment Method) within [*] days after receiving the other Party’s report pursuant to Section 9.7.3 (Reports).”

2.34 The first two sentences of Section 9.11 (Audits) of the Agreement is hereby deleted in its entirety and replaced with the following:

“Novartis shall keep complete and accurate records pertaining to Novartis Development Costs and to the underlying revenue and expenses data relating to the calculation of Net Sales for the Licensed Products in the Territory in sufficient detail to permit Amgen to confirm the accuracy of all payments due hereunder, including Amgen’s obligation to reimburse Novartis for Amgen’s share of Novartis Development Costs pursuant to Section 9.7 (Development Cost Sharing) of this Agreement and, solely with respect to Development Costs with respect to Franchise Product 1, Section 8.6.1.3 of the US Collaboration Agreement. Amgen shall keep complete and accurate records pertaining to Amgen Development Costs of Licensed Products in sufficient detail to permit Novartis to reasonably confirm the accuracy of all payments due hereunder with respect to Novartis’s obligation to reimburse Amgen for Novartis’s share of Amgen Development Costs pursuant to Section 9.7 (Development Cost Sharing) of this Agreement and, solely with respect to Development Costs with respect to Franchise Product 1, Section 8.6.1.3 of the US Collaboration Agreement.”

2.35 Section 10.2.1.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“10.2.1.1 *Amgen Primary Prosecution*. Amgen shall control, itself or through outside counsel reasonably acceptable to Novartis and directed by Amgen, 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*”) related to Licensed Amgen Patents specific to a Licensed Product, Licensed Amgen Trademarks and Joint Patents (in which case the prosecution will be in the name of both Parties), in each case solely in the Territory (collectively, the “*Territory Patents and Trademarks*”), as well as preparation and filing for any patent term extensions or similar protections therefor. Novartis shall be responsible for reasonable, documented costs incurred by or on behalf of Amgen in connection with such activities with respect to the Territory Patents and Trademarks (other than the costs associated with the creative development of Trademarks and related availability searches). Within [*] days following each Calendar Quarter, Amgen shall provide Novartis an invoice setting forth such costs in reasonable detail, and Novartis shall pay such invoice within [*] days of receipt thereof. From and after the Effective Date, with respect to Territory Patents and Trademarks specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks specific to Franchise Product 3, (i) Amgen shall provide Novartis with copies of and an opportunity to review and comment upon the text of the applications relating to such Territory Patents and Trademarks 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 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 Territory Patents and Trademarks reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within such Territory 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 Territory 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’s comments on the communications, filings and submissions for such Territory Patents and Trademarks.”

2.36 The first sentence of Section 10.2.1.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

“From and after the Effective Date, with respect to Territory Patents and Trademarks specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks specific to Franchise Product 3, if Amgen proposes to abandon or fail to maintain any patent, trademark or application within such Territory Patents and Trademarks, it shall give Novartis reasonable notice thereof (with sufficient time for Novartis to assume control thereof and continue the prosecution or maintenance of such patent, trademark or application) and thereafter Novartis may, upon written notice to Amgen and at Novartis’s sole cost, control Patent and Trademark Matters with respect to such patent, trademark or application within the Territory Patents and Trademarks thereafter in accordance with this Section 10.2.1.3 (Novartis Secondary Prosecution) (any patent, trademark or application so assumed, a “*Novartis Assumed Item*”).”

2.37 Section 10.2.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“10.2.2 *Outside Territory*. Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, Amgen shall control and be solely responsible for all Patent and Trademark Matters with respect to its patent rights, trademark rights and other intellectual property outside the Territory, at its sole cost and expense. Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, Amgen shall control and be solely responsible for Patent and Trademark Matters with respect to Joint Patents outside the Territory, at its sole cost and expense. Notwithstanding the other provisions of this Section 10.2.2 (Outside 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 [*] the Licensed Amgen Patents or the research, Development, conduct of Medical Affairs Activities with respect to, use or Commercialization of Licensed Products [*].”

2.38 The first sentence of Section 10.3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“From and after the Effective Date, with respect to Territory Patents and Trademarks specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks specific to Franchise Product 3, 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 Licensed Product in the Territory by Novartis, Novartis shall have the sole right to defend against any such assertions at its sole cost.”

2.39 The last sentence of Section 10.3.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“In the event Novartis 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, offer for sale, sale or importation of the Licensed Product; (ii) settlement discussions of an interference involving a patent corresponding to a Licensed Amgen Patent specific to a Licensed Product or a trademark corresponding to a Licensed Amgen Trademark; or (iii) cross-license discussions with respect to a patent corresponding to a Licensed Amgen Patent specific to a Licensed Product or a trademark corresponding to a Licensed Amgen Trademark; and, in each such case, such Third Party patent right or trademark right corresponds to a patent right or trademark right outside the Territory: (a) Novartis shall keep Amgen reasonably informed of the status of such discussions; and (b) Novartis shall consider in good faith any comments or suggestions of Amgen.”

2.40 The first sentence of Section 10.3.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“From and after the Effective Date, with respect to Licensed Amgen Patents, Licensed Amgen Trademarks and Joint Patents, in each case, except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, outside the Territory, (collectively, the “*Ex-Territory Patents and Trademarks*”) specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Ex-Territory Patents and Trademarks specific to Franchise Product 3, 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 Licensed Product, except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, outside the Territory, by Amgen, Amgen shall have the sole right to defend against any such assertions at its sole cost.”

2.41 The last sentence of Section 10.3.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“In the event Amgen 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 Licensed Product; (ii) settlement discussions of an interference involving a patent corresponding to a Licensed Amgen Patent specific to a Licensed Product or a trademark corresponding to a Licensed Amgen Trademark; or (iii) cross-license discussions with respect to a patent corresponding to a Licensed Amgen Patent specific to a Licensed Product or a trademark corresponding to a Licensed Amgen Trademark; and, in each such case, such Third-Party patent right or trademark right corresponds to a patent right or trademark right inside the Territory: (a) Amgen shall keep Novartis reasonably informed of the status of such discussions; and (b) Amgen shall consider in good faith any comments or suggestions of Novartis. For clarity, notwithstanding the foregoing, Amgen shall have no obligation to share with Novartis any Licensed Product manufacturing or CMC information or any information related to products other than the Licensed Products.”

2.42 The first sentence of Section 10.4.1.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“From and after the Effective Date, with respect to Territory Patents and Trademarks specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks specific to Franchise Product 3, Novartis shall have the first right, but not the obligation, to enforce Territory Patents and Trademarks against any actual, alleged or threatened infringement or misappropriation by Third Parties in the Territory, at Novartis’s sole cost, subject to Section 10.5 (Cooperation).”

2.43 The first sentence of Section 10.4.1.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

“From and after the Effective Date, with respect to Territory Patents and Trademarks specific to Franchise Product 1 and Franchise Product 2, and from and after the Option Exercise Date, with respect to Territory Patents and Trademarks specific to Franchise Product 3, in the event Novartis does not commence an enforcement action or otherwise take action to abate any alleged infringement or misappropriation of any such Territory Patents and Trademarks within [*] days after Amgen requests Novartis to do so in writing (or, if later, within [*] days 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 at Amgen’s sole cost and Novartis will cooperate with Amgen.

2.44 Section 10.4.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“10.4.2 *Outside Territory*. Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, 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 outside the Territory against any actual, alleged or threatened infringement or misappropriation by Third Parties outside the Territory, and to settle any such matters in its sole discretion subject to Section 10.3 (Defense and Settlement of Third Party Claims). Except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, Novartis shall have no right to enforce such rights outside the Territory.”

2.45 The last sentence of Section 10.6 of the Agreement is hereby deleted in its entirety and replaced with the following:

“Amgen shall have the sole right to retain (i) any and all Recoveries from actions brought by Amgen with respect to Territory Patents and Trademarks related to Franchise Product 3 prior to the Option Exercise Date, (ii) any and all recoveries with respect to the enforcement of any Amgen intellectual property or proprietary right or Joint Patents, except as expressly set forth in the US Collaboration Agreement with respect to Franchise Product 1, outside the Territory, (iii) any and all Recoveries with respect to enforcement of Licensed Amgen Patents to the extent not specifically related to a Licensed Product and (iv) any and all Recoveries from actions brought by Amgen after termination of this Agreement.”

2.46 The second sentence of Section 11.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“Novartis shall have no right to and shall not utilize any Confidential Information of Amgen for activities outside the Territory except as required under the applicable Development Plan or as expressly permitted under the US Collaboration Agreement.”

2.47 The last sentence of Section 11.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

“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 Territory): (i) [*]; and (ii) [*].”

2.48 Section 11.6.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

“present findings with respect to any Licensed Product at symposia and other meetings of healthcare professionals, and international, national or regional 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 Section 11.6 (Publications and Presentations) and Section 11.7 (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 (a) in the case of Novartis, outside the Territory, or (b) in the case of Amgen, within the Territory or, with respect to Franchise Product 1 during the term of the US Collaboration Agreement, the United States, without the other Party's prior written consent, not to be unreasonably withheld."

2.49 Section 12.3 of the Agreement is hereby deleted in its entirety and replaced with the following:

"Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES AND COVENANTS) OR ARTICLE 11 (REPRESENTATIONS, WARRANTIES AND COVENANTS) OF THE US COLLABORATION AGREEMENT, NOVARTIS AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, THE LICENSED PRODUCTS, THE LICENSED AMGEN PATENTS, LICENSED AMGEN TRADEMARKS, LICENSED AMGEN KNOW-HOW, LICENSED NOVARTIS PATENTS, LICENSED NOVARTIS TRADEMARKS, LICENSED NOVARTIS KNOW-HOW, 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 12 (Representations, Warranties and Covenants) or Article 11 (Representations, Warranties and Covenants) of the US Collaboration Agreement, all licenses by Novartis to Amgen under the Licensed Novartis Know-How and Licensed Novartis Patents shall be granted "as-is" and all licenses by Amgen to Novartis under the Licensed Amgen Know-How, Licensed Amgen Trademarks and Licensed Amgen Patents shall be granted "as-is"."

2.50 Section 15.2.5 of the Agreement is hereby deleted in its entirety and replaced with the following:

"15.2.5 *Novartis Termination for Convenience for Franchise Product 2 and Franchise Product 3.* Novartis shall have the right to terminate this Agreement with respect to Franchise Product 2 or Franchise Product 3:

15.2.5.1 from and after [*] until [*], upon [*] prior written notice to Amgen, and in the event of such termination, (i) for purposes of clarity, Novartis's obligations to fund its share of Development Costs pursuant to Section 9.7 (Development Cost Sharing) and to use Commercially Reasonable Efforts to Commercialize such Licensed Product(s) pursuant to Section 7.1 (Commercially Reasonable Efforts) shall continue during such [*] notice period, and (ii) Novartis shall additionally pay to Amgen an amount equal to (a) the amount of Development Costs borne (whether or not actually paid as of such termination) by Novartis pursuant to Section 9.7 (Development Cost Sharing) with respect to such Licensed Product(s) from the Effective Date through the effective date of such termination, multiplied by (b) [*]; and

15.2.5.2 from and after [*] after [*], upon [*] prior written notice to Amgen, and in the event of such termination, for purposes of clarity Novartis's obligations to fund its share of Development Costs pursuant to Section 9.7 (Development Cost Sharing) with respect to such Licensed Product(s) and to use Commercially Reasonable Efforts to Commercialize such Licensed Product(s) pursuant to Section 7.1 (Commercially Reasonable Efforts) shall continue during such [*] notice period.

