# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

# Form 10-Q

(Mark One)

 $\mathbf{X}$ 

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

For the quarterly period ended September 30, 2009

OR

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

Commission file number 000-12477

# Amgen Inc.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of

incorporation or organization) One Amgen Center Drive, Thousand Oaks, California

(Address of principal executive offices)

Identification No.) 91320-1799

95-3540776

(I.R.S. Employer

(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 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  $\boxtimes$  No  $\square$ 

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, or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  $\boxtimes$ 

Accelerated filer  $\Box$ 

Non-accelerated filer  $\Box$ 

Smaller reporting company 
(Do not check if a smaller reporting company)

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

As of November 2, 2009, the registrant had 1,012,138,434 shares of common stock, \$0.0001 par value, outstanding.

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# **PART I - FINANCIAL INFORMATION**

# Item 1. FINANCIAL STATEMENTS

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

		e months ended ptember 30,	Nine months ended September 30,			
	2009	2008	2009	2008		
Revenues:						
Product sales	\$ 3,73	6 \$ 3,784	\$ 10,608	\$ 11,013		
Other revenues	7	6 91	225	239		
Total revenues	3,81	2 3,875	10,833	11,252		
Operating expenses:						
Cost of sales (excludes amortization of certain acquired intangible assets						
presented below)	54	5 677	1,553	1,738		
Research and development	64	7 729	1,973	2,232		
Selling, general and administrative	93	2 900	2,640	2,678		
Amortization of certain acquired intangible assets	7	4 74	221	221		
Other charges	1	9 12	63	306		
Total operating expenses	2,20	7 2,392	6,450	7,175		
Operating income	1,60	5 1,483	4,383	4,077		
Interest expense, net	13	9 133	436	419		
Interest and other income, net	7	4 62	182	264		
Income before income taxes	1,54	0 1,412	4,129	3,922		
Provision for income taxes	15	4 291	455	795		
Net income	\$ 1,38	6 \$ 1,121	\$ 3,674	\$ 3,127		
Earnings per share:						
Basic	\$ 1.3	6 \$ 1.06	\$ 3.60	\$ 2.91		
Diluted	\$ 1.3		\$ 3.58	\$ 2.90		
Shares used in calculation of earnings per share:						
Basic	1,01	6 1,058	1,020	1,075		
Diluted	1,02	2 1,064	1,025	1,079		

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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

	September 30, 2009	De	cember 31, 2008
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 3,577	\$	1,774
Marketable securities	10,436		7,778
Trade receivables, net	2,331		2,073
Inventories	2,155		2,075
Other current assets	1,475		1,521
Total current assets	19,974		15,221
Property, plant and equipment, net	5,743		5,879
Intangible assets, net	2,674		2,988
Goodwill	11,335		11,339
Other assets	1,214		1,000
Total assets	\$ 40,940	\$	36,427

# LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 613	\$ 504
Accrued liabilities	3,290	3,382
Current portion of other long-term debt	1,000	1,000
Total current liabilities	4,903	4,886
Convertible notes	4,447	4,257
Other long-term debt	6,089	4,095
Other non-current liabilities	2,643	2,304

# Commitments and contingencies

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Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750 shares authorized; outstanding - 1,016		
shares in 2009 and 1,047 shares in 2008	26,853	26,441
Accumulated deficit	(4,042)	(5,673)
Accumulated other comprehensive income	47	117
Total stockholders' equity	22,858	 20,885
Total liabilities and stockholders' equity	\$ 40,940	\$ 36,427

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

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

	Nine months ended September 30,		
	2009	2008	
Cash flows from operating activities:			
Net income	\$ 3,674	\$ 3,127	
Depreciation and amortization	792	799	
Stock-based compensation expense	209	195	
Other items, net	146	69	
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(258)	16	
Inventories	(60)	(22)	
Other current assets	(33)	(29)	
Accounts payable	43	136	
Accrued income taxes	33	88	
Other accrued liabilities	(66)	(125)	
Deferred revenue	33	337	
Net cash provided by operating activities	4,513	4,591	
Cash flows from investing activities:			
Purchases of property, plant and equipment	(386)	(494)	
Cash paid for acquisitions, net of cash acquired	(500)	(50)	
Purchases of marketable securities	(10,889)	(7,794)	
Proceeds from sales of marketable securities	7,026	5,002	
Proceeds from maturities of marketable securities	1,340	625	
Other	46	93	
Net cash used in investing activities	(2,863)	(2,618)	
Cash flows from financing activities:			
Repurchases of common stock	(1,997)	(1,568)	
Repayment of debt	(1,557)	(1,000)	
Net proceeds from issuance of debt	- 1,980	(1,000) 992	
	1,900	992 114	
Net proceeds from issuance of common stock in connection with the Company's equity award programs Other	24		
		(13)	
Net cash provided by (used in) financing activities	153	(1,475)	
Increase in cash and cash equivalents	1,803	498	
Cash and cash equivalents at beginning of period	1,774	2,024	
Cash and cash equivalents at end of period	\$ 3,577	\$ 2,522	

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

# AMGEN INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2009 (Unaudited)

#### 1. Summary of significant accounting policies

**Business** 

Amgen Inc. is a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology.

## Basis of presentation

The financial information for the three and nine months ended September 30, 2009 and 2008 is unaudited but includes all adjustments (consisting of only normal recurring adjustments, unless otherwise indicated), which Amgen Inc., including its subsidiaries (referred to as "Amgen," "the Company," "we," "our" or "us"), considers necessary for a fair presentation of the 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, 2008.

#### Financial Accounting Standards Board ("FASB") Accounting Standards Codification

During the three months ended September 30, 2009, the FASB Accounting Standards Codification ("ASC" or "Codification") became the authoritative source of accounting principles generally accepted in the United States ("GAAP") recognized by the FASB. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, FASB staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards Updates that update the Codification. Rules and interpretive releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

#### Change in method of accounting for convertible debt instruments

Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for convertible debt that may be partially or wholly settled in cash. As required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt. Under this method of accounting, the debt and equity components of our convertible notes are bifurcated and accounted for separately. The equity components of our convertible notes, including our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, are included in "Common stock and additional paid-in capital" in the Condensed Consolidated Balance Sheets, with a corresponding reduction in the carrying values of these convertible notes as of the date of issuance or modification, as applicable. The reduced carrying values of our convertible notes are being accreted back to their principal amounts through the recognition of non-cash interest expense. This results in recognizing interest expense on these borrowings at effective rates approximating what we would have incurred had we issued nonconvertible debt with otherwise similar terms. See Note 2, "Change in method of accounting for convertible debt instruments" and Note 9, "Financing arrangements."

#### Principles of consolidation

The condensed consolidated financial statements include the accounts of Amgen as well as its wholly 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 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.

#### Fair value measurement

We adopted a new accounting standard that defines fair value and establishes a framework for fair value measurements effective January 1, 2008 for financial assets and liabilities and effective January 1, 2009 for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is generally defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. The adoption of this accounting standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

During the three months ended June 30, 2009, we adopted a new accounting standard that modifies the guidance used in determining whether the impairment of a debt security is other-than-temporary. Under this accounting standard, the impairment of a debt security is considered other-than-temporary if an entity concludes that it intends to sell the impaired security, that it is more likely than not it will be required to sell the security before the recovery of its cost basis or that it does not otherwise expect to recover the entire cost basis of the security. This accounting standard also amends the presentation requirements of other-than-temporarily impaired debt securities and expands disclosure requirements in the financial statements for investments in both debt and equity securities. The adoption of this accounting standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

During the three months ended June 30, 2009, we adopted two new accounting standards that require disclosures at each interim balance sheet date of the fair value of financial instruments and valuation techniques used to determine fair value. Previously, these disclosures were only required annually. One of these accounting standards also provides additional guidance in estimating fair value when the market volume and level of activity for an asset or liability have significantly decreased and identifying circumstances that indicate a transaction may not be orderly. The adoption of these two accounting standards did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

See Note 11, "Fair value measurement."

#### Derivative instruments

Effective January 1, 2009, we adopted a new accounting standard that requires disclosures about our derivative instruments and hedging activities. This standard requires that the objectives for using derivative instruments be disclosed to better convey the purpose of derivative use in terms of the risks that we are intending to manage. This standard also requires disclosure of how derivatives and related hedged items affect our financial statements. The adoption of this standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows. See Note 12, "*Derivative instruments*."

# Inventories

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out ("FIFO") method.

#### Property, plant and equipment, net

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation of \$4.5 billion and \$4.1 billion as of September 30, 2009 and December 31, 2008, respectively.

# Goodwill

Goodwill principally relates to our 2002 acquisition of Immunex Corporation ("Immunex"). We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

# Product sales

Product sales primarily consist of sales of Aranesp® (darbepoetin alfa), EPOGEN® (Epoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim) and Enbrel® (etanercept).

Sales of our products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, discounts and other incentives (collectively "sales incentives") and returns. Taxes assessed by government authorities on the sale of the Company's products, primarily in Europe, are excluded from revenues.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We have the exclusive right to sell Epoetin alfa for dialysis, certain diagnostics and all non-human, non-research uses in the United States. We sell Epoetin alfa under the brand name EPOGEN®. We granted to Ortho Pharmaceutical Corporation (which has assigned its rights under the product license agreement to Ortho Biotech Products, L.P. ("Ortho Biotech")), a subsidiary of Johnson & Johnson ("J&J"), a license relating to Epoetin alfa for sales in the United States for all human uses except dialysis and diagnostics. This license agreement, which is perpetual, may be terminated for various reasons, including upon mutual agreement of the parties, or default. The parties are required to compensate each other for Epoetin alfa sales that either party makes into the other party's exclusive market, sometimes referred to as "spillover." Accordingly, we do not recognize product sales we make into the exclusive market of J&J and do recognize the product sales made by J&J into our exclusive market. Sales in our exclusive market are derived from our sales to our customers, as adjusted for spillover. We are employing an arbitrated audit methodology to measure each party's spillover based on estimates of and subsequent adjustments thereto of third-party data on shipments to end users and their usage.

#### Research and development costs

Research and development ("R&D") costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of Kirin-Amgen Inc. ("KA"), and costs and cost recoveries associated with collaborative R&D and in-licensing arrangements, including upfront fees and milestones paid to collaboration partners in connection with technologies that have no alternative future use. Net payment or reimbursement of R&D costs for R&D collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

#### Selling, general and administrative costs

Selling, general and administrative ("SG&A") expenses are primarily comprised of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses and other general and administrative costs.

SG&A expenses include costs and cost recoveries associated with certain collaborative arrangements. Net payment or reimbursement of SG&A costs for collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

# Subsequent events

During the three months ended June 30, 2009, we adopted a new accounting standard that establishes general standards for the accounting and disclosing of events that occur after the balance sheet date that are not addressed elsewhere in the Codification. This standard requires entities to disclose the date through which subsequent events have been evaluated and whether that date is the date the financial statements were issued. We have evaluated subsequent events through the date of issuance of our financial statements in this Form 10-Q.

#### Recent accounting pronouncements

In June 2009, the FASB issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise's involvement in the variable interest entity. This standard is effective for us for interim and annual reporting periods beginning on or after January 1, 2010. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In August 2009, the FASB issued a new accounting standard which clarifies guidance for determining the fair value of a liability when a quoted price in an active market for an identical liability is not available. This standard provides for the use of one or more valuation techniques including use of quoted prices of identical or similar liabilities when traded as assets, quoted prices of similar liabilities and other techniques consistent with the fair value measurement framework, such as the amount an entity would pay to transfer the identical liability or would receive to enter into the identical liability. This standard is effective for us for interim and

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

annual periods beginning on or after October 1, 2009. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us for annual periods beginning on or after January 1, 2011. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

#### 2. Change in method of accounting for convertible debt instruments

As discussed in Note 1, "Summary of significant accounting policies - Change in method of accounting for convertible debt instruments," effective January 1, 2009, we adopted a new accounting standard which changed the method of accounting for certain types of convertible debt and, as required by this standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt.

The following tables illustrate the impact of adopting this accounting standard on the Condensed Consolidated Statements of Income (in millions, except per share information):

	Three months ended September 30, 2009							
	Exclu	ıding the			Inclu	iding the		
	acc	effect of the accounting standard		ct of the ounting indard	acc	ct of the ounting indard		
Operating income	\$	1,605	\$	-	\$	1,605		
Interest expense, net		76		63		139		
Interest and other income, net		74		-		74		
Income before income taxes		1,603		(63)		1,540		
Provision for income taxes		178		(24)		154		
Net income	\$	1,425	\$	(39)	\$	1,386		
Faminge per charo:								

Earnings per share:			
Basic	\$ 1.40	\$ (0.04)	\$ 1.36
Diluted	\$ 1.39	\$ (0.03)	\$ 1.36

	Three months ended September 30, 2008					
	s originally reported	0 0			evised"	
Operating income	\$ 1,483	\$	-	\$	1,483	
Interest expense, net	74		59		133	
Interest and other income, net	62		-		62	
Income before income taxes	 1,471		(59)		1,412	
Provision for income taxes	313		(22)		291	
Net income	\$ 1,158	\$	(37)	\$	1,121	
Earnings per share:						
Basic	\$ 1.09	\$	(0.03)	\$	1.06	
Diluted	\$ 1.09	\$	(0.04)	\$	1.05	

	Nine months ended September 30, 2009							
		Excluding the		Excluding the effect of the		( - f +]		uding the ect of the
	acc	ounting oundard	ng accounting		aco	accounting standard		
Operating income	\$	4,383	\$	-	\$	4,383		
Interest expense, net		250		186		436		
Interest and other income, net		182		-		182		
Income before income taxes		4,315		(186)		4,129		
Provision for income taxes		525		(70)		455		
Net income	\$	3,790	\$	(116)	\$	3,674		
Earnings per share:								
Basic	\$	3.72	\$	(0.12)	\$	3.60		
Diluted	\$	3.70	\$	(0.12)	\$	3.58		

	Nine months ended September 30, 2008					
	As originally reported		Effect of the accounting standard		"R	evised"
Operating income	\$	4,077	\$	-	\$	4,077
Interest expense, net		245		174		419
Interest and other income, net		264		-		264
Income before income taxes		4,096		(174)		3,922
Provision for income taxes		861		(66)		795
Net income	\$	3,235	\$	(108)	\$	3,127
Earnings per share:						
Basic	\$	3.01	\$	(0.10)	\$	2.91
Diluted	\$	3.00	\$	(0.10)	\$	2.90

The following tables illustrate the impact of adopting this accounting standard on the Condensed Consolidated Balance Sheets (in millions):

	September 30, 2009					
	effe acc	Excluding the effect of the Effect of the accounting accounting standard standard		accounting		uding the ect of the counting andard
Non-current assets:						
Other assets	\$	1,227	\$	(13)	\$	1,214
Non-current liabilities:						
Convertible notes		5,082		(635)		4,447
Other non-current liabilities		2,404		239		2,643
Stockholders' equity:						
Common stock and additional paid-in capital		25,939		914		26,853
Accumulated deficit		(3,511)		(531)		(4,042)

	 December 31, 2008								
	As originally reported		ct of the ounting ndard	"R	evised"				
Non-current assets:									
Other assets	\$ 1,016	\$	(16)	\$	1,000				
Non-current liabilities:									
Convertible notes	5,081		(824)		4,257				
Other non-current liabilities	1,995		309		2,304				
Stockholders' equity:									
Common stock and additional paid-in capital	25,527		914		26,441				
Accumulated deficit	(5,258)		(415)		(5,673)				

The effect of this accounting standard on "Other non-current liabilities" in the Condensed Consolidated Balance Sheets reflects the impact of deferred taxes. In addition, the effect of this accounting standard on "Common stock and additional paid-in capital" in the Condensed Consolidated Balance Sheets reflects, principally, the impact of the equity component of our convertible debt partially offset by deferred taxes.

As a result of the accounting change, our accumulated deficit as of January 1, 2008, increased from \$7.2 billion, as originally reported, to \$7.4 billion after applying this accounting standard. There was no impact resulting from this accounting change on our cash flows from operating activities, investing activities or financing activities as reflected in the Condensed Consolidated Statements of Cash Flows.

# 3. Income taxes

The effective tax rates for the three and nine months ended September 30, 2009 and September 30, 2008 are different from the federal statutory tax rate 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. In addition, the effective tax rates for the three and nine months ended September 30, 2009 were further reduced by favorable resolution of certain matters with tax authorities for prior periods.

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 can arise with these tax authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations. We are no longer subject to U.S. federal income tax examinations for years ending on or before December 31, 2004 or to California state income tax examinations for years ending on or before December 31, 2003.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2009, we have settled the examinations of our U.S. income tax returns with the Internal Revenue Service for certain matters for the years ended December 31, 2005 and 2006 and have remeasured our unrecognized tax benefits ("UTBs") accordingly. As of September 30, 2009, we have also settled the examinations of our California state income tax returns for certain matters for the years ended December 31, 2004 and 2005 and have remeasured our UTBs accordingly.

During the three and nine months ended September 30, 2009, the gross amount of our UTBs increased approximately \$80 million and \$225 million, respectively, as a result of tax positions taken during the current year. During the three and nine months ended September 30, 2009, the gross amount of our UTBs increased approximately \$37 million as a result of tax positions taken during prior periods. During the three and nine months ended September 30, 2009, the gross amount of our UTBs decreased approximately \$140 million and \$310 million, respectively, primarily as a result of resolving certain tax matters related to prior periods. The majority of our UTBs as of September 30, 2009, if recognized, would affect our effective tax rate.

# 4. Earnings per share

Basic earnings per share ("EPS") is based upon the weighted-average number of common shares outstanding. Diluted EPS is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options, restricted stock (including restricted stock units) and other equity awards under our employee compensation plans and potential issuance of stock upon the assumed conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, as discussed below, and upon the assumed exercise of our warrants using the treasury stock method (collectively "dilutive securities"). The convertible note hedges purchased in connection with the issuance of our 2011 Convertible Notes and 2013 Convertible Notes are excluded from the calculation of diluted EPS as their impact is always anti-dilutive.

Upon conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, the principal amount or accreted value would be settled in cash and the excess of conversion value over the principal amount or accreted value may be settled in cash and/or shares of common stock. Therefore, only the shares of common stock potentially issuable with respect to the excess of the notes' conversion value over their principal amount or accreted value, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the three and nine months ended September 30, 2009 and 2008, the conversion values for our convertible notes were less than the related principal amounts or accreted value and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS. For further information regarding our convertible notes, see Note 9, *"Financing arrangements."* 

The following table sets forth the computation for basic and diluted EPS (in millions, except per share information):

	Three months ended September 30,				led ,				
	 2009		2008		2008		2009		2008
Income (Numerator):	 								
Net income for basic and diluted EPS	\$ 1,386	\$	1,121	\$	3,674	\$	3,127		
Shares (Denominator):									
Weighted-average shares for basic EPS	1,016		1,058		1,020		1,075		
Effect of dilutive securities	6		6		5		4		
Weighted-average shares for diluted EPS	 1,022		1,064		1,025	_	1,079		
Basic EPS	\$ 1.36	\$	1.06	\$	3.60	\$	2.91		
Diluted EPS	\$ 1.36	\$	1.05	\$	3.58	\$	2.90		

For the three and nine months ended September 30, 2009, there were employee stock options, calculated on a weighted average basis, to purchase 31 million and 43 million shares, respectively, with exercise prices greater than the average market prices of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. For the three and nine months ended September 30, 2008, there were employee stock options, calculated on a weighted average basis, to purchase 35 million and 47 million shares, respectively, with exercise prices greater than the average market prices of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. For the three and nine months ended September 30, 2008, there were employee stock options, calculated on a weighted average basis, to purchase 35 million and 47 million shares, respectively, with exercise prices greater than the average market prices of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. In addition, shares which may be issued upon conversion of our convertible debt or upon exercise of our warrants are not included in any of the periods presented above as their impact on diluted EPS would have been anti-dilutive. Shares which may be

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

issued under our 2007 and 2009 performance award programs were also excluded for the applicable periods because conditions under the programs were not met.

#### 5. Related party transactions

We own a 50% interest in KA, a corporation formed in 1984 with Kirin Holdings Company, Limited ("Kirin") for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA's profits or losses in "Selling, general and administrative" in the Condensed Consolidated Statements of Income. During the three and nine months ended September 30, 2009, our share of KA's profits was \$13 million and \$49 million, respectively. During the three and nine months ended September 30, 2009, our share of KA's profits was \$12 million and \$49 million, respectively. During the three and nine months ended September 30, 2008, our share of KA's profits was \$405 million and \$356 million, respectively, and is included in non-current "Other assets" in the Condensed Consolidated Balance Sheets. KA's revenues consist of royalty income related to its licensed technology rights. All of our rights to manufacture and market certain products, including darbepoetin alfa, pegfilgrastim, granulocyte colony-stimulating factor ("G-CSF") and recombinant human erythropoietin, are pursuant to exclusive licenses from KA, which we currently market under the brand names Aranesp®, Neulasta®, NEUPOGEN® and EPOGEN®, respectively. KA receives royalty income from us, as well as from Kirin, J&J and F. Hoffmann-La Roche Ltd. ("Roche") under separate product license agreements for certain geographic areas outside of the United States. During the three and nine months ended September 30, 2008, KA earned royalties from us of \$85 million and \$237 million, respectively. During the three and nine months ended September 30, 2009, KA earned royalties from us of \$85 million and \$237 million, respectively. During the three and nine months ended September 30, 2009, KA earned royalties from us of \$85 million and \$243 million, respectively. These amounts are included in "Cost of sales (excludes amortization of certain acquired intangible assets)" in the Condensed Co

KA's expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and nine months ended September 30, 2009, we earned revenues from KA of \$27 million and \$81 million, respectively, for certain R&D activities performed on KA's behalf. During the three and nine months ended September 30, 2008, we earned revenues from KA of \$41 million and \$100 million, respectively, for certain R&D activities performed on KA's behalf. These amounts are included in "Other revenues" in the Condensed Consolidated Statements of Income.

# 6. Restructuring

On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoiesis-stimulating agent ("ESA") products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. Key components of our restructuring plan initially included: (i) worldwide staff reductions, (ii) rationalization of our worldwide network of manufacturing facilities and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases primarily for certain R&D facilities that will not be used in our operations. Subsequently, we identified certain additional initiatives designed to further assist in improving our cost structure, including outsourcing certain non-core business functions, most notably certain of our information systems' infrastructure services, as well as abandoning leases for certain additional facilities that will no longer be used in our operations. As of September 30, 2009, we have substantially completed all of the actions and incurred all related costs included in our restructuring plan and subsequently identified initiatives.

Through September 30, 2009, we have incurred \$952 million of costs related to the above-noted actions. The charges included \$214 million of separation costs, \$476 million of asset impairments, \$148 million of accelerated depreciation and \$114 million of other net charges, which primarily include \$165 million of loss accruals for leases, \$10 million loss on the disposal of certain less significant marketed products, \$35 million for implementation costs associated with certain cost saving initiatives and \$19 million of other charges, offset by \$115 million of cost recoveries from Pfizer Inc. ("Pfizer") (formerly Wyeth).

The following tables summarize the charges (credits) related to the above-noted actions by type of activity (in millions):

	Separation costs		Asset impairments						Total	
Three months ended September 30, 2009										
R&D	\$	-	\$	3	\$	-	\$	3		
SG&A		-		-		6		6		
Other charges		(3)		-		4		1		
	\$	(3)	\$	3	\$	10	\$	10		
Three months ended September 30, 2008										
Other charges	\$	-	\$	1	\$	7	\$	8		
Interest and other income, net		-		-		9		9		
	\$	-	\$	1	\$	16	\$	17		
Nine months ended September 30, 2009 Cost of sales (excludes amortization of certain acquired intangible assets) R&D SG&A	\$	- (3) (2)	\$	1 8	\$	- 1 25	\$	1 6 23		
Other charges		31		-		4		35		
	\$	26	\$	9	\$	30	\$	65		
Nine months ended September 30, 2008										
Cost of sales (excludes amortization of certain acquired intangible assets)	\$	-	\$	1	\$	-	\$	1		
R&D		3		-		-		3		
SG&A		-		-		(1)		(1)		
Other charges		4		15		20		39		
Interest and other income, net		-	_	-		9		9		
	\$	7	\$	16	\$	28	\$	51		

The following table summarizes the charges and spending relating to the above actions (in millions):

	Sepa	ration				
	C	osts	O	ther	Total	
Restructuring reserves as of January 1, 2009	\$	4	\$	162	\$	166
Expense		26		30		56
Payments		(24)	_	(54)		(78)
Restructuring reserves as of September 30, 2009	\$	6	\$	138	\$	144

# 7. Available-for-sale securities

We consider our investment portfolio and marketable equity investments available-for-sale and, accordingly, these investments are recorded at fair value with unrealized gains and losses generally recorded in other comprehensive income. For the three months ended September 30, 2009 and 2008, realized gains related to these investments were \$22 million and \$18 million, respectively, and realized losses related to these investments were \$8 million and \$26 million, respectively. For the nine months ended September 30, 2009 and 2008, realized gains related to these investments were \$90 million and \$94 million, respectively, and realized losses related to these investments were \$00 million and \$94 million, respectively, and realized losses related to these investments were \$63 million and \$62 million, respectively. The cost of securities sold is based on the specific identification method.

The fair values of available-for-sale investments by type of security, contractual maturity and classification in the Condensed Consolidated Balance Sheets are as follows (in millions):

September 30, 2009	Amortized cost		· · · · · · ·		Gross unrealized losses		Estimate fair value	
Type of security:								
U.S. Treasury securities	\$	1,590	\$	16	\$	(1)	\$	1,605
Obligations of U.S. government agencies and FDIC guaranteed bank debt		4,303		85		(1)		4,387
Corporate debt securities		3,976		96		(3)		4,069
Mortgage and asset backed securities		311		5		-		316
Other short-term interest bearing securities		3,530		-		-		3,530
Total debt securities		13,710		202		(5)		13,907
Equity securities		71		10		-		81
	\$	13,781	\$	212	\$	(5)	\$	13,988

December 31, 2008	Amortized cost		Gross I unrealized gains		Gross unrealized losses		 timated fair value
Type of security:							
U.S. Treasury securities	\$	1,896	\$	58	\$	(2)	\$ 1,952
Obligations of U.S. government agencies and FDIC guaranteed bank debt		3,396		100		(3)	3,493
Corporate debt securities		1,432		10		(72)	1,370
Mortgage and asset backed securities		508		2		(6)	504
Other short-term interest bearing securities		2,126		-		-	 2,126
Total debt securities		9,358		170		(83)	9,445
Equity securities		65		-		(8)	57
	\$	9,423	\$	170	\$	(91)	\$ 9,502

Contractual maturity	Sept	ember 30, 2009	cember 31, 2008	
Maturing in one year or less	\$	4,140	\$ 3,179	
Maturing after one year through three years		5,895	3,724	
Maturing after three years through five years		3,454	2,199	
Maturing after five years		418	 343	
Total debt securities		13,907	9,445	
Equity securities		81	57	
	\$	13,988	\$ 9,502	

Classification in the Condensed Consolidated Balance Sheets	Sept	September 30, 2009		December 31, 2008		
Cash and cash equivalents	\$	3,577	\$	1,774		
Marketable securities		10,436		7,778		
Other assets – noncurrent		81	_	30		
		14,094		9,582		
Less cash		(106)		(80)		
	\$	13,988	\$	9,502		

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

We review periodically our available-for-sale securities for other-than-temporary declines in fair value below their cost basis and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. As of September 30, 2009 and December 31, 2008, the Company believes that the cost basis for our available-for-sale securities were recoverable in all material respects.

#### 8. Inventories

Inventories consisted of the following (in millions):

	-	ember 30, 2009	ember 31, 2008
Raw materials	\$	109	\$ 112
Work in process		1,565	1,519
Finished goods		481	444
	\$	2,155	\$ 2,075

# 9. Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements (dollar amounts in millions):

	Sept	September 30, 2009		mber 31, 2008
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$	2,307	\$	2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)		2,058		1,970
5.85% notes due 2017 (2017 Notes)		1,099		1,099
4.00% notes due 2009 (2009 Notes)		1,000		1,000
4.85% notes due 2014 (2014 Notes)		1,000		1,000
5.70% notes due 2019 (2019 Notes)		998		-
6.40% notes due 2039 (2039 Notes)		995		-
6.375% notes due 2037 (2037 Notes)		899		899
6.15% notes due 2018 (2018 Notes)		499		499
6.90% notes due 2038 (2038 Notes)		499		498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)		82		81
Other		100		100
Total borrowings		11,536		9,352
Less current portion		1,000		1,000
Total non-current debt	\$	10,536	\$	8,352

# 2019 Notes and 2039 Notes

In January 2009, we issued \$1.0 billion aggregate principal amount of notes due in 2019 (the "2019 Notes") and \$1.0 billion aggregate principal amount of notes due in 2039 (the "2039 Notes") in a registered offering. The 2019 Notes and the 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and the 2039 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a "make-whole" amount, as defined. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. The total debt discount on issuance and debt issuance costs were \$7 million and \$13 million, respectively, and are being amoutized over the lives of the notes.

# Convertible notes

Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for certain types of convertible debt and, as required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt (see Note 2, "*Change in method of accounting for convertible debt instruments*"). Under this method of accounting, the debt and equity components of our convertible notes are bifurcated and accounted for separately. The equity components of our convertible notes, including our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, are included in "Common stock and additional paid-in capital" in the Condensed Consolidated Balance Sheets, with a corresponding reduction in the carrying values of these convertible notes as of the date of issuance or modification, as applicable. The reduced carrying values of our convertible notes are being accreted back to their principal amounts through the recognition of non-cash interest expense. This results in recognizing interest expense on these borrowings at effective rates approximating what we would have incurred had we issued nonconvertible debt with otherwise similar terms.

The 2011 Convertible Notes and the 2013 Convertible Notes were issued at par and pay interest at a rate of 0.125% and 0.375%, respectively. The discounts associated with these notes resulting from the adoption of this new accounting standard are being amortized over periods that end on the scheduled maturity dates of these notes and result in effective interest rates of approximately 6.24% for the 2011 Convertible Notes and approximately 6.35% for the 2013 Convertible Notes.

For both the three and nine months ended September 30, 2009 and 2008, interest expense for the 2011 Convertible Notes was approximately \$1 million and \$2 million, respectively, based on the contractual coupon rates. For both the three and nine months ended September 30, 2009 and 2008, interest expense for the 2013 Convertible Notes was approximately \$2 million and \$7 million, respectively, based on the contractual coupon rates.

For the three and nine months ended September 30, 2009, amortization of the discount for the 2011 Convertible Notes was approximately \$34 million and \$101 million, respectively. For the three and nine months ended September 30, 2008, amortization of the discount for the 2011 Convertible Notes was approximately \$33 million and \$96 million, respectively. For the three and nine months ended September 30, 2009, amortization of the discount for the 2013 Convertible Notes was approximately \$30 million and \$88 million, respectively. For the three and nine months ended September 30, 2009, amortization of the discount for the 2013 Convertible Notes was approximately \$28 million and \$82 million, respectively.

The 2011 Convertible Notes and the 2013 Convertible Notes may, subject to certain conditions, be converted based on a conversion rate of 12.5247 and 12.5814 shares, respectively, per \$1,000 principal amount of notes (which represents a conversion price of approximately \$79.84 and \$79.48 per share, respectively). Upon conversion, a holder would receive the conversion value, as defined, in: (i) cash equal to the lesser of the principal amount of the note or the conversion value and (ii) shares of our common stock, cash or a combination of shares of our common stock and cash, at our option, to the extent the conversion value exceeds the principal amount of the note. As of September 30, 2009, these notes were not convertible and the principal values exceeded the conversion values.

The principal balances, unamortized discounts and net carrying amounts of the liability components and the equity components of our 2011 Convertible Notes and our 2013 Convertible Notes are as follows (in millions):

		I	Liability	y compone	ent		quity ponent
	Principal balance		Unamortized discount		Net carrying		arrying 10unt
Balance as of September 30, 2009							
2011 Convertible Notes	\$	2,500	\$	193	\$	2,307	\$ 643
2013 Convertible Notes	\$	2,500	\$	442	\$	2,058	\$ 829
Balance as of December 31, 2008							
2011 Convertible Notes	\$	2,500	\$	294	\$	2,206	\$ 643
2013 Convertible Notes	\$	2,500	\$	530	\$	1,970	\$ 829

The 2032 Modified Convertible Notes were issued in 2005 in exchange for zero-coupon, 30-year convertible notes that we issued in 2002. Like the notes for which they were exchanged, no interest is currently payable on the 2032 Modified Convertible Notes. These notes were issued at a discount from their principal amount (prior to the adoption of the new accounting standard). The

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

reduced carrying value resulting from issuing these notes at a discount is being accreted back to the principal amount based on a contractual interest rate of 1.125% over the life of the notes. In March 2007, substantially all of the holders of the 2032 Modified Convertible Notes exercised their option to put these convertible notes to us. The additional discount on the 2032 Modified Convertible Notes recognized pursuant to the retrospective application of the new accounting standard (in excess of the discount recognized under the contractual terms of these securities) was amortized as non-cash interest expense prior to the holders putting these convertible notes to us. We continue to recognize interest expense for the amortization of the discount based on the contractual rate for the 2032 Modified Convertible Notes that remain outstanding. Such amounts were not material for the three and nine months ended September 30, 2009 and 2008.

Holders of the remaining outstanding 2032 Modified Convertible Notes may, subject to certain conditions, convert each of their notes based on a conversion rate of 8.8601 shares of our common stock. The conversion price per share of the convertible notes as of any day will equal the accreted value on that day, divided by the conversion rate, or \$87.76, as of September 30, 2009. If converted, the 2032 Modified Convertible Notes will be settled in cash for an amount equal to the lesser of the accreted value of the 2032 Modified Convertible Notes at the conversion date or the conversion value, as defined, and shares of our common stock, if any, to the extent the conversion value exceeds the amount paid in cash. As of September 30, 2009, these notes were not convertible and the accreted value exceeded the amount that would have been received upon conversion. As of September 30, 2009 and December 31, 2008, the equity component of the 2032 Modified Convertible Notes was approximately \$29 million.

#### Other facilities

As of September 30, 2009, we have a \$2.3 billion syndicated, unsecured, revolving credit facility which matures in November 2012 and is available for general corporate purposes or as a liquidity backstop to our commercial paper program. In late 2008, a participating financial institution in the credit facility, which had provided \$178 million of such commitment declared bankruptcy. Subsequently, this financial institution, which is a subsidiary of Lehman Brothers Holdings, Inc. ("Lehman"), was removed from the credit facility and the aggregate commitment was reduced to its current level of \$2.3 billion.

# 10. Stockholders' equity

#### Stock repurchase programs

A summary of activity under our stock repurchase programs is as follows (in millions):

	20	009	2	008	
	Shares	Dollars	Shares	Dollars	
First quarter	37.5	\$ 1,997	-	\$ -	
Second quarter	-	-	32.7	1,549 (1)	)
Third quarter	-	-	-	19 (1)	)
Total	37.5	\$ 1,997	32.7	\$ 1,568	

(1)

The total cost of shares repurchased during the three months ended June 30, 2008 excludes approximately \$19 million paid in July 2008 in connection with the final settlement of an accelerated share repurchase program entered into in May 2008.

As of September 30, 2009, \$2.2 billion remained available for stock repurchases as authorized by our Board of Directors. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a variety of factors, including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

#### **11. Fair value measurement**

We use various valuation approaches in determining the fair value of our financial assets and liabilities 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 the 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 the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down 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 based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly
- 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 to measure 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.

U.S. Treasury securities, money market funds (included within "Other short-term interest bearing securities") and equity securities are valued using quoted market prices with no valuation adjustment. Accordingly, these securities are categorized in Level 1. Obligations of U.S. government agencies and FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities and other short-term interest bearing securities are valued using quoted market prices of recent transactions or are benchmarked to transactions of very similar securities. Accordingly, these securities are categorized in Level 2.

Our derivative assets and liabilities include interest rate swaps and foreign currency forward and option contracts. The fair values of these derivatives are determined using models based on market observable inputs, including interest rate curves and both forward and spot prices for foreign currencies. All of these derivative contracts are categorized in Level 2.

The following fair value hierarchy tables present information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis (in millions):

	Fair value measurement at September 30, 2009 using:							
	Quoted prices in active markets for identical assets (Level 1)		Significant other observable inputs (Level 2)		unobs in	ificant servable puts vel 3)	Total	
Assets:								
Available-for-sale securities:								
U.S. Treasury securities	\$	1,605	\$	-	\$	-	\$ 1,605	
Obligations of U.S. government agencies and FDIC								
guaranteed bank debt		-		4,387		-	4,387	
Corporate debt securities		-		4,069		-	4,069	
Mortgage and asset backed securities		-		316		-	316	
Other short-term interest bearing securities		3,425		105		-	3,530	
Equity securities		81		-		-	81	
		5,111		8,877		-	13,988	
Derivatives		-		158		-	158	
Total	\$	5,111	\$	9,035	\$	-	\$14,146	
Liabilities:								
Derivatives	\$		\$	181	\$	-	\$ 181	
Total	\$	-	\$	181	\$	-	\$ 181	
		Fair va	lue measur	ement at Decen	ıber 31, 20	08 using:		
		observ	icant other vable inputs vevel 2)	Sign unobs in (Le	Total			
Assets:	<u> </u>					ver 5)	Total	
Available-for-sale securities	\$	3,575	\$	5,927	\$	-	\$ 9,502	
Derivatives	Ψ	-	Ψ	415	Ψ	-	415	
Total	\$	3,575	\$	6,342	\$	-	\$ 9,917	
Liabilities:								
Derivatives	\$	-	\$	66	\$	-	\$ 66	
Total	\$	-	\$	66	\$	-	\$ 66	
			-		· · · · · · · · · · · · · · · · · · ·			

There were no material remeasurements to fair value during the nine months ended September 30, 2009 and 2008 of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair value of other financial instruments

Short-term assets and liabilities

The fair values of cash equivalents, accounts receivable and accounts payable approximate their carrying values due to the short-term nature of these financial instruments.

## Notes payable

The following tables present the carrying value and fair value of our convertible notes, modified convertible notes and other long-term notes. The fair values of the convertible notes and modified convertible notes were estimated using discounted cash flow models based upon significant observable inputs (Level 2). The fair values of our other long-term notes were estimated using quoted prices, which were corroborated by market prices in active markets (Level 2) (in millions):

	Septemb	er 30, 2009
	Carrying value	Fair value
2011 Convertible Notes	\$ 2,307	\$ 2,454
2013 Convertible Notes	2,058	2,359
2017 Notes	1,099	1,173
2009 Notes	1,000	1,004
2014 Notes	1,000	1,067
2019 Notes	998	1,099
2039 Notes	995	1,155
2037 Notes	899	1,017
2018 Notes	499	574
2038 Notes	499	606
2032 Modified Convertible Notes	82	80
Other	100	119
Total	<u>\$ 11,536</u>	\$ 12,707

	Decemb	er 31, 2008
	Carrying	
	value	Fair value
2011 Convertible Notes	\$ 2,206	\$ 2,300
2013 Convertible Notes	1,970	2,080
2017 Notes	1,099	1,140
2009 Notes	1,000	1,017
2014 Notes	1,000	994
2037 Notes	899	948
2018 Notes	499	536
2038 Notes	498	567
2032 Modified Convertible Notes	81	58
Other	100	111
Total	\$ 9,352	\$ 9,751

# **12. Derivative instruments**

The Company is exposed to certain risks related to its business operations. The primary risks that we manage by using derivatives are foreign exchange rate risk and interest rate risk. We use financial instruments, including foreign currency forward, foreign currency option and interest rate swap contracts, to reduce our risk to these exposures. We do not use derivatives for speculative trading purposes and are not a party to any leveraged derivatives.

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Condensed Consolidated Balance Sheets (see Note 11, *"Fair value measurement"*). The accounting for changes in the fair value of a derivative instrument depends on whether it has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and periodically thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings.

We are exposed to possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with our international product sales denominated in Euros. Increases or

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by the corresponding increases and decreases in 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 over a three-year time horizon. As of September 30, 2009, we had outstanding foreign currency forward and option contracts, primarily Euro-based, with notional amounts of \$2.7 billion and \$428 million, respectively.

In connection with the issuance of long-term debt, we may enter into forward interest rate contracts in order to hedge 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 is issued. In connection with the issuance of our 2019 Notes and 2039 Notes in January 2009, we entered into forward interest rate contracts related to a portion of these borrowings.

These foreign currency forward and option contracts and forward interest rate contracts are designated as cash flow hedges, and accordingly, the effective portion of gains and losses on these contracts are reported in "Accumulated other comprehensive income" in the Condensed Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged transactions affect earnings.

The following table reflects the effective portion of the gain/(loss) recognized in Other Comprehensive Income ("OCI") for our cash flow hedge contracts (in millions):

	Three mo	onths ended	Nine months ended			
Derivatives in cash flow hedging relationships	Septemb	er 30, 2009	September 30, 2009			
Interest rate contracts	\$	-	\$	(11)		
Foreign exchange contracts		(162)		(239)		
Total	\$	(162)	\$	(250)		

The following table reflects the location in the Condensed Consolidated Statements of Income and the effective portion of the gain/(loss) reclassified from Accumulated OCI into income for our cash flow hedge contracts (in millions):

	Statement of	Three months ended		Nine mo	onths ended
Derivatives in cash flow hedging relationships	Income location	Septemb	oer 30, 2009	Septemb	oer 30, 2009
Interest rate contracts	Interest expense, net	\$	-	\$	-
Foreign exchange contracts	Product sales		(9)		20
Total		\$	(9)	\$	20

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness and ineffective portions of these hedging instruments resulted in less than \$1 million of expense recorded in "Interest and other income, net" and "Interest expense, net" in the Condensed Consolidated Statements of Income for both the three and nine months ended September 30, 2009. As of September 30, 2009, the amounts expected to be reclassified from Accumulated OCI into income over the next 12 months are approximately \$72 million of losses on foreign currency forward and option contracts and \$1 million of losses on forward interest rate contracts.

We have interest rate swap agreements, which qualify and are designated as fair value hedges, to achieve a desired mix of fixed and floating interest rate debt. The terms of the interest rate swap agreements correspond to the related hedged debt instruments and effectively convert a fixed interest rate coupon to a LIBOR-based floating rate coupon over the lives of the respective notes. As of September 30, 2009, we had interest rate swap agreements with an aggregate notional amount of \$2.5 billion on our notes due in 2009, 2014 and 2018. For derivative instruments that are designated and qualify as a fair value hedge, the gain or loss on the derivative as well as the offsetting loss or gain on the hedged item attributable to the hedged risk are recognized in current earnings. For the three and nine months ended September 30, 2009, we included the loss on the hedged debt of \$22 million and gain on the hedged debt of \$81 million, respectively, in the same line item, "Interest expense, net" in the Condensed Consolidated Statements of Income, as the offsetting gain of \$22 million and loss of \$81 million, respectively, on the related interest rate swap agreements.

We enter into foreign currency forward contracts to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies which are not designated as hedging transactions. These exposures are hedged on a month-to-month basis. As of September 30, 2009, the total notional amount of these foreign currency forward contracts was \$466 million.

The following table reflects the location in the Condensed Consolidated Statements of Income and amount of gain/(loss) recognized in income of the derivative instruments not designated as hedging instruments (in millions):

Derivatives not designated as		Three mo	onths ended	Nine mo	onths ended	
hedging instruments Statement of Income location		Septemb	er 30, 2009	September 30, 2009		
Foreign exchange contracts	Interest and other income, net	\$	(34)	\$	(30)	

The following table reflects the fair values of both derivatives designated as hedging instruments and not designated as hedging instruments included in the Condensed Consolidated Balance Sheet as of September 30, 2009 (in millions):

	Derivative assets	Derivative assets					
	Balance Sheet location	Fair	value	Balance Sheet location	Fair	r value	
Derivatives designated as hedging instruments:							
Interest rate contracts	Other current assets/Other non- current assets	\$	125	Accrued liabilities/Other non-current liabilities	\$	_	
Foreign exchange contracts	Other current assets/Other non- current assets		33	Accrued liabilities/Other non-current liabilities		181	
Total derivatives designated as hedging instruments			158			181	
Derivatives not designated as hedging instruments:							
Foreign exchange contracts	Other current assets		-	Accrued liabilities		-	
Total derivatives not designated as hedging instruments			-			-	
Total derivatives		\$	158		\$	181	

Our foreign exchange contracts that were in a liability position as of September 30, 2009 contain certain credit risk related contingent provisions that are triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts.

# 13. Commitments and contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters that are complex in nature and have outcomes that are difficult to predict. We record accruals for such contingencies to the extent that we conclude that it is probable that a liability will be incurred and the amount of the related loss can be reasonably estimated. See Note 10, "*Contingencies*" to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2008, Note 11, "*Contingencies*" to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and Note 13, "*Commitments and Contingencies*" to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 for further discussion of certain of our legal proceedings and other matters.

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

# Average Wholesale Price ("AWP") Litigation

Final approval hearing of the Track Two settlement before the U.S. District Court for the District of Massachusetts (the "Massachusetts District Court") was scheduled for October 21, 2009. However, plaintiffs filed for an extension of the final approval

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

hearing due to continued deficiencies in executing notices and the Massachusetts District Court rescheduled the hearing for February 2, 2010.

#### Roche Matters

# Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al.

On September 15, 2009, the Court of Appeals for the Federal Circuit (the "Federal Circuit Court") affirmed the Massachusetts District Court's October 2, 2008 judgment that the Roche Defendants' peg-EPO product, Mircera®, infringes four Amgen patents, specifically U.S. Patent No. 5,547,933 ("the '933 Patent"), U.S. Patent No. 5,955,422 ("the '422 Patent"), U.S. Patent No. 5,618,698 ("the '698 Patent") and U.S. Patent No. 5,441,868 ("the '868 Patent"). Regarding the fifth patent-in-suit, U.S. Patent No. 5,756,349 ("the '349 Patent"), the Federal Circuit Court reversed the holding of non-infringement by the District Court and remanded that issue for a new trial which would allow Amgen to prove that the Roche Defendants' peg-EPO product infringes that patent as well. The Federal Circuit Court also affirmed the validity of Amgen's patents except for a single issue of obviousness-type double patenting which only impacts Amgen's later expiring patents ('933, '422 and '349 Patents). The Federal Circuit Court remanded this validity issue to the Massachusetts District Court for further analysis. The Federal Circuit Court left undisturbed the permanent injunction that prohibits the Roche Defendants from selling its peg-EPO product, Mircera® in the United States until expiry of the infringed patents.