For purposes of clarity, from [*] until [*] thereafter, Novartis shall not have any right to terminate this Agreement with respect to Franchise Product 2 or Franchise Product 3 under this Section 15.2.5 (Novartis Termination for Convenience)."

2.51 The following language shall be added as a new Section 15.2.6 of the Agreement at the end of Section 15.2 of the Agreement:

"15.2.6 *Novartis Termination for Convenience for Franchise Product 1.* Novartis shall have the right to terminate this Agreement with respect to Franchise Product 1 from and after [*] days following the fifth anniversary of the first Regulatory Approval of Franchise Product 1 in the United States, upon [*] prior written notice to Amgen, and in the event of such termination, for purposes of clarity Novartis's obligations to fund its share of Development Costs pursuant to Section 9.7 (Development Cost Sharing) with respect to Franchise Product 1 and to use Commercially Reasonable Efforts to Commercialize Franchise Product 1 pursuant to Section 7.1 (Commercially Reasonable Efforts) shall continue during such [*] notice period."

2.52 Clause (viii) of Section 15.3.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

"(viii) Section 4.2 (Licensed Novartis 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 Licensed Products as of the date of termination or, if later, the date of expiration or earlier termination of the US Collaboration Agreement) shall survive [*];"

2.53 The last sentence of Section 15.3.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

"In the event of any termination of this Agreement and the US Collaboration Agreement by Amgen pursuant to and as set forth in Section 7.4 ([*] Divestiture), (a) the licenses granted to Novartis under Sections 4.1 (Licensed Amgen Patents and Know-How) and 4.5.1 (Grant to Novartis) and under Sections 3.1 (Amgen Technology) and 3.5.2 (Grant to Novartis) of the US Collaboration 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 Licensed Products as of the date of termination) shall survive, (b) Amgen shall continue to Manufacture and supply Licensed Product for the Territory for a period of up to [*] months in accordance with the Supply Agreement, (c) Novartis shall continue to pay to Amgen royalties on annual Net Sales of each Licensed Product in the Territory for each Calendar Year (or portion thereof) during the applicable Royalty Term pursuant to Section 9.1 (Royalty

Payments); *provided* that the royalties set forth in Section 9.1 (Royalty Payments) shall [*] *provided* that in no event shall the royalties payable to Amgen for Franchise Product 1 [*] and for each of Franchise Product 2 and Franchise Product 3 [*], (d) Novartis shall pay Amgen royalties on annual Net Sales (as defined in the US Collaboration Agreement) of Franchise Product 1 in the United States for each Calendar Year (or portion thereof) until [*], at a rate of [*] percent ([*]%) (with such definition of “Net Sales” applying *mutatis mutandis* to sales by or on behalf of Novartis or any of its Affiliates or sublicensees), and (e) the Parties shall negotiate in good faith a process for the transition of ongoing activities necessary to allow Novartis to exercise its rights under such license and allow Novartis to continue to Develop, Manufacture and Commercialize the Licensed Product in the Territory and, with respect to Franchise Product 1, the United States, including assistance from Amgen for the transfer of Manufacturing to a contract manufacturing organization mutually agreed by the Parties.”

2.54 The following language shall be added as a new Section 15.3.3 of the Agreement at the end of Section 15.3 of the Agreement:

“15.3.3 *Additional Termination Effects*. In addition to the effects of termination set forth in Section 15.3.2 (Termination Effects), in the event of termination of this Agreement by [*] pursuant to Section [*], commencing on the effective date of termination (the “*Termination Date*”) and continuing until the [*] anniversary of the Termination Date, Amgen shall pay to Novartis, a royalty on annual Net Sales of Franchise Product 1 in the Territory for each Calendar Year (or portion thereof) at a rate of [*] percent ([*]%) (with the definition of “Net Sales” applying *mutatis mutandis* to sales by or on behalf of Amgen or any of its Affiliates or sublicensees).”

2.55 Section 15.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

“15.4 Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.3 (Effect of Termination) and the provisions that are expressly stated to survive termination, in the event of any expiration or termination of this Agreement the following provisions shall survive: Articles 1 (Definitions); 11 (Confidentiality and Publications) (except with respect to Section 11.6 (Publications and Presentations), 11.7 (Scientific Papers; Abstracts and Posters), 11.8 (Deferral of Disclosures) and 11.9 (Failure to Object to Disclosure), *provided* that in the event that this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, such Sections shall survive solely with respect to Franchise Product 1 and solely for the term of the US Collaboration Agreement); 13 (Limitations of Liability; Insurance); 14 (Indemnification); 15 (Term and Termination) and 16 (Miscellaneous); Sections 3.1 (Conduct of the Collaboration) through 3.6 (Interactions Between the Joint Management Committee, the Joint Steering Committee, and Joint Project Teams) (inclusive) (solely in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, solely with respect to Development activities and Medical Affairs Activities with respect to Franchise Product 1, and solely for the term of the US Collaboration Agreement); 5.1 (Responsibility for Development) through 5.3 (Development Outside the Territory by Novartis or Inside the Territory by Amgen) (inclusive) (solely in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, solely with respect to Franchise Product 1 and solely for the term

of the US Collaboration Agreement); 5.5 (Safety Matters) through 5.6 (Cooperation Generally) (solely in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, solely with respect to Franchise Product 1 and solely for the term of the US Collaboration Agreement); 7.2 (Activities Outside the Collaboration) through 7.4 ([*] Divestiture) (inclusive) (solely in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, solely with respect to any Franchise Product 1 Distracting Program and solely for the term of the US Collaboration Agreement); 9.1 (Royalty Payments) through 9.6 (No Wrongful Reductions) (inclusive) (with respect to sales made prior to such termination or, if later, prior to completion of the transition by Novartis pursuant to Section 15.5 (Transition Period)); 9.7 (Development Cost Sharing) (with respect to Development Costs reasonably incurred prior to such termination and, in the event this Agreement expires or earlier terminates prior to the expiration or earlier termination of the US Collaboration Agreement, during the term of the US Collaboration Agreement solely Sections 9.7.2 (Annual Development Budget Overruns) through 9.7.5 (Budget Deadlocks) (inclusive) with respect to Development Costs for Franchise Product 1, for purposes of the cost allocation under Section 8.6.1.3 of the US Collaboration Agreement); 9.8 (Sublicense Payments) (with respect to amounts incurred prior to such termination); 9.10 (Payment Method) through 9.16 (Late Payment) (inclusive); 10.1 (Ownership and Cooperation); 10.6 (Allocation of Recoveries) (with respect to periods prior to termination); and 12.3 (Disclaimer of Warranties).”

- 2.56 The following sentence shall be added following the table entitled “Drug Product (including Drug Substance)” set forth in the section entitled “[*]” of the Commercial Supply Schedule:

“Notwithstanding anything to the contrary in the Supply Agreement for commercial supply of Franchise Product 1 (the “*Commercial Supply Agreement*”), [*] percent ([*]%) [*] percent ([*]%) [*] percent ([*]%) [*].”

3. PHARMACOVIGILANCE AGREEMENT

Within ninety (90) days following the Amendment No. 2 Effective Date, the Parties shall amend that certain Pharmacovigilance Agreement between the Parties, dated as of [*], to include Canada.

4. INTEGRATION

Except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement remain and shall remain in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

5. APPLICABLE LAW & JURISDICTION

This Amendment shall be governed by, and construed in accordance with, the laws which govern the Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Agreement.

6. COUNTERPARTS

This Amendment 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 Amendment may be exchanged by facsimile or other electronic means without affecting the validity thereof.

[Remainder of Page Intentionally Left Blank – Signature Page to Follow]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives.

NOVARTIS PHARMA AG

By: /s/ Nigel Sheail

Name: Nigel Sheail

Title: Novartis Pharma AG Head Business Development & Licensing
Forum 2-6.04
4002 Basel

Date: April 21, 2017

By: /s/ Natalie Tan/

Name: Natalie Tan

Title: Head Legal Respiratory Franchise

Date: April 21, 2017

AMGEN INC.

By: /s/ Robert A. Bradway

Name: Robert A. Bradway

Title: Chairman of the Board, President
& Chief Executive Office

Date: April 21, 2017

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

LICENSED AMGEN PATENTS FOR LICENSED PRODUCTS IN CANADA SCHEDULE

Country	Application No.	Filing Date	Title
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

Amgen ref. no. 2015641252-005

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

COLLABORATION AGREEMENT

BY AND BETWEEN

AMGEN INC.

AND

NOVARTIS PHARMA AG

DATED

APRIL 21, 2017

Table of Contents

PAGE

1.	Definitions	1
2.	Collaboration Scope and Governance	14
2.1	<u>Conduct of the Collaboration</u>	14
2.2	<u>US Committees and Teams</u>	14
2.3	<u>US Committee Co-Chairs</u>	16
2.4	<u>US Committee Meetings</u>	17
2.5	<u>Decision Making</u>	17
2.6	<u>Interactions between the Joint US Leadership Team, US Collaboration Team, Joint Project Teams, Sub-Committees and Collaboration Teams</u>	18
2.7	<u>Alliance Managers</u>	18
2.8	<u>Cost Overruns</u>	18
2.9	<u>Commercialization Budget Deadlocks</u>	19
2.10	<u>Amgen Territory</u>	19
3.	Grant of License	19
3.1	<u>Amgen Technology</u>	19
3.2	<u>Novartis Technology</u>	19
3.3	<u>Sublicensing</u>	19
3.4	<u>Provision of Know-How</u>	20
3.5	<u>Trademarks</u>	20
3.6	<u>Retained Rights and Limitations</u>	22
4.	Development, Regulatory and Medical Affairs Activities	22
4.1	<u>Responsibility for Development</u>	22
4.2	<u>Regulatory Matters</u>	22
4.3	<u>Safety Agreement</u>	24
4.4	<u>Cooperation Generally</u>	24
4.5	<u>Medical Affairs Activities</u>	24
4.6	[*]	24
5.	Commercialization	24
5.1	<u>Responsibility for Commercialization</u>	25
5.2	<u>Materials</u>	25
5.3	<u>Training</u>	26
5.4	<u>Information Concerning the Product</u>	26
5.5	<u>Cooperation Generally</u>	26
5.6	<u>Commercialization in the Amgen Territory</u>	26
5.7	<u>Detailing Reports and Audit Rights</u>	27
5.8	<u>Sales Force</u> [*]	27
6.	Manufacture and Supply	28
6.1	<u>Responsibility for Manufacturing</u>	28
6.2	<u>Distribution</u>	28
6.3	<u>Responsibility for Regulatory Filings with Respect to Manufacturing; Inspections of Manufacturing Facilities</u>	28
6.4	<u>Supply</u> [*]	28

- 7. Diligence 28
 - 7.1 Commercially Reasonable Efforts 28
 - 7.2 Proper Conduct Practices Standards 28
 - 7.3 Violation of Laws 29
 - 7.4 Use of Affiliates and Third Party Contractors 29
- 8. Payment 29
 - 8.1 Upfront Payment 29
 - 8.2 Milestone Payments 29
 - 8.3 Royalty Payments and Royalty Reduction for Biosimilar Competition 30
 - 8.4 Reports 30
 - 8.5 No Wrongful Reductions 31
 - 8.6 Cost Allocation 31
 - 8.7 Sublicense Payments 33
 - 8.8 Payment Method 33
 - 8.9 Audits 33
 - 8.10 Blocked Currency 34
 - 8.11 Taxes 34
 - 8.12 Withholding 34
 - 8.13 VAT 35
 - 8.14 Late Payment 35
 - 8.15 Appropriate Measure of Value 35
- 9. Intellectual Property 35
 - 9.1 Ownership and Cooperation 35
 - 9.2 Prosecution and Maintenance 36
 - 9.3 Defense and Settlement of Third Party Claims 38
 - 9.4 Infringement Notice; Enforcement 39
 - 9.5 Cooperation 41
 - 9.6 Patent Term Extensions 41
 - 9.7 Employee Agreements 41
- 10. Confidentiality 42
 - 10.1 Confidentiality; Exceptions 42
 - 10.2 Authorized Disclosure 42
 - 10.3 Use of Confidential Information and Data with Distracting Programs 43
 - 10.4 Terms and Conditions Confidential 43
 - 10.5 Attorney-Client Privilege 43
- 11. Representations, Warranties and Covenants 44
 - 11.1 Mutual Representations and Warranties 44
 - 11.2 Novartis Representations and Warranties 45
 - 11.3 Amgen Representations and Warranties 45
 - 11.4 Disclaimer of Warranties 46
 - 11.5 Mutual Covenants 46
 - 11.6 Novartis Covenant 48
- 12. Limitations of Liability; Insurance 48
 - 12.1 Limitations of Liability 48
 - 12.2 Insurance 48

- 13. Indemnification 48
 - 13.1 Sharing of Liability Expenses 48
 - 13.2 Indemnification by Novartis 49
 - 13.3 Indemnification by Amgen 49
 - 13.4 Claim for Indemnification 49
- 14. Term and Termination 50
 - 14.1 Term 50
 - 14.2 Termination 50
 - 14.3 Effect of Termination 51
 - 14.4 Additional Surviving Provisions 52
 - 14.5 Transition Period 53
- 15. Miscellaneous 53
 - 15.1 Affiliates 53
 - 15.2 Assignment 53
 - 15.3 Governing Law; Jurisdiction 53
 - 15.4 Construction 54
 - 15.5 Counterparts 54
 - 15.6 Entire Agreement 54
 - 15.7 Force Majeure 54
 - 15.8 Further Assurances 55
 - 15.9 Headings 55
 - 15.10 No Set-Off 55
 - 15.11 Notices 55
 - 15.12 Relationship of the Parties 55
 - 15.13 Severability 56
 - 15.14 Third Party Beneficiaries 56
 - 15.15 Waivers and Modifications 56

SCHEDULES

Amgen Patents

Press Release

[*]

COLLABORATION AGREEMENT

PREAMBLE

This Collaboration Agreement (this “*Agreement*”), effective as of April 21, 2017 (the “*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 “*Existing License Agreement*”); and

WHEREAS, Amgen wishes to collaborate with Novartis, and Novartis wishes to collaborate with Amgen, in each case 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) in accordance with the terms and conditions hereof; and

WHEREAS, simultaneously herewith, the Parties are amending the Existing License Agreement to include Canada within the Territory and to amend, modify and restate certain terms and conditions of the Existing License Agreement in connection with this Agreement; and

WHEREAS, the Amgen and Novartis are parties to that certain Pharmacovigilance Agreement, which sets forth the operating procedure respecting adverse event reporting and safety information exchange with respect to the Product (the “*Safety 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 Existing License Agreement; *provided* that any references to “Licensed Product” in any such definition shall, for purposes of this Agreement, mean the Product.

- 1.1 “[*]” has the meaning set forth in Section [*].
- 1.2 “*Agreement*” has the meaning set forth in the Preamble.
- 1.3 “*Alliance Managers*” has the meaning set forth in Section 2.7 (Alliance Managers).
- 1.4 “*Amgen*” has the meaning set forth in the Preamble.
- 1.5 “*Amgen Assumed Item*” has the meaning set forth in Section 9.2.4 (Amgen Secondary Prosecution).

1.6 “*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 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.

1.7 “*Amgen Indemnitees*” has the meaning set forth in Section 13.2 (Indemnification by Novartis).

1.8 “*Amgen Know-How*” means, with respect to the Product, Information Controlled by Amgen or its Affiliates (including Amgen Development Data), as of the 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.

1.9 “*Amgen Patents*” means, with respect to the Product, those patents and patent applications set forth on the Amgen Patents 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 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.

1.10 “*Amgen Patent Schedule*” means the schedule of Amgen Patents attached hereto, which may be updated by Amgen from time to time upon reasonable notice to Novartis.

1.11 “*Amgen Product Trademarks*” means, with respect to the Product, any trademark rights Controlled or adopted by Amgen or its Affiliates on or after the 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).

1.12 “*Amgen Technology*” means (i) the Amgen Know-How and (ii) the Amgen Patents.

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

1.14 “*Amgen Territory Patents and Trademarks*” has the meaning set forth in Section 9.3.2 (Amgen Territory Patents and Trademarks).

1.15 “[*]” has the meaning set forth in Section [*].

1.16 “*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.

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

1.18 “*Claims*” has the meaning set forth in Section 13.2 (Indemnification by Novartis).

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

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

1.21 “*Co-Chair*” has the meaning set forth in Section 2.3 (US Committee Co-Chairs).

1.22 “*Commercial Lead*” has the meaning set forth in Section 5.1 (Responsibility for Commercialization).

1.23 “*Commercialization Budget*” means the budget of Commercialization Costs established by the USCT and approved by the JUSLT, covering all activities contemplated by the applicable Commercialization Plan, as such budget may be updated annually by the JUSLT in connection with updates to such Commercialization Plan. The initial Commercialization Budget for the Product shall be agreed in writing by the Parties on the Effective Date.

1.24 “*Commercialization Costs*” means all Costs incurred by a Party and its Affiliates during the Term in connection with Commercialization activities hereunder in accordance with the applicable Commercialization Plan and Commercialization Budget, 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 8.6.5 (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 (a) [*] and (b) included in the Commercialization Plan

and Commercialization Budget. 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 a Party'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 such Party's cost accounting policies, as consistently applied across such Party's entire portfolio and [*]. For the avoidance of doubt, Commercialization Costs shall exclude Medical Affairs Activities Costs.

1.25 "*Commercialization Plan*" means a strategic and operational commercialization plan for the Product in the Field in the United States (which plan will be updated and approved on a periodic basis but no less than annually by the JUSLT), which sets forth, among other things, (i) a multi-year Commercialization strategy that includes plans for market research, health economics, pricing and reimbursement, value added initiatives, (ii) a multi-year communications strategy that includes plans for public relations, conferences and exhibitions and other external meetings and communications, publications and symposia, internet activities and core brand package, (iii) an operating plan for the implementation of such strategies on an annual basis, including without limitation, information related to product positioning, target customers, core messages to be communicated, share of voice requirements and pricing strategies, all as developed and approved by the JUSLT, (iv) a level of Detailing activity that would be [*] for a product having similar market potential, (v) a Commercialization Budget, and (vi) all other activities to be conducted in connection with the Commercialization of the Product in the Field in the United States. The Commercialization Plan shall be consistent with the Global Brand Plan and shall include the United States Brand Plan.

1.26 "*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).

1.27 "*Commercially Reasonable Efforts*" means, with respect to the efforts to be expended by a Party 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.

1.28 "*Compliance Executive Officers*" means the [*] for Novartis and the [*] for Amgen.

1.29 “*Compliance Laws*” has the meaning set forth in Section 1.70 (“Material and Program Matter”).

1.30 “*Confidential Information*” has the meaning set forth in Section 10.1 (Confidentiality; Exceptions).

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

1.32 “*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).

1.33 “*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.

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

1.35 “*Critical Matter*” means all decisions made by the JUSLT that, in the reasonable opinion of either Party, are likely to have any of the following impacts: (i) [*] under the Commercialization Plan; or (ii) [*] to a Commercialization Plan or any change to a Commercialization Plan that results in an increase, or decrease, of [*] percent ([*]%) or more to the then-current budgeted amount of Commercialization Costs for any specific Calendar Year under the applicable Commercialization Budget.

1.36 “*Detail*” means an interactive, one-on-one, face-to-face 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 Novartis (or their respective Affiliates) 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, E-details, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing face-to-face sales calls or not specifically trained with respect to a pharmaceutical product. When used as a verb, “*Detail*” or “*Detailing*” shall mean to engage in a Detail.

1.37 “*Development Lead*” has the meaning set forth in Section 4.1 (Responsibility for Development).

1.38 “*Effective Date*” has the meaning set forth in the Preamble.

1.39 “*Executive Officers*” means the [*] for Novartis and the [*] for Amgen.

1.40 “*Existing License Agreement*” has the meaning set forth in the Recitals.

1.41 “[*]” has the meaning set forth in Section [*].

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

1.43 “*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. Sales for clinical study purposes or compassionate, named patient or similar use shall not constitute a First Commercial Sale.

1.44 “*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.

1.45 “*First Position Detail Equivalent Basis*” has the meaning set forth in Section 8.6.5 (Calculation of Sales Force Costs).

1.46 “*Force Majeure*” has the meaning set forth in Section 15.7 (Force Majeure).

1.47 “*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 or Novartis based upon a total of [*] days or [*] hours per year undertaken in connection with the conduct of Commercialization in accordance with the applicable Commercialization 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.

1.48 “*FTE Rate*” means the rates agreed by the Parties in writing as of the Effective Date with respect to each of the functions identified by the Parties in writing as of the Effective Date, each per FTE per year (as of the Effective Date), increasing by [*] percent ([*]%) of the then-current FTE Rate on [*] and each subsequent Calendar Year. 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).

1.49 “*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.

1.50 “*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.

1.51 “*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.

1.52 “*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.

1.53 “*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 “*Initial Commercialization Guidance*” has the meaning set forth in Section 5.1 (Responsibility for Commercialization).

1.58 “*Joint Compliance Contacts*” has the meaning set forth in Section 2.2.5 (Joint Compliance Contacts).

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

1.60 “*Joint Project Team*” or “*JPT*” has the meaning set forth in Section 2.2.6 (Joint Project Teams).

1.61 “*Joint US Leadership Team*” or “*JUSLT*” has meaning set forth in Section 2.2.1 (Joint US Leadership Team).

1.62 “*JSC*” means the Joint Steering Committee under the Existing License Agreement established pursuant to Article 3 (Collaboration Scope and Governance) of the Existing License Agreement.

1.63 “*Liability*” has the meaning set forth in Section 13.1 (Sharing of Liability Expenses).

1.64 “[*]” has the meaning set forth in Section [*].

1.65 “*Losses*” has the meaning set forth in Section 13.2 (Indemnification by Novartis).

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

1.67 “*MAA*” means a BLA in the United States.

1.68 “*Manager*” has the meaning set forth in Section 5.1 (Responsibility for Commercialization).

1.69 “*Manufacturing Lead*” has the meaning set forth in Section 6.1 (Responsibility for Manufacturing).

1.70 “*Material and Program Matters*” means those matters specifically relating to (i) the Commercialization activities or Medical Affairs Activities of the Parties with respect to the Product in the United States contemplated by this Agreement and (ii) a Material and Program Matters Item, which matters, in the reasonable opinion of either Party, are likely to impact compliance with (a) statutes, regulations and written directives of Medicare, Medicaid, or any other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), (b) statutes, regulations, or written directives of the FDA, (c) the Pharmaceutical Researchers and Manufacturers of America (PhRMA) Code or (d) any CIA to which either of the Parties is subject (collectively ((a) through (d)), “*Compliance Laws*”).

1.71 “*Material and Program Matters Items*” means those materials and programs matters as agreed by the Parties in writing on the Effective Date. The Parties may add or remove items to the Material and Program Matters Items upon mutual written agreement in order to address changes to any Compliance Laws.