On October 26, 2009, Amgen and the Roche Defendants each filed Combined Petitions For Rehearing And Rehearing En Banc with the Federal Circuit Court. Amgen requested that the Federal Circuit Court rehear its September 15<sup>th</sup> determination and affirm the District Court's judgment that Amgen is entitled to the statutory safe harbor protection against validity challenges to the '933, '422 and '349 Patents on the issue of obviousness-type double patenting. The Roche Defendants requested that the Federal Circuit Court rehear its September 15<sup>th</sup> determination that the '868 Patent and the '698 Patent were not invalid for obviousness-type double patenting in view of Amgen's now expired U.S. Patent 4,703,008 and its determination that the '933 Patent and the '422 Patent were infringed by the Roche Defendants' peg-EPO product while still being valid in view of the prior art. The parties have both been invited to file responsive briefs by no later than November 10, 2009.

# U.S. International Trade Commission ("ITC")

On August 31, 2009, Amgen filed a motion for summary determination of violation with a request for entry of a limited exclusion order. On September 1, 2009, the Roche respondents notified the ITC that it was not opposing Amgen's motion for summary determination and request for remedy. Also on September 1, 2009, the Roche defendants withdrew their pending motions for a stay and to terminate the investigation. The Office of Unfair Import Investigations filed its response on September 17, 2009, supporting Amgen's motion for summary determination but deferring comment on remedy until a remedy phase of the investigation. No decision has been issued on Amgen's motion.

# Human Genome Sciences ("HGS") Litigations

On October 14, 2009, the Federal Circuit Court entered an order on HGS' motion to dismiss HGS' appeal from the U.S. District Court for the District of Delaware (the "Delaware District Court"). HGS had filed the action in Delaware District Court under 35 U.S.C. § 146 after it received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,240.

On October 21, 2009, the Delaware District Court entered an order on a stipulated motion dismissing with prejudice HGS' action under 35 U.S.C. § 146 which had been filed by HGS after it had received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,380.

On October 21, 2009, the Delaware District Court entered an order on a stipulated motion dismissing with prejudice HGS' action under 35 U.S.C. § 146 which had been filed by HGS after it had received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,381.

# Sensipar® Abbreviated New Drug Application ("ANDA") Litigation

On May 21, 2009, Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd.", and together with Teva USA, "Teva") and Barr Pharmaceuticals Inc. ("Barr") filed a First Amended Answer, Defenses and Counterclaims with the Delaware District Court. On June 15, 2009, Amgen filed answers to Teva's and Barr's First Amended Counterclaim. On July 27, 2009,

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Teva and Barr filed a motion for an order that the parties proceed on representative claims. Amgen filed its answering brief in opposition to this motion on August 13, 2009 and Defendants filed their reply brief on August 26, 2009. The Delaware District Court set a status conference for September 23, 2009 and on September 24, 2009 and the Delaware District Court issued an order that the parties proceed on representative claims to be selected by Amgen on or before October 23, 2009.

# Teva U.S. Patent No. 7,449,603 ('603) Litigation

On August 10, 2009, Amgen filed an answer and counterclaims to Teva Ltd.'s amended complaint with the U.S. District Court for the Eastern District of Pennsylvania. On August 24, 2009, Teva Ltd. filed an answer to Amgen's Counterclaims.

#### Federal Securities Litigation — In re Amgen Inc. Securities Litigation

A class certification hearing before the U.S. District Court for the Central District of California (the "California Central District Court"), was held on July 17, 2009 and on August 12, 2009, the California Central District Court granted Plaintiffs' motion for class certification. Amgen filed a petition for permission to appeal with the U.S. Court of Appeals for the 9th Circuit (the "9<sup>th</sup> Circuit") under Rule 23(f) on August 28, 2009. Defendants filed their opposition on September 25, 2009, Amgen filed its reply brief on September 30, 2009 and there is no time frame in which the 9th Circuit must respond. In the meantime, the parties are scheduled to appear before the California Central District Court for a joint status conference on November 16, 2009.

#### State Derivative Litigation

#### Birch v. Sharer, et al.

Oral argument on Amgen and the individual defendants' motions to dismiss were heard on September 4, 2009 before the Los Angeles County Superior Court and the court granted the motions to dismiss but allowed the plaintiff an opportunity to amend her complaint by October 21, 2009. Plaintiff filed a request for dismissal without prejudice with the court on October 23, 2009. On October 29, 2009, Amgen received from plaintiff Birch a stockholder demand on the Board of Directors to take action to remedy breaches of fiduciary duties by the directors and certain executive officers of the Company. The stockholder alleges that the directors and certain executive officers violated their core fiduciary principles, causing Amgen to suffer damages. The stockholder demands that the Board of Directors take action against each of the officers and directors to recover damages and to correct deficiencies in the Company's internal controls that allowed the misconduct to occur.

#### ERISA Litigation

#### Harris v. Amgen Inc., et al. & Ramos v. Amgen Inc., et al.

On October 13, 2009, the California Central District Court granted plaintiffs Steve Harris' and Dennis Ramos' motion to be appointed interim colead counsel. Plaintiffs have until November 12, 2009 to file a consolidated and amended complaint and defendants have until December 14, 2009 to file their responsive pleading.

# Qui Tam Actions

On September 1, 2009, the U.S. government filed a notice of non-intervention and 14 states and the District of Columbia filed notices of intervention. The Massachusetts District Court gave the states and the private relator 60 days from September 1 to file an amended complaint. Amgen filed a motion to unseal the record with regard to the Massachusetts Qui Tam Action on October 23, 2009. On October 30, 2009, 14 states and the District of Columbia filed an amended complaint in the Massachusetts District Court entitled *The United States of America, States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New Mexico, New York, Tennessee and Texas and the Commonwealths of Massachusetts and Virginia and the District of Columbia, ex rel Kassie Westmoreland v. Amgen Inc., Integrated Nephrology Network, AmerisourceBergen Specialty Group, ASD Healthcare and AmerisourceBergen Corporation. The relator, Kassie Westmoreland, also filed a second amended complaint with the Massachusetts District Court on the same day. The complaints allege violations of the federal Anti-Kickback Statute and violations of state false claims act statutes with regard to Amgen's marketing of overfill in vials of Aranesp® and with regard to Amgen's relationship with the Integrated Nephrology Network, a group purchasing organization. The relator's seconded amended complaint also alleges that Amgen retaliated against and wrongfully terminated Westmoreland.* 



# Warren General Hospital v. Amgen

On September 25, 2009, Warren General Hospital of Warren, Pennsylvania (on its behalf and all others similarly situated) filed a class action in the U.S. District Court for the District of New Jersey against Amgen alleging Federal antitrust violations under Section 1 of the Sherman Act and Section 3 of the Clayton Act based on Amgen's contracting practices. The complaint seeks damages including treble damages, attorneys' fees and costs. Amgen has until December 11, 2009 to respond to the allegations.

#### Kennedy Institute v. Amgen Inc. and Wyeth

On October 27, 2009, The Mathilda and Terence Kennedy Institute of Rheumatology Trust filed suit in the Delaware District Court alleging that Amgen and Wyeth have infringed U.S. Patent Number 6,270,766 by the distribution and sale of ENBREL for the treatment of arthritis by co-administration with methotrexate. The Complaint has not yet been served.

#### Other

On August 19, 2009, Amgen was served with a third supplemental subpoena from the U.S. Attorney's Office for the Western District of Washington related to the '219 clinical trial. Amgen intends to cooperate fully with the government's requests.

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those discussed in this Note. While it is not possible to accurately predict or determine the eventual outcome of these items, one or more of these items currently pending could have a material adverse effect on our condensed consolidated results of operations, financial position or cash flows.

# 14. Other charges

In the three and nine months ended September 30, 2009, we recorded loss accruals for settlements of certain commercial legal proceedings aggregating \$8 million and \$28 million, respectively. In the three and nine months ended September 30, 2008, we recorded loss accruals for settlements of certain commercial legal proceedings aggregating \$4 million and \$267 million, respectively, principally related to the settlement of the Ortho Biotech antitrust suit. Such expenses are included in "Other charges" in the Condensed Consolidated Statements of Income.

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

# Forward looking statements

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, 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. Words such as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume," "continue," variations of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and 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 and trends. 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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to assist the reader in understanding the business of Amgen. MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2008.

We are a global biotechnology company that discovers, develops, manufactures and markets human therapeutics based on advances in cellular and molecular biology. Our mission is to serve patients. As a science-based, patient-focused organization, we discover and develop innovative therapies to treat grievous illness. We operate in one business segment – human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

We primarily earn revenues and income and generate cash from sales of human therapeutic products in the areas of supportive cancer care, nephrology and inflammation. Our principal products include Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and ENBREL, all of which are sold in the United States. ENBREL is marketed under a co-promotion agreement with Pfizer in the United States and Canada. Our international product sales consist principally of European sales of Aranesp®, Neulasta® and NEUPOGEN®. International product sales represented 22% of total product sales for both the three and nine months ended September 30, 2009. International product sales represented 23% and 22% of total product sales for the three and nine months ended September 30, 2008, respectively.

Aranesp® and EPOGEN® stimulate the production of red blood cells to treat anemia and belong to a class of drugs referred to as ESAs. Aranesp® is used for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN® is used to treat anemia associated with chronic renal failure ("CRF"). Neulasta® and NEUPOGEN® selectively stimulate the production of neutrophils, one type of white blood cell that helps the body fight infections. ENBREL blocks the biologic activity of tumor necrosis factor ("TNF") by inhibiting its binding to TNF receptors, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis and psoriasis. For both the three and nine months ended September 30, 2009, our principal products represented 93% of worldwide product sales. For both the three and nine months ended September 30, 2008, our principal products represented 94% of worldwide product sales. For additional information about our principal products, their approved indications and where they are marketed, see "*Item 1*. *Business – Marketed Products and Selected Product Candidates*" in Part I of our Annual Report on Form 10-K for the year ended December 31, 2008.

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business. Government authorities in the United States and in other countries regulate the manufacturing and marketing of our products and our ongoing R&D activities. The regulatory environment is evolving and there is increased scrutiny on drug safety and increased authority being granted to regulatory bodies, in particular the U.S. Food and Drug Administration ("FDA"), to assist in ensuring the safety of therapeutic products, which may lead to fewer products being approved by the FDA or other regulatory bodies,

delays in receiving approvals or additional safety-related requirements or restrictions on the use of our products, including expanded safety labeling, required risk management activities, including a risk evaluation and mitigation strategy ("REMS"), and/or additional or more extensive clinical trials as part of postmarketing commitments ("PMCs") or a pharmacovigilance program. For example as discussed in more detail below, in October 2009, the FDA issued complete response letters for our biologic license applications ("BLAs") for Prolia<sup>™</sup> (denosumab) in the treatment and prevention of postmenopausal osteoporosis ("PMO") and in the treatment and prevention of bone loss due to Hormone Ablation Therapy ("HALT") in breast and prostate cancer patients requesting additional information in connection with their review of our applications for product approval, which has extended the review time for our BLAs beyond their October 19, 2009 Prescription Drug User Fee Act ("PDUFA") date. In addition, the FDA has determined that a REMS is necessary for Prolia<sup>™</sup> and has requested a new clinical program to support approval of Prolia<sup>™</sup> for the prevention of PMO. (The FDA has provisionally approved the trade name Prolia<sup>™</sup> in the indications noted above, for which the drug is administered twice yearly subcutaneously at a 60 milligram ("mg") dose. The trade name is only for these indications and may not apply for other indications of denosumab.)

Most patients receiving our principal products for approved indications are covered by either government or private payer healthcare programs, which are placing greater emphasis on cost containment, including requiring that the economic value of products be clearly demonstrated. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products and private insurers may be influenced by government reimbursement methodologies. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Therefore, sales of our principal products have and will continue to be affected by the availability and extent of reimbursement from third-party payers, including government and private insurance plans, and administration of those programs. Additionally, ongoing healthcare reform efforts may also have a significant impact on our business. For example, the 2008 U.S. general elections resulted in a renewed focus on healthcare issues in the United States. Healthcare reform is a top priority for President Obama and Congress is now considering several different bills which would make wide-ranging changes to the United States healthcare system in order to expand and to fund coverage to millions of uninsured Americans, to substantially reduce the rate of increase in the costs of governmentsponsored healthcare programs and to improve the quality and portability of healthcare. Bills on healthcare reform have been passed by key Congressional committees and are expected to be considered by the full Congress before the end of 2009. Further, a number of states, including California, Colorado, Connecticut, New York and Pennsylvania, are considering or have recently enacted legislative proposals that would significantly alter their healthcare systems. If healthcare reform legislation in the United States is passed, it may include reducing the coverage and reimbursement of our products by Medicare, Medicaid and other government programs and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, each of which could have a significant impact on our business.

Further, safety signals, trends, adverse events or results from clinical trials, including sub-analyses, studies or meta-analyses (a meta-analysis is the review of studies using various statistical methods to combine results from previous separate, but related, studies) performed by us or by others (including our licensees or independent investigators) or from the marketed use of our products may expand safety labeling, restrict the use of our approved products or may result in additional regulatory requirements, such as requiring risk management activities, including a REMS, and/or additional or more extensive clinical trials as part of PMCs or a pharmacovigilance program, and may negatively impact sales or coverage or reimbursement of our products. For example, as discussed in more detail below, we announced on October 30, 2009, the publication of results from TREAT (the Trial to Reduce Cardiovascular Endpoints with Aranesp® Therapy), a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of patients with chronic kidney disease ("CKD") not on dialysis, moderate anemia and type-2 diabetes. The study failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to end-stage renal disease ("ESRD"). We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete.

Certain regulatory and reimbursement developments have and may continue to negatively impact sales of certain of our products or require us to incur additional expenditures to obtain approval to market our products or to maintain approval once obtained, in particular in the United States where the impact of these developments on our business has thus far been more pronounced. As a result, we continue to focus on improving our cost structure and achieving greater efficiencies in how we conduct our business while continuing to support critical R&D and operational priorities, including preparing for the launch of Prolia<sup>TM</sup>.

Worldwide product sales for the three and nine months ended September 30, 2009 were \$3,736 million and \$10,608 million, respectively, representing decreases of 1% and 4%, respectively, compared to the corresponding periods in the prior year. U.S. product sales for the three months ended September 30, 2009 totaled \$2,918 million, relatively unchanged compared to the prior year as the decline in U.S. Aranesp® sales of \$125 million was largely offset by increased U.S. sales of our other principal products. U.S. product sales for the nine months ended September 30, 2009 were \$8,253 million compared to \$8,560 million for the nine months ended September 30, 2008, representing a decrease of 4%. For the nine months ended September 30, 2009, the decline in U.S. product sales was largely attributable to declines in Aranesp® sales of \$327 million and ENBREL sales of \$101 million, partially

offset by increased sales of our other principal products. The decline in U.S. Aranesp® sales for the three and nine months ended September 30, 2009 principally reflects the negative impact, primarily in the supportive cancer care setting, of additional safety-related product label changes that occurred in August 2008. In addition, U.S. Aranesp® sales in the three and nine months ended September 30, 2008, benefited from a \$54 million change in the accounting estimate related to product sales return reserves recorded in the three months ended September 30, 2008. The decline in ENBREL sales for the nine months ended September 30, 2009 primarily reflects a \$120 million benefit to ENBREL's sales in 2008 related to the initial wholesaler inventory stocking resulting from a change in ENBREL's distribution model. During the three months ended March 31, 2008, ENBREL's distribution model was converted from being primarily drop shipped to pharmacies to a wholesaler distribution model similar to our other products, which resulted in this initial wholesaler stocking. International product sales were \$818 million for the three months ended September 30, 2009 compared to \$855 million for the three months ended September 30, 2009 compared to \$855 million for the three and nine months ended September 30, 2009 reflects unfavorable foreign currency exchange rate changes of \$76 million and \$248 million, respectively. Excluding the impact of foreign currency exchange rate changes, international product sales for the nine months ended September 30, 2009. Excluding the impact of foreign currency exchange rate changes, international product sales for the nine months ended September 30, 2009. Excluding the impact of foreign currency exchange rate changes, international product sales for the three and nine months ended September 30, 2009 increased 5% and 6%, respectively.

For the three months ended September 30, 2009, net income was \$1,386 million and diluted earnings per share were \$1.36 compared to \$1,121 million and \$1.05, respectively, for the three months ended September 30, 2008, representing increases of 24% and 30%, respectively. For the nine months ended September 30, 2009, net income was \$3,674 million and diluted earnings per share were \$3.58 compared to \$3,127 million and \$2.90, respectively, for the nine months ended September 30, 2008, representing increases of 17% and 23%, respectively. Net income and diluted earnings per share for the three and nine months ended September 30, 2009 were favorably impacted by lower Cost of sales and R&D expenses and a lower effective tax rate. In addition, for the nine months ended September 30, 2008, operating expenses were negatively impacted by \$267 million in loss accruals for settlements of certain commercial legal proceedings.

As of September 30, 2009, cash, cash equivalents and marketable securities aggregated \$14.0 billion, of which approximately \$11.1 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds were repatriated for use in our U.S. operations, we would be required to pay additional U.S. federal and state income taxes at the applicable marginal tax rates (see "*Item 1A. Risk Factors – Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and activities could have a material adverse effect on our financial results.*" in Part II herein). Our total debt outstanding was \$11.5 billion as of September 30, 2009 of which \$1.0 billion is due on November 18, 2009, which we expect to repay without incurring additional indebtedness.

The following is a discussion of selected key factors that have impacted and may continue to impact our business.

#### Denosumab Developments

Prolia<sup>™</sup> for the Prevention and Treatment of PMO and the Prevention and Treatment of Bone Loss in Patients Undergoing HALT for either Prostate Cancer or Breast Cancer

On August 13, 2009, we announced the results of our meeting with the FDA's Advisory Committee for Reproductive Health Drugs ("ACRHD") to review the potential use of Prolia<sup>TM</sup> for the prevention and treatment of PMO and the prevention and treatment of bone loss in patients undergoing HALT for either prostate cancer or breast cancer. The Committee recommended against approval of Prolia<sup>TM</sup> for the treatment of PMO and for the treatment of bone loss in patients undergoing HALT for prostate cancer. The Committee recommended against approval of Prolia<sup>TM</sup> to treat or prevent bone loss in women with breast cancer undergoing HALT until additional data are available. The Committee also recommended against approval of Prolia<sup>TM</sup> to prevent bone loss in low-risk patients in all three populations. Finally, the panel recommended that Prolia<sup>TM</sup> have a REMS, which could include a medication guide and a healthcare provider communications plan. The ACRHD is an advisory committee of external experts who advise the FDA about the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology and related specialties. This committee is advisory only and FDA officials are not bound to or limited by their recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

In October 2009, the FDA issued complete response letters for our BLAs for Prolia<sup>TM</sup> in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to HALT in breast and prostate cancer patients. The FDA issues complete response letters to request additional information needed to complete the review of applications for product approval.

The complete response letter related to the Prolia<sup>™</sup> applications for the treatment and prevention of PMO requested several items, including further information on the design and background adverse event rates that will inform the methodology of our

previously submitted post-marketing surveillance program although the letter did not require additional pre-marketing clinical trials to complete the review of the treatment indication. The FDA has also requested a new clinical program to support approval of Prolia<sup>TM</sup> for the prevention of PMO. In addition, the FDA has determined that a REMS is necessary for Prolia<sup>TM</sup> and must include a medication guide, a communication plan and a timetable for submission of assessments of the REMS. The FDA acknowledged receipt of our previously submitted proposed REMS materials. The FDA has also requested all updated safety data related to Prolia<sup>TM</sup>.

The complete response letter on the Prolia<sup>TM</sup> HALT applications requested additional information regarding the safety of Prolia<sup>TM</sup> in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving androgen deprivation therapy ("ADT"). Specifically, the FDA has requested results from additional adequate and well-controlled clinical trials demonstrating that  $Prolia^{TM}$  has no detrimental effects on either time-to-disease progression or overall survival.

Amgen is reviewing both complete response letters and will work with the FDA to determine the appropriate next steps regarding these applications.

We also have submitted Prolia<sup>™</sup> for approval in PMO and bone loss in breast and prostate cancer patients due to HALT in the European Union ("EU"), Switzerland, Australia and Canada. We are working closely with regulatory agencies in each of these regions.

Denosumab Phase 3 Clinical Trials for the Prevention of Skeletal Related Events ("SRE") Due to the Spread of Cancer to the Bone

# Multiple Solid Tumors and Multiple Myeloma

On September 21, 2009, we announced detailed results from a phase 3 trial evaluating denosumab administered subcutaneously versus Zometa® (zoledronic acid) administered as an intravenous infusion in the treatment of bone metastases in 1,776 advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma. These detailed results were presented at the 2009 Congresses of the European CanCer Organization ("ECCO") and European Society for Medical Oncology ("ESMO") in Berlin, Germany. Top line results of this study were previously reported on August 3, 2009.

This was an international, phase 3, randomized, double-blind, active-comparator-controlled study comparing denosumab with Zometa® in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. Patients enrolled in this event-driven study were randomized in a one-to-one ratio to receive either 120 mg of denosumab subcutaneously every four weeks or Zometa® administered intravenously at a dose of 4 mg delivered as a single, 15-minute infusion every four weeks.

In clinical trials thus far to test new medications for bone metastases, treatment success has been measured by whether the bone complications, or SREs, caused by the tumor are reduced or delayed. The primary and secondary endpoints of the denosumab bone metastases studies use a composite endpoint of four SREs—fracture, the need for radiation to bone, the need for bone surgery and spinal cord compression—to measure the effectiveness of denosumab versus Zometa<sup>®</sup>.

The primary endpoint was to evaluate if denosumab is non-inferior to Zometa® with respect to the time to first on-study SRE in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma and bone metastases. Secondary endpoints were to evaluate if denosumab is superior to Zometa® with respect to the time to first on-study SRE, as well as time to first-and-subsequent on-study SREs, and to assess the safety and tolerability of denosumab compared with Zometa®.

For the primary endpoint of this study, the median time to first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) was 20.6 months for those patients receiving denosumab and 16.3 months for those patients receiving Zometa® (hazard ratio ("HR") 0.84, [95% Confidence Interval ("CI"): 0.71-0.98]), which is statistically significant for non-inferiority (p=0.0007). Although numerically greater, the delay in the time to first SRE associated with denosumab was not statistically superior compared to Zometa® based upon the statistical testing strategy (adjusted p=0.06) (secondary endpoint). The time to first-and-subsequent SRE was also numerically greater but not statistically superior compared to Zometa® (HR 0.90, [95% CI: 0.77-1.04], p=0.14) (secondary endpoint). Denosumab also delayed the median time to first on-study SRE or hypercalcemia of malignancy ("HCM") compared to Zometa® (HR 0.83, [95% CI: 0.71-0.97], p=0.02). The median time to first on-study SRE or HCM was 19.0 months for denosumab and 14.4 months for Zometa®.

In an exploratory analysis, patients on the denosumab arm reported worsening of pain later than those on the Zometa® arm (57 days versus 36 days, respectively). Adverse events rates (96% denosumab, 96% Zometa®) and serious adverse events (63% denosumab, 66% Zometa®) were similar between groups and were consistent with what has previously been reported for these two agents. Rates of osteonecrosis of the jaw ("ONJ") were balanced and infrequent in both treatment groups (10 patients receiving

denosumab as compared with 11 patients receiving Zometa®). Infectious adverse events were balanced between the two treatment arms, as was overall survival (HR 0.95, [95% CI: 0.83-1.08], p=0.43) and the time to cancer progression (HR 1.00, [95% CI: 0.89-1.12], p=1.0). In certain populations, such as non-small cell lung cancer ("NSCLC"), which represented 39% of the treated population, there was a difference in overall survival that favored denosumab, which was nominally statistically significant. For multiple myeloma, there was a difference in overall survival that favored Zometa®, which was nominally statistically significant.

## Breast Cancer

On September 22, 2009, we announced detailed results from a phase 3, head-to-head trial evaluating denosumab versus Zometa® (zoledronic acid) in the treatment of bone metastases in 2,046 patients with advanced breast cancer that met its primary and secondary endpoints and demonstrated superior efficacy compared to Zometa®. These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. Top line results of this study were previously reported on July 7, 2009.

This was an international, phase 3, randomized, double-blind study comparing denosumab with Zometa® in the treatment of bone metastases in patients with advanced breast cancer. Patients enrolled in the study were randomized in a one-to-one ratio to receive either 120 mg of denosumab subcutaneously every four weeks or Zometa® administered intravenously at a dose of 4 mg in a 15-minute infusion every four weeks as per the label instructions.

In clinical trials testing new medications for bone metastases, treatment success has been measured by whether the bone complications, or SREs, caused by the tumor are reduced or delayed. The primary and secondary endpoints of the denosumab bone metastases studies use a composite endpoint of four SREs—fracture, the need for radiation to bone, the need for bone surgery and spinal cord compression—to measure the effectiveness of denosumab versus Zometa<sup>®</sup>.

The primary endpoint was to evaluate if denosumab is non-inferior to Zometa® with respect to the first, on-study SRE in patients with advanced breast cancer and bone metastases. Secondary endpoints were to evaluate if denosumab was superior to Zometa® with respect to the first, on-study SRE, as well as the first-and-subsequent on-study SREs, and to assess the safety and tolerability of denosumab compared with Zometa®.

Denosumab administered subcutaneously demonstrated superiority for both delaying the time to the first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) (HR 0.82, [95% CI: 0.71-0.95]), and delaying the time to first-and-subsequent SREs (HR 0.77, [95% CI: 0.66-0.89]). Both results were statistically significant in this 34 month study. The median time to first on-study SRE was not reached for denosumab and therefore could not be estimated. The median time to first on-study SRE was 26.5 months for Zometa®, the current standard of care.

Denosumab also delayed the median time to first on-study SRE or HCM compared to Zometa® (HR 0.82, [95% CI: 0.70-0.95], p=0.007). The median time to first on-study SRE or HCM was not reached for denosumab and therefore could not be estimated. The median time to first on-study SRE or HCM was 25.2 months for Zometa®.

In a pre-specified exploratory analysis, patients on the denosumab arm reported worsening of pain later than those on the Zometa® arm (88 days versus 64 days, respectively; HR 0.87, [95% CI: 0.79-0.97], p=0.009). Overall, the incidence of adverse events (96% denosumab, 97% Zometa®) and serious adverse events (44% denosumab, 46% Zometa®) was consistent with what has previously been reported for these two agents. Adverse events potentially associated with renal toxicity occurred in 4.9% of patients treated with denosumab compared to 8.5% in patients treated with Zometa®. ONJ was seen infrequently in both treatment groups (20 patients receiving denosumab (2.0%) as compared with 14 patients (1.4%) receiving Zometa®). There was no statistically significant difference in the rate of ONJ between the two treatment arms. Overall survival (HR 0.95, [95% CI: 0.81-1.11], p=0.50) and time to cancer progression (HR 0.99, [95% CI: 0.89-1.11], p=0.90) was balanced between treatment arms.

#### ESA Developments

Our ESA products have and will continue to face future challenges. For example, on August 6, 2008, we revised the ESA product labeling, as the FDA directed, based on a complete response letter, received on July 30, 2008, from the FDA to the revisions to the ESA labeling we proposed following the March 13, 2008 Oncologic Drugs Advisory Committee ("ODAC") meeting. The revised labeling included, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at hemoglobin ("Hb") levels <sup>3</sup> 10 grams per deciliter ("g/dL") and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. Additionally, in response to the FDA's request under authority prescribed by the Food and Drug Administration Amendments Act of 2007 (the "FDAAA"), we have submitted a proposed REMS and continue to work closely with the FDA to develop a REMS program for the class of ESA products. The

components of the REMS approved by the FDA could be different for the use of ESAs in the oncology and nephrology indications. Further, we are working with the FDA to make Aranesp® product package insert changes associated with the Physician's Labeling Rule ("PLR") conversion process. During the PLR conversion process from an old format to the new PLR format, the FDA may evaluate the package insert information to ensure that it accurately reflects current knowledge and may revise, add or remove information in the old format that could substantively impact the content of the product package insert for the new format.

# TREAT study

On October 30, 2009, we announced the publication of results from TREAT, a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of 4,038 patients with CKD not on dialysis, moderate anemia and type-2 diabetes. Results of this study were previously reported on October 21, 2009 and top line results were released on August 25, 2009. The study, published on October 30, 2009 in the *New England Journal of Medicine* and presented at the 2009 annual meeting of the American Society of Nephrology, failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to ESRD.

The primary endpoints of the study were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or ESRD. Among the components of the primary cardiovascular composite endpoint, the risk of stroke increased by almost two-fold in patients in the Aranesp® arm (101 patients [5.0%] versus 53 patients [2.6%]; HR 1.92, [95% CI: 1.38-2.68], p<0.001). Although stroke is a recognized risk with ESA therapy, and has been identified in warnings in U.S. labeling since 2001, the risk observed in TREAT is of higher magnitude than that seen in previous clinical trials in CKD patients not on dialysis.

A post hoc analysis indicates that there were no significant differences between treatment arms in the number of patients with a reported diagnosis of cancer (139 in the Aranesp® group [6.9%] and 130 in the placebo group [6.4%] [p=0.53]) or of all-cause deaths in patients who developed cancer during the trial (53 in the Aranesp® group [2.6%] and 50 in the placebo group [2.5%]). Overall, 39 deaths were attributed to cancer in the 2012 patients in the Aranesp® group and 25 deaths were attributed to cancer in the 2026 patients in the placebo group (p=0.08 by the log-rank test). This analysis also showed an excess in overall mortality among patients in the Aranesp® arm with a history of cancer that requires further investigation. Specifically, among patients with a history of cancer at baseline, there were 60 deaths from any cause in the 188 patients assigned to Aranesp® and 37 deaths in the 160 patients assigned to placebo (p=0.002 by the log-rank test). In this subgroup, 14 of the 188 patients assigned to Aranesp® died from cancer, as compared with 1 of the 160 patients assigned to placebo (p=0.002 by the log-rank test).

TREAT was designed as a superiority study to demonstrate improved cardiovascular outcomes and is the largest study of ESA use in CKD patients to date. Patients enrolled in the study were randomized in a one-to-one ratio to receive either treatment with Aranesp® to a target Hb of 13 g/dL or placebo. Due to the increased risk of negative outcomes associated with low Hb levels, patients in the control arm whose Hb fell below 9 g/dL were given Aranesp® as a rescue medication until their Hb level reached 9 g/dL. Investigators were blinded to this intervention.

TREAT had two primary endpoints. The first evaluated the time to all-cause mortality or cardiovascular morbidity, including heart attack (myocardial infarction), congestive heart failure, hospitalization for angina (myocardial ischemia), or stroke (cerebrovascular accident). The second primary endpoint evaluated the time to all-cause mortality or chronic dialysis. TREAT was not designed to determine the appropriate Hb target in this patient population.

The TREAT results demonstrate that in many diabetic CKD patients not on dialysis with moderate anemia, the risk of treatment to a target Hb level of 13 g/dL will exceed the benefit of reducing the need for transfusions.

We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete.

#### Proposed bundled payment system

On September 15, 2009, the Centers for Medicare and Medicaid Services ("CMS") released its proposed rule to implement the bundled prospective payment system for ESRD that, in accordance with the 2008 Medicare Improvements for Patients and Providers Act ("MIPPA"), requires the CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. Under the proposed rule, the bundled payment system will include dialysis services covered under the current composite rate, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including our ESAs products, intravenous iron, and intravenous vitamin D, as well as "oral equivalent" forms of these intravenous drugs. In addition, the proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, specifically Sensipar® and phosphate binders. The bundled reimbursement rate will be phased in

over a four year period in equal increments starting in 2011. Providers have the option to move to a full Medicare bundled payment system in 2011 or may elect to adopt certain components of the bundled payment system beginning in 2010.

# Medicare Evidence Development & Coverage Advisory Committee ("MEDCAC")

In August 2009, the CMS announced it had scheduled a meeting on March 24, 2010 of the MEDCAC to review the available evidence on the use of ESAs to manage anemia in patients who have CKD. While a MEDCAC provides advice and recommendations to the CMS about the adequacy of scientific evidence and votes on certain questions proposed by the CMS, it functions as an independent advisory body and its advice and recommendations to the CMS are advisory only.

#### Preoperative Epirubicin Paclitaxel Aranesp® ("PREPARE") study

Further, as we previously disclosed, in 2008 the FDA and European Medicines Agency ("EMEA") reviewed interim results from the PREPARE study in neo-adjuvant breast cancer, a PMC study, which were ultimately incorporated into the ESA labeling in both the United States and the EU. We have since received the final results from the PREPARE study, which were substantially consistent with the interim results, and provided that data to the FDA and EMEA.

We believe that certain of the above-noted developments could have a material adverse impact on the future sales of Aranesp® and EPOGEN®. In addition, the proposed rule to implement the bundled Medicare payment system could have a material adverse impact on the future sales of Sensipar®.

#### Vectibix® (panitumumab) Developments

'203 trial

On September 24, 2009, we announced detailed results from the phase 3 '203 or PRIME ("Panitumumab Randomized trial In combination with chemotherapy for Metastatic colorectal cancer to determine Efficacy") trial evaluating Vectibix® administered in combination with FOLFOX4 (an oxaliplatinbased chemotherapy) as the first-line treatment of metastatic colorectal cancer ("mCRC"). These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. On November 5, 2009, we announced that the '203 trial failed to meet a secondary endpoint of overall survival. Top line results of this study were previously reported on August 6, 2009.

Patients enrolled in the '203 trial were randomized to receive either 6.0 mg/kilogram ("kg") of Vectibix® and FOLFOX4 once every two weeks or FOLFOX4 alone once every two weeks. The primary endpoint of the study is progression-free survival ("PFS") by KRAS status and secondary endpoints include overall survival, objective response rate, time to progression, duration of response and safety.

Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in KRAS in the tumor itself. Tumor KRAS status was ascertained in more than 90% of the 1,183 patients enrolled in the trial.

We announced on September 24, 2009 that in this trial Vectibix® significantly improved median PFS by 1.6 months (9.6 versus 8.0 months for patients treated with FOLFOX4 alone, (HR 0.80, p=0.02)) in patients with *KRAS* wild-type mCRC (primary endpoint). Further, the addition of Vectibix® to chemotherapy also improved response rate in the *KRAS* wild-type patient population as measured by blinded central review (55% versus 48% in the FOLFOX4 only arm). Importantly, in patients with tumors harboring activating *KRAS* mutations, PFS was significantly inferior in the Vectibix® arm. For patients with mutant KRAS tumors, median PFS was 7.3 months with Vectibix® in combination with FOLFOX4 versus 8.8 months with FOLFOX4 alone (HR 1.29, p=0.02). These data confirm previous findings when oxaliplatin-based chemotherapy and an anti-epidermal growth factor receptor ("EGFR") antibody are combined in patients bearing tumors with activating *KRAS* mutations. The median overall survival for patients with *KRAS* wild-type mCRC had not yet been reached.

The final overall survival results for the '203 study were announced on November 5, 2009 and showed that Vectibix®, when added to a FOLFOX4 chemotherapy regimen in patients with KRAS wild-type mCRC, resulted in a median overall survival of 23.9 months compared to 19.7 months for patients treated with FOLFOX4 alone. The median overall survival difference of 4.2 months in the Vectibix® arm did not reach statistical significance (HR 0.83, p=0.072). Consistent with an interim analysis, overall survival appeared to be reduced in patients with KRAS mutant tumors receiving Vectibix®. Although not statistically significant, this result emphasizes the importance, as described in product labeling, of ensuring that patients receiving Vectibix® do not bear tumors containing KRAS mutations.

Adverse event rates were comparable across arms with the exception of known toxicities associated with anti-EGFR therapy such as rash, diarrhea and hypomagnesemia. Vectibix®-related grade 3 infusion reactions were reported for two patients (less than 1%).

# ʻ181 Trial

On September 22, 2009, we announced detailed results from the phase 3 '181 trial evaluating Vectibix® in combination with FOLFIRI (an irinotecan based chemotherapy), as a second-line treatment for mCRC. These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. Top line results of this study were previously reported on August 17, 2009.

The '181 trial is a global, multicenter, randomized phase 3 study. Patients enrolled in the study were randomized to receive either 6.0 mg/kg of Vectibix® and FOLFIRI once every two weeks or FOLFIRI alone once every two weeks. The independently tested co-primary endpoints were PFS and overall survival. Secondary endpoints included objective response rate, time to progression, duration of response and safety by *KRAS* status.

Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in *KRAS* in the tumor itself. Tumor *KRAS* status was ascertained in 91% of the 1,186 patients enrolled in this trial, the highest number ever reported for a second-line trial.

In this trial, Vectibix® significantly improved PFS in patients with *KRAS* wild-type mCRC. The addition of Vectibix® to FOLFIRI significantly improved median PFS (co-primary endpoint) by two months (5.9 versus 3.9 months for patients treated with FOLFIRI alone, HR 0.73, p=0.004) in patients with *KRAS* wild-type mCRC. Although numerically greater (14.5 months versus 12.5 months, HR 0.85), the improvement in median overall survival (co-primary endpoint) in the Vectibix® arm did not achieve statistical significance (p=0.115) in the same patient population. Further, the addition of Vectibix® to FOLFIRI resulted in greater than a three-fold improvement (35% versus 10%) in response rate in the *KRAS* wild-type patient population as measured by a blinded central review.

In general, adverse events rates were comparable across arms with the exception of known toxicities associated with anti-EGFR therapy such as rash, diarrhea, and hypomagnesemia. Vectibix®-related grade <sup>3</sup>/<sub>4</sub> infusion reactions were reported in less than 1% of patients.

There were no differences in PFS, overall survival and response rates among patients with mutated KRAS who received Vectibix®.

#### Competition

On September 15, 2009, we announced that the Federal Circuit Court affirmed the Massachusetts District Court's October 2, 2008 judgment that the Roche Defendants' peg-EPO product, Mircera®, infringes four Amgen patents, specifically the '933 Patent, the '422 Patent, the '698 Patent and the '868 Patent. Regarding the fifth patent-in-suit, the '349 Patent, the Federal Circuit Court reversed the holding of non-infringement by the District Court and remanded that issue for a new trial which would allow Amgen to prove that the Roche Defendants' peg-EPO product infringes that patent as well. The Federal Circuit Court also affirmed the validity of Amgen's patents except for a single issue of obviousness-type double patenting which only impacts Amgen's later expiring patents ('933, '422 and '349 Patents). The Federal Circuit Court remanded this validity issue to the Massachusetts District Court for further analysis. The Federal Circuit Court left undisturbed the permanent injunction that prohibits the Roche Defendants from selling its peg-EPO product, Mircera® in the United States until expiry of the infringed patents.

Certain of our marketed products are under increased competitive pressures, including from biosimilar and other products in Europe, which compete or are expected to compete with Aranesp®, NEUPOGEN® and Neulasta®, as well as our marketed products in the United States, including ENBREL. For example, we have experienced and expect to continue to experience increased competition throughout Europe, including from a number of biosimilar erythropoietin products, which compete with Aranesp®. In addition, a number of G-CSF biosimilar products have received or are expected to receive marketing authorization from the European Commission, and have been or are expected to be launched and compete with NEUPOGEN® and Neulasta®. Further, in the United States, ENBREL will continue to face increased competition primarily due to the launch of new products, including competition from J&J's Stelara<sup>TM</sup> (ustekinumab) which was approved by the FDA in September 2009. Furthermore, as part of the broad healthcare reform initiatives in the United States, legislation has been proposed to create a regulatory pathway for the abbreviated approval of biosimilars, including limiting the period of time during which the data submitted in an innovator's regulatory application may not be relied upon or referenced by others in their application for approval to the FDA. This legislation may be passed into law as early as 2009.

There are many factors that affect us and our industry in general, including, among others, those relating to increased complexity and cost of R&D due, in part, to greater scrutiny of clinical trials with respect to safety which may lead to fewer treatments being approved by the FDA or other regulatory bodies and/or safety-related label changes for approved products; increasing restrictions on the use of our products; increasingly intense competition for marketed products and product candidates, including biosimilars; reimbursement changes; healthcare provider prescribing behavior; regulatory or private healthcare organization medical guidelines and reimbursement practices; complex and expanding regulatory requirements and intellectual property protection. See *"Item 1. Business"* in Part I of our Annual Report on Form 10-K for the year ended December 31, 2008 and *"Item 1A. Risk Factors"* in Part II herein for further information on these economic and industry-wide factors and their impact and potential impact on our business.

# **Results of Operations**

Product sales

Worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	Three months ended						Nine months ended						
	September 30,						September 30,						
	2009 © 695			2008	Change		2009		2008	Change			
Aranesp®	\$	\$ 685		845	(19)%	\$	2,004	4 \$ 2,43		31 (18)%			
EPOGEN®		663		634	5%		1,866		1,810	3%			
Neulasta®/NEUPOGEN®		1,210		1,192	2%		3,441		3,479	(1)%			
ENBREL		924		893	3%		2,581		2,685	(4)%			
Sensipar®		165	161		2%	480			444	8%			
Other		89		59	51%		236		164	44%			
Total product sales	\$	3,736	\$	3,784	(1)%	\$	10,608	\$	11,013	(4)%			
Total U.S.	\$	2,918	\$	2,929	0%	\$	8,253	\$	8,560	(4)%			
Total International		818		855	(4)%		2,355		2,453	(4)%			
Total product sales	\$	3,736	\$	3,784	(1)%	\$	10,608	\$	11,013	(4)%			

Product sales are influenced by a number of factors, some of which may impact sales of certain of our existing products more significantly than others, including: demand, third-party reimbursement availability and policies, government programs, regulatory developments or guidelines, clinical trial outcomes, clinical practice, contracting and pricing strategies, wholesaler and end-user inventory management practices, patient population growth, fluctuations in foreign currency exchange rates, new product launches and indications, expansion into new countries, competitive products, product supply and acquisitions. In addition, general economic conditions may effect, or in some cases amplify, certain of these factors with a corresponding impact on our product sales.

#### *Aranesp*®

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

				onths ei nber 30		Nine months ended September 30,				
	2009		2008		Change	2009		2008		Change
Aranesp® - U.S.	\$	333	\$	458	(27)%	\$	963	\$	1,290	(25)%
Aranesp® - International		352		387	(9)%		1,041		1,141	(9)%
Total Aranesp®	\$	685	\$	845	(19)%	\$	2,004	\$	2,431	(18)%

U.S. Aranesp® sales for the three and nine months ended September 30, 2009 decreased 27% and 25%, respectively. U.S. sales of Aranesp® in the three and nine months ended September 30, 2008 benefited from a \$54 million change in the accounting estimate related to product sales return reserves. Excluding the positive impact of this prior year change in accounting estimate, U.S. sales of Aranesp® decreased 18% and 22% compared to the three and nine months ended September 30, 2008, respectively. These decreases were driven by a decline in demand reflecting the negative impact, primarily in the supportive cancer care setting, of additional safety-related product label changes which occurred in August 2008 and a decrease in the average net sales price. In addition, the decreases in sales also reflect, to a lesser degree, a slight loss of segment share.

International Aranesp® sales for both the three and nine months ended September 30, 2009 decreased 9%, due to the unfavorable impact of changes in foreign currency exchange rates and, to a lesser extent, segment decline. For the three months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately \$29 million, international Aranesp® sales decreased 2%. For the nine months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately \$100 million, international Aranesp® sales remained unchanged. Through September 30, 2009, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total Aranesp® segment share.

In addition to other factors mentioned in the "Product sales" section above, future Aranesp® sales will be dependent, in part, on such factors as:

- regulatory developments, including:
  - the proposed REMS for the class of ESAs, which we are discussing with the FDA, or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;
  - future product label changes, including those we are currently discussing with regulatory authorities;
- · reimbursement developments, including those resulting from:
  - government's and/or third-party payer's reaction to regulatory developments, including the proposed REMS for the class of ESAs which we are discussing with the FDA, and future product label changes;
  - CMS' MEDCAC meeting on March 24, 2010 to review the available evidence on the use of ESAs to manage anemia in patients who have CKD;
  - changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid, such as the proposed bundled payment system, which becomes effective in 2011, for dialysis services, drugs and biologicals furnished for treatment of ESRD that are currently billed separately;
  - cost containment pressures by third-party payers, including governments and private insurance plans;
- proposed healthcare reform in the United States;
- severity and duration of the current global economic downturn;
- adverse events or results from clinical trials, including sub-analyses, studies, including our TREAT study, or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), which have and could further impact product safety labeling, negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- · governmental or private organization regulations or guidelines relating to the use of our product;
- our ability to maintain worldwide segment share and differentiate Aranesp® from current and potential future competitive therapies or products, including J&J's Epoetin alfa product marketed in the United States and certain other locations outside of the United States and other competitors' products outside of the United States, including biosimilar products that have been launched;
- our contracting and related pricing strategies;
- patient population growth; and
- 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.

Certain of the above factors could have a material adverse impact on future sales of Aranesp®.

See the "Overview" section above and "Item 1A. Risk Factors" in Part II herein for further discussion of certain of the above factors that could impact our future product sales.

#### **EPOGEN**®

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

		Thre	e mo	onths er	nded	Nine	e mo	onths end	led	
		Se	epter	nber 30	),	Se	epte	mber 30	,	
	20	)09	2	008	Change	2009		2008	Change	
GEN® - U.S.	\$	663	\$	634	5%	\$ 1,866	\$	1,810	3%	

EPOGEN® sales for the three and nine months ended September 30, 2009 increased 5% and 3%, respectively, primarily due to an increase in demand. The increase in demand for both periods was principally due to patient population growth and, to a lesser extent, an increase in the average net sales price. In addition, demand was also favorably impacted, to a lesser extent, by an increase in dose/utilization for the three months ended September 30, 2009.