1.72 “*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 [*].

1.73 “*Materials Review Process*” has the meaning set forth in Section 5.2 (Materials).

1.74 “*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 the applicable Party’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 agreed by the Parties in writing.

1.75 “*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 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.

1.76 “*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 physicians regarding medical issues associated with the Product, and are not sales representatives or otherwise engaged in direct selling or promotion of the Product.

1.77 “*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 [*] percent ([*]%) 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.

1.78 "*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 Existing License Agreement.

1.79 "*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 and are mutually approved by the Parties on a periodic basis, no less than annually, 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 of [*].

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

1.81 "*Novartis Assumed Item*" has the meaning set forth in Section 9.2.2 (Novartis Secondary Prosecution).

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

1.83 "*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 Novartis Product Trademarks, 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.

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

1.85 "*Novartis Know-How*" means, with respect to the Product, Information Controlled, as of the 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.

1.86 "*Novartis Patents*" means, with respect to the Product, Patents Controlled by Novartis or its Affiliates on or after the 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.

1.87 “*Novartis Technology*” means (i) the Novartis Know-How and (ii) the Novartis Patents.

1.88 “*Novartis Product Trademarks*” means, with respect to the Product, any trademark rights Controlled by Novartis or its Affiliates and designated by the Parties 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).

1.89 “*Obligations*” has the meaning set forth in Section 11.2.3.

1.90 “*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), 9.4.3 (Novartis Secondary 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 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 Effective Date, including with respect to [*]; and (vi) Costs incurred by the Parties pursuant to Section 13.1 (Sharing of Liability Expenses).

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 (i) Amgen’s proprietary monoclonal antibody against calcitonin gene-related peptide (CGRP) receptor, known as AMG 334 or erenumab or (ii) [*].

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; and (ii) Other Costs; *provided that*, in clause (i) above such costs shall be included within “Program Costs” for the Product only to the extent consistent with the applicable Commercialization 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*” has the meaning set forth in Section 5.2 (Materials).

1.96 “*RACI Documents*” means, with respect to the Product, the document jointly developed and agreed in writing by the Parties on the Effective Date setting forth certain operational responsibilities of each Party with respect to Commercialization, Medical Affairs Activities and other Product-related activities in the United States.

1.97 “*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.

1.98 “*Regulatory Lead*” has the meaning set forth in Section 4.2.1 (Regulatory Responsibility, Communications and Filings).

1.99 “*Safety Agreement*” has the meaning set forth in the Recitals.

1.100 “*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 Field in the United States in accordance with this Agreement, calculated in accordance with Section 8.6.5 (Calculation of Sales Force 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 8.6.5 (Calculation of Sales Force Costs) (i.e., contract sales force costs shall in no event exceed the costs associated with a Party’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 or Novartis based upon a total of [*] days 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 [*] be counted [*] toward the number of hours that are used to calculate the Sales Force FTE contribution.

1.102 “*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 [*] percent ([*]%) of the then-current Sales Force FTE Rate on [*] 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).

1.103 “*Sales Milestone*” has the meaning set forth in Section 8.2.2.

1.104 “*Sales Milestone Threshold*” has the meaning set forth in Section 8.2.2.

1.105 “*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.

1.106 “*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 mutually approved by the Parties on a periodic basis, no less than annually, for Detailing the Product.

1.108 “[*]” means the [*] set forth on the [*] Schedule.

1.109 “[*]” has the meaning set forth in Section [*].

1.110 “*Targets*” means Non-Specialty Targets and/or Specialty Targets, as the context admits.

1.111 “*Technology*” means Information and Patents.

1.112 “*Term*” means the period beginning on the Effective Date and continuing for as long as the Product is Commercialized by one or both Parties in the Field in the United States, unless otherwise terminated pursuant to Article 14 (Term and Termination).

1.113 “*Termination Date*” has the meaning set forth in Section 14.3.3.1 (Additional Termination Effects).

1.114 “*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.

1.115 “*Transition Period*” has the meaning set forth in Section 14.5 (Transition Period).

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

1.117 “*United States Brand Plan*” means, with respect to the Product, the United States-specific strategic and high-level tactical, cross-functional Commercialization plan jointly developed by Novartis and Amgen (including through the JUSLT) for the Product in the United States, including the United States Payer Plan and the United States Pricing Policy.

1.118 “*United States Novartis Patents and Trademarks*” has the meaning set forth in Section 9.2.3 (Novartis Primary Prosecution).

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

1.120 “*United States Payer Plan*” means, with respect to the Product, the United States-specific plan for the Product jointly prepared by Novartis and Amgen (including through the JUSLT) that sets forth the strategic direction, positioning, value proposition, pricing strategy, value evidence generation plan, economic modeling strategy and reimbursement for the Product in the United States.

1.121 “*United States Pricing Policy*” means, with respect to the Product, the United States-specific plan for the Product jointly prepared by Amgen and Novartis (including through the JUSLT) that sets forth the proposed price range, rebates and discounts range, target population and reimbursement target for the Product in the United States.

1.122 “*United States Senior Officers*” means the [*] for Novartis and the [*] for Amgen.

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

1.124 “*US Collaboration*” has the meaning set forth in Section 2.1 (Conduct of the Collaboration).

1.125 “*US Collaboration Team*” or “*USCT*” has the meaning set forth in Section 2.2.2 (US Collaboration Team).

1.126 “*US Committee*” has the meaning set forth in Section 2.2.3.

1.127 “*US Medical Affairs JPT*” means the Joint Project Team established by the JSC pursuant to the Existing License Agreement to oversee Development activities, Medical Affairs Activities and publications, in each case to the extent relating solely to the United States.

2. COLLABORATION SCOPE AND GOVERNANCE

2.1 Conduct of the Collaboration. The Parties shall cooperate to conduct Medical Affairs Activities with respect to the Product in the Field in the United States, and 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*”).

2.2 US Committees and Teams.

2.2.1 *Joint US Leadership Team.* Promptly but not later than thirty (30) days following the Effective Date, the Parties shall establish a cross-functional Joint US Leadership Team (the “*Joint US Leadership Team*” or “*JUSLT*”) to, upon such formation, (i) review and approve plans and strategies for, and the conduct and progress of, activities by each Party relating to Commercialization in the United States with respect to the Product, including the applicable Commercialization Plan and RACI Documents, and facilitate coordination of such activities with Medical Affairs Activities with respect to the Product in the United States; (ii) monitor the Parties’ activities under this Agreement pursuant to the applicable Commercialization Plan, United States Brand Plan, Commercialization Budget and RACI Documents; (iii) review and annually approve the applicable Commercialization Budget no later than [*] of each Calendar Year; (iv) approve the draft supply forecast for the Product in the United States; (v) review sales forecasts for the Product in the United States; (vi) review any anticipated disruption to supply of the Product in the United States; (vii) direct and oversee any JPT, sub-committee and collaboration team established by the JUSLT, on all significant issues that fall within the responsibilities of such JPTs, sub-committees and collaboration team; (viii) update the RACI Documents no later than [*] of each Calendar Year commencing in Calendar Year [*] (i.e., for Calendar Year [*]); (ix) attempt to resolve issues presented to it by, and disputes within, the USCT, the JPTs, sub-committees and collaboration team in accordance with Section 2.5 (Decision Making); and (x) make such determinations as are expressly delegated to it under the terms of this Agreement. In accordance with Section 2.4 (US Committee Meetings), each Party shall keep the Joint US Leadership Team informed of the progress

and results of its activities under the Commercialization Plan, United States Brand Plan and RACI Documents through its members on the Joint US Leadership Team and as otherwise provided herein.

2.2.2 *US Collaboration Team.* Promptly but not later than thirty (30) days following the Effective Date, the Parties shall also establish a US Collaboration Team (the “*US Collaboration Team*” or “*USCT*”) to have primary responsibility for Commercialization matters in the United States. These responsibilities shall include (i) preparing the Commercialization Plan, Commercialization Budget and annual (or any other) updates thereto; (ii) overseeing particular Commercialization projects and activities with respect to the Product in the United States and facilitating coordination of such projects and activities with particular Medical Affairs Activities projects and activities with respect to the Product in the United States, (iii) preparing a draft supply forecast for the Product for the United States; (iv) preparing annually a [*] year sales forecast for the Product for the United States; (v) discussing any anticipated disruption to supply of the Product in the United States; and (vi) recommending to the JUSLT (a) the appropriate allocation of Commercialization activities in the United States to Novartis or Amgen on an activity-specific basis and (b) whether operational responsibility for any such activity should be transferred from Novartis to Amgen or vice versa.

2.2.3 Each of the Joint US Leadership Team and the US Collaboration Team (each a “*US Committee*”) will have solely the roles and responsibilities assigned to it in this Article 2 (Collaboration Scope and Governance) and as otherwise expressly set forth in this Agreement. Neither the US Committees nor a Party exercising its final decision making authority pursuant to Section 2.5 (Decision Making) will have authority to amend, modify or waive compliance with this Agreement, to make decisions that conflict with the terms and conditions of this Agreement, or to create new financial or other obligations for a Party not specified in this Agreement.

2.2.4 Each US Committee shall be comprised of an equal number of representatives from each of Amgen and Novartis. The number of such representatives shall be, with respect to each US Committee, up to [*] for each of Amgen and Novartis, or such other number as the Parties may agree in writing; *provided* that no representative, other than a representative in the medical affairs function, shall be permitted to serve on (i) both the JUSLT and the USCT, or (ii) either of the JUSLT or the USCT and any Committee (as defined in the Existing License Agreement) established under the Existing License Agreement. Each US Committee shall be composed of members of relevant functional specialties and expertise. The members of each US Committee shall have the appropriate level of seniority, decision-making authority and expertise commensurate with the responsibilities of the US Committee to which they are appointed. The Alliance Managers appointed by Amgen and Novartis pursuant to Section 2.7 (Alliance Managers) are *ex officio* members of the JUSLT and the USCT. Either Party may replace its respective US Committee representatives at any time upon prior written notice to the other Party. In the event a US Committee member from either Party is unable to attend or participate in a US Committee meeting, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion, the identity of whom shall be communicated in advance to the other Party, in which case no specific notice shall be required. In the event both the US Committee member and its substitute representative are unable to attend or participate in a US Committee meeting, the Party who designated such representatives may designate an *ad hoc* representative for the meeting in its sole discretion, with prior notice to the US Committee.

2.2.5 *Joint Compliance Contacts*. Promptly but not later than thirty (30) days following the Effective Date, the Parties shall each identify one representative to manage Material and Program Matters in connection with this Agreement (the “*Joint Compliance Contacts*”). The Joint Compliance Contacts shall be responsible for ensuring that the Commercialization and Medical Affairs Activities of the Parties with respect to the Product in the United States contemplated by this Agreement occur in accordance with each Party’s healthcare compliance policies and any CIA to which either of the Parties is subject. In the event either Party becomes party to a new CIA after the Effective Date, the Parties will discuss in good faith the implications of such new CIA. The Parties shall instruct the Joint Compliance Contacts to work with the appropriate personnel of each Party to accomplish the goals set forth in this Section 2.2.5 (Joint Compliance Contacts). The review of any matter referred to the Joint Compliance Contacts in accordance with this Agreement shall be conducted with the goal of resolving, or creating a solution for, any issue presented to the Joint Compliance Contacts arising from the Commercialization and Medical Affairs Activities of the Parties with respect to the Product in the United States, taking into account each Party’s healthcare compliance policies, any CIA to which either of the Parties is subject, and any guidance received by the Parties during the proposal process in respect of the matter which presented the issue referred to the Joint Compliance Contacts for review. If, after [*] Business Days following referral of the matter to the Joint Compliance Contacts, the Joint Compliance Contact of either Party believes that the Joint Compliance Contacts have reached an irreconcilable impasse despite following the escalation procedures set forth in the Materials Review Process (to the extent applicable) and cannot agree to a common approach, the Joint Compliance Contact of either Party may escalate the issue to the Compliance Executive Officers for review; *provided* that if, in the good faith determination of the Joint Compliance Contact of either Party, resolution of such Material and Program Matter requires [*] pursuant to applicable Law (e.g., upon an Governmental Authority request to withdraw a Promotional Material), the Joint Compliance Contact of such Party will have the right to immediately escalate the issue to the Compliance Executive Officers for review. All such Material and Program Matters so escalated to the Compliance Executive Officers shall [*].

2.2.6 *Joint Project Teams*. From time to time, the Joint US Leadership Team or the Parties 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 Joint US Leadership Team 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 Joint US Leadership Team for resolution as provided in Section 2.5 (Decision Making).

2.2.7 *Other Sub-Committees and Teams*. The Parties may also establish other committees, sub-committees or collaboration teams as the Parties deem appropriate.

2.3 US Committee Co-Chairs. Each Party shall appoint one of its members in each US Committee to co-chair such US Committee’s meetings (each, a “*Co-Chair*”). The Co-Chairs shall (i) ensure the orderly conduct of the US Committee’s meetings; (ii) attend each US Committee meeting (either in person, by videoconference or telephonically); and (iii) ensure the preparation and issuance of written minutes of each meeting within [*] Business Days thereafter accurately reflecting the discussions and decisions of such meeting. Unless otherwise agreed, the US Committee shall have at least one (1) representative with relevant decision-making authority from each Party such that the US Committee is able to effectuate all of its decisions within the scope of its responsibilities. In the event the Co-Chair from either Party is unable to attend or participate in

a US Committee meeting, the Party who designated such Co-Chair may designate a substitute Co-Chair for the meeting in its sole discretion.

2.4 US Committee Meetings. Each of the Joint US Leadership Team and the US Collaboration Team shall meet [*], or more or less often as otherwise mutually agreed by the Parties, but in no event less than [*] and such meetings may be conducted by telephone, videoconference or in person as determined by the Co-Chairs of such US Committee. As appropriate, and provided that not less than two (2) Business Days' prior written notice has been given to the other Party, other employees of the Parties may attend US Committee meetings as observers, but a Party shall not bring a Third Party to a meeting without the other Party's prior consent. Either Party may also call for special meetings of the US Committee (in person, by videoconference or teleconference) with reasonable prior written notice (it being agreed that at least ten (10) Business Days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making responsibility of such US Committee. Each Co-Chair shall ensure that its US Committee members receive adequate notice of such meetings. Each US Committee shall have a secretary who may be an ex officio member of that US Committee and shall prepare minutes for meetings he or she attends. The Co-Chairs of each US Committee shall alternate responsibility for naming the secretary at each meeting of such US Committee.

2.5 Decision Making. Other than as set forth herein, in order to make any decision required of it hereunder, each US 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 JUSLT and USCT by mutual agreement of the Co-Chairs. If the USCT is unable to reach a decision on any matter after endeavoring in good faith to do so, the USCT Co-Chair of either Party may cause such dispute to be referred to (i) the Joint Compliance Contacts for resolution pursuant to Section 2.2.5 (Joint Compliance Contacts), if a Material and Program Matter, (ii) the US Medical Affairs JPT for resolution, if a Medical Affairs Activity matter or (iii) the JUSLT for resolution, if any matter other than a Material and Program Matter or Medical Affairs Activity matter. If a dispute (originating at either the USCT or the JUSLT) arises on a Critical Matter which cannot be resolved within the JUSLT within [*] Business Days following referral to the JUSLT, the Co-Chair of either Party may cause such dispute to be referred to the Alliance Managers for escalation to the JSC for Critical Matters that are strategic or scientific issues, or to the United States Senior Officers for all other Critical Matters (including budget or resource allocation issues). If such Critical Matter cannot be resolved between the United States Senior Officers within [*] Business Days following referral to the United States Senior Officers, either United States Senior Officer may cause such dispute to be referred to the Alliance Managers for escalation to the Executive Officers. All such Critical Matters so escalated to the Executive Officers [*]. Within the Joint US Leadership Team, disputes (originating at either the USCT or the JUSLT) regarding any matters that are not Critical Matters shall be resolved as follows:

2.5.1 the Co-Chair of the Manufacturing Lead at the JUSLT shall have the deciding vote with respect to all Manufacturing matters for the Product; and

2.5.2 the Co-Chair of the Commercial Lead for the Product at the JUSLT shall have the deciding vote with respect to all Commercialization matters for the Product in the United States, including any amendments to the Commercialization Plan or Commercialization Budget relating to the Product in the United States; *provided* that [*].

For clarity, all Development, regulatory and Medical Affairs Activities matters will be discussed and resolved at the JSC pursuant to Section 3.5 (Decision Making) of the Existing License Agreement, taking into account recommendations of the US Medical Affairs JPT and the JUSLT.

2.6 Interactions between the Joint US Leadership Team, US Collaboration Team, Joint Project Teams, Sub-Committees and Collaboration Teams. The Parties recognize that while they will establish the Joint US Leadership Team, US Collaboration Team, 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 Joint US Leadership Team, US Collaboration Team, 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.

2.7 Alliance Managers. Promptly but not later than thirty (30) days following the Effective Date, each of Amgen and Novartis shall appoint 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 JUSLT, USCT, Joint Project Teams, sub-committees and collaboration teams. Consistent with the Commercialization Plan and Section 2.5 (Decision Making), each Alliance Manager, on behalf of the applicable Party's Co-Chair of the JUSLT and on behalf of the United States Senior Officers and Executive Officers, will also be responsible for:

- 2.7.1 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
- 2.7.2 identifying and raising disputes to the JSC, JUSLT, United States Senior Officers or Executive Officers for discussion in a timely manner.

During the term of the Existing License Agreement, the Alliance Managers appointed under the Existing License Agreement shall also serve as the Alliance Managers under this Agreement. The Alliance Managers shall be entitled to attend all JUSLT and USCT meetings, and shall have the right to attend all JPT, sub-committee and collaboration team meetings. Consistent with Section 2.5 (Decision Making), each Alliance Manager may bring any matter to the attention of the JSC, JUSLT, United States Senior Officers or the Joint Compliance Contacts, where such Alliance Manager reasonably believes that such matter requires attention of the JSC, JUSLT, United States Senior Officers, Executive Officers or the Joint Compliance Contacts.

[*]

2.8 Cost Overruns. With respect to the Product, each Party, through the JUSLT, shall promptly notify the other Party upon becoming aware that its Program Costs to be incurred in

performing the applicable Commercialization Plan for a Calendar Year will be in excess of the amounts budgeted to be incurred by or on behalf of such Party for its Commercialization activities in the applicable budget. If the applicable Program Costs incurred by a Party for performing the applicable Commercialization Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of such Party for its Commercialization activities in the applicable budget, the other Party shall reimburse the performing Party for the applicable percentage set forth above of such excess; *provided* that in no event shall either Party be responsible for reimbursement for such excesses to the extent the Program Costs of the other Party in performing the Commercialization Plan for a Calendar Year exceed the amounts budgeted to be incurred by or on behalf of such other Party for its Commercialization activities in the applicable budget by more than [*] percent ([*]%), *provided* that a Party shall be responsible for reimbursement for such excesses to the extent the applicable Program Costs are attributable to (i) a change in applicable Law; (ii) a Force Majeure event; or (iii) a mutually agreed amendment to the applicable Commercialization Plan.

2.9 **Commercialization Budget Deadlocks.** In the event that the JUSLT is unable to approve a Commercialization Budget for a Calendar Year prior to the start of such Calendar Year, then, until approval of such budget by the JUSLT, (i) the Commercialization Budget most recently approved by the JUSLT for such Calendar Year (or if not JUSLT approved, the initial apportioned amount for such Calendar Year in the initial Commercialization Budget) shall apply and (ii) if not approved by the JUSLT and no apportioned amount for such Calendar Year is included in such applicable budget, then the apportionment for the prior Calendar Year shall apply.

2.10 **Amgen Territory.** Unless expressly set forth in this Agreement or the Existing License 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 Existing License 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.

3. GRANT OF LICENSE

3.1 **Amgen Technology.** Amgen hereby grants to Novartis, during the Term, effective as of the Effective Date, [*] 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).

3.2 **Novartis Technology.** Novartis hereby grants to Amgen, effective as of the Effective Date, [*], perpetual license (i.e., [*]), 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 license 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) to subcontractors in the ordinary course of business consistent with the Commercialization 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), 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 Provision of Know-How. Following the Effective Date, the Parties shall cooperate to establish procedures for the provision of the Amgen Know-How relating to the Product to Novartis and Novartis Know-How relating to the Product to Amgen, in each case to the extent [*] 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, Amgen shall use [*] to provide all Amgen Know-How related to the Product to Novartis, and Novartis shall [*] to provide all Novartis Know-How related to the Product to Amgen, in each case to the extent [*] 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 Amgen Know-How or Novartis 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 Amgen Know-How or Novartis Know-How, as the case may be, that is (i) proprietary or trade secret with respect to such Party and (ii) not [*] for the other Party to exercise its rights and perform its obligations in accordance with this Agreement. Unless otherwise agreed by the Parties, information shared under this Section 3.4 (Provision of Know-How) shall be disclosed in the English language.

3.5 Trademarks.

3.5.1 Grant to Amgen. Novartis hereby grants to Amgen, effective as of the Effective Date (without any further action by either Party), [*], royalty-free right and license during the Term, subject to the terms and conditions hereof, solely to sell, import, conduct Medical Affairs Activities with respect to, and otherwise Commercialize the Product in the Field in the United States under Novartis Product Trademarks designated by the Parties for use with the Product in accordance with the Commercialization Plan and this Agreement. Novartis hereby grants to Amgen [*], royalty-free license to use the Novartis Housemarks solely as set forth in the Promotional Materials, Non-Promotional Materials and other materials provided to it by Novartis, 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 accordance with the Commercialization Plan and this Agreement. Such licenses shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.5.2 *Grant to Novartis.* Amgen hereby grants to Novartis, effective as of the Effective Date (without any further action by either Party), [*], royalty-free right and license during the Term, 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 in accordance with the Commercialization Plan and this Agreement. Amgen hereby grants to Novartis [*], royalty-free license 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 in accordance with the Commercialization Plan and this Agreement. Such licenses shall include the right to sublicense only as set forth in Section 3.3 (Sublicensing).

3.5.3 *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 Product Trademark or 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.

3.5.4 *Domain Names.* Novartis shall be [*] entitled to register, own and use any Domain Names corresponding to or containing a Novartis Product Trademark or 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 Product Trademark or Novartis Housemark throughout the world. Amgen shall be [*] 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.

3.5.5 *Housemarks*. Promotional Materials and all packaging and package inserts for the Product in the Field in the United States will display the Novartis Housemarks and the Amgen Housemarks in equal prominence to the extent allowed by applicable Law and in accordance with the applicable Commercialization Plan, and to the extent reasonably practicable; *provided* that, in the event that it is not reasonably practicable to display the Novartis Housemarks on any packaging or package inserts, the Parties shall discuss such matter, and the Novartis Housemarks shall be displayed as soon as reasonably practicable. Except for the use of the Novartis Housemarks and the Amgen Housemarks as may be expressly set forth in the applicable Commercialization Plan, each Party will promote the Product in the Field in the United States only under the Novartis Product Trademarks or Amgen Product Trademarks, as applicable.