In addition to other factors mentioned in the "Product sales" section above, future EPOGEN® sales will be dependent, in part, on such factors as:

- · reimbursement developments, including those resulting from:
  - changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid, such as the proposed bundled payment system, which becomes effective in 2011, for dialysis services, drugs and biologicals furnished for treatment of ESRD that are currently billed separately;
  - the federal government's reaction to regulatory developments, including the proposed REMS for the class of ESAs which we are discussing with the FDA, and future product label changes;
  - CMS' MEDCAC meeting on March 24, 2010 to review the available evidence on the use of ESAs to manage anemia in patients who have CKD;
  - changes in healthcare providers' prescribing behavior resulting in dose fluctuations due to the CMS' revisions to its Erythropoietin Monitoring Policy ("EMP"), which became effective January 1, 2008;
  - cost containment pressures from the federal and state governments on healthcare providers;
- regulatory developments, including those resulting from:
  - the proposed REMS for the class of ESAs, which we are discussing with the FDA, or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;
  - future product label changes;
- proposed healthcare reform in the United States;
- severity and duration of the current global economic downturn;
- governmental or private organization regulations or guidelines relating to the use of our products, including changes in medical guidelines and legislative actions;
- adverse events or results from clinical trials, including sub-analyses, studies or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), which have and could further impact product safety labeling, negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- our contracting and related pricing strategies;
- patient population growth;
- · changes in dose/utilization; and



• development of new modalities or therapies to treat anemia associated with CRF.

Certain of the above factors could have a material adverse impact on future sales of EPOGEN®.

See the "Overview" section above and "Item 1A. Risk Factors" in Part II herein for further discussion of certain of the above factors that could impact our future product sales.

#### Neulasta®/NEUPOGEN®

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

	Three months ended					Nine months ended				
		Se	epte	mber 30	,		Se	epte	mber 30	,
	2009		2009 2008		2008 Change		2009	2008		Change
Neulasta® - U.S.	\$	657	\$	633	4%	\$	1,876	\$	1,850	1%
NEUPOGEN® - U.S.		240		223	8%		672		667	1%
U.S. Neulasta®/NEUPOGEN® - Total		897		856	5%		2,548		2,517	1%
Neulasta® - International		214		219	(2)%		603		620	(3)%
NEUPOGEN® - International		99		117	(15)%		290		342	(15)%
International Neulasta®/NEUPOGEN® - Total		313		336	(7)%		893		962	(7)%
Total Neulasta®/NEUPOGEN®	\$	1,210	\$	1,192	2%	\$	3,441	\$	3,479	(1)%

U.S. sales of Neulasta®/NEUPOGEN® for the three months ended September 30, 2009 increased 5%, primarily due to an increase in demand. The increase in demand was driven by increases in units sold and the average net sales price. U.S. sales of Neulasta®/NEUPOGEN® for the nine months ended September 30, 2009 increased 1%, primarily due to an increase in demand as a result of an increase in the average net sales price.

International Neulasta®/NEUPOGEN® sales for both the three and nine months ended September 30, 2009 decreased 7%, due to the unfavorable impact of changes in foreign currency exchange rates, partially offset by an increase in demand driven by segment growth, including expansion into additional countries in central and eastern Europe, and by the continued conversion from NEUPOGEN® to Neulasta®. For the three and nine months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately \$33 million and \$106 million, respectively, international Neulasta®/NEUPOGEN® sales increased 3% and 4%, respectively. Through September 30, 2009, biosimilars in Europe have not had a significant impact on total Neulasta®/NEUPOGEN® segment share.

In addition to other factors mentioned in the "*Product sales*" section above, future Neulasta®/NEUPOGEN® sales will be dependent, in part, on such factors as:

- proposed healthcare reform in the United States;
- severity and duration of the current global economic downturn;
- 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;
- · the availability, extent and access to reimbursement by government and third-party payers;
- penetration of existing segments;
- competitive products, including biosimilar products that have been or may be approved and launched in the EU;
- adverse events or results from clinical trials, including sub-analyses, studies or meta-analyses performed by us or by others (including our licensees or independent investigators), which could impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- governmental or private organization regulations or guidelines relating to the use of our products;
- cost containment pressures from governments and private insurers on healthcare providers;

- our contracting and related pricing strategies; and
- patient population growth.

See the "Overview" section above and "Item 1A. Risk Factors" in Part II herein for further discussion of certain of the above factors that could impact our future product sales.

#### ENBREL

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

	Three months ended September 30,						onths end mber 30,	
	2	009	2	800	Change	 2009	2008	Change
ENBREL - U.S.	\$	872	\$	838	4%	\$ 2,430	\$ 2,531	(4)%
ENBREL - Canada		52		55	(5)%	151	154	(2)%
Total ENBREL	\$	924	\$	893	3%	\$ 2,581	\$ 2,685	(4)%

ENBREL sales for the three months ended September 30, 2009 increased 3%, primarily due to an increase in demand, partially offset by a favorable change in the accounting estimate recorded in the three months ended September 30, 2008 related to the accruals for sales incentives. The increase in demand was principally due to a high-single digit increase in the average net sales price partially offset by a decrease in units sold due to share declines as a result of competitive activity in the dermatology segment. ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

ENBREL sales for the nine months ended September 30, 2009 declined 4%, which primarily reflects a \$120 million benefit to ENBREL's sales in 2008 related to the initial wholesaler inventory stocking resulting from a change in ENBREL's distribution model. During the three months ended March 31, 2008, ENBREL's distribution model was converted from being primarily drop shipped to pharmacies to a wholesaler distribution model similar to our other products, which resulted in this initial wholesaler stocking. Excluding this positive impact to sales for the nine months ended September 30, 2008, ENBREL sales increased approximately 1%, primarily driven by an increase in demand, as a result of a mid-single digit increase in the average net sales price partially offset by a decline in units sold. The decline in units sold for the nine months ended September 30, 2009 reflects a slower rate of segment growth in the three months ended March 31, 2009 and share declines as a result of increased competitive activity.

In addition to other factors mentioned in the "Product sales" section above, future ENBREL sales will be dependent, in part, on such factors as:

- the effects of competing products or therapies, including new competitive products coming to market, such as J&J's Simponi<sup>™</sup> (golimumab) and Stelara<sup>™</sup> (ustekinumab) and UCB/Nektar Therapeutics' Cimzia<sup>®</sup> (PEGylated anti-TNF alpha) and, in part, our ability to differentiate ENBREL based on a combination of its safety profile and efficacy;
- severity and duration of the current global economic downturn;
- proposed healthcare reform in the United States;
- the availability, extent and access to reimbursement by government and third-party payers;
- future product label changes;
- risk management activities, including a REMS, undertaken by us or required by the FDA or other regulatory authorities;
- growth in the rheumatology and dermatology segments;
- adverse events or results from clinical trials, including sub-analyses, studies or meta-analyses performed by us or by others (including our licensees or independent investigators), which could impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- governmental or private organization regulations or guidelines relating to the use of our product;
- · cost containment pressures from governments and private insurers on healthcare providers;
- our contracting and related pricing strategies; and

• patient population growth.

See the "Overview" section above and "Item 1A. Risk Factors" in Part II herein for further discussion of certain of the above factors that could impact our future product sales.

#### Selected operating expenses

The following table summarizes selected operating expenses (dollar amounts in millions):

	Three months ended September 30,					Nine months endeo September 30,								
	2	2009 2008		2008	Change 2009		2009		2009		2009 2008		2008	Change
Operating expenses:														
Cost of sales (excludes amortization of certain acquired intangible assets)	\$	545	\$	677	(19)%	\$	1,553	\$	1,738	(11)%				
% of product sales		15%		18%			15%		16%					
Research and development	\$	647	\$	729	(11)%	\$	1,973	\$	2,232	(12)%				
% of product sales		17%		19%			19%		20%					
Selling, general and administrative	\$	932	\$	900	4%	\$	2,640	\$	2,678	(1)%				
% of product sales		25%		24%			25%		24%					
Amortization of certain acquired intangible assets	\$	74	\$	74	0%	\$	221	\$	221	0%				
Other charges	\$	9	\$	12	(25)%	\$	63	\$	306	(79)%				

#### Cost of sales

Cost of sales, which excludes the amortization of certain acquired intangible assets, ("Cost of sales") decreased 19% and 11% for the three and nine months ended September 30, 2009, respectively, primarily driven by lower royalty expenses and lower excess capacity charges, partially offset by higher fill and finish costs resulting from lower utilization at our manufacturing facility in Puerto Rico. The decrease in Cost of sales for the three and nine months ended September 30, 2009 was also driven by lower excess inventory write-offs, primarily due to the \$84 million write-off of inventory resulting from a strategic decision to change manufacturing processes in the three months ended September 30, 2008. The decrease in Cost of sales for the nine months ended September 30, 2009 was also driven by lower sales volume.

#### Research and development

R&D costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of KA, and costs and cost recoveries associated with collaborative R&D and in-licensing arrangements, including upfront fees and milestones paid to collaboration partners in connection with technologies that have no alternative future use. Net payment or reimbursement of R&D costs for R&D collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

R&D expenses decreased 11% for the three months ended September 30, 2009, which was primarily attributable to lower clinical trial costs of \$34 million, including those associated with our marketed products, and lower staff-related expenses of \$29 million, due in part to the optimization of our clinical supply network.

R&D expenses decreased 12% for the nine months ended September 30, 2009, which was primarily attributable to lower clinical trial costs of \$114 million, including those associated with our denosumab and Vectibix® registrational studies, our marketed products and the delay of the phase 3 motesanib NSCLC trial. Additionally, we incurred lower licensing fees related to the \$100 million expense in the nine months ended September 30, 2008 resulting from the upfront payment associated with the Kyowa Hakko collaboration, partially offset by the \$50 million expense resulting from the payment to Cytokinetics in the nine months ended September 30, 2009. Also, staff-related costs were \$49 million lower in the nine months ended September 30, 2009, due in part to the optimization of our clinical material supply network.

#### Selling, general and administrative

SG&A expenses are primarily comprised of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses and other general and administrative costs. SG&A expenses include costs and cost recoveries associated with certain collaborative arrangements. Net payment or reimbursement of SG&A costs for collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

For the three months ended September 30, 2009, the 4% increase in SG&A was primarily due to higher product promotional expenses of \$53 million, including increased spending for activities in anticipation of the approval and launch of Prolia<sup>™</sup>, and higher expenses associated with the Pfizer profit share expense of \$8 million, partially offset by lower litigation expenses of \$13 million, lower staff-related costs of \$8 million and \$12 million of expense recoveries associated with our GlaxoSmithKline collaboration agreement for Prolia<sup>™</sup> in PMO in Europe, Australia, New Zealand and Mexico. For the three months ended September 30, 2009 and 2008, the Pfizer profit share expense was \$306 million and \$298 million, respectively. Excluding Pfizer profit share expense, SG&A expenses increased 4% compared to the three months ended September 30, 2008.

For the nine months ended September 30, 2009, the 1% decrease in SG&A was primarily due to the lower staff-related costs of \$57 million, lower litigation expenses of \$42 million, lower global ERP system related expenses of \$28 million, lower expenses associated with the Pfizer profit share expense of \$31 million and \$12 million of expense recoveries associated with our GlaxoSmithKline collaboration agreement for Prolia<sup>™</sup>, partially offset by higher product promotional expenses of \$138 million, including increased spending for activities in anticipation of the approval and launch of Prolia<sup>™</sup>, and higher restructuring and related costs of \$24 million. For the nine months ended September 30, 2009 and 2008, the Pfizer profit share expense was \$855 million and \$886 million, respectively. Excluding Pfizer profit share expense, SG&A expenses remained relatively unchanged compared to the nine months ended September 30, 2008.

#### Other charges

For the three and nine months ended September 30, 2009, the Company recorded loss accruals for settlements of certain commercial legal proceedings aggregating \$8 million and \$28 million, respectively. For the three and nine months ended September 30, 2008, the Company recorded loss accruals for settlements of certain commercial legal proceedings aggregating \$4 million and \$267 million, respectively, principally related to the settlement of the Ortho Biotech antitrust suit.

For the three and nine months ended September 30, 2009, we incurred \$1 million and \$35 million, respectively, in connection with certain cost saving initiatives. For the three and nine months ended September 30, 2008, we incurred \$8 million and \$39 million, respectively, in connection with our restructuring plan announced in 2007 and in connection with certain additional cost saving initiatives.

#### Interest and other income, net

For the three months ended September 30, 2009 and 2008, interest and other income, net was \$74 million and \$62 million, respectively. This increase is primarily due to higher net gains on sales of investments of \$15 million, higher foreign currency exchange gains of \$15 million and the loss accrued in the three months ended September 30, 2008 on the sale of certain less significant marketed products and related assets of \$9 million, partially offset by lower interest income of \$19 million, principally due to lower portfolio investment returns.

For the nine months ended September 30, 2009 and 2008, interest and other income, net was \$182 million and \$264 million, respectively. This decrease is primarily due to lower interest income of \$43 million, principally due to lower portfolio investment returns, losses on certain leases that will no longer be used in our operations of \$31 million and lower net gains on sales of investments of \$19 million partially offset by higher foreign currency exchange gains of \$12 million and the loss accrued in the three months ended September 30, 2008 on the sale of certain less significant marketed products and related assets of \$9 million.

#### Income taxes

Our effective tax rates for the three and nine months ended September 30, 2009 were 10.0% and 11.0%, respectively, compared to 20.6% and 20.3%, respectively, for the same periods last year. The decrease in our effective tax rate was primarily due to: (i) favorable resolution of certain prior years' matters with tax authorities during the three and nine months ended September 30, 2009, (ii) increased manufacturing and profit in Puerto Rico, (iii) the inclusion of the benefit of the federal research and experimentation ("R&E") tax credit in the three and nine months ended September 30, 2009 (the federal R&E credit was not in effect during 2008 until it was retroactively reinstated during the three months ended December 31, 2008), and (iv) a benefit in the nine

months ended September 30, 2009 relating to adjustments to previously established deferred taxes due to changes in California tax law effective for future periods. The resolution of prior years' tax matters recognized in the three months ended September 30, 2009 reduced the effective tax rates for the three and nine months ended September 30, 2009 by 6.4% and 5.2%, respectively.

See Note 3, "Income taxes" to the Condensed Consolidated Financial Statements for further discussion.

#### Recent accounting pronouncements

In June 2009, the FASB issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise's involvement in the variable interest entity. This standard is effective for us for interim and annual reporting periods beginning on or after January 1, 2010. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In August 2009, the FASB issued a new accounting standard which clarifies guidance for determining the fair value of a liability when a quoted price in an active market for an identical liability is not available. This standard provides for the use of one or more valuation techniques including use of quoted prices of identical or similar liabilities when traded as assets, quoted prices of similar liabilities and other techniques consistent with the fair value measurement framework, such as the amount an entity would pay to transfer the identical liability or would receive to enter into the identical liability. This standard is effective for us for interim and annual periods beginning on or after October 1, 2009. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us for annual periods beginning on or after January 1, 2011. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

#### **Financial Condition, Liquidity and Capital Resources**

The following table summarizes selected financial data. The amounts reflect the adoption of a new accounting standard which changed the method of accounting for our convertible debt (see Note 2, "*Change in method of accounting for convertible debt instruments*" to the Condensed Consolidated Financial Statements for further discussion of our adoption of this new accounting standard, effective January 1, 2009)(in millions):

	Sept	ember 30, 2009	December 31, 2008		
Cash, cash equivalents and marketable securities	\$	14,013	\$	9,552	
Total assets		40,940		36,427	
Current debt		1,000		1,000	
Non-current debt		10,536		8,352	
Stockholders' equity		22,858		20,885	

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future. In addition, we plan to opportunistically pursue our stock repurchase program and other business initiatives, including acquisitions and licensing activities. Our liquidity needs can be met through a variety of sources, including: cash provided by operating activities, sale of marketable securities, borrowings through commercial paper and/or our syndicated credit facility and other debt and equity markets. In addition, we expect that we will repay the \$1.0 billion of our 4.00% notes due on November 18, 2009 without incurring additional indebtedness.

#### Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at September 30, 2009, approximately \$11.1 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds were repatriated for use in our U.S. operations, we would be required to pay additional U.S. federal and state income taxes at the applicable marginal tax rates (see "*Item 1A. Risk Factors - Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and activities could have a material adverse effect on our financial results.*" in Part II herein).

#### Financing arrangements

The following table identifies our long-term borrowings under our various financing arrangements and the amounts reflect, where applicable, the adoption of the new accounting standard that changed the method of accounting for our convertible debt (dollar amounts in millions):

	Sep	otember 30, 2009	mber 31, 2008
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$	2,307	\$ 2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)		2,058	1,970
5.85% notes due 2017 (2017 Notes)		1,099	1,099
4.00% notes due 2009 (2009 Notes)		1,000	1,000
4.85% notes due 2014 (2014 Notes)		1,000	1,000
5.70% notes due 2019 (2019 Notes)		998	-
6.40% notes due 2039 (2039 Notes)		995	-
6.375% notes due 2037 (2037 Notes)		899	899
6.15% notes due 2018 (2018 Notes)		499	499
6.90% notes due 2038 (2038 Notes)		499	498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)		82	81
Other		100	100
Total borrowings		11,536	 9,352
Less current portion		1,000	1,000
Total non-current debt	\$	10,536	\$ 8,352

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of September 30, 2009. None of our financing arrangements contain any financial covenants. Our outstanding convertible notes and our other outstanding long-term notes are rated "A+" with a stable outlook by Standard & Poor's, "A3" with a stable outlook by Moody's Investors Service, Inc. and "A" with a stable outlook by Fitch, Inc.

See Note 9, "*Financing arrangements*" to the Condensed Consolidated Financial Statements for further discussions of our long-term borrowings and Note 2, "*Change in method of accounting for convertible debt instruments*" to the Condensed Consolidated Financial Statements for further discussion of our adoption of the new accounting standard that changed the method of accounting for our convertible debt.

#### Cash flows

The following table summarizes our cash flow activity (in millions):

	Nine months en	ded Septemb	er 30,
	2009 2008		
Net cash provided by operating activities	\$ 4,513	\$	4,591
Net cash used in investing activities	(2,863)		(2,618)
Net cash provided by (used in) financing activities	153		(1,475)

#### Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2009 decreased \$78 million primarily due to the prior year receipt of \$300 million for an upfront milestone payment related to our licensing agreement with Takeda Pharmaceutical Company Limited; the negative impact of the timing and amounts of receipts from customers and payments to vendors and others;

partially offset by higher net income of \$547 million. The prior year receipt of the \$300 million upfront milestone payment is included in "Changes in deferred revenue" in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2008.

#### Investing

Cash used in investing activities during the nine months ended September 30, 2009 increased primarily due to the net purchases of marketable securities. Net purchases of marketable securities were \$2.5 billion for the nine months ended September 30, 2009 compared to net purchases of \$2.2 billion for the nine months ended September 30, 2009, compared to \$494 million during the corresponding period of the prior year. The capital expenditures during the nine months ended September 30, 2009 were primarily associated with manufacturing capacity expansions in Puerto Rico and other site development. The capital expenditures during the nine months ended September 30, 2009 were primarily associated with manufacturing capacity expansions in Puerto Rico and Fremont, other site developments and investment in our global ERP system. We currently estimate 2009 spending on capital projects and equipment to be less than \$600 million.

#### Financing

In January 2009, we issued \$1.0 billion aggregate principal amount of notes due in 2019 (the "2019 Notes") and \$1.0 billion aggregate principal amount of notes due in 2039 (the "2039 Notes") in a registered offering. The 2019 Notes and 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and 2039 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a "make-whole" amount, as defined. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. The total debt discount on issuance and debt issuance costs were \$7 million and \$13 million, respectively, and are being amortized over the life of the notes.

During the nine months ended September 30, 2009, we repurchased 37.5 million shares of our common stock at a total cost of \$2.0 billion. During the nine months ended September 30, 2008, we repurchased 32.7 million shares of our common stock at a total cost of \$1.6 billion. As of September 30, 2009, we had \$2.2 billion available for stock repurchases as authorized by our Board of Directors. Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. The manner of purchases, amount we spend and the number of shares repurchased will vary based on a number of factors including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock. Employee stock option exercises provided \$146 million and \$114 million of cash during the nine months ended September 30, 2009 and 2008, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of our stock relative to the exercise price of such options.

#### 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 September 30, 2009.

Management determined that, as of September 30, 2009, 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, "*Commitments and contingencies*" to the Condensed Consolidated Financial Statements for a discussion which is limited to certain recent developments concerning our legal proceedings. This discussion should be read in conjunction with Note 10, "*Contingencies*" to our Consolidated Financial Statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2008, Note 11, "*Contingencies*" to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and Note 13, "*Commitments and Contingencies*" to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.

## 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 or others on our behalf, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties facing our business. The risks described below 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 also may impair our business, operations, liquidity and stock price materially and adversely.

Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.

We and certain of our licensees and partners conduct research, preclinical testing and clinical trials for our product candidates and marketed products for both their existing indications as well as for new and/or expanded indications. In addition, we manufacture and contract manufacture, and certain of our licensees and partners manufacture our products and product candidates, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the EMEA in European countries and similar regulatory bodies in Canada and Australia. Currently, we are required in the United States and in foreign countries to obtain approval from those countries' regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to refuse to approve commencement of, suspend or terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, mandate product withdrawals and require changes in labeling (including eliminating certain therapeutic indications) of our products. In 2007, the FDAAA was signed into law significantly adding to the FDA's authority including allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk; (ii) mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information and (iii) require sponsors to implement a REMS for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements to assure safe use of the drug, as the FDA deems are nec

We expect that regulatory reform efforts currently under discussion by U.S. policymakers may include changes to applicable laws and regulations that could have a significant impact on our business. Regulatory agencies could change existing, or promulgate new, regulations at any time that could affect our ability to obtain or maintain approval of our existing or future products and/or require significant additional costs to obtain or maintain such approvals. We are unable to predict when and whether any changes to regulatory policy affecting our business could occur, and such changes could have a material adverse impact on our business, operations and financial condition.

In our experience, obtaining regulatory approval has been and continues to be increasingly difficult and costly and takes many years, and, after it is obtained, is increasingly costly to maintain. For example, we recently announced that we had received complete response letters from the FDA for the BLA for our late-stage product candidate Prolia<sup>TM</sup> in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to HALT in breast and prostate cancer patients. The complete response letter related to the PMO indication requested several items, including further information on the design and background adverse event rates that will inform the methodology of our previously submitted post-marketing surveillance program although the letter did not

require additional pre-marketing clinical trials to complete the review of the treatment indication. The FDA also requested a new clinical program to support approval of Prolia<sup>TM</sup> for the prevention of PMO, updated safety data and stated that a REMS is necessary for Prolia<sup>TM</sup> and must include a medication guide, a communication plan, and a timetable for submission of assessments of the REMS. The FDA acknowledged receipt of our previously submitted proposed REMS materials. The complete response letter related to the HALT indications requested additional information regarding the safety of Prolia<sup>TM</sup> in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving ADT and specifically requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia<sup>TM</sup> has no detrimental effects on either time-to-disease progression or overall survival. Although we are working with the FDA to determine the appropriate next steps regarding our applications, a significant delay in regulatory approval to market and sell Prolia<sup>TM</sup> for the treatment of PMO could have a material adverse affect on our business and results of operations.

In addition, certain companion diagnostics or devices required to be approved as part of the BLA or other regulatory approval application for certain of our products or product candidates may be provided by single-source unaffiliated third-party companies. Our product candidates or expanded indications of our products may not be approved if the companion diagnostic or device does not gain or maintain regulatory approval. We are dependent on the sustained cooperation and effort of these third-party companies in conducting the studies required for such approval by the applicable regulatory agencies. Delays in the studies, including the third-party company's failure to obtain the necessary rights to all of the elements of the companion diagnostic or device, or failure of the third party company to obtain regulatory approval of the companion diagnostic or device, could negatively impact our product candidate or the expanded indication or our product through increased development costs, delays in regulatory approval and associated delays in a product candidate reaching the market or the expansion of existing product labels for new indications.

With the occurrence of a number of high profile safety events relating to certain pharmaceutical products, regulatory authorities, and, in particular, the FDA, members of Congress, the U.S. Government Accountability Office, Congressional committees, private health/science foundations and organizations, medical professionals, including physicians and investigators, and the general public are increasingly concerned about potential or perceived safety issues associated with pharmaceutical and biological products, whether under study for initial approval or already marketed. For example, in 2007 we received letters from the House Subcommittee on Oversight and Investigation, Committee on Energy and Commerce and the United States Senate Committee on Finance with inquiries with respect to our ESA studies, promotion of our ESAs and other products, our rebates and contracting strategies and our pharmacovigilance program, to which we have fully cooperated by submitting our responses and meeting with Congressional staff. To the extent that there is resulting legislation or changes in CMS or FDA policy or regulatory activity as a result of Congressional concerns, such developments could have a material adverse effect on the use of our ESA products that are the subject of such developments.

As a result of this increasing concern, potential or perceived safety signals and safety concerns, from clinical trials, use by the market or other sources, are receiving greater scrutiny, which may lead to (i) fewer treatments being approved by the FDA or other regulatory bodies, (ii) revised labeling of an approved product or a class of products for safety reasons, potentially including a boxed warning or additional limitations on the use of approved products in specific therapeutic areas (possibly until additional clinical trials can be designed and completed), (iii) mandated PMCs or pharmacovigilance programs for approved products and/or (iv) requirement of risk management activities (including a REMS) related to the promotion and sale of a product. In addition, significant concerns about the safety and effectiveness of our products could ultimately lead to the revocation of marketing approval of the products within particular therapeutic areas, or in total, which would have a material adverse effect on the use, sales and reimbursement of the affected products and on our business and results of operations. (See "— Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.")

Certain specific labeling or label changes of our approved products or product candidates may be necessary or required for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns with respect to any of our products by regulatory agencies, an increased rate or number of previously-identified safety-related events, the discovery of significant problems or safety signals or trends with a similar product that implicates an entire class of products, subsequent concerns about the sufficiency of the data or studies underlying the label or changes to the underlying safety/efficacy analysis related to results from clinical trials, including sub-analyses, or meta-analysis of clinical trials or clinical data performed by us or others. Label changes may also be required as a result of new legislation. Under new FDA legislation implemented in 2006, the PLR requires changes to the existing format of U.S. product package inserts for human prescription drug and biological products with the intent of making product information more easily accessible. The PLR requires revised standards of content and format of labeling and provides timelines for when new and previously approved products must comply with the new regulations. During the PLR conversion process from an old format to the new PLR format, the FDA may evaluate the package insert information to ensure that it accurately reflects current knowledge and may revise, add or remove information in the old format that could substantively impact the content of the product package insert for the new format. In addition, before or after any of our products are approved for commercial use, regulatory bodies could decide that the product labels need to include certain warning language as part of an evolving label change to a particular class

of products. For example, in March and November 2007, and in March and August 2008, the U.S. labels for the class of ESA products, including Aranesp® and EPOGEN®, were updated to include revised boxed warnings, restrictions on the use of ESAs in specific therapeutic areas and other safety-related product labeling changes. (See "— Our ESA products continue to be under review and receive scrutiny by regulatory authorities, and further regulatory action or adverse clinical trial or meta-analysis results could adversely impact the use, sales and reimbursement of our ESAs.")

Additionally, on June 4, 2008, the FDA issued an Early Communication regarding the ongoing safety review of TNF-blockers and the possible association between the use of these medicines and the development of lymphoma and other cancers in children and young adults and stated that it had decided to conduct further analyses to evaluate the risk and benefits of TNF-blockers in pediatric patients. On August 4, 2009, the FDA issued an announcement regarding the results of the safety review of TNF-blockers and as a result of this review the FDA has required strengthened warnings about the occurrence of lymphoma and other cancers in children, adolescents and young adults using these medicines. In addition, the FDA conducted analyses related to the occurrence of leukemia and new-onset psoriasis in patients treated with TNF-blockers. We are working with the FDA to update the U.S. prescribing information ("PI") and medication guide for ENBREL with this information as well as to communicate the revised product labeling to both healthcare providers and patients. The FDA has determined that we are required to conduct additional post-marketing clinical studies to assess the known serious risk of malignancies in pediatric patients and we will work with FDA to define what the studies would consist of. Further, on June 18, 2008, we participated in a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee ("DODAC") to review data supporting the supplemental BLA submitted by us for the use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy and the DODAC recommended, with an 8-5 vote, to approve ENBREL in the treatment of chronic moderate to severe plaque psoriasis in children. On July 24, 2008, we received notification from the FDA through a complete response letter that the FDA would like additional information from us regarding the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis and recommended we conduct additional clinical trials. In August 2009, we informed the FDA that after careful consideration of the FDA's recommendations, we concluded that it was not feasible to implement the suggested FDA approaches because the limited number of eligible pediatric patients with moderate to severe plaque psoriasis was too small to conduct clinical trials of sufficient magnitude to adequately inform the FDA's concerns and that, as a result, we were withdrawing the supplemental BLA for this expanded use of ENBREL in pediatric patients. Further revisions to the ENBREL label or other actions by the FDA, including additional advisory committee meetings, could have a material adverse impact on the use and sales of ENBREL which could have a material adverse effect on our business and results of operations.

A revision of product labeling or the regulatory actions described above could be required even if there is no clearly established connection between the product and the safety or efficacy concerns that have been raised or if the product is not indicated for a particular use. For example, in October 2007 we announced that we and the FDA adopted changes to the U.S. labeling for Vectibix® based on the results of the Panitumumab Advanced Colorectal Cancer Evaluation ("PACCE") trial highlighting to clinicians the greater risk seen when Vectibix® is combined with Avastin® and the specific chemotherapy used in the PACCE trial to treat patients with first-line mCRC. Vectibix® is not indicated for the first-line treatment of mCRC and the additional safety information applies to an unapproved use of Vectibix®.

If we or others identify safety concerns before approval of the product or after a product is on the market, the regulatory agencies such as the FDA or the EMEA may impose risk management activities upon us (including a REMS) which may require substantial costs and resources to negotiate, develop and implement, including sales force time to educate physicians on REMS requirements and compliance, and/or may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. Further, risk management activities, including a REMS, required by regulatory agencies such as the FDA could also modify, restrict or otherwise impact the ability of healthcare providers to prescribe, dispense or use our products, strongly discourage or affirmatively limit patient access to our products, place administrative burdens on healthcare providers in prescribing our products or affect our ability to compete against products that do not have a REMS, any of which could have a negative effect on our ability to launch our affected products and could have a material adverse effect on sales of the affected products and on our business and results of operations. For example, we have submitted a proposed REMS for our ESAs in response to the FDA's requests and continue to work closely with the FDA to finalize the REMS program for our ESA products under authority prescribed by the FDAAA. Although we cannot predict what the final REMS for ESAs will include, the components of the REMS may include a medication guide, communication plan and elements to assure safe use in the oncology indication and may include a medication guide and communication plan in the nephrology indication. A REMS program for our ESA products could have a material adverse impact on the reimbursement, use and sales of our ESA products, which would have a material adverse effect on our business and results of operations. Additionally, as part of the approval for Nplate®, a REMS was developed with the FDA to assure the safe use of Nplate® while minimizing risk. The Nplate® REMS involves, among other things, healthcare provider and patient enrollment registries, tracking of patient medical history and data and follow-up safety questionnaires to healthcare providers, all of which require extensive discussion with and education of healthcare providers. This requirement has placed Nplate® at a disadvantage versus other products used for the same indication where no REMS requirement exists which could adversely affect the sales of Nplate®. Additionally, following the FDA web-alert on September 4, 2008 regarding their review of histoplasmosis and other

opportunistic fungal infections in patients treated with TNF-blockers, the FDA requested that the boxed warning and WARNINGS sections of the U.S. PI and the medication guide for ENBREL (and other TNF-blockers) be strengthened to include the risk of unrecognized histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. In December 2008, we agreed with the FDA on the required revisions to the U.S. PI, and we continue to work with the FDA to finalize the requested updates to the ENBREL REMS. Our efforts to comply with the requirements of our existing REMS and any additional REMS or other risk management activities required of us in the future could restrict or otherwise impact our existing promotional activities for ENBREL and our other products as well which could have a material adverse effect on product sales, our business and results of operations.

Additionally, some products are approved by regulators on a conditional basis. For example, the original approvals of Vectibix® in both the United States and EU were conditioned on us conducting additional clinical trials of the use of Vectibix® as a therapy in treating mCRC. Our conditional approval of Vectibix® in the EU is reviewed annually by the European Committee for Medicinal Products for Human Use, and in December 2008 we agreed as a condition of the renewal of the conditional approval to conduct an additional clinical trial in the existing approved indication. If results from clinical trials as part of a PMC, pharmacovigilance program or comparable agreement with regulatory authorities are negative, it could result in the revocation of the marketing or conditional marketing approvals or revised labeling of our products, which could have a material adverse effect on sales of the affected products and on our business and results of operations.

Substantially all of our marketed products are currently approved in the United States and most are approved in Europe and in other foreign countries for specific uses. However, later discovery of unknown problems with our products could result in the regulatory activities described above or even the potential withdrawal of the product in certain therapeutic areas or certain product presentations, or completely, from the market. If new medical data or product quality issues suggest an unacceptable safety risk or previously unidentified side-effects, we may voluntarily withdraw, or regulatory authorities may mandate we withdraw, such product in certain therapeutic areas, or completely recall a product presentation from the market for some period or permanently. For example in 2006, we initiated a voluntary recall of the Neulasta® SureClick® pre-filled pen in Europe because of the potential risk to patients of receiving an incomplete dose and we conducted a voluntary wholesaler recall of a limited number of lots of ENBREL as a result of a small number of reports of missing, detached or loose rubber caps on the needleless syringe filled with diluent liquid by a third-party contract manufacturer and packaged with the vials of ENBREL. In addition, in August 2008, we voluntary recalled two manufacturing lots of EPOGEN® and our licensee, Ortho Biotech, voluntarily recalled one manufacturing lot of PROCRIT® (Epoetin alfa) that was manufactured in our manufacturing facilities after having identified cracks in the necks of a small number of vials upon postmanufacturing inspection. In September 2009, we initiated a voluntary wholesaler recall of a limited number of ENBREL SureClick® lots due to a defect in the glass syringe barrel which resulted in a small number of broken syringes following assembly of the autoinjector device. Although there have been no observable adverse event trends associated with these recalls, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends which may adversely affect the sales of our products. Additionally, if other parties (including our licensees, such as J&J and Pfizer, or independent investigators) report or fail to effectively report to regulatory agencies side effects or other safety concerns that occur from their use of our products in clinical trials or studies or from marketed use, regulatory approval may be withdrawn for a product for the therapeutic area in question, or completely, or other risk management activities may be required by regulators which could adversely affect the sales of our products and our business and results of operations.

If regulatory authorities determine that we or our licensees or partners conducting R&D activities on our behalf have not complied with regulations in the R&D of a product candidate, new indication for an existing product or information to support a current indication, then they may not approve the product candidate or new indication or maintain approval of the current indication in its current form or at all, and we will not be able to market and sell it. If we were unable to market and sell our products or product candidates, our business and results of operations would be materially and adversely affected. Additionally, safety signals, trends, adverse events or results from clinical trials or studies performed by us or by others (including our licensees or independent investigators) from the marketed use of our drugs that result in revised safety-related labeling or restrictions on the use of our approved products could negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private health organization medical guidelines and reimbursement for our products all of which would have a material adverse effect on our business and results of operations. (See "— *Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products."* and "— *Guidelines and recommendations published by various organizations can reduce the use of our products."* 

Our ESA products continue to be under review and receive scrutiny by regulatory authorities, and further regulatory action or adverse clinical trial or meta-analysis results could adversely impact the use, sales and reimbursement of our ESAs.

As a result of adverse safety results involving ESA products that were observed beginning in 2006 in various studies exploring the use of ESAs in settings different from those outlined in the FDA-approved label, our ESA products have been the subject of ongoing review and scrutiny from regulatory authorities over the past several years. In the United States, we have engaged and continue to engage in discussions with the FDA regarding the benefit/risk profile of ESAs, which have resulted and could result in future changes to ESA labeling and usage. For example, on July 30, 2008, we received a complete response letter from the FDA to the revisions to the ESA labeling we proposed earlier in the year. The letter proposed, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels <sup>3</sup> 10 g/dL and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. We revised the ESA labeling on August 6, 2008, as the FDA directed, and have experienced a reduction in our ESA sales, in particular Aranesp® sales in the U.S. supportive cancer care setting, since that time. Although we cannot predict what further impact the revised ESA labels may have on our business, the revised ESA labeling or any future labeling changes, including any required in connection with our ongoing discussions with the FDA regarding the conversion of the format of our ESA U.S. labels in accordance with the PLR or other changes required by the FDA, could have a material adverse impact on the reimbursement, use and sales of our ESA products, which would have a material adverse effect on our business and results of operations. We continue to work closely with the FDA to develop a REMS program for the class of ESA products under authority prescribed by FDAAA. (See "- Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.")

We also have ongoing PMC studies for our ESAs. These clinical trials must be conducted by us to maintain regulatory approval and marketing authorization. For example, we have agreed with the FDA to a robust pharmacovigilance program to continue to study the safety surrounding the use of ESAs in the oncology setting and we initiated Study 782 as part of our Aranesp® pharmacovigilance program, a randomized double-blind, placebo controlled, phase 3 non-inferiority study evaluating overall survival when comparing NSCLC patients on Aranesp® to patients receiving placebo. We are currently identifying clinical sites for Study 782 and have begun enrolling patients in the study. (See "— *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected."*) Further, as we previously disclosed, in 2008 the FDA and EMEA reviewed interim results from the PREPARE study in neo-adjuvant breast cancer, a PMC study, which were ultimately incorporated into the ESA labeling in both the United States and the EU. We have since received the final results from the PREPARE study, which were substantially consistent with the interim results, and provided that data to the FDA and EMEA. Although we cannot predict the results or the outcomes of ongoing clinical trials, or the extent to which regulatory authorities may require additional labeling changes as a result of these or other trials, we cannot exclude the possibility that adverse results from clinical trials could have a material adverse impact on the reimbursement, use and sales of our ESAs, which would have a material adverse effect on our business and results of operations.

In addition, regulatory authorities outside the United States have also reviewed and scrutinized the use of our ESA products. On March 5, 2008, we announced that the European Commission reached its decision to amend the product labeling for the class of ESAs, including Aranesp®, which set uniform target Hb range for all ESAs of 10 g/dL to 12 g/dL with guidance to avoid sustained Hb levels above 12 g/dL. Subsequently, on June 26, 2008, the EMEA recommended updating the product information for ESAs with a new warning for their use in cancer patients, which was approved by the European Commission in October 2008. The product information for all ESAs was updated to advise that in some clinical situations blood transfusions should be the preferred treatment for the management of anemia in patients with cancer and that the decision to administer ESAs should be based on a benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context and that factors that should be considered in the assessment should include the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference. Since the October 2008 revision, we have experienced a reduction of Aranesp® sales in the supportive cancer care setting in the EU and, although we cannot predict what further impact the revised EU ESA product information could have on our business, the reimbursement, use and sales of Aranesp® in Europe could further be materially adversely affected, which would have a material adverse effect on our business and results of operations.

Moreover, we continue to receive results from meta-analyses or previously initiated clinical trials using ESAs. For example, on September 30, 2008, we announced that we had received a summary of preliminary results from the Cochrane Collaboration's independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating ESAs in cancer patients which we submitted to the FDA and the EMEA. These results were also presented by the Cochrane Haematological Malignancies Group in December at the 2008 American Society of Hematology Congress, and a final manuscript was published in

May 2009. This Cochrane meta-analysis of patient level data from previous studies corroborates prior analyses indicating that the use of ESAs may increase the risk of death in cancer patients. The studies in the analysis all predate the current label, which advises using the least amount of ESA necessary to avoid transfusion. The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. PI (HR: 1.08 [95% CI 0.99-1.18]). The ESA treatment arm had increased on-study deaths (HR: 1.17 [95% CI 1.06-1.30]) and decreased overall survival (HR: 1.06 [95% CI 1.00-1.12]) compared to controls. The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. The ESA treatment arm had increased on-study deaths (HR: 1.10 [95% CI 0.98-1.24]) and decreased overall survival (HR: 1.04 [95% CI 0.97-1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label.

Further, on October 30, 2009, we announced the publication of results from TREAT, a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of 4,038 patients with CKD not on dialysis, moderate anemia and type-2 diabetes. Results of this study were previously reported on October 21, 2009 and top line results were released on August 25, 2009. The study, published on October 30, 2009 in the *New England Journal of Medicine* and presented at the 2009 annual meeting of the American Society of Nephrology, failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to ESRD.

The primary endpoints of the study were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or ESRD. Among the components of the primary cardiovascular composite endpoint, the risk of stroke increased by almost two-fold in patients in the Aranesp® arm (101 patients [5.0%] versus 53 patients [2.6%]; HR 1.92, [95% CI: 1.38-2.68], p<0.001). Although stroke is a recognized risk with ESA therapy, and has been identified in warnings in U.S. labeling since 2001, the risk observed in TREAT is of higher magnitude than that seen in previous clinical trials in CKD patients not on dialysis. A post hoc analysis indicates that there were no significant differences between treatment arms in the number of patients with a reported diagnosis of cancer (139 in the Aranesp® group [6.9%] and 130 in the placebo group [6.4%] [p=0.53]) or of all-cause deaths in patients who developed cancer during the trial (53 in the Aranesp® group [2.6%] and 50 in the placebo group [2.5%]). Overall, 39 deaths were attributed to cancer in the 2012 patients in the Aranesp® group and 25 deaths were attributed to cancer in the 2026 patients in the placebo group (p=0.08 by the log-rank test). This analysis also showed an excess in overall mortality among patients in the Aranesp® arm with a history of cancer that requires further investigation. Specifically, among patients with a history of cancer at baseline, there were 60 deaths from any cause in the 188 patients assigned to Aranesp® died from cancer, as compared with 1 of the 160 patients assigned to placebo (p=0.002 by the log-rank test).

TREAT was designed as a superiority study to demonstrate improved cardiovascular outcomes and is the largest study of ESA use in CKD patients to date. Patients enrolled in the study were randomized in a one-to-one ratio to receive either treatment with Aranesp® to a target Hb of 13 g/dL or placebo. Due to the increased risk of negative outcomes associated with low Hb levels, patients in the control arm whose Hb fell below 9 g/dL were given Aranesp® as a rescue medication until their Hb level reached 9 g/dL. Investigators were blinded to this intervention. TREAT was not designed to determine the appropriate Hb target in this patient population.

The TREAT results demonstrate that in many diabetic CKD patients not on dialysis with moderate anemia, the risk of treatment to a target Hb level of 13 g/dL will exceed the benefit of reducing the need for transfusions. We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete. The FDA may also require that we update the proposed REMS for ESAs or possibly call an advisory committee meeting to discuss the results from the study. In addition, CMS may consider the results from the TREAT study at the upcoming March 2010 MEDCAC meeting and based on MEDCAC's recommendations, CMS could enact a national coverage determination ("NCD") for ESAs used in CKD. All of these activities could have a material adverse impact on the coverage, reimbursement, and sales of our ESAs, which would have a material adverse effect on our business and results of operations.

Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought or our existing products are safe and effective for use in humans in new indications sought. Additionally, we may be required to conduct additional trials as a condition of the approval of our label or as a

result of perceived or existing safety concerns. The results of these clinical trials are used as the basis to obtain regulatory approval from regulatory authorities such as the FDA. Clinical trials are experiments conducted using our products or product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking or to support our existing label. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate or the extent of the safety concerns, post-marketing issues and/or exposure to patients and therefore, we may spend several years and incur substantial expense in completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, the rate of occurrence of the clinical trial events being studied, regulatory and institutional review board approval, availability of clinical study material and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals, associated delays in product candidates reaching the market and revisions to existing product labels. In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, India, East Asia and some Central and South American countries either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and regulatory diverse clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially adversely affected. Additional information on our clinical trials can be found on our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.)

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigator's clinical trials of our products or product candidates that may delay the clinical program, require additional or longer trials to gain approval, prohibit regulatory approval of our product candidates or additional indications for our currently approved products, may render the product candidate commercially unfeasible or limit our ability to market existing products in certain therapeutic areas or at all. Delays may sometimes be substantial. For example, as a result of observing an increased frequency of cholecystitis (inflammation of the gall bladder) in patients treated with our late-stage product candidate motesanib, we delayed our phase 3 trial in first-line NSCLC, which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. Following initiation of the trial, in November 2008, we and our development partners announced that enrollment in this phase 3 trial had been temporarily suspended following a planned safety data review of 600 patients by the study's independent Data Monitoring Committee ("DMC"). The study's DMC also recommended that patients with squamous NSCLC immediately discontinue motesanib therapy but did not recommend discontinuation of motesanib therapy for patients with non-squamous NSCLC. In February 2009, the DMC recommended the trial resume enrollment of patients with non-squamous NSCLC, and, in June 2009, we reinitiated enrollment in this patient population following an FDA-approved revision to the study protocol. Clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on an out of date standard of medical care, limiting the utility and application of such trials. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval for new product candidates, product label extensions or maintenance of our current labels on this basis. Further, clinical trials conducted by others, including our licensees, partners or independent investigators, may result in unfavorable clinical trials results that may call into question the safety of our products in off-label or on label uses that may result in label restrictions and/or additional trials.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. For example, we are moving forward with Study 782 as part of our Aranesp® pharmacovigilance program. (See "— *Our ESA products continue to be under review and receive scrutiny by regulatory authorities, and further regulatory action or adverse clinical trial or meta-analysis results could adversely impact the use, sales and reimbursement of our ESAs.*"). The addition of this or other clinical trials to our pharmacovigilance program and any additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and their outcomes could result in additional label restrictions or the loss of regulatory approval for an approved indication, each of which may have a material adverse effect on our business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our ESA products.

In connection with our efforts to improve our cost structure, we refocused our spending on critical R&D and operational priorities and sought greater efficiencies in how we conduct our business, including optimizing ongoing clinical trials and trial initiation. To the extent future sales are negatively affected as a result of additional regulatory and reimbursement developments or other challenges, we may be required to further adjust our R&D investment plans. Such actions could result in delays in obtaining approval or reductions in the number of indications and market potential of our product candidates.

Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Our products are predominantly sold in the United States and we rely in large part on the reimbursement of our principal products through government programs such as Medicare and Medicaid. Further, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. The 2008 U.S. general elections resulted in a renewed focus on healthcare issues in the United States. Healthcare reform is a top priority for President Obama and Congress is now considering several different bills which would make wide-ranging changes to the United States healthcare system in order to expand and to fund coverage to millions of uninsured Americans, to substantially reduce the rate of increase in the costs of government-sponsored healthcare programs and to improve the quality and portability of healthcare. Bills on healthcare reform have been passed by key Congressional committees and are expected to be considered by the full Congress before the end of 2009. If healthcare reform legislation in the United States is passed, it may include reducing the coverage and reimbursement of our products by Medicare, Medicaid and other government programs and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, each of which could have a significant impact on our business. Additionally, it is possible that applicable statutes, such as the Medicare Prescription Drug Improvement and Modernization Act, could be modified or new regulation introduced in 2009 or later that could also include a focus on reducing drug costs and change coverage and reimbursement methodologies for government healthcare programs. Further, a number of states, including California, Colorado, Connecticut, New York and Pennsylvania, are considering or have recently enacted legislative proposals that would significantly alter their healthcare systems. Although we cannot predict what final legislation on healthcare reform affecting coverage and reimbursement from third-party payers will include, any such legislation which changes and/or reduces the coverage and reimbursement of our products or the way our products are used or prescribed would cause our sales to decrease and our revenues to decline.

Adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand the safety information in the labeling for our approved products which could negatively impact worldwide reimbursement for our products. For example, on January 14, 2008, CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice. A more detailed discussion of the Decision Memorandum follows below. (See also "— Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market." and "— Guidelines and recommendations published by various organizations can reduce the use of our products.")

An increasing focus on cost containment by public and private insurers has resulted, and could result in the future, in lower reimbursement rates for our products. Most patients receiving our principal products for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare programs' payment policies for drugs and biologics are subject to various laws and regulations. Effective January 1, 2009 in the hospital outpatient setting, most of our products are reimbursed under a Medicare Part B payment methodology that reimburses each product at 104% of its average sales price ("ASP") (sometimes referred to as "ASP+4%"). The rate of reimbursement in the hospital outpatient setting has been reduced twice since the inception of ASP-based payment in this setting, with reimbursement rates set at ASP+5% for 2008 and ASP+6% from 2006 to 2007. CMS has the regulatory authority to alter or maintain the Medicare payment rates for Part B drugs and biologicals in the future for the hospital outpatient setting. Effective January 1, 2005, in the physician office setting, Aranesp®, Neulasta® and NEUPOGEN® are reimbursed under a Medicare Part B payment methodology that reimburses each product at ASP+6%. A product's ASP is calculated and reported to CMS on a quarterly basis and may change each quarter. The ASP in effect for a given quarter (the "Current Period") is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP-based payment rate for Aranesp® that will be in effect for the third quarter of 2009 is based in part on certain historical sales and sales incentive data for Aranesp® from July 1, 2008 through June 30, 2009. ASP-based

reimbursements of products under Medicare may, in some circumstances, be below the cost that medical providers paid for such products, which could adversely affect sales of our products.

We face certain risks relating to the calculation of ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. CMS further defines the statutory formula through regulations and other CMS guidance. However, the statute, regulations, and CMS guidance do not define specific methodologies for all aspects of the calculation of ASP. For example, in the Medicare Physician Fee Schedule Proposed Rule for 2010, CMS did not address a proposed methodology for treatment of bundled price concessions. Consequently, the current CMS guidance that manufacturers may make "reasonable assumptions" in their calculation of ASP, consistent with the general requirements and the intent of the Medicare statute, federal regulations and their customary business practices, finalized in the Medicare Physician Fee Schedule Final Rule for 2009 remains in effect. While we believe that any assumptions it employs in its ASP calculation methodology satisfy this reasonable assumption standard, such assumptions require us to apply judgment and are subject to CMS review, and CMS or other third parties may not agree with our assessment as to the reasonableness of our assumptions. If our reasonable assumptions are subsequently advised to have been incorrect, it could subject us to substantial fines and penalties which could have a material adverse effect on our results of operations. CMS stated that it will continue to monitor this issue and may provide more specific guidance in the future. Any such specific guidance could result in a change in our ASP calculation methodology, which, if significant, could have a material adverse effect on our results of operations.

In the dialysis setting, our products may also be subject to downward pressure on reimbursement rates. In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the ESRD Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement methodology is established by federal law and is monitored and implemented by CMS. Currently, the ESRD reimbursement rate for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is set at ASP+6%. Although we cannot predict the payment levels of EPOGEN® in future quarters or the extent to which Medicare payments for dialysis drugs may be modified by future federal regulation or legislation, a decrease in the reimbursement rate for EPOGEN® may have a material adverse effect on our business and results of operations. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician office setting, dialysis facility setting and hospital outpatient setting. These calculations are regularly reviewed for completeness and based on such review, we have revised our reported ASPs to reflect calculation changes both prospectively and retroactively. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN® was reduced for the third quarter of 2007. Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to an EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and hematocrit outcomes of dialysis patients. The EMP was revised, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient's Hb is above 13 g/dL for three or more consecutive months. In addition, the revised EMP reduced the monthly dosing limits to 400,000 international units ("IUs") of EPOGEN®, from 500,000 IUs, and to 1,200 micrograms ("mcgs") of Aranesp®, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN® sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. While this dose decline subsequently stabilized in 2008, it may further fluctuate in the future, which could have a material adverse effect on sales of EPOGEN® and our business and results of operations.

On July 15, 2008, the 2008 MIPPA became law with a number of Medicare and Medicaid reforms including a broader payment bundle for dialysis services and drugs which will require CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. On September 15, 2009, CMS released its proposed rule to implement the bundled prospective payment system for ESRD. Under the proposed rule, the bundled payment system will include dialysis services covered under the current composite rate, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including ESAs, intravenous iron, and intravenous vitamin D, as well as "oral equivalent" forms of these intravenous drugs. In addition, the proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, specifically Sensipar® and phosphate binders. The public comment period ends on November 16, 2009. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. Providers have the option to move to a full Medicare bundled payment system in 2011 or may elect to adopt certain components of the bundled payment system beginning in 2010. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011. Beginning in 2012, facilities would be subject to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, including performance standards related to anemia management and dialysis adequacy. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services will include, implementation of the bundled payment, Although we cannot predict what the final rule on the bundled payment system for ESRD services will include, implementation of the rule as proposed could have a mater

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the March 9, 2007 FDA labeling changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in nonrenal disease applications as part of a national coverage analysis ("NCA") which is generally CMS' first step toward developing a NCD. Generally, an NCD is a national policy statement granting, limiting or excluding Medicare coverage for a specific medical item or service. On May 14, 2007, CMS issued a proposed NCD that was open for public comment through June 13, 2007. On July 30, 2007, CMS issued its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions, and established Medicare coverage parameters for FDA-approved ESA use in oncology. We believe this restriction on reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, to our knowledge, although no private payers have fully implemented the Decision Memorandum to date, many private payers have implemented the portions of the restrictions included in the Decision Memorandum, most commonly the provisions that reflect the prescriber package insert. Further, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage. While we cannot fully predict the furth

In addition, the FDA held a joint meeting of the Cardiovascular-Renal Drug Advisory Committee and the Drug Safety and Risk Management Advisory Committee on September 11, 2007 to evaluate safety data on ESA use in renal disease. On July 30, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process, which included as potential topics the use of ESAs in ESRD and CKD. Also included in the initial potential future NCD topic list is the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate<sup>®</sup>. Medicare currently does not have a NCD for the use of ESAs for anemia in patients who have CKD. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD, or for thrombopoiesis stimulating agents and we cannot predict whether either ESAs in the renal setting or thrombopoiesis stimulating agents will be the subject of a future NCD; however, any final NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in Decision Memorandum for treatment of anemia in oncology with ESAs, could negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. More recently, in August 2009, CMS announced it had scheduled a meeting for March 24, 2010 of the MEDCAC to review the available evidence on the use of ESAs to manage anemia in patients who have CKD. While a MEDCAC provides advice and recommendations to CMS about the adequacy of scientific evidence and votes on certain questions proposed by CMS, it functions as an independent advisory body and its advice and recommendations to CMS are advisory only.

If, and when, reimbursement rates or availability for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales, which could have a material adverse effect on us and our results of operations. For example, the use of EPOGEN® in the United States in connection with treatment for ESRD is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration, instituted a reimbursement change for EPOGEN®, which materially and adversely affected our EPOGEN® sales until the policies were revised. In addition, following the update to the ESA labeling and associated revisions in compendia, nearly all Medicare contractors discontinued coverage for Aranesp® for anemia of cancer ("AoC"). (See "— *Guidelines and recommendations published by various organizations can reduce the use of our products.*") When a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain and a failure to demonstrate clear clinical and/or comparative value associated with the use of a new therapeutic product as compared to existing therapeutic products or practices may result in inadequate or no reimbursement. We cannot predict the availability or amount of reimbursement for our approved products or products are and will be affected by government and private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and results of operations.

# If our intellectual property positions are challenged, invalidated, circumvented or expire, or if we fail to prevail in present and future intellectual property litigation, our business could be adversely affected.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies' patents. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or

technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We are currently, and in the future may be, involved in patent litigation. However, a patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market and we may be subject to competition during certain periods of litigation. Further, under the Hatch-Waxman Act, products approved by the FDA under a new drug application ("NDA") may be the subject of patent litigation with generic competitors before the five year period of data exclusivity provided for under the Hatch-Waxman Act has expired and prior to the expiration of the patents listed for the product. For example, on July 25, 2008, we, NPS Pharmaceuticals and Brigham and Women's Hospital filed a lawsuit against Teva and Barr Barr for infringement of four Sensipar® patents. The lawsuit is based on ANDAs filed by Teva and Barr which seek approval to market generic versions of Sensipar® before expiration of the patents. This lawsuit is described in Note 10, *"Contingencies*" to the Consolidated Financial Statements in our 2008 Form 10-K and in Note 13, *"Commitments and contingencies*" to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities; be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab, romiplostim and our product candidate denosumab. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab and romiplostim products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), Enbrel® (etanercept), Sensipar®/Mimpara® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim), respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States.

In recent years, policymakers have proposed reforming U.S. patent laws and regulations. For example, patent reform legislation was introduced in both houses of Congress in 2009, and the Senate Judiciary Committee approved a patent reform bill on April 2, 2009. In general, the proposed legislation attempts to address issues surrounding the increase in patent litigation by, among other things, establishing new procedures for challenging patents. While we cannot predict what form any new patent reform laws or regulations ultimately may take, final legislation could introduce new substantive rules and procedures for challenging patents, and certain reforms that make it easier for competitors to challenge our patents could have a material adverse effect on our business.

We also have been granted or obtained rights to patents in Europe relating to erythropoietin, G-CSF, pegfilgrastim (pegylated G-CSF), etanercept, darbepoetin alfa, cinacalcet, panitumumab and romiplostim. Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. As these patents have expired, some companies have and we believe others may receive approval for and market biosimilar (as they are generally known in the EU) and other products to compete with these products in the EU presenting additional competition to our products. (See "— Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.")

#### We may not be able to develop commercial products.

We intend to continue to make significant R&D investments. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects produce a commercial product. Product candidates or new indications for existing products (collectively, "product candidates") that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- · the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness
- · the product candidate had harmful side effects in humans or animals
- the necessary regulatory bodies, such as the FDA, did not approve our product candidate for an intended use
- the product candidate was not economical for us to manufacture and commercialize

- other parties have or may have proprietary rights relating to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all
- the product candidate is not cost effective in light of existing therapeutics
- we and certain of our licensees, partners or independent investigators may fail to effectively conduct clinical development or clinical manufacturing activities
- · the regulatory pathway to approval for product candidates is uncertain or not well-defined

For example, we announced that after discussions with the FDA we have decided not to file for approval of motesanib in refractory thyroid cancer until there is more clarity on what would constitute an appropriate regulatory filing package for that indication. We believe that the safety concerns around our ESAs expressed by the FDA must be addressed to the agency's satisfaction before new indications or expanded labeling of our ESA products will likely be approved.

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor ("BDNF"), Megakaryocyte Growth and Development Factor ("MGDF") and Glial Cell Lined-Derived Neurotrophic Factor ("GDNF"). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig's Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson's disease did not meet the primary study endpoint upon completion of nine months of the double-blind treatment phase of the study even though a small phase 1 pilot investigator-initiated open-label study over a threeyear period appeared to result in improvements for advanced Parkinson's disease patients. Subsequently, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson's disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data in rhesus monkeys showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials of GDNF and, as a part of that decision and based on thorough scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See "- Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers."; "- Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market." and "- Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.")

#### Our business may be affected by government investigations or litigation.

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, our business operations, government requests for information and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Note 10, "*Contingencies*" to the Consolidated Financial Statements in our 2008 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Civil and criminal litigation is inherently unpredictable, and the outcome can result in excessive verdicts, fines, penalties and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our results of operations, financial position or cash flows.

We have received subpoenas from a number of government entities, including the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington, as well as the Attorneys General of New York and New Jersey. The federal subpoenas have been issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), while the Attorneys General subpoenas have been issued pursuant to state specific statutes relating to consumer fraud laws and state false claims acts. In general, the subpoenas request documents relating to the sales and marketing of our products, and our collection

and dissemination of information reflecting clinical research as to the safety and efficacy of our ESAs. Based on representations in a U.S. government filing that became public on or about May 7, 2009 relating to the Massachusetts Qui Tam Action, we now believe the subpoenas we received from the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington also relate to nine additional Qui Tam Actions which are purportedly pending against Amgen, including eight pending in the U.S. District Court for the Eastern District of New York and one pending in the U.S. District Court for the Western District of Washington. The U.S. government filing further alleges that a large number of states (17) are involved in the Qui Tam investigations, led by the State of New York. These investigations are represented to be joint criminal and civil investigations. On October 30, 2009 fourteen states and the District of Columbia's state attorneys' general filed an amended complaint in intervention against Amgen alleging violations of the federal Anti-Kickback Statute and various state false claims acts. Additionally, the U.S. government may seek to intervene in the lawsuit filed by the states at any time. (See Note 10, *"Contingencies"* to the Consolidated Financial Statements in our 2008 Form 10-K, and Note 13, *"Commitments and contingencies"* to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.)

Although we cannot predict whether additional proceedings may be initiated against us, or predict when these matters may be resolved, it is not unusual for investigations such as these to continue for a considerable period of time and to require management's attention and significant legal expense. To the extent it is alleged in a proceeding that we are in violation of the various federal and state laws that govern the sales and marketing of our products, a decision adverse to our interests could result in federal criminal liability and/or federal or state civil or administrative liability, and thus could result in substantial financial damages or criminal penalties and possible exclusion from future participation in the Medicare and Medicaid programs. In addition, we may see new governmental investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our results of operations, financial position or cash flows in the period in which such liabilities are incurred.

Our revenues may fluctuate and our operating results are subject to fluctuations and these fluctuations could cause financial results to be below expectations and our stock price is volatile, which could adversely affect your investment.

Our revenues and operating results may fluctuate from period to period for a number of reasons, some of which we cannot control. Even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections as some of our operating expenses are fixed in the short term and cannot be reduced within a short period of time to offset reductions in revenue. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Changes in credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to September 30, 2009, the trading price of our common stock has ranged from a high of \$64.76 per share to a low of \$44.96 per share.

Our revenues, operating results and stock price may be affected by a number of factors, such as:

- actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators, including our clinical trials for denosumab and Aranesp®, in particular TREAT
- significant delay in approval of a product candidate, in particular Prolia™
- regulatory matters or actions, label changes or risk management activities, including a REMS
- adverse developments regarding the safety or efficacy of our products
- changes in the government's or private payers' reimbursement policies, particularly for supportive cancer care products, or prescribing guidelines for our products
- · proposed healthcare reform in the United States
- · current volatility and disruption of the financial markets
- severity and duration of the current global economic downturn
- · development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy
- · inability to maintain regulatory approval of marketed products or manufacturing facilities

- business development or licensing activities
- · product development or other business announcements by us or our competitors
- lower than expected demand for our products or a change in product mix, either or both of which may result in less than optimal utilization of our manufacturing facilities and the potential to incur excess capacity or impairment charges
- · changes in our product contracting and related pricing strategies
- · changes in wholesaler buying patterns
- · increased competition from new or existing products
- · fluctuations in foreign currency exchange rates
- · announcements in the scientific and research community
- · intellectual property and legal matters
- · actual or anticipated product supply constraints
- · broader economic, industry and market trends unrelated to our performance

Of course, there may be other factors that affect our revenues, operating results and stock price in any given period. In addition, if our revenues, earnings or other financial results in any period fail to meet the investment community's expectations, there could be an immediate adverse impact on our stock price.

Recent levels of market volatility have been unprecedented and adverse capital and credit market conditions may affect our ability to access costeffective sources of funding and our investment in marketable securities may be subject to market, interest and credit risk that could reduce their value.

The capital and credit markets have recently experienced extreme volatility and disruption which, particularly during the latter part of 2008 and continuing into the first half 2009, has led to uncertainty and liquidity issues for both borrowers and investors. Historically, we have occasionally and opportunistically accessed the capital markets to support certain business activities including acquisitions, in-licensing activities, share repurchases and to refinance existing debt. In the event of adverse capital and credit market conditions, we may not be able to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Based on our current liquidity, we currently expect that we will repay the \$1.0 billion of our 4.00% notes due on November 18, 2009 without incurring additional indebtedness.

We have some exposure to financial institutions which came under significant pressure during the recent credit crisis. For example, we have previously had 16 financial institutions participate in our revolving credit facility including a subsidiary of Lehman, which had a \$178 million commitment. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008, and we thereafter removed them from our facility and correspondingly reduced the amount available for borrowing under the facility. Additionally, the conversion feature of our 0.125% Convertible Notes due 2011 and our 0.375% Convertible Notes due 2013 are hedged pursuant to transactions entered into with two financial institutions. We have also entered into interest rate swap agreements for certain of our outstanding debt and routinely enter into foreign currency exchange contracts with financial institutions as counterparties. Deterioration in the financial condition of these counterparties could adversely impact the accounting for these transactions. Further, additional bankruptcies in the financial sector could limit our ability to replace these transactions on favorable terms, or at all, or to manage the risks inherent in our business which could have a material adverse effect on our business and results of operations.

Additionally, we maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Condensed Consolidated Balance Sheet. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors which may result in other than temporary declines in the value of our investments. Any of these events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on the sale of investments. We seek to mitigate these risks with the help of our investment advisors by generally investing in high quality securities and continuously monitoring the overall risk of our portfolio. To date in 2009, we have not realized any material impairments within our investment portfolio.

#### Current economic conditions may magnify certain risks that affect our business.

Our operations and performance have been, and may continue to be, affected by economic conditions. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. (See "— *Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.*") As a result of the current global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement from government programs, including Medicare and Medicaid, and/or private payer healthcare programs could have a material adverse affect on the sales of our products, our business and results of operations.

In addition, as a result of the economic downturn, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. These economic conditions may affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies and/or foregoing healthcare insurance coverage. In addition to its effects on consumers, the economic downturn may have also increased cost sensitivities among medical providers in the United States, such as oncology clinics, particularly in circumstances where providers may experience challenges in the collection of patient co-pays or be forced to absorb treatment costs as a result of coverage decisions or reimbursement terms. Collectively, we believe that these changes have resulted and may continue to result in reduced demand for our products, which could continue to adversely affect our business and results of operations. Any resulting decrease in demand for our products could also cause us to experience excess inventory write-offs and/or excess capacity or impairment charges at certain of our manufacturing facilities.

Additionally, we rely upon third-parties for certain parts of our business, including licensees and partners, wholesale distributors of our products, contract clinical trial providers, contract manufacturers and single third-party suppliers. Because of the recent volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third-parties which could have a material adverse affect on our business and results of operations. Current economic conditions may adversely affect the ability of our distributors, customers and suppliers to obtain liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Further, economic conditions appear to have affected, and may continue to affect, the business practices of our wholesale distributors in a manner that has and may continue to contribute to lower sales of our products. For example, in the first quarter of 2009, certain of our wholesale distributors lowered their levels of inventory on hand, which we believe was done to reduce their carrying costs and improve their results of operations, and inventory levels remained relatively unchanged in the second quarter of 2009. In addition, although we monitor our distributors', customers' and suppliers' financial condition and their liquidity, in order to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could negatively impact our business and results of operations.

We rely on single third-party suppliers for some of our raw materials, medical devices and components; if these third-parties fail to supply these items, we may be unable to supply our products.

Certain raw materials necessary for commercial and clinical manufacturing and formulation of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for formulation, fill and finish of our products are provided by singlesource unaffiliated third-party suppliers. Certain of these raw materials, medical devices and components are the proprietary products of these unaffiliated thirdparty suppliers and, in some cases, such proprietary products are specifically cited in our drug application with regulatory agencies so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the regulatory agency approved such supplier.

We would be unable to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party singlesource suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including:

- · regulatory requirements or action by regulatory agencies or others
- adverse financial developments at or affecting the supplier

- unexpected demand for or shortage of raw materials, medical devices or components
- labor disputes or shortages, including the effects of a pandemic flu outbreak or otherwise
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall

These events could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. For example, we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility without impact on our ability to supply these products. However, we may experience these or other shortages in the future resulting in delayed shipments, supply constraints and/or stock-outs of our products. Also, certain of the raw materials required in the commercial and clinical manufacturing and the formulation of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. Some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. We are investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances as such raw materials may be subject to contamination and/or recall.

A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials, which may be sourced from other countries, used in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. Further, any disruptions or delays by us or by third-party suppliers or partners in converting to alternatives to certain biologically derived substances and alternative manufacturing processes or our ability to gain regulatory approval for the alternative materials and manufacturing processes could increase our associated costs or result in the recognition of an impairment in the carrying value of certain related assets, which could have a material and adverse affect on our results of operations.

Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.

We currently manufacture all of our principal products, and we plan to manufacture many of our product candidates. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently manufacture our products and product candidates at our manufacturing facilities located in Thousand Oaks and Fremont, California; Boulder and Longmont, Colorado; West Greenwich, Rhode Island and Juncos, Puerto Rico. (See "— Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.")

Additionally, we currently use third-party contract manufacturers to produce or assist in the production of ENBREL, Sensipar®/Mimpara® and Nplate® as well as our late-stage product candidate denosumab and plan to use contract manufacturers to produce a number of our other late-stage product candidates. Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which is impacted by many manufacturing variables including:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier
- · capacity of our facilities and those of our contract manufacturers
- · facility contamination by microorganisms or viruses
- labor disputes or shortages, including the effects of a pandemic flu outbreak
- · compliance with regulatory requirements
- changes in forecasts of future demand



- timing and actual number of production runs
- updating of manufacturing specifications
- production success rates and bulk drug yields
- timing and outcome of product quality testing

If we have problems in one or more of these or other manufacturing variables, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from Boehringer Ingelheim Pharma KG. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could materially and adversely affect our product sales and results of operations.

We manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Although we have obtained regulatory approval for our marketed products, these products and our manufacturing processes and those of our third-party contract manufacturers must undergo a potentially lengthy FDA or other regulatory approval process and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build and license a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. In order to maintain supply, mitigate risks associated with the majority of our formulation, fill and finish operations being performed in a single facility and to adequately prepare to launch a number of our late-stage product candidates, in particular denosumab, we must successfully implement a number of manufacturing projects on schedule, including construction and the related qualification and licensure of a new formulation and filling facility at our Puerto Rico site, expansion and the related qualification and licensure of our existing bulk protein facilities at our Puerto Rico site, operate our facilities at appropriate production capacity over the next few years, optimize manufacturing asset utilization, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us for any reason, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. If we are unable to manufacture, market and sell our products, our business and results of operations would be materially and adversely affected. Additionally, we distribute a substantial volume of our commercial products through a single distribution center in Louisville, Kentucky for the United States and another in Breda, the Netherlands for Europe and the rest of the world. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers and our third-party logistics providers.

We manufacture and formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products.

We currently perform all of the formulation, fill and finish for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®, some formulation, fill and finish operations for ENBREL, and all of the bulk manufacturing for Aranesp®, Neulasta® and NEUPOGEN® at our manufacturing facility in Juncos, Puerto Rico. In addition, the Puerto Rico facility will be the primary facility producing Prolia<sup>TM</sup> drug product, upon FDA approval. Our global supply of these products is significantly dependent on the uninterrupted and efficient operation of this facility. A number of factors could adversely affect our operations, including:

- power failures and/or other utility failures
- breakdown, failure or substandard performance of equipment
- · improper installation or operation of equipment

- · labor disputes or shortages, including the effects of a pandemic flu outbreak
- · inability of third-party suppliers to provide raw materials and components
- natural or other disasters, including hurricanes
- · failures to comply with regulatory requirements, including those of the FDA

For example, this facility in Puerto Rico has experienced manufacturing component shortages and there was evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output in the past. Although these experiences in Puerto Rico have not impacted our ability to supply product in the past, the same or other problems may result in our being unable to supply these products, which could adversely affect our product sales and operating results materially. Although we have obtained limited insurance to protect against certain business interruption losses, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. The extent of the coverage of our insurance could limit our ability to mitigate for lost sales and such losses could adversely affect our product sales and operating results materially. In addition to the factors associated with the Puerto Rico facility, it is also subject to the same difficulties, disruptions or delays in manufacturing seen among our other manufacturing facilities. For example, the limited number of lots of ENBREL voluntarily recalled in September 2009 were manufactured at our Puerto Rico facility and we have made commitments to the FDA to address the causes behind the recall. Our failure to adequately address the FDA's expectations could lead to new inspections of the facility or regulatory actions. (See "— *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers."*)

Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases for which our products may be indicated. For example, in the United States, Aranesp® competes with PROCRIT®, which is marketed by J&J, in the supportive cancer care and pre-dialysis settings. In Europe, we face competition from the following products: (i) EPREX® and ERYPO® by Janssen-Cilag; (ii) NeoRecormon® by Roche; (iii) Retacrit<sup>TM</sup>/Silapo® by Hospira Enterprises B.V. and Stada Arzneimittel AG; (iv) Binocrit®/Epoetin alfa Hexal®/Abseamed® by Sandoz GmbH/Hexal Biotech Gorschungs GmbH/Medice Arzneimittel Pütter GmbH & Company KG and (v) MIRCERA® by Roche, which competes with Aranesp® in the nephrology segment only. Any products or technologies that are directly or indirectly successful in addressing anemia associated with CRF could negatively impact product sales of EPOGEN® and Aranesp®. In the United States, EPOGEN® and Aranesp® compete with each other, primarily in the U.S. hospital dialysis clinic setting.

In addition to competition from the above-noted marketed products, a number of companies are developing products that could potentially compete with Aranesp® and/or EPOGEN® in the future. Affymax Inc. and Takeda are co-developing Hematide<sup>TM</sup>, an ESA for the treatment of anemia in renal patients. FibroGen is developing FG-2216 and FG-4592, orally active ESAs, for the treatment of anemia and for the treatment in anemia in CKD. Ratiopharm is developing a biosimilar ESA, EpoTheta, expected to launch in the EU in 2009. Additionally in December 2008, Merck & Company, Inc. ("Merck") announced the formation of a new biotech division, Merck Bioventures, which is developing a pegylated ESA (MK-2578), which they have announced they expect to launch in 2012. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See "— *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.")* 

ENBREL competes in certain circumstances with products marketed by J&J, Abbott Laboratories ("Abbott"), Biogen IDEC Inc., Barr, Genentech, Inc., Bristol-Myers Squibb Corporation, Novartis AG and Sanofi-Aventis and others, as well as the generic drug methotrexate. ENBREL now faces competition from J&J's Simponi<sup>™</sup> (golimumab), which was approved by the FDA in April 2009 for the treatment of moderate-to-severe rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis, UCB/Nektar Therapeutic's Cimzia<sup>®</sup> (PEGylated anti-TNF alpha), which was approved by the FDA in May 2009 for the treatment of adult patients with moderately to severely active rheumatoid arthritis, and J&J's Stelara<sup>™</sup> (ustekinumab), which was approved in September 2009 for the treatment of moderate or severe psoriasis. ENBREL may also face competition from other potential therapies being developed, including Roche's Actemra (tocilizumab), Abbott's ABT-874 and Pfizer's JAK-3 inhibitor CP-690,550. Additionally, in the first quarter of 2008 Abbott received approval from the FDA to market HUMIRA<sup>®</sup> as a treatment for adult

patients with moderate to severe chronic plaque psoriasis and HUMIRA® now competes with ENBREL in both the rheumatology and dermatology segments and ENBREL has experienced and continues to experience share loss to competitors.

Certain of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in R&D in areas where we have products or where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. As with Merck's recent announcement of its intention to expand into biotechnology and with Pfizer's merger with Wyeth, pharmaceutical companies and generic manufacturers that have traditionally developed and marketed "small molecule" pharmaceutical products are expanding into the biotechnology field with increasing frequency, and some of these companies are seeking to develop biosimilar products that may compete with our products. Large biopharmaceutical companies may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do, and our products may compete against products that have lower prices, equivalent or superior performance, are easier to administer or that are otherwise competitive with our products. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. Business combinations among our competitors may also increase competition and the resources available to our competitors.

#### We currently face competition from biosimilar products, and we expect to face increasing competition from biosimilar products in the future.

We currently face competition in Europe from biosimilar products, and we expect to face increasing competition from biosimilars in the future. Lawmakers in the United States have proposed bills to create a regulatory pathway for the abbreviated approval of biosimilars, and the EU has already created such a regulatory pathway. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader marketing approval for biosimilars, our products will become subject to increased competition. Expiration or successful challenge of applicable patent rights could trigger such competition, and we could face more litigation regarding the validity and/or scope of our patents.

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product classspecific guidelines for biosimilar approvals issued over the past few years. In 2006, the EMEA developed and issued final regulatory guidelines related to the development and approval of biosimilar products. The final guidelines included clinical trial guidance for certain biosimilar products, including erythropoietins and G-CSFs, recommending that applicants seeking approval of such biosimilar products conduct pharmacodynamic, toxicological and clinical safety studies as well as a pharmacovigilance program. Some companies have received and other companies are seeking approval to market erythropoietin and G-CSF biosimilars in the EU, presenting additional competition for our products. (See "— *Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.*") For example, following the expiration of the principal European patent relating to recombinant G-CSF on August 22, 2006, the European Commission issued marketing authorizations for the first G-CSF biosimilar products to Ratiopharm's Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel's Biograstim® and Teva's Tevagrastim® in September 2008. These companies launched their G-CSF biosimilar product in certain EU countries in 2008 and 2009 and are expected to launch in other European markets in 2009. In February 2009, the European Commission issued marketing authorizations for an additional G-CSF biosimilar product to Sandoz's Zarzio® and Hexal's Filgrastim Hexal®. Sandoz and Hexal launched their G-CSF biosimilar product in certain EU countries in 2009 and are expected to launch in other countries. There are currently two G-CSF biosimilars available in the EU marketed by different companies and these G-CSF biosimilar products compete with NEUPOGEN® and Neulasta®. We cannot predict to what extent the entry of biosi

In the United States, there currently is no regulatory pathway for the abbreviated approval of BLAs for biosimilars, but legislation on biosimilars may be enacted in the coming months or years. Such biosimilars would reference biotechnology products already approved under the U.S. Public Health Service Act. Under current law, potential competitors may introduce biotechnology products in the United States only by filing a complete BLA. Before biosimilar products could enter the U.S. market through an abbreviated approval process, Congress would need to pass legislation to create a new approval pathway and the FDA may also then promulgate associated regulations or guidance. The Obama Administration has expressed support for the creation of such an approval pathway for biosimilars, including as a part of its broader healthcare reform effort, which the Administration has identified as one of its top priorities. In each of 2007, 2008 and 2009, a number of bills that would create a legal framework for approving biosimilars have been introduced by members of Congress. In July 2009, the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce passed, out of committee, bills that would provide twelve years of

data exclusivity for innovative biological products. Data exclusivity protects the data in the innovator's regulatory application by, for a limited period of time, prohibiting others from gaining FDA approval based in part by relying on or referencing the innovator's data in their application to the FDA. The debate on biosimilars continues, however, with a number of members of Congress supporting a shorter period of data exclusivity. We cannot predict what the specific provisions of any final legislation might be or the timing of implementation of the pathway by the FDA. To the extent that an abbreviated biosimilar pathway is created through legislation in the United States, we would likely face greater competition and downward pressure on our product prices, sales and revenues, subject to our ability to enforce our patents. Further, biosimilar manufacturers with approved products in Europe may seek to quickly obtain U.S. approval if an abbreviated regulatory pathway for biosimilars is adopted.

The absence of an abbreviated approval pathway for biosimilar products may not be a complete barrier to the introduction of biosimilar-type products in the United States. For example, in February 2009, Teva announced its intention to introduce its version of NEUPOGEN® in the United States by filing a complete BLA under the existing statutory framework. Teva did not indicate whether it would wait for our U.S. patents on G-CSF to expire before attempting to enter the market.

Concentration of sales at certain of our wholesaler distributors and consolidation of free-standing dialysis clinic businesses may negatively impact our bargaining power and profit margins.

The substantial majority of our U.S. product sales are made to three pharmaceutical product wholesaler distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. One of these products, EPOGEN®, is primarily sold to free-standing dialysis clinics, which have experienced significant consolidation. Two organizations, DaVita Inc. and Fresenius Medical Care North America, Inc. ("Fresenius") own or manage a large number of the outpatient dialysis facilities located in the United States and account for a significant majority of all EPOGEN® sales in the free-standing dialysis clinic setting. In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius, on its behalf and on behalf of certain of its affiliates, whereby they have agreed to purchase, and we have agreed to supply, all of Fresenius' commercial requirements for ESAs for use in managing the anemia of its hemodialysis patients in the United States and Puerto Rico, based on forecasts provided by Fresenius and subject to the terms and conditions of the agreement.

These entities' purchasing leverage has increased due to this concentration and consolidation which may put pressure on our pricing by their potential ability to extract price discounts on our products or fees for other services, correspondingly negatively impacting our bargaining position and profit margins. The results of these developments may have a material adverse effect on our product sales and results of operations.

#### Our marketing of ENBREL is dependent in part upon Pfizer (formerly Wyeth).

On October 15, 2009, Pfizer and Wyeth completed their merger and our relationship with Pfizer may be different than our prior relationship with Wyeth, including changes in management, strategy or otherwise. Under a co-promotion agreement, we and Pfizer market and sell ENBREL in the United States and Canada. A management committee comprised of an equal number of representatives from us and Pfizer is responsible for overseeing the marketing and sales of ENBREL including strategic planning, the approval of an annual marketing plan and the establishment of a brand team. The brand team, with equal representation from us and Pfizer, prepares and implements the annual marketing plan, which includes a minimum level of financial and sales personnel commitment from each party, and is responsible for all sales activities. If Pfizer fails to effectively deliver on its marketing commitments to us or if we and Pfizer fail to coordinate our efforts effectively, our sales of ENBREL may be materially adversely affected.

#### We may experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our restructuring plan.

As a result of various regulatory and reimbursement developments that began in 2007 and, in particular those affecting our marketed ESA products, we recently completed a restructuring of our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. As part of these actions, we reduced staff, made changes to certain capital projects, closed certain production operations and abandoned leases primarily for certain R&D facilities that will not be used in our operations. We may not realize, in full or in part, all of the anticipated benefits and savings from these efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve or maintain all of the resulting savings or benefits to our business or other unforeseen events occur, our business and results of operations may be adversely affected.

Our business continues to face a variety of challenges. As a result, we may be forced to undertake further cost saving and/or restructuring initiatives in the future to achieve increased operating efficiencies, improve our competitive standing or results of operations and/or to address unfavorable economic conditions. The current economic climate has forced many U.S. companies to cut

costs in order to maintain their competitive standing, including through restructurings and reorganizations. As a result of the global economic downturn, we have worked, and we continue to work, to increase cost efficiencies and to reduce discretionary expenditures, and in the event of further deterioration of the economy, we may also be required to consider further steps to improve our cost structure. Additionally, the anticipated benefits of our cost reduction initiatives are based on forecasts which could vary substantially from actual results, and we cannot provide assurance that any such cost saving initiatives will not have a material adverse effect on our business.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. (See "— Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.") Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and healthcare providers could result in decreased use and/or dosage of our products. Some examples of agency and organizational guidelines include:

- On July 31, 2009, the Kidney Disease: Improving Global Outcomes group ("KDIGO") released its Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder ("CKD-MBD"). The guideline includes detailed recommendations for the diagnosis and evaluation of the three components of CKD-MBD: abnormalities of serum markers (calcium, phosphorus, parathyroid hormone and vitamin D), vascular calcification and disorders of the bone, followed by recommendations for treatment. These recommendations could affect how healthcare providers prescribe Sensipar® for ESRD patients. KDIGO is a global non-profit foundation managed by the National Kidney Foundation (the "NKF") that is dedicated to improving the care and outcomes of kidney disease patients worldwide through promoting coordination, collaboration, and integration of initiatives to develop and implement clinical practices guidelines. While it is uncertain just how the KDIGO guidelines will be viewed in the context of existing regional guidelines for managing mineral and bone disorders among those with kidney disease such as the NKF-KDOQI™ Guidelines in the United States and others in Europe, Canada, Australia and the United Kingdom, the impact of the new recommendations on clinical practice or the use of Sensipar® is not yet known.
- On August 30, 2007, the NKF distributed to the nephrology community final updated Kidney Disease Outcomes Quality Initiative ("KDOQI") clinical practice guidelines and clinical practice recommendations for anemia in CKD. The NKF's Anemia Work Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, the NKF-KDOQI<sup>™</sup> Anemia Work Group recommended in their 2007 Update to the NKF-KDOQI<sup>™</sup> Anemia Management Guidelines that physicians target Hb in the range of 11 g/dL to 12 g/dL, and also stipulated that the target not be above 13 g/dL.
- On February 2, 2007, following the reported results from our AoC 103 Study, the United States Pharmacopoeia Dispensing Information Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, Aranesp® use in AoC essentially ceased.

Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could adversely affect our product sales and operating results materially. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price for our common stock.

Our corporate compliance and risk mitigation programs cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and/or that we effectively manage all operational risks.

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, are subject to extensive federal and state regulation in the United States and to extensive regulation in foreign countries. (See "— Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical

trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market." and "— Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.") While we have developed and instituted a corporate compliance program, we cannot guarantee you that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. If we or our agents fail to comply with any of these regulations and/or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Additionally, while we have implemented numerous risk mitigation measures, we cannot guarantee that we will be able to effectively mitigate all operational risks, our product supply may be materially adversely affected, which could have a material adverse effect on our product sales and results of operations.

#### We may be required to defend lawsuits or pay damages for product liability claims.

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention, and adversely affect our reputation and the demand for our products. Amgen and Immunex have previously been named as defendants in product liability actions for certain of our products.

# Continual process improvement efforts may result in the carrying value of certain existing manufacturing facilities or other assets becoming impaired or other related charges being incurred.

In connection with our continuous process improvement activities, we evaluate our processes and procedures in order to identify opportunities to achieve greater efficiencies in how we conduct our business in order to reduce costs. In particular, we evaluate our manufacturing practices and related processes to increase production yields and/or success rates as well as capacity utilization to gain increased cost efficiencies. Depending on the timing and outcomes of these process improvement initiatives, the carrying value of certain manufacturing or other assets may not be fully recoverable and could result in the recognition of impairment charges and/or the recognition of other related charges. The recognition of such charges, if any, could have a material and adverse affect on our results of operations.

# Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and activities could have a material adverse effect on our financial results.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on the results of operations. For example, our effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. taxes have been provided because such earnings are intended to be invested indefinitely outside the United States. Substantial reform of U.S. tax law regarding tax on certain foreign profits could result in an increase in our effective tax rate, which could have a material adverse effect on our financial results. (See also "*Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Financial Condition, Liquidity and Capital Resources – Cash, cash equivalents and marketable securities*" in Part I herein and Note 3, "*Income taxes*" to the Condensed Consolidated Financial Statements.)

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

Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a number of factors including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

During the three months ended September 30, 2009, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended September 30, 2009 is as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced programs_	Maximum \$ value that may yet be purchased under the programs <sup>(1)</sup>
July 1 - July 31	-	\$ -	-	\$ 2,174,252,048
August 1 - August 31	7,133	62.16	-	2,174,252,048
September 1 - September 30	-	-	-	2,174,252,048
	7,133(2)	62.16	_ (2)	

<sup>(1)</sup> In July 2007, the Board of Directors authorized us to repurchase up to an additional \$5.0 billion of our common stock. As of September 30, 2009, \$2.2 billion was available for stock repurchase under our stock repurchase program.

<sup>(2)</sup> The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us for the payment of taxes upon vesting of certain employees' restricted stock.

## Item 6. EXHIBITS

(a) 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)

By:

Date: November 6, 2009

/S/ ROBERT A. BRADWAY Robert A. Bradway

Executive Vice President and Chief Financial Officer

reference.)

# AMGEN INC.

# INDEX TO EXHIBITS

Exhibit	
No.	Description
3.1	Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31,
	2005 on March 10, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for
	the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	Certificate of Elimination of the Certificate of Designations of the Series A Junior Participating Preferred Stock (As Eliminated December
	10, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
3.5	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for
	the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.6	Certificate of Correction of the Restated Certificate of Incorporation (As Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.7	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated October 6, 2009). (Filed as an exhibit to Form 8-K filed on
	October 7, 2009 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	Two Agreements of Resignation, Appointment and Acceptance in the same form as the previously filed Exhibit 4.3 hereto are omitted pursuant to instruction 2 to Item 601 of Regulation S-K. Each of these agreements, which are dated December 15, 2008, replaces the current trustee under the agreements listed as Exhibits 4.9 and 4.16, respectively, with Bank of New York Mellon. Amgen Inc. hereby agrees to furnish copies of these agreements to the Securities and Exchange Commission upon request.
4.5	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.6	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Officer's Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of 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 filed on April 8, 1997 and incorporated herein by reference.)
4.8	Form of Liquid Yield Option™ Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.10	First Supplemental Indenture, dated March 2, 2005. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.11	Indenture, dated as of August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by

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Exhibit No.	Description
4.12	Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.13	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.14	Officers' Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014.
	(Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.15	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.16	Indenture, dated as of May 6, 2005. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.17	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.125% Convertible Senior Note due 2011). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.18	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.375% Convertible Senior Note due 2013). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.19	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.)
4.20	Officers' Certificate of Amgen Inc. dated as of 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.)
4.21	Registration Rights Agreement, dated as of May 30, 2007, among Amgen Inc. and Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., J.P. Morgan Securities Inc. and Lehman Brothers Inc. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
10.1+	Amgen Inc. 2009 Equity Incentive Plan. (Filed as Appendix A to Amgen Inc.'s Proxy Statement on March 26, 2009 and incorporated herein by reference.)
10.2+*	Form of Stock Option Agreement and Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan.
10.3+*	Amgen Inc. 2009 Performance Award Program (As Amended and Restated on October 5, 2009).
10.4+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program.
10.5+	Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.6+	Form of Grant of Non-Qualified Stock Option Agreement and Restricted Stock Unit 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.)
10.7+	Amgen Supplemental Retirement 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.)
10.8+	Amendment and Restatement of the Amgen Change of Control Severance Plan (As Amended December 9, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.9+	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.)
10.10+	Amgen Inc. Executive Nonqualified Retirement 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.)
10.11+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q

Exhibit	
No.	Description
10.12+	2002 Special Severance Pay Plan for Amgen Employees. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.13	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between Amgen and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.14	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.)
10.15	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.)
10.16	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.)
10.17	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.)
10.18	Amendment No. 13 to the Shareholders' Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.19	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985, between Kirin- Amgen, Inc. and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.20	Research, Development Technology Disclosure and License Agreement: PPO, dated January 20, 1986, by and between Kirin Brewery Co., Ltd. and Amgen Inc. (Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement on March 11, 1986 and incorporated herein by reference.)
10.21	Amendment Agreement, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.)
10.22	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.)
10.23	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.)
10.24	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.)

Exhibit	
No.	Description
10.25	Agreement Regarding Governance and Commercial Matters, dated December 16, 2001, by and among American Home Products
	Corporation, American Cyanamid Company and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit
	to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.26	Amended and Restated Promotion Agreement, dated as of December 16, 2001, by and among Immunex Corporation, American Home Products Corporation and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to
40.05	Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.27	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as of July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation, (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.28	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective as of April 20, 2004, by and among Wyeth,
10.20	Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Form S-4/A on June 29, 2004 and incorporated herein by reference.)
10.29	Amendment No. 3 to Amended and Restated Promotion Agreement, effective as of January 1, 2005, by and among Wyeth, Amgen Inc. and
10.20	Immunex Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended
	March 31, 2005 on May 4, 2005 and incorporated herein by reference.)
10.30	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch
	International related to the 0.125% Convertible Senior Notes Due 2011. (Filed as an exhibit to Form 10-K for the year ended December 31,
	2005 on March 10, 2006 and incorporated herein by reference.)
10.31	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch
	International related to 0.375% Convertible Senior Notes Due 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.32	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co.
	International Limited related to the 0.125% Convertible Senior Notes Due 2011 Notes. (Filed as an exhibit to Form 10-K for the year ended
	December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.33	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring
	in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.34	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring
	in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.35	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co. International Limited for
	warrants maturing in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated
10.00	herein by reference.)
10.36	Purchase Agreement, dated May 24, 2007, among Amgen Inc., Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith
	Incorporated and the Initial Purchasers Names in Schedule A thereof. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.37	Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International. (Filed as an exhibit to Form 10-Q for the
10.57	quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.38	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information
10.50	deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated
	herein by reference.)
10.39	Credit Agreement, dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as
	syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks
	party thereto. (Filed as an exhibit to Form 8-K filed on November 2, 2007 and incorporated herein by reference.)

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Exhibit	
No.	Description
10.40	Amendment No. 1, dated May 18, 2009, to the Credit Agreement dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., a
	administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers
	and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 of
	August 10, 2009 and incorporated herein by reference.)
10.41	Multi-product License Agreement with Respect to Japan between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February
	1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 or
	May 12, 2008 and incorporated herein by reference.)
10.42	License Agreement for motesanib diphosphate between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.43	Supply Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidentia
	information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated
	herein by reference.)
10.44	Sale and Purchase Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain
	confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and
	incorporated herein by reference.)
10.45	Variable Term Accelerated Share Repurchase Transaction dated May 28, 2008, between Amgen Inc. and Lehman Brothers, Inc. acting a
	Agent Lehman Brothers OTC Derivatives Inc., acting as Principal. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 or
	August 8, 2008 and incorporated herein by reference.)
10.46	Underwriting Agreement, dated May 20, 2008, among Amgen Inc. with Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith
	Incorporated, as the representatives of the underwriters. (Filed as an exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
10.47	Underwriting Agreement, dated January 13, 2009, by and among the Company and Goldman, Sachs & Co., Merrill Lynch, Pierce, Fenner &
	Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
10.48	Master Services Agreement, dated October 22, 2008, between Amgen Inc. and International Business Machines Corporation (with certain
	confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009
	and incorporated herein by reference.)
10.49	Integrated Facilities Management Services Agreement, dated February 4, 2009 between Amgen Inc. and Jones Lang LaSalle Americas, Inc.
	(with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 or
	February 27, 2009 and incorporated herein by reference.)
10.50*	Collaboration Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly-owned subsidiary o
	GlaxoSmithKline plc (with certain confidential information deleted therefrom).
10.51*	Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly-owned subsidiary of GlaxoSmithKline
	plc (with certain confidential information deleted therefrom).
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS**	XBLR Instance Document.
101.SCH**	XBLR Taxonomy Extension Schema Document.
101.CAL**	XBLR Taxonomy Calculation Linkbase Document.
101.LAB**	XBLR Taxonomy Label Linkbase Document.
101.PRE**	XBLR Taxonomy Presentation Linkbase Document.