3.6 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 Existing License 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 Effective Date, responsibility for Development shall be as set forth in the Existing License 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 JUSLT 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 Existing License 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 Existing License 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 Effective Date, upon the request of Amgen, Novartis shall provide a sublicenseable 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 Existing License Agreement, the Co-Chair (as defined in the Existing License 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 Existing License 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 Existing License Agreement, the [*] 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. Promptly following the Effective Date, Amgen and Novartis shall amend the Safety Agreement to include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the Product sufficient to permit each Party, its Affiliates, permitted sublicensees and licensees to comply with Law, including, to the extent applicable, those obligations contained in FDA regulations. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed amendment to the Safety Agreement which shall be entered into within ninety (90) days after the Effective Date (or any other longer period as may be agreed between the Parties).

4.4 Cooperation Generally. From and after the Effective Date, subject to the oversight of the JUSLT, 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. From and after the Effective Date, subject to the oversight of the US Medical Affairs JPT and the JSC, the Parties shall be jointly responsible for determining and providing all Medical Affairs Activities relating to the Product in the Field in the United States. The US Medical Affairs JPT will (i) allocate Medical Affairs Activities to Novartis or Amgen on an activity-specific basis, and (ii) determine whether operational responsibility for any such activity should be transferred from Novartis to Amgen or vice versa. Except as expressly set forth herein or in the Existing License 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.

4.6 Additional Products [*]

5. COMMERCIALIZATION

5.1 Responsibility for Commercialization. Consistent with this Section 5.1 (Responsibility for Commercialization), the Parties, through the USCT, will jointly (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. From and after the Effective Date, the Parties shall jointly Commercialize the Product in the Field in the United States in accordance with the applicable Commercialization Plan. Amgen shall serve as the distributor and the obligor of sale transactions with respect to the Product in the United States (*i.e.*, having responsibility for contracting, billing and interacting with wholesaler customers and governmental or similar payors, as well as government price reporting) (the “*Commercial Lead*”), and shall have authority to [*], and shall [*].

In accordance with this Section 5.1 (Responsibility for Commercialization), the USCT shall recommend and the JUSLT shall approve either Novartis or Amgen or both as the “*Manager*” for specific Commercialization activities on an activity-specific basis. The Manager shall have operational responsibility for the execution of any such assigned Commercialization activities. The other Party shall support the Manager by providing strategic input and operational support for the Manager’s Commercialization activities.

With respect to Detailing efforts, the Parties shall use Commercially Reasonable Efforts to divide Detailing activities between the Parties so that (a) the Parties shall co-Detail Specialty Targets [*], and (b) as between the Parties, Amgen shall Detail the Non-Specialty Targets; *provided that*, [*]. The guiding principles for the initial Commercialization Plan for the Product (the “*Initial Commercialization Guidance*”) shall be agreed in writing by the Parties on the Effective Date. Within [*] following the Effective Date, the Parties shall agree in writing to the initial Commercialization Plan for the Product, which shall be based on and consistent with the Initial Commercialization Guidance. [*] Calculation of such Details shall be included in such Party’s Sales Force Costs, in accordance with Section 8.6.5 (Sales Force Costs). Subject to the foregoing, Novartis and Amgen shall share Commercialization responsibilities as provided in the applicable Commercialization Plan in the United States including with respect to: (w) 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); (x) determination of packaging and labeling; (y) creation of promotional materials regarding the Product which are intended for distribution to Third Parties (including medical professionals) and to such Party’s sales force (subject to Section 3.5.3 (Trademark and Housemark Quality Standards) and Section 5.2 (Materials)); and (z) 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. [*]

5.2 Materials. On the Effective Date, the Parties shall agree in writing to a process (the “*Materials Review Process*”) by which the Parties will, in accordance with the RACI Documents, jointly develop, review, comment on and, subject to Sections 2.2.5 (Joint Compliance Contacts) and 2.5 (Decision Making), approve (i) 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 (collectively and including translations, “*Promotional Materials*”), (ii) all Non-Promotional Materials, including disease awareness programs, for the United States, and (iii) training materials and programs for the Product in the United States other than healthcare compliance or other non-Product training materials. All Promotional Materials, Non-Promotional Materials and training materials shall comply with applicable Law, FDA requirements and any CIA and shall include, to the extent permitted by applicable Law, the Novartis Housemarks and the Amgen Housemarks; *provided* that [*]. Unless otherwise determined by the US Collaboration Team, the Manager for Promotional Materials, Non-Promotional Materials and training materials production and delivery will be responsible for ensuring the production and delivery to the other Party of Promotional Materials, Non-Promotional Materials and training materials for use in such other Party’s Detailing obligations hereunder. Other than a Party’s use and distribution of Promotional Materials, Non-Promotional Materials and training materials that are approved in accordance with the foregoing process and used and distributed in connection with a Party’s Detailing of the Product, neither Party will produce or modify (other than as concepts for consideration by the other Party), or distribute, disseminate or otherwise use any other promotional material, non-promotional material or training material relating to the Product in the United States. If so instructed by the US Collaboration Team, a Party will immediately cease to use any Promotional Materials, Non-Promotional Materials and training materials and will collect and destroy any such materials from its field sales teams (and record and document such collection and destruction (and provide a copy of such documentation to the other Party upon request)). The Parties shall jointly own 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 Housemarks of the other Party included in any Promotional Materials, Non-Promotional Materials and training materials).

5.3 Training. The training of the Parties’ 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 in accordance with the process set forth in Section 5.2 (Materials). Each Party 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, all in accordance with the applicable Commercialization Plan.

5.4 Information Concerning the Product. Each Party will ensure that no claims or representations in respect of the Product or the characteristics thereof are made by or on behalf of it or its Affiliates (by sales force members or otherwise) in the United States that have not been approved by both Parties through the joint review process as set forth in the Materials Review Process and 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 Cooperation Generally. Subject to the oversight of the JUSLT, the Parties shall cooperate generally with respect to the Commercialization of the Product in the Field in the United States.

5.6 Commercialization in the Amgen Territory. Except as expressly set forth herein or in the Existing License 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.

5.7 Detailing Reports and Audit Rights.

5.7.1 *Reporting*. Each Party will provide the other Party with a report, in such form and manner as determined by the JUSLT, within [*] calendar days after the end of each [*], setting forth the following information regarding the efforts of the reporting Party's sales force in Detailing the Product in the United States during the preceding [*]: (i) the total number of Details made by such 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 specified by the JUSLT. Each Party will provide the other Party with a report, in such form and manner as determined by the JUSLT, within [*] calendar days after the end of each Calendar Quarter, setting forth the following information regarding the efforts of the reporting Party's sales force in Detailing the Product in the United States during the preceding Calendar Quarter: [*]. Notwithstanding the foregoing, in the event that any Detail(s) conducted by a Party in a given calendar [*] were not included in such Party's report for such [*] or Calendar Quarter, as applicable, such Party 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 5.7.1 (Reporting).

5.7.2 *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 5.7.1 (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 5.7.2 (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 [*] percent ([*]%) of the correct amount for the audited period, then the audited Party will pay the reasonable out-of-pocket cost of such inspection.

5.8 Sales Force [*]. During the Term, if either Party intends to [*] percent ([*]%) [*] in the United States that [*] in the United States, then such Party shall provide the other Party with at least [*] prior written notice. In such event, at the request of either Party, the United States Senior Officers and each Party's Co-Chair of the JUSLT shall meet to generate a plan to [*] (with escalation to the United States Senior Officers if the JUSLT is unable to agree on such a plan). Such plan and any meetings or discussions related thereto shall be kept in strict confidence by the United States

Senior Officers and each Party's Co-Chair of the JUSLT, in accordance with the confidentiality obligations set forth in Article 10 (Confidentiality). The Party that has [*] will [*] during the applicable period (but not to exceed [*]) that are [*].

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 [*] percent ([*]%) [*] (a "*Supply* [*]"), [*] a Supply [*] for purposes of this Section 6.4 (Supply [*])[*], then Amgen shall provide Novartis written notice thereof within [*] Business Days of the occurrence of such Supply [*]. Amgen shall also provide Novartis prompt written notice [*] percent ([*]%) [*] ("[*]"). Amgen's notice of [*] shall include [*]. If a Supply [*], Novartis shall [*].

7. DILIGENCE

7.1 Commercially Reasonable Efforts. From and after the Effective Date, the Parties 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; and (ii) following the issuance of Regulatory Approval for the Product in the Field in the United States, Commercialize the Product in the Field in the United States in accordance with the Commercialization Plan; *provided* that the Parties acknowledge that such Commercialization activities shall be subject to the United States Brand Plan and in accordance with the Global Brand Plan. In addition, Amgen shall use Commercially Reasonable Efforts to Manufacture the Product for the United States.

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 subject to the other Party's prior written consent, such consent not to be unreasonably withheld; *provided* that (i) subject to Section 7.4.2, either Party shall have the right to perform its activities hereunder through subcontractors in the ordinary course of business consistent with the Commercialization Plan and (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 as of the Effective Date, Amgen shall have the right to continue to perform such activities through such Third Parties. Cost overruns resulting from either Party's use of a Third Party to conduct any such activities will be subject to Section 2.8 (Cost Overruns). Each Party will be responsible for compliance by its respective Affiliates and Third Party contractors with this Agreement and will be responsible for all acts and omissions of such Affiliates and Third Party contractors as if committed or omitted by the applicable Party.

7.4.2 Notwithstanding the provisions of Section 7.4.1, [*].

8. PAYMENT

8.1 Upfront Payment. As partial consideration for the rights granted to Novartis hereunder, Novartis shall pay Amgen a one-time [*],[*] upfront payment of [*] within [*] days 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:

8.2.1 Novartis shall pay Amgen 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) equals or exceeds [*]; and

8.2.2 Novartis shall pay to Amgen a one-time [*], [*] 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 that [*].

8.2.3 Notwithstanding the foregoing, [*].

[*] For clarity, the Sales Milestone payments set forth under Section 8.2.2 and 8.2.3 are 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 8.2.2 and 8.2.3 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 [*] percent ([*]%).

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, if [*] 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 [*] days 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. Except as otherwise set forth herein:

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 Commercialization Costs; *provided* that in any given Calendar Year, [*]. For clarity, [*] (i) [*] and (ii) [*] percent ([*]%) [*] percent ([*]%)[*];

8.6.1.3 Novartis shall pay [*] percent ([*]%) 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 Existing License 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 Existing License Agreement, *provided* that Novartis shall have no obligation to fund Development Costs 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 Effective Date. For clarity, following such payment by Novartis of such [*] in Development Costs (including Medical Affairs Activities Costs) with respect to the Product, Novartis will effectively pay [*] percent ([*]%) 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 Existing License 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 Existing License Agreement;

8.6.1.4 for the Calendar Year 2017 only, (i) Novartis shall pay one hundred percent (100%) of Commercialization Costs up to a cap of [*] in the aggregate, inclusive of a [*] payment to Amgen on or prior to [*] (as a contribution toward [*]), provided that Novartis shall have the right to prorate such payments over the remaining Calendar Quarters in 2017, and (ii) Amgen shall be responsible for any and all Commercialization Costs in Calendar Year 2017 above the [*] in Commercialization Costs paid by Novartis;

8.6.1.5 for the Calendar Year 2018 only, (i) Novartis shall pay one hundred percent (100%) of Commercialization Costs up to a cap of [*] in the aggregate, inclusive of a [*] payment to Amgen on or prior to [*] (as a contribution toward [*]), provided that Novartis shall have the right to prorate such payments over the four (4) Calendar Quarters in 2018, and (ii) Amgen shall be responsible for any and all Commercialization Costs in Calendar Year 2018 above the [*] in Commercialization Costs paid by Novartis, and

8.6.1.6 for the Calendar Year 2019 and for each Calendar Year thereafter, each Party shall pay fifty percent (50%) of all Commercialization Costs.

8.6.2 *Payment of Costs.* Subject to reconciliation as provided in Section 8.6.4 (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.

8.6.3 *Reports.* Without limitation of Section 5.7 (Detailing Reports and Audit Rights), within [*] days after the end of each Calendar Quarter, each Party shall provide the other Party with a report specifying in reasonable detail (which shall include system-generated time-tracking data, if available) 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 a Party in a given Calendar Quarter [*], such Party shall [*] such Sales Force Costs, and such Sales Force Costs shall [*]. Such Program Costs shall be attributed by such Party 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 Existing License Agreement.

8.6.4 *Payments.* Within [*] days 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 8.6.3 (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 [*] days after receiving such invoice. For clarity, reconciliation payments with respect to Development Costs shall be governed by Section 9.7.4 (Payments) of the Existing License Agreement.

8.6.5 *Calculation of Sales Force Costs.* Sales Force Costs for each of the Parties in the United States will be determined by including in Commercialization Costs a pro rata portion of the Sales Force FTE Costs of a Detail performed by such Party 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 Commercialization 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 Commercialization 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 Commercialization Plan and details only [*] ([*]) other products; (iv) [*] percent ([*]%) if such sales representative Details the Product as a Second Position Detail and details only [*] ([*]) or [*] ([*]) other product(s); and (v) [*] percent ([*]%) [*] ((i) through (v), as applicable, the “*First Position Detail Equivalent Basis*”).

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 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 activities under the Commercialization Plan, (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 Existing License 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 Existing License 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 Commercial Lead.

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, Novartis 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, Novartis 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, Novartis 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 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 [*] days for new patent application filings and [*] days 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.

9.2.2 *Novartis Secondary Prosecution.* From and after the Effective Date, with respect to United States Patents and Trademarks specific to the Product, if Amgen proposes to abandon or fail to maintain any patent, trademark or application within such United States Patents and Trademarks, it shall give Novartis reasonable notice thereof (with sufficient time for Novartis to assume control thereof and continue the prosecution or maintenance of such patent, trademark or application) and thereafter Novartis may, upon written notice to Amgen, control Patent and Trademark Matters with respect to such patent, trademark or application within such United States Patents and Trademarks thereafter in accordance with this Section 9.2.2 (Novartis Secondary Prosecution) (any patent, trademark or application so assumed, a “*Novartis Assumed Item*”). Novartis shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Novartis, Patent and Trademark Matters with respect to Novartis Assumed Items in the United States, as well as preparation and filing for any patent term extensions or similar protections therefor. Novartis shall provide Amgen with a copy of each material submission made to and document received from a patent or trademark authority regarding any Novartis Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Novartis Assumed Items as filed together with notice of its filing date and application number.

9.2.3 *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 and Novartis Product Trademarks, in each case solely in the United States (collectively, the “*United States Novartis Patents and Trademarks*”), as well as preparation and filing for any patent term extensions or similar protections therefor. From and after the Effective Date, with respect to United States Novartis Patents and Trademarks 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 and Trademarks 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) Novartis 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 such United States Novartis 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 Novartis Patents and Trademarks 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 Trademarks, 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) Novartis shall reasonably consider in good faith Amgen’s comments on the communications, filings and submissions for such United States Novartis Patents and Trademarks.

9.2.4 *Amgen Secondary Prosecution.* From and after the Effective Date, with respect to United States Novartis Patents and Trademarks specific to the Product, if Novartis proposes to abandon or fail to maintain any patent, trademark or application within such United States Novartis Patents and Trademarks, 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 Novartis, control Patent and Trademark Matters with respect to such patent, trademark or application within such United States Novartis Patents and Trademarks thereafter in accordance with this Section 9.2.4 (Amgen Secondary Prosecution) (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 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 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.

9.2.5 *Amgen Territory.* Except to the extent expressly provided otherwise in the Existing License 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 9.2.5 (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 [*] the Amgen Patents, the Novartis Patents or the conduct of Medical Affairs Activities with respect to or Commercialization of the Product [*].

9.2.6 *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 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 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 Existing License 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 and Trademarks are infringed or misappropriated by a Third Party in the United States.

9.4.2 *Amgen Primary Enforcement.* From and after the Effective Date, with respect to United States Patents and Trademarks specific to the Product, Amgen shall have 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 Third Parties 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, 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 Amgen Manufacturing information and any information relating to any product other than the Product from any such materials).

9.4.3 *Novartis Secondary Enforcement.* From and after the 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 within [*] days after Novartis

requests Amgen to do so in writing (or, if later, within [*] days 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 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 Effective Date, with respect to United States Novartis Patents and Trademarks specific to the Product, Novartis shall have the first right, but not the obligation, to enforce such United States Novartis Patents and Trademarks 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 Effective Date, with respect to United States Novartis Patents and Trademarks 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 and Trademarks within [*] days after Amgen requests Novartis to do so in writing (or, if later, within [*] days 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 Existing License 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 Existing License 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 and Novartis Product Trademarks 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 Effective Date, with respect to United States Patents and Trademarks and United States Novartis Patents and Trademarks, in each case specific to the Product, each Party shall provide reasonable assistance to the other Party in connection with obtaining SPCs 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 SPC 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 SPC 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 under the Commercialization Plan or as expressly permitted under the Existing License 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 Existing License 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 regards 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, the Parties shall agree upon and each Party shall release, at a date(s) and time(s) to be mutually agreed by the Parties, a press release to announce the execution of this Agreement in the applicable form attached hereto as the Press Release Schedule; thereafter, Novartis and Amgen may each disclose to Third Parties the information contained in such press release 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 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 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 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 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 Effective Date no government authorization, consent, approval, license, exemption 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 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 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 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 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 Effective Date, it has sufficient legal and/or beneficial title and ownership under the Novartis Technology, Novartis Product Trademarks (if any) 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 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 EXISTING LICENSE 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 PRODUCT TRADEMARKS, 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 Existing License Agreement, all licenses by Novartis to Amgen under the Novartis Technology, Novartis Product Trademarks 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 approved by the JUSLT, 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 Covenant. Novartis shall [*].

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 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 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 [*] following the fifth anniversary of Regulatory Approval of the Product in the United States upon [*] prior written notice to Amgen. For clarity, Novartis may provide written notice of termination to Amgen at any time from or after [*] following [*], such that this Agreement may be terminated by Novartis effective any time from or after [*] following the fifth anniversary of Regulatory Approval of the Product in the United States.

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 for [*].* 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) the Parties shall transition responsibility for Commercialization,

Medical Affairs Activities and any other activities as requested by Amgen with respect to the Product in the United States to Amgen in accordance with Section 14.5 (Transition Period); (iii) 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 and Trademarks specific to the Product to Amgen; (iv) all sublicenses granted by Novartis shall terminate; (v) 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; (vi) 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 [*]; (vii) Amgen shall have a fully-paid, royalty-free [*] right and license to use the Novartis Product Trademarks (if any) (and the associated goodwill) in connection with the Product in all indications within the United States; and (viii) 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 [*] and (d) [*]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 5.7 (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).

14.5 Transition Period. Without limitation of Section 14.3 (Effect of Termination), in the event of any termination of this Agreement by Amgen pursuant to Section [*] or by Novartis pursuant to Section [*], then upon Amgen's reasonable request, during the [*] month period following provision of notice of termination (or, in each case, for such shorter period as Amgen shall reasonably request) (the "*Transition Period*"), the Parties shall cooperate to transition the Medical Affairs Activities with respect to and Commercialization of the Product in the Field in the United States to Amgen with respect to such activities. Novartis shall take all 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. Subject to Section 14.3.2 (Termination Effects), the Parties shall each be responsible for their own costs incurred in accordance with this Section.

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 Existing License 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)

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

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

NOVARTIS PHARMA AG

By: /Nigel Sheail/

Name: Nigel Sheail

Title: Novartis Pharma AG Head Business

Development & Licensing

Forum 2-6.04

4002 Basel

AMGEN INC.

By: /Robert A. Bradway/

Name: Robert A. Bradway

Title: Chairman of the Board, President &
Chief Executive Officer

NOVARTIS PHARMA AG

By: /Natalie Tan/

Name: Natalie Tan

Title: Head Legal Respiratory Franchise

Amgen Ref. No. 2017747574

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

**Schedule
Amgen Patents**

US Application No.	Filing Date	Title
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

Amgen Ref. No. 2017747574

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Press Release

(see attached)



Press Release

Amgen Announces Expanded Commercial Collaboration With Novartis For Erenumab In Migraine

Collaboration Designed to Maximize the Launch of First-in-Class Program and to More Effectively Reach People Living With Migraine

THOUSAND OAKS, Calif., April 24, 2017 /PRNewswire/ - Amgen (NASDAQ:AMGN) today announced an expanded commercial collaboration with Novartis for erenumab, which is being investigated for the prevention of migraine. This expanded commercial collaboration builds on a global neuroscience collaboration in Alzheimer's disease and migraine established in 2015 between Novartis and Amgen. This expanded collaboration leverages Novartis' strong and established presence in neuroscience to more effectively reach people with migraine. The companies have agreed to combine capabilities to co-commercialize erenumab in the U.S. Amgen retains exclusive commercialization rights in Japan. Novartis gains exclusive rights to commercialize erenumab in Canada, and retains its existing commercialization rights in rest of the world. The companies will continue global co-development.

Erenumab is a fully human monoclonal antibody specifically designed to target and block the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to have a critical role in mediating the incapacitating pain of migraine. Positive data from a Phase 2 study and positive top-line results for two Phase 3 studies in migraine prevention were announced in 2016. Detailed results from the Phase 3 studies will be presented at the annual meeting of the American Academy of Neurology and submitted for publication. These data will help support discussions with regulatory agencies, with filing anticipated in the second quarter of 2017.

Under the terms of the agreement, Amgen will receive milestone payments from Novartis expected to begin in 2017. Novartis will share U.S. commercialization costs with Amgen. Amgen will book sales of erenumab in the U.S., and will pay a royalty to Novartis on net sales in the U.S. Novartis will book sales in the rest of the world, excluding Japan, and will pay Amgen royalties on the net sales in those countries. Amgen will book sales in Japan, since it will remain an exclusive territory for the Company. Novartis will assume agreed upon remaining global development costs up to a cap and share global development costs thereafter.

"Migraine is a debilitating disease and today many patients are sub-optimally treated due to tolerability issues with existing therapies," said Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen. "Combining the U.S. capabilities of Amgen and Novartis in preparation for the launch of erenumab can create meaningful value over the life of this first-in-class program by enabling us to more effectively, and perhaps even more rapidly, reach people who live with the impact of migraine on a daily basis."

This is an expansion of a global collaboration with Novartis announced in September 2015 in neuroscience, involving joint development and commercialization of pioneering treatments in the field of Alzheimer's disease and migraine.