# **Table of Contents**

- (\* = 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.)

#### Form of Award Notice

# [The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website ]

This notice of Award (the "<u>Award Notice</u>") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Agreement that accompanies this Award Notice and made of part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee: Employee ID: Address: Award Type: Grant ID:	
Plan:	Amgen Inc. 2009 Equity Incentive Plan
Grant Date:	
Grant Price:	\$
Number of Shares:	
Expiration Date:	The $[\_\_\_\_\_]$ anniversary of the date of this Award
Vesting Date:	Means the vesting date indicated in the Vesting Schedule
Vesting Schedule:	Means the schedule of vesting set forth under Vesting Details
Vesting Details:	Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting.

#### GRANT OF STOCK OPTION AGREEMENT

# THE SPECIFIC TERMS OF YOUR STOCK OPTION ARE FOUND IN THE PAGES RELATING TO THE GRANT OF STOCK OPTIONS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE "AWARD NOTICE") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS GRANT OF STOCK OPTIONS.

On the Grant Date, specified in the Award Notice, Amgen Inc., a Delaware corporation (the "<u>Company</u>"), has granted to you, the grantee named in the Award Notice, under the plan specified in the Award Notice (the "<u>Plan</u>"), an option (the "<u>Option</u>") to purchase the number of shares of the \$.0001 par value common stock of the Company (the "<u>Shares</u>") specified in the Award Notice, pursuant to the terms set forth in this Stock Option Agreement, any special terms and conditions for your country set forth in the attached <u>Appendix A</u> and the Award Notice (together, the "<u>Agreement</u>"). This Option is not intended to qualify and will not be treated as an "incentive stock option" within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended (together with the regulations and other official guidance promulgated thereunder, the "<u>Code</u>"). Capitalized terms not defined herein shall have the meanings assigned to such terms in the Plan.

The provisions of your Option are as follows:

I. Subject to the terms and conditions of the Plan and this Agreement, on each Vesting Date the Option shall vest with respect to the number of Shares indicated on the Vesting Schedule, provided that you have remained continuously and actively employed with the Company or an Affiliate (as defined in the Plan) through each applicable Vesting Date, unless (i) your employment has terminated due to your Voluntary Termination (as defined in Section IV(A)(5)) or (ii) a Change of Control (as defined in Section IV(A)(6)) occurs, or as otherwise determined by the Company in the exercise of its discretion as provided in Section IV(A)(7). This Option may only be exercised for whole shares of the Common Stock, and the Company shall be under no obligation to issue any fractional Shares to you. Subject to the limitations contained herein, this Option shall be exercisable with respect to each installment on or after the applicable Vesting Date. Notwithstanding anything herein to the contrary, the Vesting Schedule may be accelerated (by notice in writing) by the Company in its sole discretion at any time during the term of this Option. In addition, if not prohibited by local law, vesting may be suspended by the Company in its sole discretion during a leave of absence as provided from time to time according to Company policies and practices.

II. (1) The per share exercise price of this Option is the Grant Price as defined in the Award Notice, being not less than the Fair Market Value of the Common Stock on the date of grant of this Option.

(2) To the extent permitted by applicable statutes and regulations,

payment of the exercise price per share is due in full upon exercise of all or any part of each installment which has become exercisable by you by means of (i) cash or a check, (ii) any cashless exercise procedure through the use of a brokerage arrangement approved by the Company, or (iii) any other form of legal consideration that may be acceptable to the Board or the Committee in their discretion.

(3) To the extent permitted by applicable statutes and regulations, if, at the time of exercise, the Company's Common Stock is publicly traded and quoted regularly in the <u>Wall Street Journal</u>, payment of the exercise price may be made by delivery of already-owned Shares of a value equal to the exercise price of the Shares for which this Option is being exercised. The already-owned Shares must have been owned by you for the period required to avoid adverse accounting treatment and owned free and clear of any liens, claims, encumbrances or security interests. Payment may also be made by a combination of cash and already-owned Common Stock.

Notwithstanding the foregoing, the Company reserves the right to restrict the methods of payment of the exercise price if necessary or advisable to comply with applicable law or regulation, as determined by the Company in its sole discretion.

III. Notwithstanding anything to the contrary contained herein, this Option may not be exercised unless the Shares issuable upon exercise of this Option are then registered under the Securities Act, or, if such Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act.

(1) such termination of your employment is due to your Permanent and Total Disability (as defined below), in which case the Option shall terminate on the earlier of the Expiration Date or five (5) years after termination of your employment and the vesting of the Option shall be accelerated and the Option shall be fully exercisable, subject to your execution of a general release and waiver in a form provided by the Company, as of the day immediately preceding such termination of your employment with respect to the Option, except that if the Option was granted in the calendar year in which such termination occurs, the Option shall be accelerated to vest with respect to a number of Shares equal to the number of Shares subject to the Option multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12);

(2) such termination of your employment is due to your death, in which case the Option shall terminate on the earlier of the Expiration Date or five (5) years after your death and the vesting of the Option shall be accelerated and the Option shall be fully exercisable as of the day immediately preceding your death with respect to the Option, except that if the Option was granted in the calendar year in which your death occurs the Option shall be accelerated to vest with respect to a number of shares equal to the number of shares subject to the Option multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12);

(3) during any part of such three (3) month period, this Option is not exercisable solely because of the condition set forth in Section III above, in which event this Option shall not terminate until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your employment;

(4) exercise of this Option within three (3) months after termination of your employment with the Company or with an Affiliate would result in liability under Section 16(b) of the Exchange Act, in which case this Option will terminate on the earlier of: (a) the tenth (10th) day after the last date upon which exercise would result in such liability; (b) six (6) months and ten (10) days after the termination of your employment with the Company or an Affiliate; or (iii) the Expiration Date;

(5) such termination of your employment is due to your voluntary termination (and such voluntary termination is not the result of Permanent and Total Disability (as defined below)) after you are at least sixty five (65) years of age, or after you are at least fifty-five (55) years of age and have been an employee of the Company and/or an Affiliate for at least ten (10) consecutive years ("<u>Voluntary Termination</u>"), in which case this Option shall terminate on the earlier of the Expiration Date or five (5) years after termination of your employment and the unvested portions of this Option will become exercisable pursuant to the Vesting Schedule without regard to your Voluntary Termination of your employment prior to the Vesting Date, subject to your execution of a general release and waiver in a form provided by the Company, with respect to the Option; if the Option was granted in the calendar year in which your Voluntary Termination occurs, the Option will become exercisable pursuant to the Vesting Schedule only with respect to a number of Shares equal to the number of Shares subject to the Option multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12); notwithstanding the definition of Voluntary Termination set forth above, if the Company receives an opinion of counsel that there has been a legal judgment and/or legal development in your jurisdiction that would likely result in the favorable treatment upon Voluntary Termination described above being deemed unlawful and/or discriminatory, then the Committee will not apply the favorable treatment described above;

(6) during the term of your employment, a Change of Control (as

defined below) occurs. In the event of the occurrence of a Change of Control during the term of your employment, then, to the extent permitted by applicable law, the Option shall, to the extent not then vested, vest and the vesting of the Option shall be accelerated and the Option shall be fully exercisable immediately prior to the Change of Control. Upon and following the acceleration of the vesting and exercise periods, at your election, the Option may be: (x) exercised or, if the surviving or acquiring corporation agrees to assume the Option or substitute a similar option, (y) assumed; or (z) replaced with a substitute option. If this Option is not exercised, substituted or assumed prior to or upon the Change of Control, it shall be terminated. The Board or the Committee, in its sole discretion, may cause any such assumption or substitution to be conducted in a manner so as not to constitute an "extension," "renewal" or "modification" (each within the meaning of Section 409A of the Code) of the Option that would cause the Option to be considered "nonqualified deferred compensation" (within the meaning of Section 409A of the Code); or

(7) the Company determines, in its sole discretion at any time during the term of this Option, in writing, to otherwise extend the period of time during which this Option will vest and may be exercised after termination of your employment.

However, in any and all circumstances and except to the extent the Vesting Schedule has been accelerated by the Company in its sole discretion during the term of this Option or as a result of your Permanent and Total Disability or death as provided in Sections IV(A)(1) or IV(A)(2) above, respectively, as a result of your Voluntary Termination as provided in Section IV(A)(5) above, as a result of a Change of Control as provided in Section IV(A)(6) above or as otherwise determined by the Company in the exercise of its discretion as provided in Section IV(A)(7) above, this Option may be exercised following termination of your employment only as to that number of Shares as to which it was exercisable on the date of termination of your employment under the provisions of Section I of this Agreement.

#### (B) For purposes of this Option:

(1) "termination of your employment" shall mean the last date you are either an active employee of the Company or an Affiliate or actively engaged as a consultant or director to the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive options and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed and will not be extended by any notice period mandated under local law (*e.g.*, active employment would not include a period of "garden leave" or similar period pursuant to local law). Your right, if any, to exercise the Option after termination of employment will be measured by the date of termination of your active employment and will not be extended by any notice period mandated under local law;

(2) "<u>Permanent and Total Disability</u>" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of your employment by (a) the U.S. Social Security Administration, (b) the comparable governmental authority applicable to an Affiliate, (c) such

other body having the relevant decision-making power applicable to an Affiliate, or (d) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case; and

(3) "Change of Control" shall mean the occurrence of any of the following:

(a) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding Shares or the combined voting power of the Company's then outstanding voting securities entitled to vote generally in the election of directors; or

(b) individuals who, as of April 2, 1991, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to April 2, 1991, whose election, or nomination for election by the Company's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board (other than an election or nomination of an individual whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of the Directors of the Company, as such terms are used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) shall be, for purposes of the Plan, considered as though such person were a member of the Incumbent Board; or

(c) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company; or

(d) any other event which the Incumbent Board, in its sole discretion, determines shall constitute a Change of Control.

(C) Notwithstanding anything herein or in any Award Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Award that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (B)(1), (B)(2), (B)(3) or (B)(4) must also constitute a "change in control event," as defined in U.S. Treasury Regulation §1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Award.

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V. (A) To the extent specified above, this Option may be exercised by delivering

a notice of exercise in person, by mail, via electronic mail or facsimile or by other authorized method designated by the Company, together with the exercise price to the Company Stock Administrator, or to such other person as the Company Stock Administrator may designate, during regular business hours, together with such additional documents as the Company may then require pursuant to Section 7.2(b) of the Plan.

(B) Regardless of any action the Company or your actual employer (the "<u>Employer</u>") takes with respect to any or all income tax, social insurance, payroll tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable to you ("<u>Tax Obligations</u>"), you acknowledge that the ultimate liability for all Tax Obligations is and remains your responsibility and may exceed the amount actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer: (a) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Option grant, including, but not limited to, the grant, vesting or exercise of the Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (b) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Option to reduce or eliminate your liability for Tax Obligations or achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

(C) Prior to any relevant taxable or tax withholding event, as applicable, you shall pay or make adequate arrangements satisfactory to the Company and/or your Employer to satisfy all Tax Obligations. In this regard, you authorize the Company and/or your Employer, or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(1) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer; or

(2) withholding from proceeds of the sale of Shares acquired upon exercise of the Option either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization).

To avoid adverse accounting treatment, the Company may withhold or account for Tax Obligations not to exceed the applicable minimum statutory withholding rates or other applicable withholding rates.

(D) Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be satisfied by the means previously described. You agree to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section V. Notwithstanding anything to the

contrary contained herein, the Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares if you fail to comply with your obligations in connection with the Tax Obligations.

VI. This Option is not transferable, except by will or the laws of descent and distribution, and is exercisable during your life only by you except if you have named a trust created for the benefit of you, your spouse, or members of your immediate family (a "Trust") as beneficiary of this Option, this Option may be exercised by the Trust after your death.

VII. Any notices provided for in this Option or the Plan shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the address specified above or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

VIII. This Option is subject to all the provisions of the Plan and its provisions are hereby made a part of this Option, including without limitation the provisions of Articles 6 and 7 of the Plan relating to Options, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Option and those of the Plan, the provisions of the Plan shall control.

IX. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Option by and among, as applicable, your Employer, the Company, or Affiliates of the Company for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and your Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number (to the extent permitted under applicable local law) or other identification number, salary, nationality, job title, residency status, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to shares awarded, canceled, vested, unvested or outstanding in your favor, for the purpose of implementing, administering and managing the Plan ("Data"). You understand that Data may be transferred to Merrill Lynch Bank & Trust Co., FSB (or any successor thereto), or any third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in your country or elsewhere including outside the European Economic Area, and that the recipient's country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize your Employer, the Company, Affiliates of the Company, Merrill Lynch Bank & Trust Co., FSB (or any successor thereto), and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to

receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purposes of implementing, administering and managing your participation in the Plan, including any requisite transfer of such Data as may be required to any other broker, escrow agent or other third party with whom the shares received upon exercise of this Option may be deposited. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. You understand that refusal or withdrawal of consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

X. The terms of this Option shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Option is made and/or to be performed.

XI. Notwithstanding any provision of this Option to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached <u>Appendix A</u> (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached <u>Appendix A</u>, the Option granted hereunder shall be subject to any special terms and conditions for your country set forth in <u>Appendix A</u> and the following additional terms and conditions:

- a. the terms and conditions of this Option, including <u>Appendix A</u>, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration to the Plan;
- b. if applicable, the effectiveness of this Option is conditioned upon its compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals; and
- c. the Company may take any other action before or after the date of this Option that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

XII. Notwithstanding the foregoing, the Company may not take any actions hereunder, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation, or the rules of any Securities Exchange. Notwithstanding anything to the contrary contained herein, the Shares issuable upon exercise of this Option shall not be issued unless such Shares are then registered under the Securities Act, or, if such Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act.

XIII. (A) In accepting this Option, you acknowledge that:

(1) the Plan is established voluntarily by the Company, is discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan;

(2) the grant of this Option is voluntary and occasional and does not create any contractual or other right to receive future awards of options, or benefits in lieu of options even if options have been awarded repeatedly in the past;

(3) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(4) your participation in the Plan is voluntary;

(5) for labor law purposes outside the United States, options are an extraordinary item that do not constitute compensation of any kind for services of any kind rendered to the Company or to your Employer, and the grant of this Option is outside the scope of your employment contract, if any;

(6) for labor law purposes outside the United States, the grant of options and the underlying Shares are not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculation of any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar payment and in no event shall be considered as compensation for, or relating in any way to, past services for the Company or any Affiliate;

(7) the grant of options and the underlying Shares are not intended to replace any pension rights or compensation;

(8) neither the grant of options nor any provision of this Option, the Plan or the policies adopted pursuant to the Plan confer upon you any right with respect to employment or continuation of current employment and shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;

(9) in the event that you are not an employee of the Company or any Affiliate, the Option shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;

(10) the future value of the underlying Shares is unknown and cannot be predicted with certainty;

(11) if the underlying Shares do not increase in value, this Option will have no value; if you exercise this Option and obtain Shares, the value of those Shares acquired upon exercise may increase or decrease in value, even below the Grant Price per share;

(12) in consideration of the grant of this Option, no claim or entitlement to compensation or damages arises from forfeiture of options resulting from termination of your employment by the Company or an Affiliate (for any reason whatsoever and whether or not in breach of local labor laws) and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim;

(13) except as otherwise provided in this Agreement or the Plan, the Option and the benefits under the Plan, if any, will not automatically transfer to another company in case of a merger, takeover or transfer of liability.

(B) The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

XIV. If one or more of the provisions of this Option shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and the invalid, illegal or unenforceable provisions shall be deemed null and void; however, to the extent permissible by law, any provisions which could be deemed null and void shall first be construed, interpreted or revised retroactively to permit this Option to be construed so as to foster the intent of this Option and the Plan.

XV. If you have received this Option or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

XVI. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Code Section 409A, but rather is intended to be exempt from the application of Code Section 409A. To the extent that this Option is nevertheless deemed to be subject to Code Section 409A for any reason, this Option shall be interpreted in accordance with Code Section 409A and U.S. Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date. Notwithstanding any provision herein to the contrary, in the event that following the Grant Date, the Committee (as defined in the Plan) determines that this Option may be or become subject to Code Section 409A, the Committee may adopt such amendments to the Plan and/or this Option or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or appropriate to (a) exempt the Plan and/or this Option from the application of Code Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to this Option, or (b) comply with the requirements of Code Section 409A; provided, however, that this paragraph shall not create an obligation on the part of the Committee to adopt any such amendment, policy or procedure or take any such other action.

XVII. By electing to accept this Option, you acknowledge receipt of this Option and hereby confirm your understanding that the terms set forth in this Option constitute, subject to the terms of the Plan, which terms shall control in the event of any conflict between the Plan and this Option, the entire agreement and understanding of the parties with respect to the matters contained herein and supersede any and all prior agreements, arrangements and understandings, both oral and written, between the parties concerning the subject matter of this Option. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

XVIII. The Company reserves the right to impose other requirements on your participation in the Plan, on this Option and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable in order to comply with local law or facilitate the administration of the Plan, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

XIX. This Option and all compensation payable with respect to it shall be subject to recovery by the Company pursuant to any and all of the Company's policies with respect to the recovery of compensation, as they shall be in effect and may be amended from time to time, to the maximum extent permitted by applicable law.

Very truly yours,

AMGEN INC.

By

Duly authorized on behalf of the Board of Directors

#### APPENDIX A

#### ADDITIONAL TERMS AND CONDITIONS OF THE AMGEN INC 2009 EQUITY INCENTIVE STOCK PLAN

#### GRANT OF STOCK OPTION (BY COUNTRY)

#### **TERMS AND CONDITIONS**

This Appendix includes additional terms and conditions that govern the Option to purchase Shares under the Plan <u>if, under applicable law, you are a resident</u> <u>of, or are deemed to be a resident of one of the countries listed below. Furthermore, the additional terms and conditions that govern the Option granted</u> <u>hereunder may apply to you if you relocate to one of the countries listed below</u>. Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix is attached.

#### **NOTIFICATIONS**

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of February 1, 2009. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you exercise the Option, acquire Shares under the Plan, or when you subsequently sell Shares acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently working, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

#### ALL NON-U.S. JURISDICTIONS

#### **TERMS AND CONDITIONS**

#### Method of Exercise. The following provision replaces Section II(A)(3):

To the extent permitted by applicable statutes and regulations, payment of the exercise price per share is due in full in cash or check upon exercise of all or any part of this Option which has become exercisable by you. Due to legal restrictions outside the U.S., you are not permitted to pay the exercise price by delivery of already-owned Shares of a value equal to the exercise price of the Shares for which this Option is being exercised. Furthermore, payment may not be made by a combination of cash and already-owned Common Stock.

## AUSTRALIA

There are no country-specific terms and conditions.

# AUSTRIA

# NOTIFICATIONS

**Consumer Protection Notification.** You may be entitled to revoke acceptance of the Option granted under the Plan on the basis of the Austrian Consumer Protection Act (the "Act") under the conditions listed below, if the Act is considered to be applicable to the Agreement and the Plan:

- (i) If you accept the Option outside the business premises of the Company, you may be entitled to revoke your acceptance of the Option, provided the revocation is made within one (1) week after such acceptance of the Option.
- (ii) The revocation must be in written form to be valid. It is sufficient if you return the applicable Agreement to the Company or the Company's representative with language which can be understood as a refusal to conclude or honor the applicable Agreement, provided the revocation is sent within the period discussed above.

**Exchange Control Notification.** When you sell Shares acquired under the Plan, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad exceeds &3,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/odder SI-Verpflichtungen*).

#### **BELGIUM**

#### TERMS AND CONDITIONS

**Tax Considerations.** The Option granted hereunder must be accepted in writing within 60 days of the offer (and will be subject to taxation on the 60th day following the offer date of the Option, the offer date being defined as the date on which these documents have been sent to you). If you do not accept the Option in writing within 60 days of the offer, you will be deemed to have refused the grant. Please refer to the Option acceptance letter that you will receive along with the applicable Agreement for a more detailed description of the tax consequences of choosing to accept the Option. You should consult your personal tax advisor regarding completion of the additional forms.

#### NOTIFICATIONS

**Tax Reporting Notification.** You are required to report any taxable income attributable to the Option granted hereunder on your annual tax return. You are also required to report any bank accounts opened and maintained outside Belgium on your annual tax return.

# **CANADA**

#### **TERMS AND CONDITIONS**

**Form of Payment**. Due to legal restrictions in Canada, you are prohibited from surrendering Shares that you already own or attesting to the ownership of Shares to pay the exercise price or any Tax Obligations in connection with the Option.

**Termination of Employment.** Section IV(B) (1) of the Agreement is amended to read as follows:

(1) "termination of your employment" shall mean the last date you are either an active employee of the Company or an Affiliate or actively engaged as a consultant or director to the Company or an Affiliate; in the event of involuntary termination of your employment (whether or not in breach of local labor laws), your right to receive the Option and vest under the Plan, if any, will terminate effective as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Company or your Employer, or (2) the date you are no longer actively employed by the Company or your Employer regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to statutory law, regulatory law and/or common law). Your right, if any, to acquire Shares pursuant to the Option after termination of employment will be measured by the date of termination of your active employment and will not be extended by any notice period mandated under local law.

#### The following provisions will apply to you if you are a resident of Quebec:

**Language Consent.** The parties acknowledge that it is their express wish that this Agreement, as well as all documents, notices, and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de cette convention ("Agreement"), ainsi que de tous documents exécutés, avis donnés et procédures judiciaries intentées, directement ou indirectement, relativement à ou suite à la présente convention.

#### Data Privacy Notice and Consent. This provision supplements Section IX of the Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration and operation of the Plan. You further authorize the Company and your Employer to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your employee file.

# CZECH REPUBLIC

#### NOTIFICATIONS

**Exchange Control Notification.** Proceeds from the sale of Shares may be held in a cash account abroad and you are no longer required to report the opening and maintenance of a foreign account to the Czech National Bank (the "CNB"), unless the CNB notifies you specifically that such reporting is required. Upon request of the CNB, you may need to file a notification within 15 days of the end of the calendar quarter in which you acquire Shares.

#### DENMARK

#### NOTIFICATIONS

**Exchange Control Information.** If you establish an account holding Shares or an account holding cash outside Denmark, you must report the account to the Danish Tax Administration. The form which should be used in this respect can be obtained from a local bank. (These obligations are separate from and in addition to the obligations described below.)

**Securities/Tax Reporting Information.** If you hold Shares acquired under the Plan in a brokerage account with a broker or bank outside Denmark, you are required to inform the Danish Tax Administration about the account. For this purpose, you must file a Form V (*Erklaering V*) with the Danish Tax Administration. The Form V must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form V, the broker or bank undertakes to forward information to the Danish Tax Administration concerning the shares in the account without further request each year. By signing the Form V, you authorize the Danish Tax Administration to examine the account.

In addition, if you open a brokerage account (or a deposit account with a U.S. bank) for the purpose of holding cash outside Denmark, you are also required to inform the Danish Tax Administration about this account. To do so, you must file a Form K (*Erklaering K*) with the Danish Tax Administration. The Form K must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form K, the broker/bank undertakes an obligation, without further request each year, to forward information to the Danish Tax Administration concerning the content of the account. By signing the Form K, you authorize the Danish Tax Administration to examine the account.

If you exercise the Option by means of the cashless method of exercise, you are not required to file a Form V because you will not hold any Shares. However, if you open a deposit account with a foreign broker or bank to hold the cash proceeds, you are required to file a Form K as described above.

# FINLAND

There are no country-specific provisions.

#### **GERMANY**

There are no country-specific provisions.

#### GREECE

There are no country-specific provisions.

#### HONG KONG

# TERMS AND CONDITIONS

**SECURITIES WARNING:** The Option and any Shares issued in respect of the Option do not constitute a public offering of securities under Hong Kong law and are available only to members of the Board, Employees and Consultants. The Agreement, including this Appendix, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, nor have the documents been reviewed by any regulatory authority in Hong Kong. The Option and any documentation related thereto are intended solely for the personal use of each member of the Board, Employee and/or Consultant and may not be distributed to any other person. If you are in doubt about any of the contents of the Agreement, including this Appendix, or the Plan, you should obtain independent professional advice.

Sale of Shares. In the event that Shares are issued in respect of Options within six (6) months of the Grant Date, you agree that you will not dispose of such Shares prior to the six-month anniversary of the Grant Date.

#### **HUNGARY**

There are no country-specific provisions.

#### **INDIA**

#### TERMS AND CONDITIONS

**Option Exercise Restriction.** Due to legal restrictions in India, you will not be permitted to pay the exercise price for Shares subject to the Option granted hereunder by a cashless "sell-to-cover" procedure, under which method a number of Shares with a value sufficient to cover the exercise price, brokerage fees and any applicable Tax Obligations would be sold upon exercise and you would receive only the remaining Shares subject to the exercised Option. The Company reserves the right to permit this procedure for payment of the exercise price in the future, depending on the development of local law.

Fringe Benefit Tax Obligation. This provision supplements Section V of the Agreement:

By accepting the Option, you consent and agree to assume liability for any fringe benefit tax ("FBT") that may be payable by the Company and/or your Employer in connection with the Option. You understand that the grant of the Option is contingent upon your agreement to assume liability for FBT payable on the Option. Further, by accepting the Option, you agree that the Company and/or your Employer may collect the FBT from you by any of the means set forth, as applicable, in Section V(C) of the Agreement, or by any other reasonable method established by the Company. You also agree to execute promptly any other consents or elections required to accomplish the foregoing, upon request of the Company.

You understand that, for the Option granted hereunder, the FBT will be calculated based on the difference between the exercise price and the fair market value (as determined under Indian law) of the underlying Shares at the time of vesting. Therefore, no FBT will be due if the Option is not "in-the-money" at vesting. On the other hand, if the Option is in-the-money at vesting and the fair market value of the Shares decreases between vesting and exercise, you will be liable for FBT on a greater amount than the benefit you will receive at exercise.

#### NOTIFICATIONS

**Exchange Control Notification.** If you remit funds out of India to purchase Shares at exercise of the Option granted hereunder, you are responsible for complying with applicable exchange control regulations.

You must repatriate the proceeds from the sale of Shares acquired under the Plan and any dividends received in relation to the Shares to India within 90 days after receipt. You must maintain the foreign inward remittance certificate received from the bank where the foreign currency is deposited in the event that the Reserve Bank of India or your Employer requests proof of repatriation.

#### IRELAND

#### **TERMS AND CONDITIONS**

Nature of Agreement. This provision supplements Section XII of the Agreement:

In accepting the Option granted hereunder, you acknowledge your understanding and agreement that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

#### NOTIFICATIONS

**Director Notification Requirements.** If you are a director, shadow director or secretary of an Irish Affiliate, you must notify the Irish Affiliate in writing within five (5) business days of receiving or disposing of an interest in the Company (*e.g.*, an Option or Shares) in the Company, or within five (5) business days of becoming aware of the event giving rise to the notification requirement, or within five (5) business days of becoming a director or secretary if such an interest exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests, if any, will be attributed to the director, shadow director or secretary).

#### ITALY

#### **TERMS AND CONDITIONS**

**Option Cashless Exercise Restriction.** Due to legal restrictions in Italy, you will be required to pay the exercise price for any Shares subject to the Option granted hereunder by a cashless sell-all exercise, such that all Shares will be sold immediately upon exercise and the cash proceeds of sale, less the exercise price, any Tax Obligations and broker's fees or commissions, will be remitted to you. The Company reserves the right to provide additional methods of exercise depending on local developments.

Data Privacy Consent. The following provision replaces Section IX of the Agreement:

You hereby explicitly and unambiguously consent to the collection, use, processing and transfer, in electronic or other form, of your personal data as described herein by and among, as applicable, your Employer, the Company and any Affiliate for the exclusive purpose of implementing, administering, and managing your participation in the Plan.

You understand that your Employer, the Company and any Affiliate may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance (to the extent permitted under Italian law) or other identification number, salary, nationality, job title, any shares or directorships held in the Company or any Affiliate, details of all option granted, or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor, for the exclusive purpose of implementing, managing and administering the Plan ("Data").

You also understand that providing the Company with Data is necessary for the performance of the Plan and that your refusal to provide such Data would make it impossible for the Company to perform its contractual obligations and may affect your ability to participate in the Plan. The Controller of personal data processing is Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., and, pursuant to Legislative Decree no. 196/2003, its Representative in Italy for privacy purposes is Amgen Dompe S.p.A., with registered offices at Via Tazzoli, 6 – 20154 Milan, Italy.

You understand that Data will not be publicized, but it may be transferred to banks, other financial institutions, or brokers involved in the management and administration of the Plan. You understand that Data may also be transferred to the independent registered public accounting firm engaged by the Company. You further understand that the Company and/or any Affiliate will transfer Data among themselves as necessary for the purpose of implementing, administering and managing your participation in the Plan, and that the Company and/or any Affiliate may each further transfer Data to third parties assisting the Company in the implementation, administration, and management of the Plan, including any requisite transfer of Data to a broker or other third party with whom you may elect to deposit any Shares acquired at vesting of the Option. Such recipients may receive, possess, use, retain, and transfer Data in electronic or other form, for the purposes of implementing, administering, and managing your participations connected with the management and administration of the Plan, it will delete Data as soon as it has completed all the necessary legal obligations connected with the management and administration of the Plan.

You understand that Data processing related to the purposes specified above shall take place under automated or non-automated conditions, anonymously when possible, that comply with the purposes for which Data is collected and with confidentiality and security provisions, as set forth by applicable laws and regulations, with specific reference to Legislative Decree no. 196/2003.

The processing activity, including communication, the transfer of Data abroad, including outside of the European Economic Area, as herein specified and pursuant to applicable laws and regulations, does not require your consent thereto, as the processing is necessary to performance of contractual obligations related to implementation, administration, and management of the Plan. You understand that, pursuant to Section 7 of the Legislative Decree no. 196/2003, you have the right to, including but not limited to, access, delete, update, correct, or terminate, for legitimate reason, the Data processing.

Furthermore, you are aware that Data will not be used for direct-marketing purposes. In addition, Data provided can be reviewed and questions or complaints can be addressed by contacting your local human resources representative.

Acknowledgement of Nature of Agreement. By accepting the Option granted hereunder, you acknowledge that (1) you have received a copy of the Plan, the Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Agreement and this Appendix.

For the Option granted, you further acknowledge that you have read and specifically and explicitly approve, without limitation, the following Sections of the Option Agreement: Section IV, Section V, Section IX (as replaced by the above consent), Section X, Section XIII, Section XV, and Section XVIII.

# **LITHUANIA**

There are no country-specific provisions.

#### MEXICO

#### **TERMS AND CONDITIONS**

Acknowledgement of the Agreement. In accepting the Option granted hereunder, you acknowledge that you have received a copy of the Plan, have reviewed the Plan and the Option Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan and the Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section XIII of the Agreement, in which the following is clearly described and established:

- (1) Your participation in the Plan does not constitute an acquired right.
- (2) The Plan and your participation in the Plan are offered by Amgen Inc. on a wholly discretionary basis.
- (3) Your participation in the Plan is voluntary.
- (4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of the Option granted and/or Shares issued under the Plan.

Labor Law Acknowledgement and Policy Statement. In accepting the Option granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of Shares do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Latin America Services, S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the benefits that you may derive from participation in the Plan do not establish any rights between you and your employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, shareholders, officers, agents or legal representatives with respect to any claim that may arise.

#### Spanish Translation

**Reconocimiento del Otorgamiento.** Al aceptar cualquier Opción bajo el presente documento, usted reconoce que ha recibido una copia del Plan, que ha revisado el mismo en su totalidad, así como también el Acuerdo de Opción, incluyendo este Apéndice, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan y del Opción, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección XIII del Acuerdo de Opción, en los que se establece y describe claramente que:

- (1) Su participación en el Plan de ninguna manera constituye un derecho adquirido.
- (2) El Plan y su participación en el mismo son ofrecidos por Amgen Inc. de forma completamente discrecional.
- (3) Su participación en el Plan es voluntaria.
- (4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de la opción otorgada y/o de las Acciones Comunes emitidas mediante el Plan.

**Reconocimiento de la Ley Laboral y Declaración de Política.** Al aceptar cualquier Opción bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Latin America Services, S.A. de C.V. ("Amgen-México"). Derivado de lo anterior, usted reconoce expresamente que el Plan y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

# NETHERLANDS

#### NOTIFICATIONS

Securities Law Notification. You should be aware of Dutch insider-trading rules, which may impact the exercise of the Option granted hereunder and the sale of Shares acquired under the Plan. In particular, you may be prohibited from effectuating certain transactions if you have insider information regarding the Company.

By accepting the Option granted hereunder and participating in the Plan, you acknowledge having read and understood this Securities Law Notification and further acknowledge that it is your responsibility to comply with the following Dutch insider trading rules:

Under Article 46 of the Act on the Supervision of the Securities Trade 1995, anyone who has "inside information" related to the Company is prohibited from effectuating a transaction in securities in or from the Netherlands. "Inside information" is knowledge of a detail concerning the issuer to which the securities relate that is not public and which, if published, would reasonably be expected to affect the stock price, regardless of the development of the price.

Given the broad scope of the definition of inside information, certain employees of the Company working at an Affiliate in the Netherlands (including person eligible to participate in the Plan) may have inside information and, thus, would be prohibited from effectuating a transaction in securities in the Netherlands at a time when in possession of such inside information.

#### **NORWAY**

There are no country-specific provisions.

#### POLAND

#### **NOTIFICATIONS**

Exchange Control Notification. Polish residents holding foreign securities (including Shares) and maintaining accounts abroad must report information to the National Bank of Poland on transactions and balances of the securities and cash deposited in such accounts if the value of such transactions or balances exceeds €10,000. If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter. The reports are filed on special forms available on the website of the National Bank of Poland.

# PORTUGAL

#### NOTIFICATIONS

**Exchange Control Notification.** If you do not hold the Shares acquired under the Plan with a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the Shares are held by a Portuguese financial intermediary, it will file the report for you.

#### PUERTO RICO

There are no country-specific provisions.

#### **RUSSIA**

#### TERMS AND CONDITIONS

**Securities Law Requirements.** The Option granted hereunder, the Agreement, including this Appendix, the Plan and all other materials you may receive regarding your participation in the Plan or the Option granted hereunder do not constitute advertising or an offering of securities in Russia. The issuance of Shares under the Plan has not and will not be registered in Russia; therefore, such Shares may not be offered or placed in public circulation in Russia.

In no event will Shares acquired under the Plan be delivered to you in Russia; all Shares will be maintained on your behalf in the United States.

You are not permitted to sell any Shares acquired under the Plan directly to a Russian legal entity or resident.

#### **NOTIFICATIONS**

**Exchange Control Notification.** If you remit funds out of Russia to purchase Shares at exercise of the Option, the funds must be remitted from a foreign currency account in your name at an authorized bank in Russia. This requirement does not apply if you use a cashless exercise procedure such that all or part of the Shares subject to the Option granted hereunder are sold immediately upon exercise and the proceeds of sale remitted to the Company to cover the exercise price for the purchased Shares and any Tax Obligations because, in this case, there is no remittance of funds out of Russia.

With respect to any Shares acquired under the Plan, you must repatriate the proceeds from the sale of such Shares and any dividends received in relation to such shares to Russia within a reasonably short period after receipt. The sale proceeds and any dividends received must be initially credited to you through a foreign currency account opened in your name at an authorized bank in Russia. After the funds are initially received in Russia, they may be further remitted to a foreign bank subject to the following limitations: (i) the foreign account may be opened only for individuals; (ii) the foreign account may not be used for business activities; (iii) the Russian tax

authorities must be given notice about the opening/closing of each foreign account within one month of the account opening/closing; and (iv) the Russian tax authorities must be given notice of the account balances of such foreign accounts as of the beginning of each calendar year.

# <u>SLOVAKIA</u>

#### NOTIFICATIONS

**Exchange Control Information.** You are required to notify the Slovak National Bank with respect to the establishment of accounts abroad within 15 days of the end of the calendar year. The notification forms may be found at the Slovak National Bank website (<u>www.nbs.sk</u>). You should consult your personal legal advisor to determine which forms you must submit and when such forms will be due.

#### **SLOVENIA**

There are no country-specific provisions.

#### **SPAIN**

#### **TERMS AND CONDITIONS**

Labor Law Acknowledgement. The following provision supplements Section XIII of the Agreement:

By accepting the Option granted hereunder, you consent to participation in the Plan and acknowledge that you have received a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant the Option under the Plan to individuals who may be employees of the Company or its Affiliates throughout the world. The decision is a limited decision, which is entered into upon the express assumption and condition that the Option granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis other than as expressly set forth in the Agreement, including this Appendix. Consequently, you understand that the Option granted hereunder is given on the assumption and condition that it shall not become a part of any employment contract (either with the Company or any of its Affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of the Option since the future value of the Option and the underlying Shares is unknown and unpredictable. In addition, you understand that the Option granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then any grant of an Option or right to an Option shall be null and void.

#### NOTIFICATIONS

**Exchange Control Notification.** When receiving foreign currency payments derived from the ownership of Shares (*i.e.*, dividends or sale proceeds), you must inform the financial institution receiving the payment of the basis upon which such payment is made. You will need to provide the institution with the following information: (i) your name, address, and fiscal identification number; (ii) the name and corporate domicile of the Company; (iii) the amount of the payment and the currency used; (iv) the country of origin; (v) the reasons for the payment; and (vi) further information that may be required.

If you acquire Shares under the Plan and wish to import the ownership title of such Shares (*i.e.*, share certificates) into Spain, you must declare the importation of such securities to the *Direccion General de Política Comercial y de Inversiones Extranjeras* ("DGPCIE").

#### **SWEDEN**

There are no country-specific provisions.

# SWITZERLAND

#### NOTIFICATIONS

Securities Law Notification. The Option offered hereunder is considered a private offering in Switzerland and is, therefore, not subject to registration in Switzerland.

#### **UNITED ARAB EMIRATES**

There are no country-specific provisions.

#### UNITED KINGDOM

#### TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section V of the Agreement:

You agree that if you do not pay or your Employer, or the Company does not withhold from you, the full amount of Tax Obligations that you owe upon exercise of the Option, or the release or assignment of the Option for consideration, or the receipt of any other benefit in connection with the Option (the "Taxable Event") within 90 days after the Taxable Event, or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003, then the amount that should have been withheld shall constitute a loan owed by you to your Employer, effective 90 days after the Taxable Event. You agree that the loan will bear interest at the official rate of HM Revenue and Customs ("HMRC") and will be immediately due and repayable by you, and the Company and/or your Employer may recover it at any time thereafter (subject to Section V of the Agreement) by withholding such amount from salary, bonus or any other funds due to you by your Employer, by withholding in Shares issued upon exercise of the

Option or from the cash proceeds from the sale of Shares or by demanding cash or a check from you. You also authorize the Company to delay the issuance of any Shares to you unless and until the loan is repaid in full.

Notwithstanding the foregoing, if you are an officer or executive director within the meaning of Section 13(k) of the Exchange Act, as amended from time to time, the terms of the immediately foregoing provision will not apply. In the event that you are an officer or executive director and Tax Obligations are not collected from you within 90 days of the Taxable Event, the amount of any uncollected Tax Obligations may constitute a benefit to you on which additional income tax and national insurance contributions may be payable. You acknowledge that the Company and/or your Employer may recover any such additional income tax and national insurance contributions at any time thereafter by any of the means referred to in Section V of the Agreement.

**Joint Election.** As a condition of the Option granted hereunder, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs"), which may be payable by the Company or your Employer with respect to the exercise of the Option and issuance of Shares subject to the Option, the assignment or release of the Option for consideration, or the receipt of any other benefit in connection with the Option.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for your Employer NICs payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorize the Company and your Employer to withhold such Employer NICs by any of the means set forth in Section V of the Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Option, without any liability to the Company or your Employer.

#### UNITED STATES

#### TERMS AND CONDITIONS

**Nature of Grant.** The following provision replaces Section IV(B)(1) of the Agreement:

(1) "termination of your employment" shall mean the last date you are either an active employee of the Company or an Affiliate or actively engaged as a consultant or director to the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive options and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed; *provided, however*, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar

periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave. Your right, if any, to exercise the options after termination of employment will be measured by the date of termination of your active employment; *provided*, *however*, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave, unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave;

#### Form of Award Notice

[The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website ]

This notice of Award (the "<u>Award Notice</u>") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Agreement that accompanies this Award Notice and made of part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee: Employee ID: Address: Award Type: Grant ID: Plan: Grant Date: Grant Price: Number of Shares: Number of Units Expiration Date: Vesting Date: Vesting Schedule: Vesting Details:

Amgen Inc. 2009 Equity Incentive Plan

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The [\_\_\_\_\_\_(\_th)] anniversary of the date of this Award Means the vesting date indicated in the Vesting Schedule Means the schedule of vesting set forth under Vesting Details Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting.

#### RESTRICTED STOCK UNIT AGREEMENT

# THE SPECIFIC TERMS OF YOUR GRANT OF RESTRICTED STOCK UNITS ARE FOUND IN THE PAGES RELATING TO THE GRANT OF RESTRICTED STOCK UNITS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE <u>"AWARD NOTICE</u>") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS RESTRICTED STOCK UNIT AGREEMENT.

On the Grant Date specified in the Award Notice, Amgen Inc., a Delaware corporation (the "<u>Company</u>"), has granted to you, the grantee named in the Award Notice, under the plan specified in the Award Notice (the "<u>Plan</u>"), the Number of Units with respect to the number of shares of the \$.0001 par value common stock of the Company (the "<u>Shares</u>") specified in the Award Notice, on the terms and conditions set forth in this Restricted Stock Unit Agreement, any special terms and conditions for your country set forth in the attached <u>Appendix A</u> and the Award Notice (together, the "<u>Agreement</u>"). The Units shall constitute Restricted Stock Units under Section 9.5 of the Plan, which is incorporated herein by reference. Capitalized terms not defined herein shall have the meanings assigned to such terms in the Plan.

#### I. <u>Vesting Schedule and Termination of Units</u>.

a. *General.* Subject to the terms and conditions of this Agreement, on each Vesting Date, the Number of Units indicated on the Vesting Schedule shall vest, provided that you have remained continuously and actively employed with the Company or an Affiliate (as defined in the Plan) through each applicable Vesting Date, unless (i) your employment has terminated due to your Voluntary Termination (as defined in paragraph (d) of this Section I below), (ii) a Change of Control (as defined below) occurs, or (iii) as otherwise determined by the Company in the exercise of its discretion as provided in paragraph (f) of this Section I. The Units represent an unfunded, unsecured promise by the Company to deliver Shares. Only whole Shares shall be issued upon vesting of the Units, and the Company shall be under no obligation to issue any fractional Shares to you. If your employment with the Company or an Affiliate is terminated for any reason or for no reason, including if your active employment is terminated by the Company or an Affiliate, except as otherwise provided in paragraphs (b), (c), (d), (e) or (f) of this Section I below, your unvested Units shall automatically expire and terminate on the date of termination of your active employment. Notwithstanding anything herein to the contrary, the Vesting Schedule may be accelerated (by notice in writing) by the Company in its sole discretion at any time during the term of the Units. In addition, if not prohibited by local law, vesting may be suspended by the Company in its sole discretion during a leave of absence as provided from time to time according to Company policies and practices.

- b. *Permanent and Total Disability.* Notwithstanding the provisions in paragraph (a) above, if your employment with the Company or an Affiliate terminates due to your Permanent and Total Disability (as defined below), then the vesting of Units granted under this Agreement shall be accelerated, subject to your execution of a general release and waiver in a form provided by the Company, to vest as of the day immediately preceding such termination of your employment with respect to all Units granted hereunder, except that if the Units were granted in the calendar year in which such termination occurs, the Units shall be accelerated to vest with respect to a number of Units equal to the number of Units subject to this Agreement multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12).
- c. Death. Notwithstanding the provisions in paragraph (a) above, if your employment with the Company or an Affiliate terminates due to your death, then the vesting of Units granted under this Agreement shall be accelerated to vest as of the day immediately preceding your death with respect to all Units granted hereunder, except that if the Units were granted in the calendar year in which your death occurs the Units shall be accelerated to vest with respect to a number of Units equal to the number of Units subject to this Agreement multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12).
- d. *Retirement*. Notwithstanding the provisions in paragraph (a) above, if you terminate your employment with the Company or an Affiliate due to your voluntary termination (and such voluntary termination is not the result of Permanent and Total Disability (as defined below)) after you are at least sixty-five (65) years of age, or after you are at least fifty-five (55) years of age and have been an employee of the Company and/or an Affiliate for at least ten (10) consecutive years ("<u>Voluntary Termination</u>"), then the Units will vest pursuant to the Vesting Schedule without regard to the termination of employment prior to the Vesting Date, subject to your execution of a general release and waiver in a form provided by the Company, with respect to all Units granted hereunder; provided, however, that if the Units were granted in the calendar year in which the Voluntary Termination occurs, the Units will vest pursuant to the Vesting Schedule provided in the Award Notice only with respect to a number of Units equal to the number of Units subject to this Agreement multiplied by a fraction, the numerator of which is the number of complete months you remained continuously and actively employed during such calendar year, and the denominator of which is twelve (12); notwithstanding the definition of Voluntary Termination set forth above, if the Company receives an opinion of counsel that there has been a legal judgment and/or legal development in your jurisdiction that would likely result in the favorable treatment upon Voluntary Termination described above being deemed unlawful and/or discriminatory, then the Committee will not apply the favorable treatment described above.

- e. *Change of Control*. Notwithstanding the provisions in paragraph (a) above, in the event of a Change of Control (as defined below), then, to the extent permitted by applicable law, the vesting of Units granted under this Agreement shall be accelerated as of immediately prior to the Change of Control. Upon and following the acceleration of the vesting period, if the surviving or acquiring corporation agrees to assume the Units or substitute similar awards, then at your election the Units may be either assumed or replaced with substitute awards. The Board or the Committee, in its sole discretion, may cause any such assumption or substitution to be conducted in a manner so as not to constitute an "extension," "renewal" or "modification" (each within the meaning of Section 409A of the U.S. Internal Revenue Code of 1986, as amended from time to time (together with the regulations and other official guidance promulgated thereunder, the "<u>Code</u>")) of any such Units that would cause any such Units to be considered "nonqualified deferred compensation" (within the meaning of Section 409A of the Code).
- f. *Continued Vesting*. Notwithstanding the provisions in paragraph (a) above, the Company may in its sole discretion at any time during the term of this Agreement, in writing, otherwise provide that the Units will vest pursuant to the Vesting Schedule without regard to the termination of employment prior to the Vesting Date, subject to any terms and conditions that the Company may determine.

#### For purposes of this Agreement:

(i) "termination of your active employment" shall mean the last date that you are either an active employee of the Company or an Affiliate or actively engaged as a Consultant or Director of the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Units and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed and will not be extended by any notice period mandated under local law (*e.g.*, active employment would not include a period of "garden leave" or similar period pursuant to local law);

(ii) "<u>Permanent and Total Disability</u>" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of your employment by (i) the U.S. Social Security Administration, (ii) the comparable governmental authority applicable to an Affiliate, (iii) such other body having the relevant decision-making power applicable to an Affiliate, or (iv) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case. Units that remain unvested as of the date of termination of your employment; and

#### (iii) "<u>Change of Control</u>" shall mean the occurrence of any of the following:

(A) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act)

of fifty percent (50%) or more of either the then-outstanding Shares or the combined voting power of the Company's then-outstanding voting securities entitled to vote generally in the election of directors; or

(B) individuals who, as of April 2, 1991, constitute the Board (the "<u>Incumbent Board</u>") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to April 2, 1991, whose election, or nomination for election by the Company's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board (other than an election or nomination of an individual whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of the Directors of the Company, as such terms are used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) shall be, for purposes of the Plan, considered as though such person were a member of the Incumbent Board; or

(C) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then-outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company; or

(D) any other event which the Incumbent Board, in its sole discretion, determines shall constitute a Change of Control.

Notwithstanding anything herein or in the Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Unit that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (A), (B), (C) or (D) must also constitute a "change in control event," as defined in U.S. Treasury Regulation § 1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Unit.

II. <u>Form and Timing of Payment</u>. Subject to satisfaction of tax or similar obligations as provided for in Section III, any vested Units shall be paid by the Company in Shares (on a one-to-one basis) on, or as soon as practicable after, the applicable Vesting Date (which, for purposes of this Section II, includes the date of any accelerated vesting under Sections I(b), (c), (d), (e) or (f) above); <u>provided</u>, <u>however</u>, that in no event shall the payment be made after the close of your taxable year which includes the applicable Vesting Date or, if later, after the 15<sup>th</sup> day of the third calendar month following the applicable Vesting Date. Shares issued in respect of a Unit shall be deemed to be issued in consideration of past services actually rendered by you to the Company or an Affiliate or for its benefit for which you have not previously been compensated or for future services to be rendered, as the case may be, which the Company deems to have a value at least equal to the aggregate par value thereof.

III. <u>Tax Withholding; Issuance of Certificates</u>. Regardless of any action the Company or your actual employer (the "<u>Employer</u>") takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, payment on account or other tax-

related items related to your participation in the Plan and legally applicable to you ("<u>Tax Obligations</u>"), you acknowledge that the ultimate liability for all Tax Obligations is and remains your responsibility and may exceed the amount actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer (i) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Units, including the grant of the Units, the vesting of Units, the conversion of the Units into Shares or the receipt of an equivalent cash payment, the subsequent sale of any Shares acquired at vesting and the receipt of any dividends, and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Units to reduce or eliminate your liability for Tax Obligations or achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

Prior to any relevant taxable or tax withholding event, as applicable, you shall pay, or make adequate arrangements satisfactory to the Company or to your Employer (in their sole discretion) to satisfy all Tax Obligations. In this regard, you authorize the Company and/or your Employer or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

- (a) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer; or
- (b) withholding from proceeds of the sale of Shares acquired upon vesting or payment of the Units either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization); or
- (c) withholding in Shares to be issued upon vesting or payment of the Units, provided that the Company and your Employer shall only withhold an amount of Shares with a fair market value equal to the Tax Obligations.

To avoid adverse accounting treatment, the Company may withhold or account for Tax Obligations not to exceed the applicable minimum statutory withholding rates or other applicable withholding rates. If the Tax Obligations are satisfied by withholding in Shares, for tax purposes, you are deemed to have been issued the full number of Shares subject to the vested Units, notwithstanding that a number of the Shares is held back solely for the purpose of paying the Tax Obligations due as a result of any aspect of your participation in the Plan (any Shares withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Plan and shall remain available for issuance thereunder).

Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be satisfied by the means previously described. You agree to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section III. Notwithstanding Section II above, the Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares if you fail to comply with your obligations in connection with the Tax Obligations.

IV. <u>Transferability</u>. No benefit payable under, or interest in, this Agreement or in the Shares that are scheduled to be issued to you hereunder shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, your or your beneficiary's debts, contracts, liabilities or torts; <u>provided, however</u>, nothing in this Section IV shall prevent transfer (i) by will or (ii) by applicable laws of descent and distribution.

V. <u>Notices</u>. Any notices provided for in this Agreement or the Plan shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

VI. <u>Plan</u>. This Agreement is subject to all the provisions of the Plan, which provisions are hereby made a part of this Agreement, including without limitation the provisions of Section 9.5 of the Plan relating to Restricted Stock Units, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Agreement and those of the Plan, the provisions of the Plan shall control.

VII. <u>Governing Law</u>. The terms of this Agreement shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Agreement is made and/or to be performed.

VIII. <u>Code Section 409A</u>. The time and form of payment of the Units is intended to comply with the requirements of Code Section 409A and this Agreement shall be interpreted in accordance with Code Section 409A and U.S. Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date. Notwithstanding any provision herein to the contrary, in the event that following the Grant Date, the Committee (as defined in the Plan) determines that it may be necessary or appropriate to do so, the Committee may adopt such amendments to the Plan and/or this Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or appropriate to (a) exempt the Plan and/or the Units from the application of Code Section 409A and/or preserve the intended tax treatment of the benefits

provided with respect to this Award, or (b) comply with the requirements of Code Section 409A; <u>provided</u>, <u>however</u>, that this paragraph shall not create an obligation on the part of the Committee to adopt any such amendment, policy or procedure or take any such other action.

IX. <u>Acknowledgement</u>. By electing to accept this Agreement, you acknowledge receipt of this Agreement and hereby confirm your understanding that the terms set forth in this Agreement constitute, subject to the terms of the Plan, which terms shall control in the event of any conflict between the Plan and this Agreement, the entire agreement and understanding of the parties with respect to the matters contained herein and supersede any and all prior agreements, arrangements and understandings, both oral and written, between the parties concerning the subject matter of this Agreement. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

X. Acknowledgment of Nature of Plan and Units. In accepting this Agreement, you acknowledge that:

- (a) the Plan is established voluntarily by the Company, is discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan;
- (b) the grant of the Units is voluntary and occasional and does not create any contractual or other right to receive future awards of Units, or benefits in lieu of Units even if Units have been awarded repeatedly in the past;
- (c) all decisions with respect to future Awards, if any, will be at the sole discretion of the Company;
- (d) your participation in the Plan is voluntary;
- (e) for labor law purposes outside the United States, Units are an extraordinary item that do not constitute wages of any kind for services of any kind rendered to the Company or to your Employer, and the grant of Units is outside the scope of your employment contract, if any;
- (f) for labor law purposes outside the United States, the grant of Units and the Shares subject to the Units are not part of normal or expected wages or salary for any purposes, including, but not limited to, calculation of any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar payments;
- (g) the grant of Units and the Shares subject to the Units are not intended to replace any pension rights or compensation;

- (h) neither the grant of Units nor any provision of this Agreement, the Plan or the policies adopted pursuant to the Plan confer upon you any right with respect to employment or continuation of current employment and shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;
- (i) the future value of the underlying Shares is unknown and cannot be predicted with certainty;
- (j) in consideration of the grant of Units hereunder, no claim or entitlement to compensation or damages arises from termination of Units, and no claim or entitlement to compensation or damages shall arise from forfeiture of the Units resulting from termination of your employment by the Company or an Affiliate (for any reason whatsoever and whether or not in breach of local labor laws) and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim; and
- (k) except as otherwise provided in this Agreement or the Plan, the Units and the benefits under the Plan, if any, will not automatically transfer to another company in case of a merger, takeover or transfer of liability.

XI. <u>No Advice Regarding Award</u>. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

XII. <u>Compliance with Laws</u>. Notwithstanding any provision of this Agreement to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached Appendix A (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached <u>Appendix A</u>, the Units granted hereunder shall be subject to any special terms and conditions for your country set forth in <u>Appendix A</u> and to the following additional terms and conditions:

- a. the terms and conditions of this Agreement, including <u>Appendix A</u>, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration of the Plan;
- b. if applicable, the effectiveness of your award of Units is conditioned upon its compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals;
- c. to the extent necessary to comply with applicable foreign laws, the payment of any earned Units shall be made in cash or Common Stock, at the Company's election; and

d. the Company may take any other action, before or after an award of Units is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding the foregoing, the Company may not take any actions hereunder, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation, or the rules of any Securities Exchange. Notwithstanding anything to the contrary contained herein, the Shares issuable upon vesting of the Unit shall not be issued unless such Shares are then registered under the Securities Act, or, if such Shares are not then so registered, the Company has determined that such vesting and issuance would be exempt from the registration requirements of the Securities Act.

XIII. <u>Data Privacy and Notice of Consent</u>. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement by and among, as applicable, your Employer, the Company, and Affiliates of the Company for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and your Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number (to the extent permitted under applicable local law) or other identification number, salary, nationality, job title, residency status, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, canceled, vested, unvested or outstanding in your favor, for the purpose of implementing, administering and managing the Plan ("Data"). You understand that Data may be transferred to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, or any third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in your country or elsewhere, including outside the European Economic Area and that the recipient's country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize your Employer, the Company, Affiliates of the Company, Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing your participation in the Plan, including any requisite transfer of such Data as may be required to any other broker, escrow agent or other third party with whom the Shares received upon vesting of the Units may be deposited. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. You understand that refusal or withdrawal of consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

XIV. <u>Severability</u>. If one or more of the provisions of this Agreement shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and the invalid, illegal or unenforceable provisions shall be deemed null and void; however, to the extent permissible by law, any provisions which could be deemed null and void shall first be construed, interpreted or revised retroactively to permit this Agreement to be construed so as to foster the intent of this Agreement and the Plan.

XV. <u>Language</u>. If you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

XVI. <u>Imposition of Other Requirements</u>. The Company reserves the right to impose other requirements on your participation in the Plan, on the Units and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable in order to comply with local law or facilitate the administration of the Plan, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

XVII. <u>Compensation Subject to Recovery</u>. The Units subject to this Award and all compensation payable with respect to them shall be subject to recovery by the Company pursuant to any and all of the Company's policies with respect to the recovery of compensation, as they shall be in effect and may be amended from time to time, to the maximum extent permitted by applicable law.

Very truly yours, AMGEN INC.

By:

Name: Title:

#### APPENDIX A

#### ADDITIONAL TERMS AND CONDITIONS OF THE AMGEN INC. 2009 EQUITY INCENTIVE PLAN

## GRANT OF RESTRICTED STOCK UNITS (BY COUNTRY)

#### TERMS AND CONDITIONS

This Appendix includes additional terms and conditions that govern any Units granted under the Plan <u>if, under applicable law, you are a resident of, or are</u> <u>deemed to be a resident of one of the countries listed below. Furthermore, the additional terms and conditions that govern any Units granted hereunder</u> <u>may apply to you if you relocate to one of the countries listed below</u>. Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix is attached.

#### **NOTIFICATIONS**

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of February 1, 2009. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you vest in the Units and acquire Shares under the Plan, or when you subsequently sell Shares acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently working, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

#### AUSTRALIA

## **TERMS AND CONDITIONS**

**Units Payable Only in Shares.** Notwithstanding any discretion in the Plan or anything to the contrary in the Agreement, the Units do not provide any right for you to receive a cash payment and shall be paid in Shares only.

# <u>AUSTRIA</u>

#### NOTIFICATIONS

**Consumer Protection Notification.** You may be entitled to revoke acceptance of any Units granted under the Plan on the basis of the Austrian Consumer Protection Act (the "Act") under the conditions listed below, if the Act is considered to be applicable to the Agreement and the Plan:

- (i) If you accept the Units outside the business premises of the Company, you may be entitled to revoke your acceptance of the Units, provided the revocation is made within one (1) week after such acceptance of the Units.
- (ii) The revocation must be in written form to be valid. It is sufficient if you return the Agreement to the Company or the Company's representative with language which can be understood as a refusal to conclude or honor the Agreement, provided the revocation is sent within the period discussed above.

**Exchange Control Notification.** When you sell Shares acquired under the Plan, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad exceeds  $\notin$ 3,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/oder SI-Verpflichtungen*).

#### **BELGIUM**

#### **NOTIFICATIONS**

**Tax Reporting Notification.** You are required to report any taxable income attributable to the Units granted hereunder on your annual tax return. You are also required to report any bank accounts opened and maintained outside Belgium on your annual tax return.

## **CANADA**

#### **TERMS AND CONDITIONS**

**Termination of Employment.** Section I(i) of the Agreement is amended to read as follows:

(i) "termination of your active employment" shall mean the last date that you are either an active employee of the Company or an Affiliate or actively engaged as a Consultant or Director of the Company or an Affiliate; in the event of involuntary termination of your employment (whether or not in breach of local labor laws), your right to receive any Units and vest under the Plan, if any, will terminate effective as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Company or your Employer, or (2) the date you are no longer actively employed by the Company or your Employer regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to

statutory law, regulatory law and/or common law). Your right, if any, to acquire Shares pursuant to the Units after termination of employment will be measured by the date of termination of your active employment and will not be extended by any notice period mandated under local law.

## The following provisions will apply to you if you are a resident of Quebec:

Language Consent. The parties acknowledge that it is their express wish that the Agreement, as well as all documents, notices, and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de cette convention ("Agreement"), ainsi que de tous documents exécutés, avis donnés et procédures judiciaries intentées, directement ou indirectement, relativement à ou suite à la présente convention.

#### Data Privacy Notice and Consent. This provision supplements Section XIII of the Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration and operation of the Plan. You further authorize the Company and your Employer to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your employee file.

## CZECH REPUBLIC

## NOTIFICATIONS

**Exchange Control Notification.** Proceeds from the sale of Shares may be held in a cash account abroad and you are no longer required to report the opening and maintenance of a foreign account to the Czech National Bank (the "CNB"), unless the CNB notifies you specifically that such reporting is required. Upon request of the CNB, you may need to file a notification within 15 days of the end of the calendar quarter in which you acquire Shares.

#### **DENMARK**

#### **NOTIFICATIONS**

**Exchange Control Information.** If you establish an account holding Shares or an account holding cash outside Denmark, you must report the account to the Danish Tax Administration. The form which should be used in this respect can be obtained from a local bank. (These obligations are separate from and in addition to the obligations described below.)

**Securities/Tax Reporting Information.** If you hold Shares acquired under the Plan in a brokerage account with a broker or bank outside Denmark, you are required to inform the Danish Tax Administration about the account. For this purpose, you must file a Form V (*Erklaering V*) with the Danish Tax Administration. The Form V must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form V, the broker or bank

undertakes to forward information to the Danish Tax Administration concerning the shares in the account without further request each year. By signing the Form V, you authorize the Danish Tax Administration to examine the account.

In addition, if you open a brokerage account (or a deposit account with a U.S. bank) for the purpose of holding cash outside Denmark, you are also required to inform the Danish Tax Administration about this account. To do so, you must file a Form K (*Erklaering K*) with the Danish Tax Administration. The Form K must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form K, the broker/bank undertakes an obligation, without further request each year, to forward information to the Danish Tax Administration concerning the content of the account. By signing the Form K, you authorize the Danish Tax Administration to examine the account.

## **GERMANY**

There are no country-specific provisions.

## **GREECE**

There are no country-specific provisions.

## HONG KONG

# TERMS AND CONDITIONS

**SECURITIES WARNING:** The Units and any Shares issued in respect of the Units do not constitute a public offering of securities under Hong Kong law and are available only to members of the Board, Employees and Consultants. The Agreement, including this Appendix, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, nor have the documents been reviewed by any regulatory authority in Hong Kong. The Units and any documentation related thereto are intended solely for the personal use of each member of the Board, Employee and/or Consultant and may not be distributed to any other person. If you are in doubt about any of the contents of the Agreement, including this Appendix, or the Plan, you should obtain independent professional advice.

**Units Payable Only in Shares.** Notwithstanding any discretion in the Plan or anything to the contrary in the Agreement, the Units do not provide any right for you to receive a cash payment and shall be paid in Shares only.

**Sale of Shares.** In the event that Shares are issued in respect of the Units within six (6) months of the Grant Date, you agree that you will not dispose of the Shares prior to the six (6)-month anniversary of the Grant Date.

## HUNGARY

There are no country-specific provisions.

# <u>INDIA</u>

# **TERMS AND CONDITIONS**

Fringe Benefit Tax Obligation. This provision supplements Section III of the Agreement:

By accepting the Units, you consent and agree to assume liability for any fringe benefit tax ("FBT") that may be payable by the Company and/or your Employer in connection with the Units. You understand that the grant of any Units is contingent upon your agreement to assume liability for FBT payable on the Units. Further, by accepting the Units, you agree that the Company and/or your Employer may collect the FBT from you by any of the means set forth, as applicable, in Section III of the Agreement, or by any other reasonable method established by the Company. You also agree to execute promptly any other consents or elections required to accomplish the foregoing, upon request of the Company.

# NOTIFICATIONS

**Exchange Control Notification.** You must repatriate the proceeds from the sale of Shares acquired under the Plan and any dividends received in relation to the Shares to India within 90 days after receipt. You must maintain the foreign inward remittance certificate received from the bank where the foreign currency is deposited in the event that the Reserve Bank of India or your Employer requests proof of repatriation.

## **IRELAND**

## TERMS AND CONDITIONS

Nature of Agreement. This provision supplements Section X of the Agreement:

In accepting any Units granted hereunder, you understand and agree that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

## NOTIFICATIONS

**Director Notification Requirements.** If you are a director, shadow director or secretary of an Irish Affiliate, you must notify the Irish Affiliate in writing within five (5) business days of receiving or disposing of an interest in the Company (*e.g.*, the Units or Shares) in the Company, or within five (5) business days of becoming aware of the event giving rise to the notification requirement, or within five (5) business days of becoming a director or secretary if such an interest exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests, if any, will be attributed to the director, shadow director or secretary).

## ITALY

# TERMS AND CONDITIONS

Data Privacy Consent. The following provision replaces Section XIII of the Agreement:

You hereby explicitly and unambiguously consent to the collection, use, processing and transfer, in electronic or other form, of your personal data as described herein by and among, as applicable, your Employer, the Company and any Affiliate for the exclusive purpose of implementing, administering, and managing your participation in the Plan.

You understand that your Employer, the Company and any Affiliate may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance (to the extent permitted under Italian law) or other identification number, salary, nationality, job title, any shares or directorships held in the Company or any Affiliate, details of all Awards granted, or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor, for the exclusive purpose of implementing, managing and administering the Plan ("Data").

You also understand that providing the Company with Data is necessary for the performance of the Plan and that your refusal to provide such Data would make it impossible for the Company to perform its contractual obligations and may affect your ability to participate in the Plan. The Controller of personal data processing is Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., and, pursuant to Legislative Decree no. 196/2003, its Representative in Italy for privacy purposes is Amgen Dompe S.p.A., with registered offices at Via Tazzoli, 6 – 20154 Milan, Italy.

You understand that Data will not be publicized, but it may be transferred to banks, other financial institutions, or brokers involved in the management and administration of the Plan. You understand that Data may also be transferred to the independent registered public accounting firm engaged by the Company. You further understand that the Company and/or any Affiliate will transfer Data among themselves as necessary for the purposes of implementing, administering and managing your participation in the Plan, and that the Company and/or any Affiliate may each further transfer Data to third parties assisting the Company in the implementation, administration, and management of the Plan, including any requisite transfer of Data to a broker or other third party with whom you may elect to deposit any Shares acquired at vesting of the Units. Such recipients may receive, possess, use, retain, and transfer Data in electronic or other form, for the purposes of implementing, administering, and managing your participation is the European Economic Area, such as in the United States or elsewhere. Should the Company exercise its discretion in suspending all necessary legal obligations connected with the management and administration of the Plan.

You understand that Data processing related to the purposes specified above shall take place under automated or non-automated conditions, anonymously when possible, that comply with the purposes for which Data is collected and with confidentiality and security provisions, as set forth by applicable laws and regulations, with specific reference to Legislative Decree no. 196/2003.

The processing activity, including communication, the transfer of Data abroad, including outside of the European Economic Area, as herein specified and pursuant to applicable laws and regulations, does not require your consent thereto, as the processing is necessary to performance of contractual obligations related to implementation, administration, and management of the Plan. You understand that, pursuant to Section 7 of the Legislative Decree no. 196/2003, you have the right to, including but not limited to, access, delete, update, correct, or terminate, for legitimate reason, the Data processing.

Furthermore, you are aware that Data will not be used for direct-marketing purposes. In addition, Data provided can be reviewed and questions or complaints can be addressed by contacting your local human resources representative.

Acknowledgement of Nature of Agreement. By accepting any Units granted hereunder, you acknowledge that (1) you have received a copy of the Plan, the Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Agreement and this Appendix.

For any Units granted, you further acknowledge that you have read and specifically and explicitly approve, without limitation, the following sections of the Agreement: Section I; Section II, Section IX, Section X, Section XIII (as replaced by the above consent), Section XV and Section XVI.

## **LITHUANIA**

There are no country-specific provisions.

## **MEXICO**

## TERMS AND CONDITIONS

Acknowledgement of the Agreement. In accepting the Award granted hereunder, you acknowledge that you have received a copy of the Plan, have reviewed the Plan and the Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan and the Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section X of the Agreement, in which the following is clearly described and established:

(1) Your participation in the Plan does not constitute an acquired right.

- (2) The Plan and your participation in the Plan are offered by Amgen Inc. on a wholly discretionary basis.
- (3) Your participation in the Plan is voluntary.
- (4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of the option granted and/or Shares issued under the Plan.

Labor Law Acknowledgement and Policy Statement. In accepting any Award granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of Shares do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Latin America Services, S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the benefits that you may derive from participation in the Plan do not establish any rights between you and your employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, shareholders, officers, agents or legal representatives with respect to any claim that may arise.

#### Spanish Translation

**Reconocimiento del Otorgamiento.** Al aceptar cualquier Otorgamiento bajo el presente documento, usted reconoce que ha recibido una copia del Plan, que ha revisado el mismo en su totalidad, así como también el Acuerdo de Opción, el Acuerdo, incluyendo este Apéndice, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan y del Otorgamiento, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección X del Acuerdo, en los que se establece y describe claramente que:

- (1) Su participación en el Plan de ninguna manera constituye un derecho adquirido.
- (2) El Plan y su participación en el mismo son ofrecidos por Amgen Inc. de forma completamente discrecional.

- (3) Su participación en el Plan es voluntaria.
- (4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de las Acciones Comunes emitidas mediante el Plan.

**Reconocimiento de la Ley Laboral y Declaración de Política.** Al aceptar cualquier Otorgamiento de Acciones bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Latin America Services, S.A. de C.V. ("Amgen-México"). Derivado de lo anterior, usted reconoce expresamente que el Plan y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

## NETHERLANDS

#### **NOTIFICATIONS**

Securities Law Notification. You should be aware of Dutch insider-trading rules, which may impact the sale of Shares acquired under the Plan. In particular, you may be prohibited from effectuating certain transactions if you have insider information regarding the Company.

By accepting any Units granted hereunder and participating in the Plan, you acknowledge having read and understood this Securities Law Notification and further acknowledge that it is your responsibility to comply with the following Dutch insider trading rules:

Under Article 46 of the Act on the Supervision of the Securities Trade 1995, anyone who has "inside information" related to the Company is prohibited from effectuating a transaction in securities in or from the Netherlands. "Inside information" is knowledge of a detail concerning

the issuer to which the securities relate that is not public and which, if published, would reasonably be expected to affect the stock price, regardless of the development of the price.

Given the broad scope of the definition of inside information, certain employees of the Company working at an Affiliate in the Netherlands (including persons eligible to participate in the Plan) may have inside information and, thus, would be prohibited from effectuating a transaction in securities in the Netherlands at a time when in possession of such inside information.

## NORWAY

There are no country-specific provisions.

## POLAND

## NOTIFICATIONS

Exchange Control Notification. Polish residents holding foreign securities (including Shares) and maintaining accounts abroad must report information to the National Bank of Poland on transactions and balances of the securities and cash deposited in such accounts if the value of such transactions or balances exceeds €10,000. If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter. The reports are filed on special forms available on the website of the National Bank of Poland.

## PORTUGAL

## **NOTIFICATIONS**

**Exchange Control Notification.** If you do not hold the Shares acquired under the Plan with a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the Shares are held by a Portuguese financial intermediary, it will file the report for you.

## PUERTO RICO

There are no country-specific provisions.

## **RUSSIA**

## TERMS AND CONDITIONS

**Securities Law Requirements.** Any Units granted hereunder, the Agreement, including this Appendix, the Plan and all other materials you may receive regarding your participation in the Plan or any Units granted hereunder do not constitute advertising or an offering of securities in Russia. The issuance of Shares under the Plan has not and will not be registered in Russia; therefore, Shares may not be offered or placed in public circulation in Russia.

In no event will Shares acquired under the Plan be delivered to you in Russia; all Shares will be maintained on your behalf in the United States.

You are not permitted to sell any Shares acquired under the Plan directly to a Russian legal entity or resident.

#### **NOTIFICATIONS**

**Exchange Control Notification.** You must repatriate the proceeds from the sale of Shares and any dividends received in relation to such Shares to Russia within a reasonably short period after receipt. The sale proceeds and any dividends received in relation to Shares must be initially credited to you through a foreign currency account opened in your name at an authorized bank in Russia. After the funds are initially received in Russia, they may be further remitted to a foreign bank subject to the following limitations: (i) the foreign account may be opened only for individuals; (ii) the foreign account may not be used for business activities; (iii) the Russian tax authorities must be given notice about the opening/closing of each foreign account within one month of the account opening/closing; and (iv) the Russian tax authorities must be given notice of the account balances of such foreign accounts as of the beginning of each calendar year.

#### **SLOVAKIA**

#### **NOTIFICATIONS**

**Exchange Control Information.** You are required to notify the Slovak National Bank with respect to the establishment of accounts abroad within 15 days of the end of the calendar year. The notification forms may be found at the Slovak National Bank website (<u>www.nbs.sk</u>). You should consult your personal legal advisor to determine which forms you must submit and when such forms will be due.

#### **SLOVENIA**

There are no country-specific provisions.

#### **SPAIN**

#### TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section X of the Agreement:

By accepting the Units granted hereunder, you consent to participation in the Plan and acknowledge that you have received a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant any Units under the Plan to individuals who may be members of the Board, Employees or Consultants of the Company or its Affiliates throughout the world. The decision is a limited

decision, which is entered into upon the express assumption and condition that any Units granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis, other than as expressly set forth in the Agreement, including this Appendix. Consequently, you understand that the Units granted hereunder are given on the assumption and condition that they shall not become a part of any employment contract (either with the Company or any of its Affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of Units since the future value of the Units and the underlying Shares is unknown and unpredictable. In addition, you understand that any Units granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then any grant of Units or right to Units shall be null and void.

## NOTIFICATIONS

**Exchange Control Notification.** When receiving foreign currency payments derived from the ownership of Shares (*i.e.*, dividends or sale proceeds), you must inform the financial institution receiving the payment of the basis upon which such payment is made. You will need to provide the institution with the following information: (i) your name, address, and fiscal identification number; (ii) the name and corporate domicile of the Company; (iii) the amount of the payment and the currency used; (iv) the country of origin; (v) the reasons for the payment; and (vi) further information that may be required.

If you acquire Shares under the Plan and wish to import the ownership title of such Shares (i.e., share certificates) into Spain, you must declare the importation of such securities to the Direccion General de Política Comercial y de Inversiones Extranjeras ("DGPCIE").

## SWEDEN

There are no country-specific provisions.

## **SWITZERLAND**

## NOTIFICATIONS

Securities Law Notification. The Units offered hereunder are considered a private offering in Switzerland and are, therefore, not subject to registration in Switzerland.

## **UNITED ARAB EMIRATES**

There are no country-specific provisions.

## UNITED KINGDOM

## TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section III of the Agreement:

You agree that if you do not pay or your Employer or the Company does not withhold from you the full amount of Tax Obligations that you owe at issuance of Shares in respect of the Units, or the release or assignment of the Units for consideration, or the receipt of any other benefit in connection with the Units (the "Taxable Event") within 90 days after the Taxable Event, or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003, then the amount that should have been withheld and/or paid shall constitute a loan owed by you to your Employer, effective 90 days after the Taxable Event. You agree that the loan will bear interest at the official rate of HM Revenue and Customs ("HMRC") and will be immediately due and repayable by you, and the Company and/or your Employer may recover it at any time thereafter (subject to Section III of the Agreement) by withholding the funds from salary, bonus or any other funds due to you by your Employer, by withholding in Shares issued in respect of the Units or from the cash proceeds from the sale of Shares or by demanding cash or a check from you. You also authorize the Company to delay the issuance of any Shares to you unless and until the loan is repaid in full.

Notwithstanding the foregoing, if you are an officer or executive director within the meaning of Section 13(k) of the Exchange Act, as amended from time to time, the terms of the immediately foregoing provision will not apply. In the event that you are an officer or executive director and Tax Obligations are not collected from you within 90 days of the Taxable Event, the amount of any uncollected Tax Obligations may constitute a benefit to you on which additional income tax and national insurance contributions may be payable. You acknowledge that the Company and/or your Employer may recover any such additional income tax and national insurance contributions at any time thereafter by any of the means referred to in Section III of the Agreement.

**Joint Election.** As a condition of the Units granted hereunder, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs"), which may be payable by the Company or your Employer with respect to the Units and/or payment of the Units and issuance of Shares pursuant to the Units, the assignment or release of the Units for consideration, or the receipt of any other benefit in connection with the Units.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for your Employer NICs payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorize the Company and your Employer to withhold such Employer NICs by any of the means set forth in Section III of the Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Units, without any liability to the Company or your Employer.

## UNITED STATES

## TERMS AND CONDITIONS

Nature of Grant. The following provision replaces Section I(i) of the Agreement:

(i) "termination of your active employment" shall mean the last date that you are either an active employee of the Company or an Affiliate or actively engaged as a Consultant or Director of the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Units and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed; *provided, however*, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave; *provided further*, that in no event shall payment of the Units be made after the close of your taxable year which includes the applicable Vesting Date or, if later, after the 15<sup>th</sup> day of the third calendar month following the applicable Vesting Date; and

# AMGEN INC. 2009 PERFORMANCE AWARD PROGRAM

(Effective March 3, 2009)

## ARTICLE I

#### PURPOSE

The purpose of this document is to set forth the general terms and conditions applicable to the Amgen Inc. 2009 Performance Award Program (the "<u>Program</u>") established by the Compensation and Management Development Committee of the Board of Directors of Amgen Inc. (the "<u>Company</u>") pursuant to, and in implementation of, Articles 5 and 9 of the Company's 2009 Equity Incentive Plan (the "<u>2009 Plan</u>"). The Program is intended to carry out the purposes of the 2009 Plan and provide a means to reinforce objectives for sustained long-term performance and value creation by awarding selected key employees of the Company with payments in Company stock based on the level of achievement of pre-established performance goals during performance periods through the award of Performance Awards pursuant to Articles 5 and 9 of the 2009 Plan, subject to the restrictions and other provisions of the Program and the 2009 Plan.

## ARTICLE II

#### DEFINITIONS

Unless otherwise defined herein, capitalized terms used herein shall have the meanings assigned to such terms in the 2009 Plan.

"Award" shall mean the earned Performance Units payable in Common Stock under the Program for a Performance Period.

"Board" shall mean the Board of Directors of the Company.

"Change of Control" shall mean the occurrence of any of the following:

(i) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding shares of Common Stock or the combined voting power of the Company's then outstanding voting securities entitled to vote generally in the election of directors; or

(ii) individuals who, as of April 2, 1991, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board, provided that any person becoming a director subsequent to April 2, 1991, whose election, or nomination for

election by the Company's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board (other than an election or nomination of an individual whose initial assumption of office is in connection with an actual or threatened election contest relating to the election of the Directors of the Company, as such terms are used in Rule 14a-11 of Regulation 14A promulgated under the Exchange Act) shall be, for purposes of the Plan, considered as though such person were a member of the Incumbent Board; or

(iii) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company; or

(iv) any other event which the Incumbent Board in its sole discretion determines constitutes a Change of Control.

Notwithstanding anything herein or in any Award Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Award that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (i), (ii), (iii) or (iv) must also constitute a "change in control event," as defined in Treasury Regulation §1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Award.

"<u>Code</u>" shall mean the Internal Revenue Code of 1986, as amended from time to time, together with the regulations and official guidance promulgated thereunder.

"Common Stock" shall mean the common stock, par value \$0.0001 per share, of the Company.

"Determination Date" shall have the meaning ascribed to it in Section 4.1.

"Participant" shall mean a key employee of the Company or an Affiliate who participates in this Program pursuant to the provisions of Article III hereof.

"<u>Performance Period</u>" shall mean a period of time with respect to which performance is measured as determined by the Committee. Performance Periods may overlap.

"Performance Goals" shall have the meaning ascribed to it in Section 5.2.

"<u>Performance Unit</u>" shall mean a right granted to a Participant pursuant to the Program to receive Common Stock, the payment of which is contingent upon achieving the Performance Goals.

"<u>Permanent and Total Disability</u>" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of a Participant's employment by (i) the Social Security Administration, (ii) the

comparable governmental authority applicable to an Affiliate of the Company, (iii) such other body having the relevant decision-making power applicable to an Affiliate of the Company, or (iv) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case.

"<u>Retirement-Eligible</u>" shall mean when a Participant is at least sixty-five (65) years of age, or when a Participant is at least fifty-five (55) years of age and has been an employee of the Company and/or an Affiliate of the Company for at least ten (10) consecutive years.

"Section 162(m) Participant" shall mean any Participant designated by the Committee as a "covered employee" within the meaning of Section 162(m) of the Code whose compensation for the fiscal year in which the Participant is so designated or a future fiscal year may be subject to the limit on deductible compensation imposed by Section 162(m) of the Code.

"Voluntary Retirement" shall mean voluntary termination of employment that is not the result of Permanent and Total Disability.

#### ARTICLE III

#### PARTICIPATION

3.1 <u>Participants</u>. Participants for any Performance Period shall be those active key employees of the Company or an Affiliate who are designated in writing as eligible for participation by the Committee within the first ninety (90) days of such Performance Period.

3.2 <u>No Right to Participate</u>. No Participant or other employee of the Company or an Affiliate shall, at any time, have a right to participate in this Program for any Performance Period, notwithstanding having previously participated in this Program.

#### ARTICLE IV

## ADMINISTRATION

4.1 <u>Generally</u>. The Committee shall establish the basis for payments under this Program in relation to specified Performance Goals, as more fully described in Article V hereof. With respect to the 162(m) Participants, the Committee shall establish the basis for payments under this Program in relation to specified Performance Goals within the first ninety (90) days of each Performance Period, but in no event after 25 percent of the Performance Period has lapsed. Following the end of each Performance Period, once all of the information necessary for the Committee to determine the Company's performance is made available to the Committee, the Committee shall determine the amount of the Award payable to each Participant; *provided*, *however*, that any such determination shall be made no later than six months following the end of such Performance Period (the date of such determination shall hereinafter be called the "Determination Date"). The Committee shall have the power and authority granted it under Article 12 of the 2009 Plan, including, without limitation, the authority to construe and interpret this Program, to prescribe, amend and rescind rules, regulations and procedures relating to its

administration and to make all other determinations necessary or advisable for administration of this Program. Decisions of the Committee in accordance with the authority granted hereby shall be conclusive and binding. Subject only to compliance with the express provisions hereof, the Committee may act in its sole and absolute discretion with respect to matters within its authority under this Program.

4.2 <u>Provisions Applicable to Section 162(m) Participants</u>. Subject to the sole discretion of the Committee, any Awards paid hereunder to a Section 162(m) Participant shall satisfy and shall be interpreted in a manner that satisfies any applicable requirements as "qualified performance-based compensation" within the meaning of Section 162(m) of the Code and any provisions, application or interpretation of the Program or the 2009 Plan that is inconsistent with this intent shall be disregarded. To the extent that any Award (i) is deemed to constitute "nonqualified deferred compensation" (within the meaning of Code Section 409A) and (ii) would nevertheless be subject to the deduction limitations imposed by Section 162(m) of the Code in the year in which such Award would otherwise be paid under this Program, the payment of such Award may, in the Committee's discretion, be delayed until the earlier of (A) the first year in which such Award would not be subject to the deduction limitations imposed by Section 162(m) or (B) such time as the Participant ceases to be a "service provider" to the Company (within the meaning of Section 409A of the Code).

4.3 <u>Provisions Applicable to Participants in Foreign Jurisdictions</u>. Notwithstanding any provision of the Program to the contrary, in order to comply with the laws in other countries in which the Company and its Affiliates operate or have employees, the Committee, in its sole discretion, shall have the power and authority to:

(i) modify the terms and conditions of any award of Performance Units granted to employees outside the United States to comply with applicable foreign laws;

(ii) condition the effectiveness of any award of Performance Units upon approval or compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption or approvals;

(iii) provide for payment of any Award in cash or Common Stock, at the Company's election, to the extent necessary to comply with applicable foreign laws; and

(iv) take any other action, before or after an award of Performance Units is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no award of Performance Units shall be granted, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation.

#### ARTICLE V

#### AWARD DETERMINATIONS

5.1 <u>Award of Performance Units</u>. The Committee shall determine the number of Performance Units (rounded down to the nearest whole number) to be awarded under this Program to each Participant with respect to such Performance Period. With respect to the Section 162(m) Participants, the Committee shall determine the number of Performance Units (rounded down to the nearest whole number) to be awarded under this Program to each Section 162(m) Participant with respect to such Performance Period, but in no event after 25 percent of the Performance Period has elapsed. Performance Units granted under the Program shall constitute Performance Awards under Article 9 of the 2009 Plan.

5.2 <u>Performance Requirements</u>. The Committee shall approve the performance goals (collectively, the "<u>Performance Goals</u>") with respect to any of the business criteria permitted under the 2009 Plan, each subject to such adjustments as the Committee may specify in writing at such time, and shall establish a formula, standard or schedule which aligns the level of achievement of the Performance Goals with the earned Performance Units.

With respect to the Section 162(m) Participants, the Committee shall approve the Performance Goals within the first ninety (90) days of such the Performance Period, but in no event after 25 percent of the Performance Period has elapsed, and the Performance Goals may not be changed during the Performance Period, but the thresholds, targets and multiplier measures of the Performance Goals shall be subject to such adjustments as the Committee may specify in writing within the first ninety (90) days of the Performance Period, but in no event after 25 percent of the Performance Period, but in no event after 25 percent of the Performance Period.

#### ARTICLE VI

#### PAYMENT OF AWARDS

6.1 <u>Form and Timing of Payment</u>. Except as set forth in Section 8.1 below, no Award payable pursuant to this Program shall be paid unless and until the Committee certifies, in writing, the extent to which the Performance Goals have been achieved and the corresponding number of Performance Units earned. The specified payment date applicable to such Awards shall be the year immediately following the tax year including the end of the Performance Period. Shares of Common Stock issued in respect of an Award shall be deemed to be issued in consideration for future services to be rendered or past services actually rendered to the Company or for its benefit, by the Participant, which the Committee deems to have a value at least equal to the aggregate par value thereof.

6.2 <u>Tax Withholding</u>. Regardless of any action the Company or its Affiliate takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, payment on account or other tax-related items related to participation in the Program and legally applicable to the Participant (<u>"Tax Obligations</u>"), the Participant acknowledges that the ultimate liability for all Tax Obligations is and remains the Participant's responsibility and may exceed the amount actually withheld by the Company and/or its Affiliate. The Participant further acknowledges that the Company and/or its Affiliate (i) make no representations or

undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Performance Units, including the grant of the Performance Units, the vesting of Performance Units, the conversion of the Performance Units into shares or the receipt of an equivalent cash payment, the subsequent sale of any shares acquired at vesting and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Performance Units to reduce or eliminate the Participant's liability for Tax Obligations or achieve any particular tax result. Furthermore, if the Participant becomes subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, the Participant acknowledges that the Company and/or its Affiliate may be required to withhold or account for Tax Obligations in more than one jurisdiction.

Prior to any relevant taxable or tax withholding event, as applicable, the Participant shall pay, or make adequate arrangements satisfactory to the Company or to its Affiliate (in their sole discretion) to satisfy all Tax Obligations. In this regard, the Participant authorizes the Company and/or its Affiliate or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(a) withholding from the Participant's wages or other cash compensation paid to the Participant by the Company and/or its Affiliate; or

(b) withholding from proceeds of the sale of shares of Common Stock acquired upon vesting or payment of the Performance Units either through a voluntary sale or through a mandatory sale arranged by the Company (on the Participant's behalf pursuant to this authorization); or

(c) withholding in shares of Common Stock to be issued upon vesting or payment of the Performance Units, provided that the Company and its Affiliate shall only withhold an amount of shares of Common Stock with a fair market value equal to the Tax Obligations.

To avoid adverse accounting treatment, the Company may withhold or account for Tax Obligations not to exceed the applicable minimum statutory withholding rates or other applicable withholding rates. If the Tax Obligations are satisfied by withholding in shares of Common Stock, for tax purposes, the Participant is deemed to have been issued the full number of shares of Common Stock subject to the vested Performance Units, notwithstanding that a number of the shares of Common Stock is held back solely for the purpose of paying the Tax Obligations due as a result of any aspect of the Participant's participation in the Program (any shares of Common Stock withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Program and shall remain available for issuance thereunder).

Finally, the Participant shall pay to the Company or its Affiliate any amount of Tax Obligations that the Company or its Affiliate may be required to withhold or account for as a result of the Participant's participation in the Program that cannot be satisfied by the means previously described. The Participant agrees to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section 6.2. Notwithstanding Section 6.1 above, the Company may refuse to issue or deliver the shares or the proceeds of the sale of shares of Common Stock if the Participant fails to comply with its obligations in connection with the Tax Obligations.

#### TERMINATION OF EMPLOYMENT

#### 7.1 Termination of Employment During Performance Period.

(a) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period by reason of such Participant's Voluntary Retirement and such Participant is Retirement-Eligible on the date of such termination, the full or prorated amount of such Participant's Award, if any, applicable to such Performance Period shall be paid in accordance with the provisions of Article VI above. For purposes of the foregoing, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such Voluntary Retirement occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such Voluntary Retirement occurs, the full amount of the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is twelve (12). Notwithstanding the foregoing, a Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(a) unless either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided, however*, that in no event shall payment of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

(b) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period by reason of such Participant's death or Permanent and Total Disability, the full or prorated amount of such Participant's Award, if any, applicable to such Performance Period shall be paid in accordance with the provisions of Article VI above. For purposes of the foregoing, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such termination occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such termination occurs, the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is twelve (12). Notwithstanding the foregoing, with respect to a Participant whose employment is terminated due to such Participant's Permanent and Total Disability, such Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(b) unless

either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided*, *however*, that in no event shall payment of such full or prorated amount of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

(c) In the event that a Participant's employment with the Company or an Affiliate is terminated prior to the last business day of a Performance Period for any reason other than as specified in Sections 7.1(a) and (b) above, all of such Participant's rights to an Award for such Performance Period shall be forfeited, unless, prior to the payment date described in Article VI above, the Company, in its sole discretion, makes a written determination to otherwise pay the full or prorated amount of the Participant's Award, if any, applicable to such Performance Period, which full or prorated amount shall be paid in accordance with the provisions of Article VI above. For purposes of the foregoing, if the payment of the Participant's Award is prorated, the amount of the Participant's Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for such Performance Period and the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months of employment during the Performance Period, and the denominator of which is the number of months in the Performance Period. Notwithstanding the foregoing, a Participant shall not be entitled to such full or prorated amount of such Participant's Award pursuant to this Section 7.1(c) unless either such Participant signs a general release and waiver in a form provided by the Company and delivers it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided, however*, that in no event shall payment of such full or prorated amount of such Participant's Award be made later than the specified payment date as set forth in Section 6.1 above.

7.2 <u>Termination of Employment After End of Performance Period</u>. In the event that a Participant's employment with the Company or an Affiliate is terminated on or after the last business day of the applicable Performance Period but prior to the Determination Date for any reason, the amount of any Award applicable to such Performance Period shall be paid to the Participant in accordance with the provisions of Article VI above.

#### ARTICLE VIII

#### CHANGE OF CONTROL

#### 8.1 Change of Control During Performance Period.

(a) Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs during the first fiscal year of a Performance Period that began prior to January 1, 2008, such Performance Period shall be shortened and shall terminate as of the last business day of the last completed fiscal quarter preceding the date of such Change of Control and each Participant employed by the Company immediately prior to such Change of Control shall be entitled to a payment equal to the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have received for such shortened Performance Period using the assumption that the target levels with respect to the Company's Revenue CAGR and

EPS CAGR of the Performance Goals have been satisfied. Any such payment shall be made as soon as practicable following such Change of Control (provided, that the Company may elect, in its sole discretion, to make any such payments in a manner that will not subject the payments to penalties under Code Section 409A) and, in the Committee's sole discretion, may be paid in cash.