About Erenumab

Erenumab is a fully human monoclonal antibody specifically designed for the prevention of migraine. Erenumab targets and blocks the Calcitonin Gene-Related Peptide (CGRP) receptor, thought to be pivotal in the genesis of migraine. Erenumab has been studied in several large global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. Positive results from a Phase 2 study and positive top-line data from two Phase 3 studies in migraine prevention were announced in 2016. These data will help support discussions with regulatory agencies, with filings anticipated in 2017.

About Migraine

Migraine is a distinct neurological disease.¹ People with migraine lose a substantial portion of their lives to this illness, experiencing significant physical impairment, frequently accompanied by head pain, nausea, vomiting and meaningful disruption of daily activities.¹ The World Health Organization ranks migraine as one of the most debilitating illnesses.² For the approximately 10 million Americans whose migraine frequency or severity impacts daily activities, preventive medications may be an option.³ Approximately 3.5 million of these patients are currently on a preventive therapy, but up to 80 percent discontinue these within one year because of intolerable side effects or limited efficacy.⁴ Migraine is associated with personal and societal burdens of pain, disability, and financial cost, and it remains under-recognized and under-treated.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. 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.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of

revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities and also depend on third

parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

CONTACT: Amgen, Thousand Oaks
Kristen Davis, 805-447-3008 (Media)
Kristen Neese, 805-313-8267 (Media)
Arvind Sood, 805-447-1060 (Investors)

References

1. Migraine Research Foundation. Migraine Fact Sheet. 2015. Available: <http://www.migraineresearchfoundation.org/fact-sheet.html>. Accessed April 7, 2017.
2. World Health Organization. Headache Disorder Fact Sheet. Available: <http://www.who.int/mediacentre/factsheets/fs277/en/>. Accessed April 7, 2017.
3. Lipton RB, et al. Migraine prevalence, disease burden, and the need for preventative therapy. *Neurology*. 2007; 68(5):343-9.
4. Marketscan data on file. 3-24-2017. Ref Type: Data File



MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis expands global collaboration with Amgen to commercialize first-in-class AMG 334 (erenumab) program in migraine prevention in the U.S. and Canada

- *Novartis and Amgen to co-commercialize AMG 334 (erenumab) in the US; Novartis to gain exclusive rights in Canada*
- *Novartis retains commercial rights in rest of world; Amgen retains commercial rights in Japan*
- *Companies to combine capabilities and leverage Novartis strong and established neuroscience presence in the US and across the globe to maximize launch of AMG 334 (erenumab)*

Basel, April 24, 2017 - Novartis today announced an expanded commercialization agreement with Amgen for AMG 334 (erenumab), which is being investigated for the prevention of migraine. This agreement builds on a 2015 global collaboration between Novartis and Amgen, and leverages almost 70 years of Novartis experience in neuroscience to more effectively reach people with migraine. Novartis and Amgen will co-commercialize AMG 334 (erenumab) in the US. Novartis will retain exclusive rights to commercialize the drug in rest of world and will gain commercialization rights in Canada. Amgen retains exclusive commercialization rights in Japan. The companies will continue global co-development.

AMG 334 (erenumab) is a fully human monoclonal antibody specifically designed for the prevention of migraine. It targets and blocks the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to play a critical role in mediating the incapacitating pain of migraine.[1] Positive results from a Phase II study and two Phase III studies of AMG 334 (erenumab) in migraine prevention were announced in 2016. In these studies, once-monthly subcutaneous AMG 334 (erenumab) significantly reduced monthly migraine days versus placebo and demonstrated a safety profile comparable to placebo.[2],[3],[4] Detailed results from the Phase

III studies are being presented at the annual meeting of the American Academy of Neurology and submitted for publication. These data will help support discussions with regulatory agencies, with filing anticipated in the second quarter of 2017.

"Migraine is a debilitating neurological disease associated with significant personal, economic, and societal burden. There is an urgent need for effective and well-tolerated preventive treatments that positively impact the lives of people with migraine," said Paul Hudson, Chief Executive Officer, Novartis Pharmaceuticals. "We are excited to expand our collaboration with Amgen. We look forward to combining capabilities and leveraging our strong heritage in neuroscience in the US and Canada to bring erenumab to more patients in need, as fast as we can."

Under the terms of the agreement, Amgen will receive milestone payments from Novartis, expected to begin in 2017. Novartis will share US commercialization costs with Amgen. Amgen will book sales of AMG 334 (erenumab) in the US, and will pay a royalty to Novartis on net sales in the US. Novartis will book sales in rest of the world, excluding Japan, and will pay Amgen royalties on the net sales in those countries. Amgen will book sales in Japan, since it will remain an exclusive territory for the company. Novartis will assume agreed upon remaining global development costs up to a cap and share global development costs thereafter.

The agreement is an expansion of a global collaboration with Amgen announced in August 2015 in neuroscience, involving joint development and commercialization of pioneering treatments in the field of Alzheimer's disease and migraine.[5]

About AMG 334 (erenumab)

AMG 334 (erenumab) is a fully human monoclonal antibody specifically designed to target and block the Calcitonin Gene-Related Peptide (CGRP) receptor, believed to play a critical role in mediating the incapacitating pain of migraine.[1] AMG 334 (erenumab) has been studied in several large global, randomized, double-blind, placebo-controlled trials to assess its safety and efficacy in migraine prevention. Following the initial Phase II dose finding study, the efficacy of AMG 334 (erenumab) in migraine prevention has been shown in a Phase II trial and two Phase III trials. The safety profile of AMG 334 (erenumab) in these studies was comparable to placebo.[2],[3],[4]

About Migraine

Migraine is a distinct neurological disease.[6] It involves recurrent attacks of moderate to severe head pain that is typically pulsating, often unilateral and associated with nausea, vomiting and sensitivity to light, sound and odors.[7]

Migraine is associated with personal pain, disability and reduced quality of life, and financial cost to society.[8] It has a profound and limiting impact on an individual's abilities to carry out everyday tasks, and was declared by the World Health Organization to be one of the top 10 causes of years lived with disability for men and women.[9] It remains under-recognized and under-treated.[8],[10] Existing preventive therapies have been repurposed from other indications and are often associated with poor tolerability and lack of efficacy, which lead to increasing discontinuation rates and dissatisfaction among patients.[11]

About the Amgen and Novartis Neuroscience Collaboration

In August 2015, Novartis entered into a global collaboration with Amgen to jointly develop and commercialize pioneering neuroscience treatments in the field of Alzheimer's disease (AD) and migraine. The companies are partnering in the development and commercialization of a beta-secretase 1 (BACE) inhibitor program in AD. Novartis' oral therapy CNP520 (currently in a Phase II/III study for AD) will be the lead molecule and further compounds from both companies' pre-clinical BACE inhibitor programs may be considered as novel follow-on molecules. The 2015 collaboration also focuses on innovative investigational Amgen drugs in the migraine field, including AMG 334 (erenumab) in migraine prevention and AMG 301 (currently in a Phase I study for migraine).

Novartis in Neuroscience

Novartis has a strong ongoing commitment to neuroscience and to bringing innovative treatments to patients suffering from neurological conditions where there is a high unmet need. We are committed to supporting patients and physicians in multiple disease areas, including Multiple Sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease, Epilepsy and Attention Deficit Hyperactivity Disorder, and have a promising pipeline in MS, AD, migraine and specialty neurology (e.g. neuropathic pain).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "to co-commercialize," "to gain," "to combine," "launch," "being investigated," "builds on," "will," "believed to," "submitted," "anticipated," "excited," "look forward," "expected," "pioneering," "may," "investigational," "ongoing," "commitment," "pipeline," or similar terms, or by express or implied discussions regarding potential marketing approvals for AMG 334, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, and other investigational compounds of Novartis and Amgen subject to the collaboration, potential new indications or labeling for products in the Novartis Neuroscience portfolio, or regarding potential future revenues from such investigational

compounds and products, and potential future revenues from the collaboration with Amgen. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that AMG 334, CNP520, AMG 301, other BACE inhibitors of Novartis and Amgen, or other investigational compounds of Novartis and Amgen subject to the collaboration will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that the collaboration with Amgen will achieve any or all of its intended goals and objectives, or be commercially successful. Nor can there be any guarantee that any product in the Novartis Neuroscience portfolio will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee that AMG 334, CNP520, AMG 301, any of the other investigational compounds subject to the collaboration with Amgen, or any product in the Novartis Neuroscience portfolio will be commercially successful in the future. In particular, management's expectations regarding such investigational compounds and products, and the collaboration with Amgen, could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing and reimbursement pressures; safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-

time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>(link is external)
For Novartis multimedia content, please visit www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

References

1. Bigal ME et al. Calcitonin Gene-Related Peptide (CGRP) and Migraine Current Understanding and State of Development. *Headache*. 2013;53(8):1230-1244.
2. Novartis presents new positive data at EHMTIC showing AMG 334 significantly reduces monthly migraine days in chronic migraine. <https://www.novartis.com/news/media-releases/novartis-presents-new-positive-data-ehmtic-showing-amg-334-significantly-reduces>. Accessed April 2017.
3. Novartis announces Phase III study shows AMG 334 significantly reduces monthly migraine data in people with episodic migraine. <https://www.novartis.com/news/media-releases/novartis-announces-phase-iii-study-shows-amg-334-significantly-reduces-monthly>. Accessed April 2017.
4. Novartis announces AMG 334 significantly reduces monthly migraine days in second pivotal Phase III episodic migraine study. <https://www.novartis.com/news/media-releases/novartis-announces-amg-334-significantly-reduces-monthly-migraine-days-second>. Accessed April 2017.
5. Novartis announces global partnership with Amgen to develop and commercialize pioneering neuroscience treatments. <https://www.novartis.com/news/media-releases/novartis-announces-global-p...> Accessed April 2017.
6. Migraine Research Foundation. Migraine Fact Sheet. 2015. <http://www.migraineresearchfoundation.org/fact-sheet.html>(link is external). Accessed April 2017.
7. National Institute for Neurological Disorders and Stroke. <https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-Page>(link is external) (link is external). Accessed April 2017.
8. World Health Organization. Headache disorders. <http://www.who.int/mediacentre/factsheets/fs277/en/>(link is external) (link is external). Accessed October 2016.
9. World Health Organization. Estimates for 2000-2012. Disease Burden. 2012.
10. Diamond S et al. Patterns of Diagnosis and Acute and Preventive Treatment

for Migraine in the United States: Results from the American Migraine Prevalence and Prevention Study. Headache. 2007;47(3):355-63.

11. Hepp Z, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. Cephalalgia. 2015; 35(6):478-88.

###

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Angela Fiorin

Novartis Global Pharma Communications

+ 41 61 324 8631 (direct)

+ 41 79 752 6955 (mobile)

angela.fiorin@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944

E-mail: investor.relations@novartis.com

Central North America North America

Samir Shah +41 61 324 7944 Richard Pulik +1 212 830 2448 Richard Pulik +1 212 830 2448

Pierre-Michel Bringer +41 61 324 1065

Thomas Hungerbuehler +41 61 324 8425

Isabella Zinck +41 61 324 7188

Note: Redacted portions have been marked with [*]. The redacted portions are subject to a request for confidential treatment that has been filed with the Securities and Exchange Commission.

Schedule

[*]

[*]

Amgen Ref. No. 2017747574

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: July 26, 2017

/s/ ROBERT A. BRADWAY

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

CERTIFICATIONS

I, David W. Meline, 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: July 26, 2017

/s/ DAVID W. MELINE

David W. Meline

Executive Vice President and Chief Financial Officer

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, 2017 (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: July 26, 2017

/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, 2017 (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: July 26, 2017

/s/ DAVID W. MELINE

David W. Meline

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.