(b) Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs during the second or third fiscal year of a Performance Period that began prior to January 1, 2008, such Performance Period shall be shortened and shall terminate as of the last business day of the last completed fiscal quarter preceding the date of such Change of Control and each Participant employed by the Company immediately prior to such Change of Control shall be entitled to a payment equal to the greater of (i) the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have received for such shortened Performance Period using the assumption that the targets levels with respect to the Company's Revenue CAGR and EPS CAGR of the Performance Goals have been satisfied, or (ii) the amount of the Participant's Award (rounded down to the nearest whole number) he or she would have been entitled to receive for such shortened Performance Period, determined based on the Company's performance as determined by the Amgen Revenue CAGR and Amgen EPS CAGR and comparative performance as determined by the Peer Group Revenue CAGR and Peer Group EPS CAGR (for the 2006-2008 Performance Period) or the Company's performance as determined by the Amgen Revenue CAGR and Amgen EPS CAGR and Total Stockholder Return (for the 2007-2009 Performance Period) for such shortened Performance Period. Any such payment shall be made as soon as practicable following such Change of Control (provided, that the Company may elect, in its sole discretion, to make any such payments in a manner that will not subject the payments to penalties under Code Section 409A) and, in the Committee's sole discretion, may be paid in cash.

(c) Notwithstanding anything to the contrary in the Program, for Performance Periods beginning on or after January 1, 2008, the Committee shall set forth the terms of any Award payable in the event of Change of Control that occurs during a Performance Period in the Performance Goals.

(d) For purposes of this Section 8.1, the following terms shall have the meanings set forth in the Performance Goals for the relevant Performance Period: "Revenue CAGR," "EPS CAGR," "Amgen Revenue CAGR," "Amgen EPS CAGR," "Peer Group Revenue CAGR," "Peer Group EPS CAGR" and "Total Stockholder Return."

8.2 <u>Change of Control After End of Performance Period</u>. Notwithstanding anything to the contrary in the Program, in the event of a Change of Control that occurs after the end of the applicable Performance Period but prior to the Determination Date, the amount of any Award applicable to such Performance Period shall be paid to the Participant in accordance with the provisions of Article VI above.

#### ARTICLE IX

#### **MISCELLANEOUS**

9.1 <u>Plan</u>. The Program is subject to all the provisions of the 2009 Plan and its provisions are hereby made a part of the Program, including without limitation the provisions of Articles 5 and 9 thereof (relating to Performance-Based Compensation and Performance Awards) and Section 13.2 thereof (relating to adjustments upon changes in the Common Stock), and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the 2009 Plan. In the event of any conflict between the provisions of the Program and those of the 2009 Plan, the provisions of the 2009 Plan shall control. Notwithstanding any provision of the Program to the contrary, any earned Performance Units paid in cash rather than shares of Common Stock shall not be deemed to have been issued by the Company for any purpose under the 2009 Plan.

9.2 <u>Amendment and Termination</u>. Notwithstanding anything herein to the contrary, the Committee may, at any time, terminate, modify or suspend this Program; *provided, however*, that, without the prior consent of the Participants affected, no such action may adversely affect any rights or obligations with respect to any Awards theretofore earned but unpaid for a completed Performance Period, whether or not the amounts of such Awards have been computed and whether or not such Awards are then payable. Notwithstanding the forgoing, at any time the Committee determines that the Performance Units may be subject to Section 409A of the Code, the Committee shall have the right, in its sole discretion, and without a Participant's prior consent to amend the Program as it may determine is necessary or desirable either for the Performance Units to be exempt from the application of Section 409A or to satisfy the requirements of Section 409A, including by adding conditions with respect to the vesting and/or the payment of the Performance Units, provided that no such amendment may change the Program's "performance goals," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code.

9.3 <u>No Contract for Employment</u>. Nothing contained in this Program or in any document related to this Program or to any Award shall confer upon any Participant any right to continue as an employee or in the employ of the Company or an Affiliate or constitute any contract or agreement of employment for a specific term or interfere in any way with the right of the Company or an Affiliate to reduce such person's compensation, to change the position held by such person or to terminate the employment of such person, with or without cause.

9.4 <u>Nontransferability</u>. No benefit payable under, or interest in, this Program shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, debts, contracts, liabilities or torts of any Participant or beneficiary; *provided, however*, that, nothing in this Section 9.4 shall prevent transfer (i) by will, or (ii) by applicable laws of descent and distribution.

9.5 <u>Compensation Subject to Recovery</u>. The Awards under this Program and all compensation payable with respect to them shall be subject to recovery by the Company

pursuant to any and all of the Company's policies with respect to the recovery of compensation, as they shall be in effect and may be amended from time to time, to the maximum extent permitted by applicable law.

9.6 <u>Nature of Program</u>. No Participant, beneficiary or other person shall have any right, title or interest in any fund or in any specific asset of the Company or any Affiliate by reason of any award hereunder. There shall be no funding of any benefits which may become payable hereunder. Nothing contained in this Program (or in any document related thereto), nor the creation or adoption of this Program, nor any action taken pursuant to the provisions of this Program shall create, or be construed to create, a trust of any kind or a fiduciary relationship between the Company or an Affiliate and any Participant, beneficiary or other person. To the extent that a Participant, beneficiary or other person acquires a right to receive payment with respect to an Award hereunder, such right shall be no greater than the right of any unsecured general creditor of the Company or other employing entity, as applicable. All amounts payable under this Program shall be paid from the general assets of the Company or employing entity, as applicable, and no special or separate fund or deposit shall be established and no segregation of assets shall be made to assure payment of such amounts. Nothing in this Program shall be deemed to give any employee any right to participate in this Program except in accordance herewith.

9.7 Governing Law. This Program shall be construed in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof.

#### Form of Award Notice

[The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website ]

This notice of Award (the "<u>Award Notice</u>") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Agreement that accompanies this Award Notice and made of part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee:	
Employee ID:	
Address:	
Award Type:	
Grant ID:	
Plan:	Amgen Inc. 2009 Equity Incentive Plan
Program	Amgen Inc. 2009 Performance Award Program
Grant Date:	
Number of Shares	
Number of Performance Units	
Resolutions:	The Resolutions of the Compensation and Management Development Committee of the Board of Directors of Amgen
	Inc., adopted on, regarding the Amgen Inc. 2009 Performance Award Program
Performance Period:	The Performance Period beginning on, 200 and ending on, 200
Expiration Date:	The [(_th)] anniversary of the date of this Award
Vesting Date:	Means the vesting date indicated in the Vesting Schedule
Vesting Schedule:	Means the schedule of vesting set forth under Vesting Details
Vesting Details:	Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting.

#### PERFORMANCE UNIT AGREEMENT

# THE SPECIFIC TERMS OF YOUR GRANT OF PERFORMANCE UNITS ARE FOUND IN THE PAGES RELATING TO THE GRANT OF PERFORMANCE UNITS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE <u>"AWARD NOTICE</u>") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS PERFORMANCE UNIT AGREEMENT.

On the Grant Date specified in the Award Notice, Amgen Inc., a Delaware corporation (the "<u>Company</u>"), has granted to you, the grantee named in the Award Notice, under the plan specified in the Award Notice (the "<u>Plan</u>"), the Number of Performance Units (the "<u>Performance Units</u>") specified in the Award Notice on the terms and conditions set forth in this Performance Unit Agreement (and any applicable special terms and conditions for your country set forth in the attached <u>Appendix A</u> (as described in greater detail in Section XIII below)) (collectively, this "<u>Agreement</u>"), the Plan, the Amgen Inc. 2009 Performance Award Program (the "Program") and the Resolutions (as defined below). Capitalized terms not defined herein shall have the meanings assigned to such terms in the Program.

I. Performance Period. The Performance Period shall have the meaning set forth in the Award Notice.

II. Value of Performance Units. The value of each Performance Unit is equal to a share of Common Stock.

III. <u>Performance Goals</u>. An amount of the Performance Units up to the maximum amount specified in the Resolutions shall be earned, depending on the extent to which the Company achieves objectively determinable Performance Goals established by the Committee pursuant to the Resolutions. The Performance Units earned shall be calculated in accordance with the Resolutions and the Program.

IV. <u>Form and Timing of Payment</u>. Subject to Section XII and except as set forth in the Program, for any Performance Units earned pursuant to Section III above, the specified payment date applicable to such Performance Units shall be the year immediately following the end of the Performance Period. Shares of Common Stock issued in respect of a Performance Unit shall be deemed to be issued in consideration of past services actually rendered by you to the Company or an Affiliate or for its benefit for which you have not previously been compensated or for future services to be rendered, as the case may be, which the Company deems to have a value at least equal to the aggregate par value thereof.

V. <u>Issuance of Certificates</u>; <u>Tax Withholding</u>. Regardless of any action the Company or your actual employer (the "Employer") takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, payment on account or other tax-related items related to your participation in the Plan and the Program and legally applicable to you (the "<u>Tax Obligations</u>"), you acknowledge that the ultimate liability for all Tax

Obligations is and remains your responsibility and may exceed the amount actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Performance Units, including the grant of the Performance Units, the vesting of the Performance Units, the conversion of the Performance Units into shares or the receipt of an equivalent cash payment, the subsequent sale of any shares acquired at settlement and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Performance Units to reduce or eliminate your liability for Tax Obligations or to achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction between the Grant Date and the date of any relevant taxable event, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

Prior to any relevant taxable or tax withholding event, as applicable, you shall pay or make adequate arrangements satisfactory to the Company or to your Employer (in their sole discretion) to satisfy all Tax Obligations. In this regard, you authorize the Company and/or your Employer, or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(a) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer;

(b) withholding from proceeds of the sale of shares of Common Stock issued upon settlement of the Performance Units, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization);

(c) withholding in shares of Common Stock to be issued upon settlement of the Performance Units provided that the Company and your Employer shall only withhold an amount of shares of Common Stock with a fair market value equal to the Tax Obligations.

To avoid adverse accounting treatment, the Company may withhold or account for Tax Obligations not to exceed the applicable minimum statutory withholding rates or other applicable withholding rates. If the Tax Obligations are satisfied by withholding in shares of Common Stock, for tax purposes, you are deemed to have been issued the full number of shares subject to the earned Performance Units, notwithstanding that a number of shares of Common Stock is held back solely for the purpose of paying the Tax Obligations due as a result of any aspect of your participation in the Plan (any shares of Common Stock withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Plan and shall remain available for issuance thereunder).

Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan and the Program that cannot be satisfied by the means previously described. You agree to take any further actions and to execute any additional documents as may be necessary to effectuate the provisions of this Section V. Notwithstanding Section IV above, the Company may refuse to issue or deliver the shares of Common Stock or the proceeds of the sale of shares of Common Stock if you fail to comply with your obligations in connection with the Tax Obligations.

VI. <u>Nontransferability</u>. No benefit payable under, or interest in, this Agreement or in the shares of Common Stock that may become issuable to you hereunder shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, your or your beneficiary's debts, contracts, liabilities or torts; *provided*, *however*, nothing in this Section VI shall prevent transfer (i) by will or (ii) by applicable laws of descent and distribution.

VII. <u>No Contract for Employment</u>. This Agreement is not an employment or service contract with the Company or an Affiliate and nothing in this Agreement shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ or service of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment or service with the Company or an Affiliate.

VIII. Nature of Grant. In accepting the grant of Performance Units, you acknowledge that:

(a) the Plan and the Program are established voluntarily by the Company, are discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan and in the Program;

(b) the grant of the Performance Units is voluntary and occasional and does not create any contractual or other right to receive future awards of Performance Units, or benefits in lieu of Performance Units, even if Performance Units have been awarded repeatedly in the past;

(c) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(d) your participation in the Plan and the Program is voluntary;

(e) for labor law purposes outside the United States, Performance Units are an extraordinary item that does not constitute compensation of any kind for services of any kind rendered to the Company or to the Employer, and the grant of Performance Units is outside the scope of your employment contract, if any;

(f) for labor law purposes outside the United States, the grant of Performance Units and the shares of Common Stock subject to the Performance Units are not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculation of any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar payments;

(g) the grant of Performance Units and the shares of Common Stock subject to the Performance Units are not intended to replace any pension rights or compensation;

(h) neither the grant of Performance Units nor any provision of this Agreement, the Plan, the Program or the policies adopted pursuant to the Plan or Program confer upon you any right with respect to employment or continuation of current employment and shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate of the Company;

(i) the future value of the shares of Common Stock that may be earned upon the end of the Performance Period is unknown and cannot be predicted with certainty;

(j) in consideration of the grant of Performance Units hereunder, no claim or entitlement to compensation or damages shall arise from forfeiture of the Performance Units resulting from termination of your employment by the Company or an Affiliate of the Company (for any reason whatsoever and whether or not in breach of local labor laws) and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim;

(k) in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Performance Units and receive shares under the Plan and the Program, if any, will terminate effective as of the date that you are no longer actively employed and will not be extended by any notice period mandated under local law (*e.g.*, active employment would not include a period of "garden leave" or similar period pursuant to local law); and

(1) the Performance Units and the benefits under the Plan and the Program, if any, will not automatically transfer to another company in case of a merger, takeover or transfer of liability.

IX. <u>No Advice Regarding Grant</u>. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan and the Program, or your acquisition or sale of the underlying shares of Common Stock. You are hereby advised to consult with your personal tax, legal and financial advisors regarding your participation in the Plan and the Program before taking any action related thereto.

X. <u>Notices</u>. Any notices provided for in this Agreement, the Plan or the Program shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

XI. <u>Resolutions, Plan and Program</u>. This Agreement is subject to all the provisions of the Resolutions, the Plan and the Program and their provisions are hereby made a part of this Agreement and incorporated herein by reference, including, without limitation, the provisions of Articles 5 and 9 of the Plan (relating to Performance-Based Compensation and Performance Awards, respectively) and Section 13.2 of the Plan (relating to adjustments upon changes in the Common Stock), and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Agreement and those of the Resolutions, the Plan and the Program, the provisions of the Plan shall control. Notwithstanding any provision of this Agreement or the Program to the contrary, any earned Performance Units paid in cash rather than shares of Common Stock shall not be deemed to have been issued by the Company for any purpose under the Plan.

XII. <u>No Compensation Deferral</u>. The Performance Units are not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the U.S. Internal Revenue Code of 1986, as amended from time to time (together with the regulations and official guidance promulgated thereunder, the "<u>Code</u>"). However, if at any time the Committee determines that the Performance Units may be subject to Section 409A of the Code, the Committee shall have the right, in its sole discretion, and without your prior consent to amend the Program as it may determine is necessary or desirable either for the Performance Units to be exempt from the application of Section 409A of the Code or to satisfy the requirements of Section 409A of the Code, including by adding conditions with respect to the vesting and/or the payment of the Performance Units, provided that no such amendment may change the Program's "performance goals," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, with respect to any person who is a "covered employee," within the meaning of Section 162(m) of the Code, sole discretion apply retroactively to this award of Performance Units.

XIII. <u>Provisions Applicable to Participants in Foreign Jurisdictions</u>. Notwithstanding any provision of this Agreement or the Program to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached <u>Appendix A</u> (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached <u>Appendix A</u>, your award of Performance Units shall be subject to any special terms and conditions for such country set forth in <u>Appendix A</u> and to the following additional terms and conditions:

(a) the terms and conditions of this Agreement, including <u>Appendix A</u>, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration of the Plan and the Program;

(b) if applicable, the effectiveness of your Award is conditioned upon its compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals;

(c) to the extent necessary to comply with applicable foreign laws, the payment of any earned Performance Units shall be made in cash or Common Stock, at the Company's election; and

(d) the Committee may take any other action, before or after an award of Performance Units is made, that it deems necessary or advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no award of Performance Units shall be granted, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation. Notwithstanding anything to the contrary contained herein, the shares issuable upon vesting of the Performance Units shall not be issued unless such shares are then registered under the Securities Act, or, if such shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act.

XIV. <u>Data Privacy and Notice of Consent.</u> You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement by and among, as applicable, the Employer, the Company, or Affiliates of the Company for the exclusive purpose of implementing, administering and managing your participation in the Plan and the Program.

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number (to the extent permitted under applicable local law) or other identification number, salary, nationality, job title, residency status, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to shares awarded, canceled, vested, unvested or outstanding in your favor, for the purpose of implementing, administering and managing the Plan and the Program ("Data"). You understand that Data may be transferred to Merrill Lynch Bank & Trust Co., FSB (or any successor thereto), any third parties assisting in the implementation, administration and management of the Plan and the Program, that these recipients may be located in your country, or elsewhere, including outside the European Economic Area and that the recipient's country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize the Employer, the Company, Affiliates of the Company Merrill Lynch Bank & Trust Co., FSB (or any successor thereto), and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan and the Program to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing your participation in the Plan and the Program, including any requisite transfer of such Data as may be required to a broker, escrow agent or other third party with whom the shares received upon vesting of the Performance Units may be deposited. You understand that you may, at any time, view

Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. You understand that refusal or withdrawal of consent may affect your ability to participate in the Plan and the Program. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

XV. <u>Language</u>. If you have received this Agreement or any other document related to the Plan and/or the Program translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

XVI. <u>Governing Law</u>. The terms of this Agreement shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Agreement is made and/or to be performed.

XVII. <u>Severability</u>. The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

XVIII. <u>Electronic Delivery</u>. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan and/or the Program by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

XIX. <u>Imposition of Other Requirements</u>. The Company reserves the right to impose other requirements on your participation in the Plan and the Program, on the Performance Units and on any shares of Common Stock acquired under the Plan and the Program, to the extent the Company determines it is necessary or advisable in order to comply with local law or facilitate the administration of the Plan, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

Very truly yours, AMGEN INC.

By:

Name: Title:

Accepted and Agreed,			
this	_ day of	, 200	

By:

Name:

#### APPENDIX A

#### ADDITIONAL TERMS AND CONDITIONS OF THE AMGEN INC. 2009 EQUITY INCENTIVE PLAN

# AWARD OF PERFORMANCE UNITS (BY COUNTRY)

#### **TERMS AND CONDITIONS**

This Appendix includes additional terms and conditions that govern any Performance Units granted to you under the Plan if you are working in one of the countries listed below. Certain capitalized terms used but not defined in this Appendix shall have the meanings set forth in the Plan, the Program and/or the Award Agreement to which this Appendix is attached.

#### **NOTIFICATIONS**

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of February 1, 2009. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you acquire shares of Common Stock under the Plan, or when you subsequently sell shares of Common Stock acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently working, the information contained herein may not be applicable to you.

# **AUSTRALIA**

# TERMS AND CONDITIONS

**Performance Units Payable Only in Shares.** Notwithstanding any discretion in the Plan or the Program or anything to the contrary in the Award Agreement, the Award does not provide any right for you to receive a cash payment and shall be paid in shares of Common Stock only.

# AUSTRIA

#### NOTIFICATIONS

**Consumer Protection Notification.** You may be entitled to revoke acceptance of the Award on the basis of the Austrian Consumer Protection Act (the "Act") under the conditions listed below, if the Act is considered to be applicable to the Award, the Plan and the Program:

- (i) If you accept the Award outside the business premises of the Company, you may be entitled to revoke your acceptance of the Award, provided the revocation is made within one (1) week after such acceptance of an Award.
- (ii) The revocation must be in written form to be valid. It is sufficient if you return the applicable Award Agreement to the Company or the Company's representative with language which can be understood as a refusal to conclude or honor the applicable Award Agreement, provided the revocation is sent within the period discussed above.

### **Exchange Control Notification.**

When you sell shares of Common Stock acquired under the Plan, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad exceeds  $\notin$  3,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/oder SI-Verpflichtungen*).

# **BELGIUM**

### NOTIFICATIONS

**Tax Reporting Notification.** You are required to report any taxable income attributable to the Award granted hereunder on your annual tax return. You are also required to report any bank accounts opened and maintained outside Belgium on your annual tax return.

# **CANADA**

# TERMS AND CONDITIONS

Termination of Service. This provision supplements Section VIII(k) of the Award Agreement:

In the event of involuntary termination of your employment (whether or not in breach of local labor laws), your right to receive an Award and vest in such Award under the Plan and the Program, if any, will terminate effective as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Company or your Employer, or (2) the date you are no longer actively employed by the Company or your Employer regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to statutory law, regulatory law and/or common law). Your right, if any, to acquire shares of Common Stock pursuant to an Award after termination of employment will be measured by the date of termination of your active employment and will not be extended by any notice period mandated under local law.

# The following provisions will apply to you if you are a resident of Quebec:

**Language Consent.** The parties acknowledge that it is their express wish that this agreement, as well as all documents, notices, and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de cette convention ("Agreement"), ainsi que de tous documents exécutés, avis donnés et procédures judiciaries intentées, directement ou indirectement, relativement à ou suite à la présente convention.

Data Privacy Notice and Consent. This provision supplements Section XIV of the Award Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration and operation of the Plan and the Program. You further authorize the Company and your Employer to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your employee file.

### CZECH REPUBLIC

### NOTIFICATIONS

**Exchange Control Notification.** Proceeds from the sale of shares of Common Stock may be held in a cash account abroad and you are no longer required to report the opening and maintenance of a foreign account to the Czech National Bank (the "CNB"), unless the CNB notifies you specifically that such reporting is required. Upon request of the CNB, you may need to file a notification within 15 days of the end of the calendar quarter in which you acquire shares of Common Stock.

# **DENMARK**

### NOTIFICATIONS

**Exchange Control Information.** If you establish an account holding shares or an account holding cash outside Denmark, you must report the account to the Danish Tax Administration. The form which should be used in this respect can be obtained from a local bank. (These obligations are separate from and in addition to the obligations described below.)

**Securities/Tax Reporting Information.** If you hold shares of Common Stock acquired under the Plan in a brokerage account with a broker or bank outside Denmark, you are required to inform the Danish Tax Administration about the account. For this purpose, you must file a Form V (*Erklaering V*) with the Danish Tax Administration. The Form V must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form V, the broker or bank undertakes to forward information to the Danish Tax Administration concerning the shares in the account without further request each year. By signing the Form V, you authorize the Danish Tax Administration to examine the account.

In addition, if you open a brokerage account (or a deposit account with a U.S. bank) for the purpose of holding cash outside Denmark, you are also required to inform the Danish Tax Administration about this account. To do so, you must file a Form K (*Erklaering K*) with the Danish Tax Administration. The Form K must be signed both by you and by the applicable broker or bank where the account is held. By signing the Form K, the broker/bank undertakes an obligation, without further request each year, to forward information to the Danish Tax Administration concerning the content of the account. By signing the Form K, you authorize the Danish Tax Administration to examine the account.

### **FINLAND**

There are no country-specific provisions.

# **GERMANY**

There are no country-specific provisions.

### **GREECE**

There are no country-specific provisions.

# HONG KONG

# TERMS AND CONDITIONS

SECURITIES WARNING: The Performance Units and any shares of Common Stock issued in respect of Performance Units do not constitute a public offering of securities under Hong Kong law and are available only to Participants under the Program. The Award Agreement, including this Appendix, the Program, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, nor have the documents been reviewed by any regulatory authority in Hong Kong. The Performance Units and any documentation related thereto are intended solely for the personal use of each Participant under the Program and may not be distributed to any other person. If you are in doubt about any of the contents of the Award Agreement, including this Appendix, the Program or the Plan, you should obtain independent professional advice.

**Performance Units Payable Only in Shares.** Notwithstanding any discretion in the Plan or the Program or anything to the contrary in the Award Agreement, the Award does not provide any right for you to receive a cash payment and shall be paid in shares of Common Stock only.

Sale of Shares of Common Stock. In the event that shares of Common Stock are issued in respect of Performance Units within six (6) months of the Grant Date, you agree that you will not dispose of such shares prior to the six-month anniversary of the Grant Date.

#### HUNGARY

There are no country-specific provisions.

# **INDIA**

#### **TERMS AND CONDITIONS**

Fringe Benefit Tax Obligation. This provision supplements Section V of the Award Agreement:

By accepting the Award, you consent and agree to assume liability for any fringe benefit tax ("FBT") that may be payable by the Company and/or your Employer in connection with the Award. You understand that the grant of the Award is contingent upon your agreement to assume liability for FBT payable on the Award. Further, by accepting the Award granted hereunder, you agree that the Company and/or your Employer may collect the FBT from you by any of the means set forth, as applicable, in Section V of the Award Agreement, or by any other reasonable method established by the Company. You also agree to execute promptly any other consents or elections required to accomplish the foregoing, upon request of the Company.

## NOTIFICATIONS

**Exchange Control Notification.** You must repatriate the proceeds from the sale of shares of Common Stock acquired under the Plan and the Program and any dividends received in relation to the shares of Common Stock to India within 90 days after receipt. You must maintain the foreign inward remittance certificate received from the bank where the foreign currency is deposited in the event that the Reserve Bank of India or your Employer requests proof of repatriation.

#### **IRELAND**

#### **TERMS AND CONDITIONS**

Nature of Grant. This provision supplements Section VIII of the Award Agreement:

In accepting the Award granted hereunder, you acknowledge your understanding and agreement that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

### NOTIFICATIONS

**Director Notification Requirements.** If you are a director, shadow director or secretary of an Irish Affiliate, you must notify the Irish Affiliate in writing within five (5) business days of receiving or disposing of an interest in the Company (*e.g.*, an Award or shares of Common Stock) in the Company, or within five (5) business days of becoming aware of the event giving rise to the notification requirement, or within five (5) business days of becoming a director or secretary if such an interest exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests, if any, will be attributed to the director, shadow director or secretary).

#### **ITALY**

### TERMS AND CONDITIONS

**Data Privacy Consent.** The following provision replaces Section XIV of the Award Agreement:

You hereby explicitly and unambiguously consent to the collection, use, processing and transfer, in electronic or other form, of your personal data as described herein by and among, as applicable, your Employer, the Company and any Affiliate for the exclusive purpose of implementing, administering, and managing your participation in the Plan and the Program.

You understand that your Employer, the Company and any Affiliate may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance (to the extent permitted under Italian law) or

other identification number, salary, nationality, job title, any shares or directorships held in the Company or any Affiliate, details of all Awards granted, or any other entitlement to shares of Common Stock awarded, canceled, exercised, vested, unvested or outstanding in your favor, for the exclusive purpose of implementing, managing and administering the Plan and the Program ("Data").

You also understand that providing the Company with Data is necessary for the performance of the Plan and the Program and that your refusal to provide such Data would make it impossible for the Company to perform its contractual obligations and may affect your ability to participate in the Plan and the Program. The Controller of personal data processing is Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., and, pursuant to Legislative Decree no. 196/2003, its Representative in Italy for privacy purposes is Amgen Dompe S.p.A., with registered offices at Via Tazzoli, 6 – 20154 Milan, Italy.

You understand that Data will not be publicized, but it may be transferred to banks, other financial institutions, or brokers involved in the management and administration of the Plan and the Program. You understand that Data may also be transferred to the independent registered public accounting firm engaged by the Company. You further understand that the Company and/or any Affiliate will transfer Data among themselves as necessary for the purposes of implementing, administering and managing your participation in the Plan and the Program, and that the Company and/or any Affiliate may each further transfer Data to third parties assisting the Company in the implementation, administration, and management of the Plan and the Program, including any requisite transfer of Data to a broker or other third party with whom you may elect to deposit any shares of Common Stock issued in respect of the Award. Such recipients may receive, possess, use, retain, and transfer Data in electronic or other form, for the purposes of implementing, administering, administering, and managing your participation in the Program. You understand that these recipients may be located in or outside the European Economic Area, such as in the United States or elsewhere. Should the Company exercise its discretion in suspending all necessary legal obligations connected with the management and administration of the Plan and the Program, it will delete Data as soon as it has completed all the necessary legal obligations connected with the management and administration of the Plan and the Program.

You understand that Data processing related to the purposes specified above shall take place under automated or non-automated conditions, anonymously when possible, that comply with the purposes for which Data is collected and with confidentiality and security provisions, as set forth by applicable laws and regulations, with specific reference to Legislative Decree no. 196/2003.

The processing activity, including communication, the transfer of Data abroad, including outside of the European Economic Area, as herein specified and pursuant to applicable laws and regulations, does not require your consent thereto, as the processing is necessary to performance of contractual obligations related to implementation, administration, and management of the Plan. You understand that, pursuant to Section 7 of the Legislative Decree no. 196/2003, you have the right to, including but not limited to, access, delete, update, correct, or terminate, for legitimate reason, the Data processing.

Furthermore, you are aware that Data will not be used for direct-marketing purposes. In addition, Data provided can be reviewed and questions or complaints can be addressed by contacting your local human resources representative.

Acknowledgement of Nature of Grant. By accepting the Award granted hereunder, you acknowledge that (1) you have received a copy of the Plan, the Program, the Award Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Program, the Award Agreement and this Appendix.

You further acknowledge that you have read and specifically and explicitly approve, without limitation, the following sections of the Award Agreement: Section III, Section IV, Section V, Section V, Section VIII, Section XIV (as replaced by the above consent), Section XV and Section XIX.

# **LITHUANIA**

There are no country-specific provisions.

# **MEXICO**

#### **TERMS AND CONDITIONS**

Acknowledgement of the Grant. In accepting the Award granted hereunder, you acknowledge that you have received a copy of the Plan and the Program, have reviewed the Plan and the Program and the Award Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan, the Program and the Award Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section VIII of the Award Agreement, in which the following is clearly described and established:

- (1) Your participation in the Plan and the Program do not constitute an acquired right.
- (2) The Plan and your participation in the Plan and the Program are offered by Amgen Inc. on a wholly discretionary basis.
- (3) Your participation in the Plan and the Program is voluntary.
- (4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of any shares of Common Stock issued with respect to the Award.

Labor Law Acknowledgement and Policy Statement. In accepting any Award granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen

Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of shares of Common Stock do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Latin America Services, S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the Program and the benefits that you may derive from participation in the Plan and the Program do not establish any rights between you and your Employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan and the Program is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, shareholders, officers, agents or legal representatives with respect to any claim that may arise.

# Spanish Translation

**Reconocimiento del Otorgamiento.** Al aceptar cualquier Otorgamiento de Acciones bajo el presente documento, usted reconoce que ha recibido una copia del Plan y del Programa, que ha revisado el Plan y el Programa, así como también el Apéndice en su totalidad, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan, del Programa y del Otorgamiento, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección VIII del Acuerdo del Otorgamiento, en los que se establece y describe claramente que:

- (1) Su participación en el Plan y en el Programa de ninguna manera constituye un derecho adquirido.
- (2) Su participación en Plan y en el Programa son ofrecidos por Amgen Inc. de forma completamente discrecional.
- (3) Su participación en el Plan y en el Programa es voluntaria.
- (4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de las Acciones Comunes emitidas mediante el Plan.

**Reconocimiento de la Ley Laboral y Declaración de Política.** Al aceptar cualquier Otorgamiento bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas

registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Latin America Services, S.A. de C.V. ("Amgen-Mexico"). Derivado de lo anterior, usted reconoce expresamente que el Plan y el Programa y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan y en el Programa es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

# **NETHERLANDS**

### NOTIFICATIONS

Securities Law Notification. You should be aware of Dutch insider-trading rules, which may impact the sale of shares of Common Stock issued in respect of the Award. In particular, you may be prohibited from effectuating certain transactions if you have insider information regarding the Company.

By accepting the Award granted hereunder and participating in the Plan and the Program, you acknowledge having read and understood this Securities Law Notification and further acknowledge that it is your responsibility to comply with the following Dutch insider-trading rules:

Under Article 46 of the Act on the Supervision of the Securities Trade 1995, anyone who has "inside information" related to the Company is prohibited from effectuating a transaction in securities in or from the Netherlands. "Inside information" is knowledge of a detail concerning the issuer to which the securities relate that is not public and which, if published, would reasonably be expected to affect the stock price, regardless of the development of the price.

Given the broad scope of the definition of inside information, certain employees of the Company working at an Affiliate in the Netherlands (including persons eligible to participate in the Plan and the Program) may have inside information and, thus, would be prohibited from effectuating a transaction in securities in the Netherlands at a time when in possession of such inside information.

# NORWAY

There are no country-specific provisions.

# POLAND

### NOTIFICATIONS

**Exchange Control Notification.** Polish residents holding foreign securities (including shares of Common Stock) and maintaining accounts abroad must report information to the National Bank of Poland on transactions and balances of the securities and cash deposited in such accounts if the value of such transactions or balances exceeds  $\leq 10,000$ . If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter. The reports are filed on special forms available on the website of the National Bank of Poland.

# PORTUGAL

### NOTIFICATIONS

**Exchange Control Notification.** If you do not hold the shares of Common Stock issued in respect of the Award with a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the shares are held by a Portuguese financial intermediary, it will file the report for you.

# PUERTO RICO

There are no country-specific provisions.

# **RUSSIA**

## **TERMS AND CONDITIONS**

Securities Law Requirements. The Award granted hereunder, the Award Agreement, including this Appendix, the Program, the Plan and all other materials you may receive regarding your participation in the Plan and the Program or the Award granted hereunder do not constitute advertising or an offering of securities in Russia. The issuance of shares of Common Stock in respect of the Award has not and will not be registered in Russia; therefore, such shares may not be offered or placed in public circulation in Russia.

In no event will shares of Common Stock acquired under the Plan be delivered to you in Russia; all shares of Common Stock will be maintained on your behalf in the United States.

You are not permitted to sell any shares acquired under the Plan directly to a Russian legal entity or resident.

# NOTIFICATIONS

**Exchange Control Notification.** You must repatriate the proceeds from the sale of shares acquired under the Plan (and any dividends received in relation to such shares) to Russia within a reasonably short period after receipt. The sale proceeds and any dividends received must be initially credited to you through a foreign currency account opened in your name at an authorized bank in Russia. After the funds are initially received in Russia, they may be further remitted to a foreign bank subject to the following limitations: (i) the foreign account may be opened only for individuals; (ii) the foreign account may not be used for business activities; (iii) the Russian tax authorities must be given notice about the opening/closing of each foreign account within one month of the account opening/closing; and (iv) the Russian tax authorities must be given notice of the account balances of such foreign accounts as of the beginning of each calendar year.

#### **SLOVAKIA**

### NOTIFICATIONS

**Exchange Control Information.** You are required to notify the Slovak National Bank with respect to the establishment of accounts abroad within 15 days of the end of the calendar year. The notification forms may be found at the Slovak National Bank website (<u>www.nbs.sk</u>). You should consult your personal legal advisor to determine which forms you must submit and when such forms will be due.

## **SLOVENIA**

There are no country-specific provisions.

# **SPAIN**

#### TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section VIII of the Award Agreement:

By accepting the Award granted hereunder, you consent to participation in the Plan and the Program and acknowledge that you have received a copy of the Plan and the Program.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant the Award under the Plan and the Program to individuals who may be employees of the Company or its Affiliates throughout the world. The decision is a limited decision that is entered into upon the express assumption and condition that the Awards granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis, other than as expressly set forth in the applicable Award Agreement, including this Appendix. Consequently, you

understand that the Award granted hereunder is given on the assumption and condition that it shall not become a part of any employment contract (either with the Company or any of its Affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of the Award since the future value of the Award and any shares of Common Stock that may be issued in respect of such Award is unknown and unpredictable. In addition, you understand that the Award granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then the grant of the Award or right to the Award shall be null and void.

# NOTIFICATIONS

**Exchange Control Notification.** When receiving foreign currency payments derived from the ownership of shares acquired under the Plan (*i.e.*, dividends or sale proceeds), you must inform the financial institution receiving the payment of the basis upon which such payment is made. You will need to provide the institution with the following information: (i) your name, address, and fiscal identification number; (ii) the name and corporate domicile of the Company; (iii) the amount of the payment and the currency used; (iv) the country of origin; (v) the reasons for the payment; and (vi) further information that may be required.

If you acquire shares of Common Stock under the Plan and wish to import the ownership title of such shares (*i.e.*, share certificates) into Spain, you must declare the importation of such securities to the *Direccion General de Política Comercial y de Inversiones Extranjeras*.

# SWEDEN

There are no country-specific provisions.

# SWITZERLAND

# NOTIFICATIONS

Securities Law Notification. The Award offered hereunder is considered a private offering in Switzerland and is, therefore, not subject to registration in Switzerland.

# UNITED ARAB EMIRATES

There are no country-specific provisions.

# UNITED KINGDOM

TERMS AND CONDITIONS

#### Tax Withholding. This provision supplements Section V of the Award Agreement:

You agree that if you do not pay or your Employer or the Company does not withhold from you the full amount of Tax Obligations that you owe due at issuance of shares of Common Stock in respect of the Performance Units, or the release or assignment of the Performance Units for consideration, or the receipt of any other benefit in connection with the Performance Units (the "Taxable Event") within 90 days after the Taxable Event, or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003, then the amount that should have been withheld shall constitute a loan owed by you to your Employer, effective 90 days after the Taxable Event. You agree that the loan will bear interest at the official rate of HM Revenue and Customs ("HMRC") and will be immediately due and repayable by you, and the Company and/or your Employer may recover it at any time thereafter by withholding (subject to Section V of the Agreement) the funds from salary, bonus or any other funds due to you by your Employer, by withholding in shares of Common Stock issued in respect of the Performance Units or from the cash proceeds from the sale of shares of Common Stock or by demanding cash or a check from you. You also authorize the Company to delay the issuance of any shares of Common Stock to you unless and until the loan is repaid in full.

Notwithstanding the foregoing, if you are an officer or executive director (as within the meaning of Section 13(k) of the U.S. Securities Exchange Act of 1934, as amended), the terms of the immediately foregoing provision will not apply. In the event that you are an officer or executive director and Tax Obligations are not collected from or paid by you within 90 days of the Taxable Event, the amount of any uncollected Tax Obligations may constitute a benefit to you on which additional income tax and national insurance contributions may be payable. You acknowledge that the Company or your Employer may recover any such additional income tax and national insurance contributions at any time thereafter by any of the means referred to in Section V of the Award Agreement.

**Joint Election.** As a condition of the Award, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs") which may be payable by the Company or your Employer with respect to the earning and/or payment of the Performance Units and issuance of shares of Common Stock in respect of the Performance Units, the assignment or release of the Performance Units for consideration or the receipt of any other benefit in connection with the Performance Units.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for the Secondary Class 1 National Insurance Contribution payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorizes the Company and your Employer to withhold such Secondary Class 1 National Insurance Contributions by any of the means set forth in Section V of the Award Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Performance Units, without any liability to the Company or your Employer.

# UNITED STATES

# TERMS AND CONDITIONS

Nature of Grant. The following provision replaces Section VIII(k) of the Award Agreement:

(k) in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Performance Units and receive shares under the Plan and the Program, if any, will terminate effective as of the date that you are no longer actively employed; *provided*, *however*, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave. In such event, payment of the Performance Units shall be made in accordance with Section IV; and

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

# GLAXO GROUP LIMITED

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#### **COLLABORATION AGREEMENT**

This Collaboration Agreement (this "Agreement") is entered into as of the 27th day of July, 2009 (the "*Effective Date*") by and between Amgen Inc., a Delaware corporation with a place of business at 1 Amgen Center Drive, Thousand Oaks, CA 91320 ("*Amgen*") and Glaxo Group Limited, registered in England as company number 305979, doing business as "GlaxoSmithKline" and having its principal office at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("*GSK*"). Amgen and GSK are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties*".

#### RECITALS

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

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

WHEREAS, Amgen and GSK desire to collaborate with respect to the commercialization of Ivory as set forth in more detail herein;

WHEREAS, Amgen and GSK desire to share certain expenses and revenues with respect to Ivory as set forth in more detail herein; and

WHEREAS, Amgen and GSK are entering into a separate agreement of even date herewith whereby GSK will conduct certain activities with respect to Ivory as specified therein in the Expansion Territory (as defined therein).

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

#### 1. **DEFINITIONS**

- 1.1. *"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 Section 1.1, "control" means: (i) in the case of corporate entities, direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors; and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein (or, in each of (i) and (ii), if applicable, such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction).
- 1.2. "Agreement" has the meaning set forth in the Preamble.
- 1.3. "Alliance Manager" has the meaning set forth in Section 2.15 (Alliance Mangers).
- 1.4. "Allocable Overhead" means overhead costs (including Employment Costs and Third Party costs) related to the manufacture or support of the manufacturing of a product (including quality, process development and process improvements). Allocable Overhead costs are Indirect Costs and include all costs for supervisory services, occupancy and similar functions and activities customarily treated as overhead, including costs attributable to: (i) depreciation of or rent/lease expenses for property, facilities and capital equipment; (ii) company and facilities management (e.g.,

supervisors, human resources and purchasing); (iii) facilities services, security, surveillance, environmental protection, utilities, maintenance and repair (e.g., engineering and production planning); (iv) logistical costs; (v) finance and accounting support, data processing, legal affairs, training and information systems services; (vi) insurance (e.g., fire, product liability and business interruption insurance); (vii) indirect materials, supplies and consumables; (viii) general services (e.g., telephones, fax, postal services, copying and office services and equipment, cleaning, health services, and energy maintenance); (ix) process development (optimization/characterization), process validation, quality assurance and quality control costs; (x) internal/external efforts required to complete and submit any regulatory or governmental approval relating to the manufacture of Ivory or a facility manufacturing Ivory; (xi) product and inventory losses; and (xii) cycle count adjustments. Allocable Overhead may be allocated based upon percent of effort, resource utilization or other reasonable measure. [\*].

- 1.5. *"Amgen"* has the meaning set forth in the Preamble.
- 1.6. *"Amgen Costs"* has the meaning set forth in Section 6.1.2 (Amgen Costs).
- 1.7. "*Amgen Housemarks*" means the corporate logo of Amgen, the trademark "Amgen" and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word "Amgen" and all intellectual property rights residing in the foregoing.
- 1.8. *"Amgen's Patent Attorneys"* means Amgen's in-house patent attorney, [\*], primarily responsible for patent matters with respect to Ivory in the Collaboration Scope.
- 1.9. "*Amgen Sales Force Costs*" means the allocable share of Amgen's (or its Affiliates') sales force costs for sales representatives responsible for Detailing Ivory in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 1.10. [\*].
- 1.11. "Applicable Laws" means, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Governmental Authorities, courts, tribunals, agencies other than Governmental Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.
- 1.12. "Assisting Party" has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.13. "Audited Party" has the meaning set forth in Section 7.4 (Audits).
- 1.14. "Auditing Party" has the meaning set forth in Section 7.4 (Audits).
- 1.15. "Brand Book" means the Product Trademark usage and style guide for Ivory established and updated from time-to-time by the JBT.

- 1.16. "Brand Plan" means the brand plan for Ivory established by the JBT.
- 1.17. *"Bundle"* means Ivory sold together with another pharmaceutical compound for a single price.
- 1.18. "Change of Control" means: (i) the acquisition, directly or indirectly, by any person, entity or "group" (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding Voting Securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party and its Affiliates; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty percent (50%) or less of the surviving entity's voting power immediately after such consolidation, merger or reorganization.
- 1.19. "Change of Control Notice" has the meaning set forth in Section 15.2 (Change of Control of Amgen).
- 1.20. "COGS" means the Standard Cost for Ivory adjusted to reflect the sum of actual Direct Costs and Indirect Costs for the Inventory Layer from which such Ivory was taken less, to the extent not previously deducted, net non-refundable taxes or duties and distribution and warehousing costs. COGS will be calculated consistently with other products and in accordance with GAAP.
- 1.21. *"Collaboration* [\*]" has the meaning set forth in Section 14.11.3.
- 1.22. "Collaboration Budget" has the meaning set forth in Section 2.10 (Joint Steering Committee).
- 1.23. "*Collaboration Field*" means the use of Ivory in any Collaboration SKU (including 60mg Collaboration SKU presentations) for the treatment, palliation or prevention of one (1) or more of the following diseases and conditions in humans: (i) post-menopausal osteoporosis; (ii) glucocorticoid induced osteoporosis; and (iii) male osteoporosis. The Collaboration Field does not include the Excluded Field.
- 1.24. *"Collaboration Losses"* has the meaning set forth in Section 6.5 (Collaboration Losses).
- 1.25. "Collaboration Review Committee" or "CRC" means the committee established to resolve issues in accordance with Article 2 (Scope and Governance).
- 1.26. "Collaboration Profit (Loss)" has the meaning set forth in Section 6.1.8 (Calculation of Profit (or Loss)).
- 1.27. "Collaboration Scope" means the Collaboration Field in the Collaboration Territory.
- 1.28. "*Collaboration SKUs*" means those SKUs pursued by Amgen and labeled for use for the treatment, palliation or prevention of one (1) or more of the following diseases and conditions in the Collaboration Territory in humans: (i) post-menopausal osteoporosis; (ii) glucocorticoid induced osteoporosis; and (iii) male osteoporosis.

- 1.29. "*Collaboration* Territory" means those countries set forth on the Collaboration Territory Schedule and any country added pursuant to Section 2.16 (Territorial Expansion).
- 1.30. *"Collaboration Territory R&D Costs"* means those costs incurred by or on behalf of either Party or its Affiliates in connection with research and development of Ivory in accordance with the Development Plan in the Collaboration Field for the primary benefit of the Collaboration Territory (including the costs of Phase IV Trials undertaken in the Collaboration Field for the benefit of the Collaboration Territory); provided, that, notwithstanding anything to the contrary in this Agreement, Collaboration Territory R&D Costs will exclude the costs of all of Amgen's internal FTEs that are involved in the conduct of research and development, which will be deemed Qualified Amgen R&D Costs.
- 1.31. "Commercially Reasonable Efforts" means, with respect to activities of a Party related to Ivory under this Agreement, the efforts and resources typically used by that Party (or, if a Party does not engage in that activity for other products or compounds, by biotechnology and/or pharmaceutical companies that are similar in size and financial resources to such Party) in the conduct of such activities with respect to products of comparable market potential, taking into account all relevant factors including, as applicable, stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Governmental Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Regulatory Approval, and actual or projected profitability. For purposes of clarity, Commercially Reasonable Efforts will be determined on a country-by-country basis within the Collaboration Territory, and it is anticipated that the level of effort may be different for different countries and may change over time, reflecting changes in the status of Ivory and the country(ies) involved.
- 1.32. *"Contract Interest Rate"* means the [\*] effective for the date that payment was due, as published by <u>The Wall Street Journal</u>, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Applicable Law.
- 1.33. "Copyright" means all right, title, and interest in and to all copyrightable works and any copyright registration or corresponding legal right.
- 1.34. "Country Plans" has the meaning set forth in Section 3.2 (Country Plans).
- 1.35. *"Country Team"* means one of the teams overseeing commercialization of Ivory in the Collaboration Field in a given country (or countries) within the Collaboration Territory in accordance with Article 2 (Scope and Governance).
- 1.36. "Designated GSK Activities" means those activities for which GSK is responsible pursuant to Section 3.1 (Allocation of Operational Responsibilities) or 3.3 (Designated GSK Activities).
- 1.37. "Defending Party" has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.38. "*Detail*" means an interactive face-to-face visit by a sales representative with a medical professional having prescribing authority or who is able to influence prescribing

decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings and/or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses. Detail includes First Position Details, Second Position Details and Other Details. Activities conducted by medical support staff (such as medical science liaisons) will not constitute Details. 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 will not constitute Details. "Detailing" means the act of performing Details and to "Detail" mean to perform Details.

- 1.39. "Detail Report" has the meaning set forth in Section 3.11.1 (Reporting).
- 1.40. "*Development Budget*" means the budget applicable to the Development Plan. The Development Budget applicable to the Initial Development Plan (the "*Initial Development Budget*") is attached hereto as the Development Budget Schedule.
- 1.41. "Development Plan" means the plan established by the JDC covering: (i) the research and development (including Phase IV Trials) of Ivory in the Collaboration Field for (a) the primary benefit of one (1) or more countries or regions in the Collaboration Territory, or (b) if not for the primary benefit of one (1) or more countries or regions in the Collaboration Territory, or (b) if not for the primary benefit of one (1) or more countries or regions in the Collaboration Territory, or (b) if not for the primary benefit of one (1) or more countries or regions in the Collaboration Territory, then otherwise useful to the Collaboration Scope; (ii) the preparation and submission of Regulatory Filings; and (iii) the obtaining, maintenance or expansion of Regulatory Approvals of Ivory in the Collaboration Scope. The initial Development Plan (the "Initial Development Plan") covering calendar years 2009 through 2012 is attached hereto as the Development Plan Schedule, and will be reviewed and updated by the JDC on an annual basis or more frequently as agreed by the Parties. For the avoidance of doubt, information contained in the Initial Development Plan covering January 1, 2009 through the Effective Date is provided for informational purposes only, and is not intended to create any obligations on GSK with respect to such development during such period, including the obligation to pay or share any costs associated with such development for such period.
- 1.42. "*Direct Costs*" means all costs incurred by or on behalf of Amgen and/or its Affiliates for resources and rights directly associated with the manufacture of Ivory, including raw materials and finishing supplies used to manufacture Ivory, payments to subcontractors with respect to the manufacture of Ivory, payments (including royalties) to Third Parties for rights used in the manufacture of Ivory, and Employment Costs for personnel directly involved in any aspect of manufacturing Ivory such as equipment operators, line mechanics, set up mechanics and material handlers to supply the line.
- 1.43. [\*]
- 1.44. [\*]
- 1.45. [\*]
- 1.46. [\*]
- 1.47. "Effective Date" has the meaning set forth in the Preamble.
- 1.48. "EMEA" means the European Medicines Agency, and any successor agency thereto.

- 1.49. "Employment Costs" means all actual costs incurred by or on behalf of a Party and/or its Affiliates with respect to any employee.
- 1.50. *"Excluded Field"* means the use of Ivory for any purpose outside the Collaboration Field, including veterinary or diagnostic purposes, and including the use of Ivory for the treatment, palliation or prevention of the following diseases and conditions in humans: (i) bone metastases; (ii) bone loss induced by cancer therapy or hormone ablation therapy; and (iii) cancer-related bone damage.
- 1.51. *"Excluded Territory"* means the United States of America, Canada, Japan, Bahrain, Jordan, Kuwait, Oman, Qatar, Egypt, Morocco, Tunisia, Algeria, Libya, Saudi Arabia, Turkey, the United Arab Emirates and any other country not included within the Expansion Territory (as defined in the Expansion Agreement) and, with respect to each of the foregoing, the territories and possessions thereof.
- 1.52. *"Expansion Agreement"* means the agreement entered into between the Parties of even date herewith, pursuant to which Amgen grants GSK certain rights with respect to Ivory in the Expansion Territory (as defined in the Expansion Agreement).
- 1.53. *"First Position Detail"* means a Detail in which the applicable pharmaceutical product is Detailed before any other product and the predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- 1.54. "For Cause Audit" has the meaning set forth in Section 3.14.4 (Manufacturing).
- 1.55. *"FTE"* means, with respect to a person (other than an employee that Details Ivory), the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of 45.5 weeks or 1,820 hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. For an employee that Details Ivory, FTEs will be calculated as set forth in Section 6.1.10 (Calculation of Sales Force Costs).
- 1.56. *"FTE Rate"* means, with respect to a particular type of employee and geography, for the period commencing on the Effective Date until such time as the JSC agrees otherwise, the fully-burdened amount set forth on the FTE Rate Schedule per full-time employee per year (as of the Effective Date), which rate will be increased by [\*] of the then-current FTE Rate on January 1 of 2010 and each subsequent calendar year. For the avoidance of doubt, the JSC may agree to continue to use the rates set forth in the FTE Rate Schedule or to use different rates, which may be higher or lower than those set forth in the FTE Rate Schedule. The FTE Rate Schedule will be updated in writing to reflect any such agreement of the JSC.
- 1.57. "*GAAP*" means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.
- 1.58. *"GDP"* means the applicable provisions governing distribution of medicinal products for human use, including European Commission Directive (2003/94/EC) (principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use), European

Commission Guidelines (94/C 63/03) (the Guidelines on Good Distribution Practice of Medicinal Products for Human Use), European Commission Directive (2001/83/EC)(relating to medicinal products for human use) and any applicable local guidelines in respect of good distribution practice for pharmaceutical products, in each case, as amended.

- 1.59. "*GMP*" means practices with respect to the manufacture of Ivory as required by the following: (i) if Ivory will be supplied to any jurisdiction adopting the International Conference on Harmonisation Guidelines other than the European Union (which is addressed below), ICHQ7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, (ii) if the site of manufacture of Ivory is within the European Union or will be supplied to a country within the European Union, the principles and guidelines of Good Manufacturing Practices for medicinal products as defined within European Commission Directive 2003/94/EC and associated European Union Guidelines to Good Manufacturing Practice, (iii) if the site of manufacture is in the United States of America, provisions of 21 C.F.R. parts 210 and 211, or (iv) if Ivory will be supplied to any other country not falling within (i)-(iii) above, then the requirements shall be no more onerous than the requirements set out in (i)-(iii) above. "*ICHQ7*" means the ICH Harmonised Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7, as amended from time to time.
- 1.60. *"Governmental Authority"* means any government or supranational administrative agency, commission or other governmental or supranational authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.
- 1.61. *"GSK"* has the meaning set forth in the Preamble.
- 1.62. "GSK Costs" has the meaning set forth in Section 6.1.1 (GSK Costs).
- 1.63. "*GSK Housemarks*" means the corporate logo of GSK, the trademarks "GSK", "GlaxoSmithKline" and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word "GlaxoSmithKline" and intellectual property rights residing in the foregoing.
- 1.64. "*GSK Inventions*" means any Invention made solely by GSK or its Affiliates (and not jointly with Amgen or any of its Affiliates) during the Term in the course of performing the activities contemplated hereunder that relates substantially to the composition of matter, formulation or use of Ivory.
- 1.65. *"GSK Sales Force Costs"* means the allocable share of GSK's (and/or its Affiliates') costs for sales representatives responsible for Detailing Ivory in the Collaboration Scope in accordance with this Agreement, calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 1.66. "IFRS" means the then current International Financial Reporting Standards, consistently applied.
- 1.67. *"Indirect Costs"* means Allocable Overhead and Employment Costs attributed to the manufacture and supply of Ivory, and not included in the definition of Direct Costs.

- 1.68. "Infringement Claim" has the meaning set forth in Section 9.7 (Defense and Settlement of Third Party Claims of Infringement).
- 1.69. *"Invention"* means any idea, concept, discovery, invention, improvement or trade secret.
- 1.70. *"Inventorship Margin"* means: (i) [\*] with respect to calendar year Ivory Net Revenues in an amount less than or equal to [\*]; (ii) [\*] with respect to calendar year Ivory Net Revenues in an amount over [\*] up to and including [\*]; and (iii) [\*] with respect to calendar year Ivory Net Revenues greater than [\*].
- 1.71. "Inventory Layer" means all amounts of Ivory manufactured at a specific site during a given calendar year.
- 1.72. "ISS" means a clinical study or research study initiated and conducted by an individual not employed by or on the behalf of a Party.
- 1.73. "Ivory" means Amgen's proprietary antibody, denosumab.
- 1.74. *"Ivory Intellectual Property"* means any Invention, Know-How, Patents, Product Trademark, trademark application, electronic media registrations (including domain names, usernames, websites, blogs and the like), or Copyright owned or controlled by Amgen or its Affiliates that is related to Ivory in the Collaboration Scope.
- 1.75. *"Ivory Net Revenues"* means: (i) the aggregate of the gross invoiced sales prices for Ivory that is sold or transferred for value by Amgen or its Affiliates to Third Parties in the Collaboration Territory and used in the Collaboration Scope, minus the following amounts incurred or paid (each as recognized by GAAP and each to the extent not already deducted when calculating COGS) by Amgen or its Affiliates with respect to such sales or transfers for value (regardless of the period in which such amounts are incurred or paid):
  - 1.75.1. trade, cash, prompt payment and/or quantity discounts;
  - 1.75.2. payments to government agencies, returns, refunds, allowances, rebates and chargebacks;
  - 1.75.3. retroactive price reductions applicable to sales of Ivory;
  - 1.75.4. fees paid to distributors, wholesalers, selling agents (excluding any sales representatives of a Party or any of its Affiliates), group purchasing organizations and managed care entities;
  - 1.75.5. the standard inventory cost (actual acquisition or manufacture cost) of devices used for dispensing or administering Ivory which are shipped with the Ivory and included in the gross invoiced sales prices;
  - 1.75.6. credits or allowances for product replacement, whether cash or trade;
  - 1.75.7. any tax, tariff, duty or governmental charge levied on the sales, transfer, transportation or delivery of Ivory (including any tax such as a value added or similar tax or government charge), other than franchise or income tax of any kind whatsoever;
  - 1.75.8. [\*];

### 1.75.9. [\*]; and

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

plus (ii) any Recoveries made pursuant to Section 9.8 (Enforcement).

- 1.76. "Ivory Patent and Trademarks" has the meaning set forth in Section 9.6 (Prosecution and Maintenance).
- 1.77. "Joint Brand Team" or "JBT" means the joint brand team established pursuant to Article 2 (Scope and Governance).
- 1.78. "Joint Claim" has the meaning set forth in Section 13.5 (Defense of Third Party Claims).
- 1.79. "Joint Development Committee" or "JDC" means the development committee established pursuant to Article 2 (Scope and Governance).
- 1.80. "Joint Invention" has the meaning set forth in Section 9.1 (Invention Ownership).
- 1.81. "Joint Steering Committee" or "JSC" means the steering committee established pursuant to Article 2 (Scope and Governance).
- 1.82. [\*].
- 1.83. *"Know-How"* means all tangible and intangible techniques, information, technology, practices, trade secrets, Inventions (whether patentable or not), methods, processes, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological, manufacturing, and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, including works of authorship and Copyrights. Know-How does not include Patents.
- 1.84. "Other Detail" means any Detail other than a First Position Detail or a Second Position Detail.
- 1.85. "Party" or "Parties" has the meaning set forth in the Preamble.
- 1.86. *"Patent Coordinator"* means those employees of each of the Parties appointed pursuant to Section 2.14 (Patent Coordinators) to serve as each such Party's primary liaison with the other Party on matters relating to intellectual property as described in this Agreement.
- 1.87. *"Patents"* means the issued patents and pending patent applications (including certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, refilings, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and patent term extensions thereof, and all international or foreign counterparts of any of the foregoing (including supplemental protection certificates, patents of addition and the like).
- 1.88. *"Person"* means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, "group" as defined in Section 13(d)(3) of the Exchange Act, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

- 1.89. "*Phase IV Trial*" means any clinical study initiated in the Collaboration Territory following the first Regulatory Approval for Ivory in the Collaboration Scope for the indication being studied. Phase IV Trials may include epidemiological studies, modeling and pharmacoeconomic studies, ISS and post-marketing surveillance studies.
- 1.90. "*Product Trademarks*" means the trademark "Prolia<sup>™</sup>," any other related trademark, trade name or service mark (whether registered or unregistered) containing the word "Prolia<sup>™</sup>," and any other trademark, trade name or service mark (whether registered or unregistered) selected by the JBT for use on, with, or to refer to Ivory (other than Amgen Housemarks and GSK Housemarks, as applicable) in the Collaboration Territory during the Term, and all intellectual property rights residing in the foregoing.
- 1.91. "Promotional Materials" has the meaning set forth in Section 3.10 (Promotional Materials).
- 1.92. *"Prosecution and Maintenance"* means the preparation, filing, and prosecution of patent applications and maintenance of patents, as well as reexaminations and reissues with respect to such patents, together with the conduct of interferences and the defense of oppositions with respect to such patent application or patent; and *"Prosecute and Maintain"* has the correlative meaning.
- 1.93. "Qualified Amgen R&D Costs" means those costs incurred by or on behalf of Amgen or its Affiliates in connection with research and development of Ivory useful to the Collaboration Scope, but excluding: (i) Collaboration Territory R&D Costs; and (ii) any costs applicable to the research and development of Ivory for the sole benefit of one (1) or more countries or regions in the Excluded Territory or Expansion Territory and not useful in the Collaboration Scope. "Qualified Amgen R&D Costs" will include the costs of all of Amgen's internal FTEs that are involved in the conduct of development of Ivory in the Collaboration Field, regardless of whether directed to the Collaboration Territory or countries outside the Collaboration Territory (including the Expansion Territory and/or the Excluded Territory). Such FTE costs will not be included in Collaboration Territory R&D Costs.
- 1.94. *"Recoveries"* means all monies received by Amgen from a Third Party in connection with the final, non-appealable judgment (or judgment with respect to which the time period for appeal has expired), award or settlement of any enforcement with respect to any Ivory Intellectual Property, to the extent such judgment, award or settlement pertains to activities within the Collaboration Scope.
- 1.95. *"Regulatory Approval"* means a product-specific approval from a Governmental Authority necessary for the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory.
- 1.96. *"Regulatory Filing"* means any filing with any Governmental Authority with respect to the research, development manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory.
- 1.97. "Remediation Plan" has the meaning set forth in Section 14.2.2.

1.99. [\*]

- 1.100. "Routine Audit" has the meaning set forth in Section 3.14.4 (Manufacturing).
- 1.101. *"Rules"* has the meaning set forth in Section 16.2 (Arbitration).
- 1.102. "Sales Forecast" means the sales forecast set forth in the Sales Forecast Schedule.
- 1.103. "Samples" has the meaning set forth in Section 3.13 (Samples).
- 1.104. "Second Position Detail" means a Detail in which the applicable pharmaceutical product is Detailed in the second position (i.e., no more than one (1) other product is presented to or discussed with the healthcare professional before Ivory) and the second most predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- 1.105. "Segregate" means, with respect to two (2) programs: (i) [\*] (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the [\*] (for the purposes of this Section 1.105, "Personnel")) [\*]; (ii) to ensure that [\*] and vice versa; (iii) to ensure that [\*] and vice versa; and (iv) from time-to-time, upon the reasonable request of the other Party, to provide information requested relating to the foregoing items (i) through (iii), and to reasonably cooperate to enable the other Party to verify that such restrictions are in place and sufficient to achieve the foregoing. For clarity, [\*] as set forth herein.
- 1.106. "Special Meeting" has the meaning set forth in Section 14.2.2.
- 1.107. *"Standard Costs"* means, with respect to a Collaboration SKU, standard cost for the Inventory Layer from which such Collaboration SKU was taken, as reflected in Amgen's accounting records at the time such Collaboration SKU is sold. Such Standard Cost, calculated annually for the period commencing January 1 and ending December 31 of the same year, is the sum of estimated Direct and Indirect Costs for Ivory produced as of such date of sale.
- 1.108. [\*]
- 1.109. [\*]
- 1.110. "Taxes" means any tax, excise or duty, other than taxes upon income.
- 1.111. *"Term"* means the period commencing on the Effective Date and ending upon [\*], unless and until sooner terminated pursuant to any provision of this Agreement.
- 1.112. "Third Party" means any Person that is not a Party, or an Affiliate of a Party.
- 1.113. "Third Party Claim" means any claim, action, lawsuit, or other proceeding brought by any Third Party. [\*]
- 1.114. *"VAT"* means the tax imposed by Council Directive 2006/112/EC of the European Community and any national legislation implementing that directive together with legislation supplemental thereto and in particular, in relation to the United Kingdom, the tax imposed by the Value Added Tax Act of 1994 or other tax of a similar nature imposed in other countries in the Collaboration Territory instead of or in addition to value added tax.

<sup>1.98. [\*]</sup> 

1.115. "Voting Securities" means securities entitled to be voted generally or in the election of directors of a Person.

#### 2. SCOPE AND GOVERNANCE

- 2.1. <u>Purpose of the Collaboration</u>. The purpose of the collaboration is for the Parties to collaborate in the commercialization of Ivory in the Collaboration Scope and for the Parties to share in certain costs and revenues related to Ivory, all as described in more detail herein.
- 2.2. <u>Co-Exclusive Appointment</u>. Subject to the terms and conditions of this Agreement, Amgen hereby retains GSK on a co-exclusive basis with Amgen to Detail Ivory in the Collaboration Scope and to conduct the Designated GSK Activities.
- 2.3. <u>Governance</u>. With respect to the Collaboration Scope, the collaboration will be governed by: (i) the CRC, which will be responsible for the resolution of issues within the collaboration that cannot be resolved by the JSC; (ii) the JSC, which will be responsible for oversight of the collaboration; (iii) the JBT, which will be responsible for developing the Brand Plan for Ivory within the Collaboration Scope; (iv) a Country Team for each country within the Collaboration Territory (provided that one (1) Country Team may oversee more than one (1) country (e.g., Benelux countries)); (v) the JDC, which will be responsible for establishing the Development Plan and discussing the activities to be conducted thereunder; and (vi) the Patent Coordinators responsible for intellectual property issues as set forth herein. All such committee and teams (the terms committee and team being used interchangeably herein) will be formed promptly following the Effective Date. Each such committee and team will oversee the activities undertaken by the Parties in the Collaboration Scope within the scope of authority of such committee or team, including monitoring progress against plans and outlining how Parties will collaborate in the conduct of such activities. It is expected that the committees and teams will develop plans and strategies assigned to it in a collaborative manner and will serve as a forum for discussion of and input into such plans and strategies.
- 2.4. <u>Decision Making Standards</u>. The decisions made and actions taken by the CRC, JSC, JBT, JDC, Country Teams and Patent Coordinators will be made with the interests of both Parties (including the Parties' interests in the collaboration) (as presented to such committee or team) duly considered in good faith. Subject to the terms of this Agreement and Applicable Law, the decisions of such teams and committees will be made in accordance with the discretion and business judgment of the members thereof.
- 2.5. <u>Membership</u>. Each of the JSC, JBT and JDC will be comprised of three (3) members appointed by Amgen, and three (3) members appointed by GSK (or such other number of members as agreed in writing by the Parties). The JSC, JBT and JDC will each be led by two (2) co-chairs, one (1) appointed by each of the Parties. Each Country Team will be comprised of four (4) members appointed by Amgen, and four (4) members appointed by GSK (or other number of members as agreed in writing by the Parties). The CRC will be comprised of one (1) member appointed by each of the Parties, and such members initially will be the President of Pharmaceuticals, Europe (or his or her designee) for GSK and Executive Vice-President, Global Commercial Operations (or

his or her designee) for Amgen. Each Party will ensure that the committee members appointed by it have the appropriate level of seniority and decisionmaking authority commensurate with the responsibilities of the committee to which they are appointed.

- 2.6. <u>Replacement of Members</u>. Each Party will have the right to replace its committee members by written notice to the other Party. In the event any committee member becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member will promptly appoint a replacement by written notice to the other Party.
- 2.7. <u>Establishment of Subcommittees</u>. Each committee will have the right to establish subcommittees or working teams with respect to issues within its area of responsibility as it sees fit (e.g., pricing, manufacturing or operations). Each Country Team will have the right to establish a local operations team to facilitate the performance of its responsibilities.
- 2.8. <u>No Authority to Amend or Modify</u>. Notwithstanding anything herein to the contrary, no committee will have any authority to amend, modify or waive compliance with this Agreement.
- 2.9. <u>Collaboration Review Committee</u>. The CRC will be responsible for resolving any issues within the collaboration that cannot be resolved by the JSC.
  - 2.9.1. *Meetings.* The CRC will meet as requested by the JSC to resolve unresolved issues, via teleconference or videoconference or as otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend CRC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. All CRC meetings must have all members in attendance.
  - 2.9.2. *Decision Making*. The CRC will make decisions by consensus with each Party having one vote. In the event of a deadlock the decision will be made by the member appointed to the CRC by Amgen.
- 2.10. Joint Steering Committee. The JSC will be responsible for overseeing the collaboration, including the commercialization of Ivory in the Collaboration Scope generally. The JSC will be a forum for: (i) discussing commercialization strategy; (ii) approving the Brand Plan established by the JBT; (iii) reviewing the allocation of operational responsibility between the Parties set forth in the Country Plans; (iv) allocating operational responsibility between the Parties for activities that are applicable to the Collaboration Scope as a whole (i.e. that are not country-specific); (v) developing and updating a rolling three (3) year Sales Forecast and supply forecast; (vi) developing and updating the expense budget (expressed in U.S. Dollars, unless otherwise agreed by the Parties) for commercialization activities to be undertaken pursuant to the collaboration based upon the Brand Plan and Country Plans (the "*Collaboration Budget*"); (vii) reviewing and approving the draft pricing and access plan proposed by the JBT; (viii) reviewing the Standard Costs of Ivory on an annual basis and additionally if and when the Standard Costs exceed, or are expected to exceed, the expected Standard Costs by [\*] or more; (ix) discussing sourcing matters related to the manufacture of
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Ivory, including: (a) to what extent Third Parties will be used to manufacture Ivory for the Collaboration Scope and any material changes to the arrangement with such Third Party manufacturer(s) in advance of implementation of such changes; and (b) methodology of allocating Inventory Layers to the Collaboration Scope; (x) discussing adequacy of supply of Ivory for the Collaboration Scope in connection with then-current forecasts and any occurrence that may require a For Cause Audit as provided in Section 3.14.4 (Manufacturing), (xi) agreeing to an amended FTE Rate Schedule, and (xii) discussing regulatory matters. The JSC will conduct its activities in consultation and/or cooperation with the JDC with respect to those matters that such committees determine appropriate, including regulatory matters and the usefulness of development to the commercial potential of Ivory in the Collaboration Scope.

- 2.10.1. *Meetings*. The JSC will meet quarterly, via teleconference or videoconference or otherwise (with at least two (2) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JSC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JSC as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JSC meetings must have at least one (1) member appointed by each Party in attendance.
- 2.10.2. *Reporting.* Each Party will keep the JSC fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JSC and as otherwise provided herein. Each Party will fully inform the JSC with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof. Notwithstanding the foregoing, Amgen will have no obligation to provide proprietary manufacturing information to GSK through any committee or otherwise.
- 2.10.3. *Decision Making*. The JSC will make decisions by consensus with each Party having one vote. In the event of a deadlock on an issue, the decision will made by the members of the JSC appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the CRC for determination. Notwithstanding the foregoing, in the event of a decision on any matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JSC appointed by Amgen will have the right to make an interim decision pending CRC determination.
- 2.11. <u>Joint Brand Team</u>. The JBT will be responsible for developing specified plans and overseeing specified commercial activities relating to Ivory in the Collaboration Scope generally. The JBT will be a forum for discussing, developing, and agreeing upon the

Brand Plan for submission to the JSC for approval. The JBT's responsibilities will include: (i) cross-functional, collaborative development and updating of the Brand Plan including strategies and tactics at the regional level; (ii) consolidation of expense and Sales Forecasts from the country level; (iii) developing and updating a draft pricing and access plan for JSC approval; (iv) tactical alignment of commercialization activities with expense budget allocations; and (v) core message element development, updating and communication to the Country Teams. The JBT will conduct its activities in consultation and/or cooperation with the Country Teams with respect to those matters that such teams determine appropriate.

- 2.11.1. *Meetings*. The JBT will meet monthly, via teleconference or videoconference or otherwise (with at least four (4) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JBT meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JBT as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JBT meetings must have at least one (1) member appointed by each Party in attendance.
- 2.11.2. *Reporting.* Each Party will keep the JBT fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JBT and as otherwise provided herein. Each Party will fully inform the JBT with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.11.3. *Decision Making*. The JBT will make decisions by consensus with each Party having one vote. In the event of a deadlock, the decision will be made by the members of the JBT appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the JSC for determination. In the event of a decision on a matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JBT appointed by Amgen will have the right to make an interim decision pending JSC determination.
- 2.12. Joint Development Committee. The JDC will be responsible for updating the Development Plan and the Development Budget, reviewing clinical protocols for studies to be conducted under the Development Plan, and overseeing the conduct and progress of the activities set forth in the Development Plan including regulatory matters. In addition to the foregoing, the JDC will discuss development to be undertaken by Amgen outside the Collaboration Scope to the extent either Party reasonably believes such development is reasonably likely to have a material adverse effect on Ivory within the Collaboration Scope (and Amgen will provide summary information of Ivory development to be undertaken by Amgen outside the Collaboration Scope in order to

enable GSK to make such determination). The JDC will conduct its activities in consultation and/or cooperation with the JSC with respect to those matters as such committees determine appropriate, including regulatory matters and the usefulness of development to the commercial potential of Ivory in the Collaboration Scope.

- 2.12.1. *Meetings*. The JDC will meet quarterly, via teleconference or videoconference or otherwise (with at least one (1) meeting per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European or global headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend JDC meetings, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the JDC as reasonably required to discuss particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All JDC meetings must have a member appointed by each Party in attendance.
- 2.12.2. *Reporting.* Each Party will keep the JDC fully and promptly informed of progress and results of activities in the Collaboration Scope for which it is responsible or that it is permitted to conduct hereunder through its members on the JDC and as otherwise provided herein. Each Party will fully inform the JDC with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.12.3. *Decision Making*. The JDC will make decisions by consensus with each Party having one vote. In the event of a deadlock, the decision will be made by the members of the JDC appointed by Amgen, provided that the members appointed by either Party will have the right to escalate to the CRC for determination decisions that: (i) involve a safety issue; (ii) are likely to have a material impact on the Development Budget; or (iii) involve development that is likely to have a material adverse effect on commercialization of Ivory in the Collaboration Scope, in each case, in the reasonable opinion of the escalating Party. In the event of a decision on a matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the JDC appointed by Amgen will have the right to make an interim decision pending CRC determination.
- 2.13. <u>Country Teams</u>. Country Teams will be responsible for localizing and implementing marketing strategy and brand planning, allocation of sales representatives, coordination of primary and specialty care sales representatives, determination of Detail frequency and weighting, determination of customer targets, planning sales implementation meetings, review of local sales performance metrics and market research, review of local forecasts for revenue and expenses and review of local access and reimbursement matters, in each case for the relevant country or countries. All such matters will be in accordance with the Brand Plan. The Country Teams will conduct their activities in consultation and/or cooperation with the JBT with respect to those matters that such teams determine appropriate.

- 2.13.1. Meetings. Each Country Team will meet six (6) times per year, or as otherwise agreed by the Parties. Meetings will be held on an alternating basis between GSK's and Amgen's headquarters for the relevant country, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Country Team meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of a Country Team as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the designated member appointed by the other Party. All Country Team meetings must have at least one (1) member appointed by each Party in attendance. At the request of the JBT, each Country Team will attend international brand strategy and/or communications summits.
- 2.13.2. *Reporting*. Each Party will keep each Country Team fully and promptly informed of progress and results of activities in the relevant region for which it is responsible or that it is permitted to conduct hereunder through its members on the relevant Country Team and as otherwise provided herein. Each Party will fully inform each Country Team with respect to its activities in the Collaboration Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.13.3. *Decision Making.* Each Country Team will make decisions by consensus. In the event of a deadlock, the decision will be made by the members of the relevant Country Team appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the JSC for determination. In the event of a decision that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the Country Team appointed by Amgen will have the right to make an interim decision pending JSC determination.
- 2.14. Patent Coordinators. The Parties will each appoint a Patent Coordinator promptly after the Effective Date of the Agreement. The Patent Coordinators will serve as the primary contacts and forum for discussion between the Parties with respect to intellectual property matters involving Ivory worldwide in the Collaboration Field, and will cooperate with respect to the activities set forth in Article 9 (Intellectual Property). A [\*] in each case within the Collaboration Scope or outside the Collaboration Scope to the extent such matter [\*]. The Patent Coordinators will meet as often as agreed by them (and at least semi-annually if requested), via teleconference or videoconference or as otherwise agreed, to discuss matters arising out of the activities set forth in Article 9 (Intellectual Property). To the extent reasonably requested by either Patent Coordinator, the Patent Coordinators will solicit the involvement of more senior members of their respective legal departments (up to the most senior intellectual property attorney, where appropriate) with respect to critical issues, and may escalate issues to the JSC for input. Each of the Patent Coordinator will have the obligation to disclose information to the extent

prohibited by obligation of confidentiality or protective order, that would result in loss of attorney-client or other relevant legal privilege, that constitutes proprietary manufacturing information or where the other Party has an actual or potential conflict of interest with respect to such information (e.g., where sharing such information would be reasonably likely to provide the recipient with a commercial advantage with respect to a product competitive to Ivory that is being developed or commercialized by such Party).

- 2.15. <u>Alliance Managers</u>. Promptly after the Effective Date, each Party will appoint a person who will oversee interactions between the Parties between meetings of the committees and teams established hereunder (each, an *"Alliance Manager"*). Unless otherwise agreed by the Parties, the Alliance Managers will attend all meetings of the JSC and will have the right to attend all meetings of the JDC and JBT, as non-voting participants at such meetings. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.
- 2.16. <u>Territorial Expansion</u>. Any country that accedes to the European Union (other than a country in the Excluded Territory) after the Effective Date will become part of the Collaboration Territory and incorporated in the collaboration. The Parties will cooperate to ensure a smooth and orderly transition of such country into the collaboration and avoid any action reasonably likely to have a material adverse effect on Ivory. If GSK is the holder of any Regulatory Filings in such country, GSK will transfer to Amgen ownership of, or if such transfer is not possible or until such transfer occurs, provide Amgen a right of reference and right of access to, any Regulatory Filings related to Ivory in the applicable country as requested by Amgen. Amgen will have the right to instruct GSK to abandon any Regulatory Filing in the Collaboration Territory for Ivory, and GSK will promptly do so if so instructed. If a country accedes to the European Union and is incorporated into the collaboration pursuant to this Section 2.16 (Territorial Expansion), Ivory Net Revenues from sales of Ivory in such country will not be included within Ivory Net Revenues for the purpose of calculating the Inventorship Margin, but will be included in Ivory Net Revenues for all other purposes hereunder.
- 2.17. <u>Internal Governance</u>. The Parties acknowledge that the committee and decision-making structure set forth herein is without prejudice to, and does not supplant, the Parties' internal decision-making structures.

# 3. COLLABORATION ACTIVITIES – ALLOCATION AND REPORTING

3.1. <u>Allocation of Operational Responsibility</u>. The JSC will be responsible for allocating non-country-specific commercial activities within the Collaboration Scope to Amgen and/or GSK and for determining whether operational responsibility for any such activity should be transferred from GSK to Amgen or vice versa. The Country Teams will be responsible for allocating country-specific commercial activities within the Collaboration Scope to Amgen and/or GSK in the applicable country or region overseen by such Country Team, and for determining whether operational responsibility for any such activity should be transferred from GSK to Amgen or vice versa. The Country Team, and for determining whether operational responsibility for any such activity should be transferred from GSK to Amgen or vice versa. The Country Teams will keep the JSC informed of the initial allocation of country-specific activities and transfers thereof between the Parties. Unless and until

determined otherwise by the JSC or the relevant Country Team in accordance with the foregoing, the Parties' initial commercial responsibilities will be as set forth in the Country Plans referenced in Section 3.2 (Country Plans), and in Sections 3.3 (Designated GSK Activities) and 3.4 (Designated Amgen Activities).

- 3.2. <u>Country Plans</u>. Allocations of commercial operational responsibility for countries and regions within the Collaboration Scope will be set forth in country plans developed by the relevant Country Team (as such plans may be updated or modified from time-to-time by the relevant Country Team and approved by the JSC), the "*Country Plans*"). Country Plans will be developed by the relevant Country Team promptly upon request by the JBT, taking into account the planned launch timing for the relevant country.
- 3.3. Designated GSK Activities. GSK will be responsible for [\*].
- 3.4. Designated Amgen Activities. Amgen will have operational responsibility to perform [\*].
- 3.5. <u>Collaboration in Commercialization Activities</u>. The allocation of operational responsibility for commercialization activities hereunder as well as the conduct of such activities by the Parties will be subject to comprehensive discussion by the JSC, JBT and Country Teams, as applicable, where each Party will consider the input of the other with respect to the conduct of such activities. The commercial activities will be allocated on a country-specific and non-country specific basis by such committees and/or teams taking into consideration all relevant factors, including the capabilities of each Party to deliver the highest quality product in the most cost-effective manner, without duplication of efforts between the Parties. Each of the JBT and Country Teams, as applicable, will endeavor to meet the goals of the Brand Plan and Country Plans within the parameters of the Collaboration Budget established by the JSC.
- 3.6. <u>Amgen Participation Increase and Transition</u>.
  - 3.6.1. *Participation Increase.* Commencing [\*], Amgen will have the right, but not the obligation, to contribute up to [\*] of the minimum number of full-time primary care sales representatives for Detailing Ivory in one (1) or more countries in the Collaboration Territory. Amgen will provide written notice to GSK via the JSC at least [\*] prior to the date on which Amgen desires to increase its participation, such notice to set forth the level of Amgen's participation and the country or countries of the Collaboration Territory in which Amgen will participate. The Country Teams will be responsible for amending the Country Plans to provide for such reallocation of resources, which will be subject to review by the JSC.
  - 3.6.2. *Potential Quid.* No later than [\*] from the Effective Date, GSK will discuss with Amgen the potential for Amgen's sales force to promote one (1) or more of GSK's products on terms mutually acceptable to the Parties. If the Parties fail to agree on an arrangement for Amgen to promote such product(s), then GSK will consider in good faith engaging in discussions with Amgen, from time-to-time, if additional product quid opportunities become available. For the avoidance of doubt, nothing herein obligates Amgen to promote, or obligates GSK to engage Amgen to promote one (1) or more of GSK's products, and any such agreement must be in a writing duly executed by each of the Parties.

- 3.7. <u>All Sales by Amgen</u>. This Agreement does not authorize GSK, its Affiliates or their respective agents or employees to sell Ivory. Amgen will have the sole right, in Amgen's discretion, to price Ivory (including with respect to trade, quantity or other discounts), determine the launch conditions and terms of sale for Ivory, take orders for and returns of Ivory, issue credits for Ivory, sell Ivory and book sales thereof and GSK will have no rights with respect to Ivory outside the Collaboration Scope. GSK will promptly forward to Amgen all orders for, and requests to order, Ivory. Amgen will have the right to refuse or cancel any order for Ivory without liability to GSK. GSK will not interfere with any agreement of Amgen or any of its Affiliates related to Ivory, including pricing and contracting for the sale of Ivory.
- 3.8. <u>Training</u>. The Parties will jointly (except where impracticable) train the sales representatives hereunder with respect to the promotion of Ivory in the Collaboration Scope (and update such training from time to time as appropriate); (including compliance training as determined by the JBT). The JBT will be responsible for developing the Ivory training programs and materials for the sales forces of Amgen and GSK with respect to Ivory in the Collaboration Scope. Training of the Parties' sales forces will be conducted using only training materials and programs developed by the JBT. Amgen will own all right, title and interest in the training materials developed hereunder (except with respect to any GSK Housemarks contained therein).
- 3.9. <u>Information Concerning Ivory</u>.
  - 3.9.1. *Public Statements.* GSK will ensure that no claims or representations in respect of Ivory or the characteristics thereof are made by or on behalf of it or its Affiliates (by sales force members or otherwise) that have not been approved by Amgen and neither Party will make any claim or representation that does not represent an accurate summary or explanation of the labeling of Ivory.
  - 3.9.2. *Ownership.* GSK will not represent to any Third Party that it has any proprietary or property right or interest in Ivory (or the Product Trademarks or any Patents claiming or covering Ivory or its manufacture, use or sale), except for the rights expressly granted to GSK hereunder. Furthermore, GSK acknowledges that it does not have any right, title or interest in Ivory or the Product Trademarks.
- 3.10. <u>Promotional Materials</u>. All written sales, promotion and advertising materials relating to Ivory (collectively "*Promotional Materials*") (including translations) will be produced by Amgen in accordance with the Brand Plan developed by the JBT and reviewed and approved by the JSC. Any Promotional Materials will include, if permitted by Applicable Law, the Amgen Housemarks and the GSK Housemarks (provided, however, that Amgen will be entitled a reasonable transition period after any required legal approval is obtained to design, order, receive and implement Promotional Materials revised to include the GSK Housemarks). Materials that include the GSK Housemarks will use such GSK Housemarks in accordance with any reasonable usage guidelines provided by GSK, and any usage not conforming with such guidelines will require GSK's prior approval as to the use of such GSK Housemarks. GSK will

respond to any such requests for approval within ten (10) business days. In the absence of such response within such period, the request will be deemed approved. Unless otherwise determined by the JSC, Amgen will be responsible for the printing and delivery to GSK of Promotional Materials for use in GSK's Detailing obligations hereunder, and costs therefor will be included as Amgen Costs for purposes of Collaboration Profit (Loss). Other than GSK's use and distribution of Promotional Materials that are approved by the JSC and used and distributed in connection with GSK's Detailing of Ivory within the Collaboration Scope, GSK will not produce or modify (other than as concepts for consideration by Amgen), or distribute or otherwise use any promotional or communications material relating to Ivory. If so instructed by Amgen, GSK will immediately cease to use any Promotional Materials and will collect and destroy any such materials from its sales representatives (and record and document such collection and destruction (and provide a copy of such documentation to Amgen upon request)). Amgen will own all right, title and interest in and to any and all Promotional Materials including applicable Copyrights and trademarks (except with respect to any GSK Housemarks included in any Promotional Materials), and GSK will execute all documents and take all actions as are reasonably requested by Amgen to vest title to such Promotional Materials, Copyrights and trademarks in Amgen.

#### 3.11. Detailing Reports and Audit Rights.

- 3.11.1. *Reporting.* Each Party will provide the other Party with a report (each a "*Detail Report*"), in such form and manner as determined by the JSC, within twenty (20) calendar days after the end of each calendar month included in the Term, setting forth the following information regarding the efforts of the reporting Party's sales force in Detailing Ivory during the preceding month: (i) the total number of Details made by such sales force, including a breakdown of First Position Details, Second Position Details and Other Details by target and frequency of Detail by customer priority; and (ii) such other information as may be specified by the JSC or JBT.
- 3.11.2. *Audits.* Each Party will keep complete and accurate records of its Detailing of Ivory in sufficient detail to permit the other Party to audit its performance of Details hereunder. During normal business hours and with not less than ten (10) days' advance written notice, a Party will permit the other Party or its authorized representatives to: (i) have access to the records of Detailing activities maintained by such Party for purposes of verifying the accuracy of reports described in Section 3.12.1 (Reporting); and (ii) audit such records; provided, that such audits may not be performed by a Party more than once per calendar year. Any and all audits undertaken pursuant to this Section 3.11.2 (Audits) will be performed at the sole and exclusive expense of the auditing Party and will not be included in Amgen Costs or GSK Costs, as the case may be, for purposes of calculating Collaboration Profit (Loss). If an audit reveals an overstatement of Details of greater than five percent (5%) of the correct amount for the audited period, then the audited Party will pay the reasonable out-of-pocket cost of such inspection.
- 3.12. <u>Medical Inquiries and Product Inquiries</u>. GSK will comply with the directions and policies which Amgen may formulate concerning responses to be made to medical

questions or inquiries from members of the medical and paramedical professions and consumers regarding Ivory (including, if so directed, by referring such questions or inquiries to Amgen) and will, if so requested by Amgen, provide Amgen with details of inquiries received and responses given (including reporting regulatory and safety information as provided in Section 10.1.5 (Regulatory and Safety Information). For questions which GSK and its professional sales representatives have not received prepared answers or which are not answered by then existing Ivory information provided by Amgen (including with respect to technical information such as identification, ingredients or stability/storage), GSK will refer such questions to Amgen. For medical inquiries related to Ivory, including those related to information outside of labeling or which GSK and its professional sales representatives are unable or not authorized under accepted national and international pharmaceutical industry codes of practices to answer, GSK will redirect such inquiries to Amgen. Unless otherwise determined by the JSC, all responses to such medical inquiries from patients, medical professionals, or other third Parties will be provided solely by Amgen. GSK will provide reasonable assistance to Amgen, at Amgen's request and expense, in an effort to fully respond to such communications.

- 3.13. <u>Samples</u>. The JBT will determine and specify in the Brand Plan whether and in what manner and quantities of samples of Ivory (*"Samples"*) will be provided to customers. If the JBT determines that Samples will be provided through the sales force, Amgen will provide GSK with such Samples which GSK will use solely in Detailing Ivory in accordance with the Brand Plan. The Parties will maintain such records with respect to Samples as are required by Applicable Law and applicable national and international pharmaceutical industry codes of practices and will allow representatives of the other Party to inspect such records on reasonable request. Amgen will be solely responsible for the filing of any necessary or required reports to Governmental Authorities with respect to Samples, and GSK will reasonably cooperate with Amgen with respect thereto. If Samples are to be provided through sales representatives, Amgen will ship the Samples to one central warehouse of GSK, as designated by GSK. GSK will be responsible for distributing Samples to its sales representatives in a timely manner. If Amgen determines that another method of Sample distribution is more appropriate, then the Parties will reasonably cooperate to facilitate such distribution. Each Party will be responsible for securing the return of and reconciling existing Sample inventories from its own discontinued field sales representatives and other personnel. Within thirty (30) days after the expiration or termination of this Agreement, or as otherwise requested by Amgen, GSK will return, or otherwise dispose of in accordance with instructions from Amgen, all remaining Samples provided by Amgen and will provide Amgen with a certified statement that all remaining Samples have been returned or otherwise properly disposed of and that GSK is no longer in possession or control of any such Samples.
- 3.14. <u>Non-Commercial Activities</u>. Unless otherwise determined by the JDC, Amgen will have the sole right to perform, itself or through its Affiliates or designees, all non-commercialization activities with respect to Ivory in the Collaboration Scope. In addition, Amgen will have the sole right to perform activities with respect to Ivory outside the Collaboration Scope and GSK will not promote or conduct any activities

with respect to Ivory outside the Collaboration Scope except as may be expressly agreed pursuant to a written agreement between the Parties. Activities to be conducted by Amgen with respect to Ivory in the Collaboration Scope include:

- 3.14.1. *Research and Development*. Global research and development activities in accordance with the Development Plan, including Phase IV Trials, generation of health economics information, and approval of requests to perform ISS;
- 3.14.2. *Regulatory*. Seeking, obtaining and holding all Regulatory Approvals and holding and controlling all Regulatory Filings for Ivory in each of the Collaboration Territory countries, as well as responsibility for all regulatory interactions and communications in the Collaboration Territory;
- 3.14.3. *Safety*. Maintaining the global safety database and core data sheet for Ivory, assessing and reporting adverse events, and handling any product complaints and/or recalls; and
- Manufacturing. All manufacturing of Ivory for all indications and uses in accordance with applicable product specifications and GMP, 3.14.4. including labeling, fill/finish, packaging, selection of presentations and manufacturing-related regulatory activities (including regulatory inspections). GSK will have the right to audit Amgen's manufacturing facilities and any Third Party manufacturing facilities used for the manufacture of Ivory in the Collaboration Scope on a periodic basis, not to exceed once every eighteen (18) months for routine audits ("Routine Audits") or as defined below with respect to for-cause audits ("For Cause Audits") (provided such request is made within sixty (60) days of GSK being informed of or becoming aware of an event that would permit a For Cause Audit in GSK's reasonable opinion). GSK will bear the cost of all Routine Audits and For Cause Audits of Amgen manufacturing facilities conducted by GSK and such costs will not be subject to cost-sharing between the Parties under this Agreement. The costs of any Routine Audits and For Cause Audits of any Third Party manufacturing facility requested by GSK will be included in GSK Costs and will be subject to the cost-sharing principles under this Agreement, unless otherwise provided below. GSK will notify Amgen in writing if GSK desires to conduct any manufacturing audit, and the Parties will mutually agree upon reasonable audit agendas in advance and reasonably cooperate in the conduct of such audit. If GSK notifies Amgen that GSK desires to conduct either a For Cause Audit or Routine Audit of a Third Party manufacturer, Amgen will notify GSK if Amgen's contract with such Third Party manufacturer permits GSK to conduct such audit, in which case Amgen will allow GSK to conduct such audit (with Amgen's participation, if it chooses). If Amgen's contract with such Third Party manufacturer does not permit GSK to conduct audits, then Amgen will conduct such audit and share the results with GSK to the extent permitted under Amgen's contract with such Third Party manufacturer. Notwithstanding the foregoing, the Parties will cooperate to coordinate and achieve reasonable efficiencies with respect to audits of Third Party manufacturers as follows: (i) if GSK requests a Routine Audit of a Third Party manufacturer, and Amgen has conducted a Routine Audit of such manufacturer in the previous [\*], then Amgen will share with GSK the

results of any Routine Audit of such Third Party (to the extent permitted under Amgen's contract with such Third Party manufacturer), (ii) if after sharing the results described under (i), GSK would like to proceed with a Routine Audit of such Third Party, then, to the extent permitted under Amgen's contract with such Third Party manufacturer, GSK may conduct such Routine Audit (or, to the extent permitted under Amgen's contract with such Third Party manufacturer, Amgen will conduct such Routine Audit if GSK is not permitted to do so under the applicable Third Party manufacturing contract) and the costs of such Routine Audit will be borne by GSK and will not be subject to costsharing under this Agreement. Any audit of a Third Party manufacturer will be subject to the terms and conditions of Amgen's contract(s) with such manufacturer and GSK will cooperate and coordinate with Amgen to comply with all reasonable terms and conditions communicated by Amgen in connection with the performance of such audit. Any audit of an Amgen manufacturing facility will comply with Amgen's reasonable policies and procedures. GSK's Routine Audits will be limited in scope to what is reasonably necessary to confirm that Amgen or a Third Party manufacturer has complied with all applicable product specifications, GMP or GDP requirements in manufacturing Ivory. GSK's For Cause Audits will be limited in scope to what is reasonably necessary to confirm that the cause for such audit has been or is being remedied. Any information disclosed to GSK in the course of any audit may only be used for the purposes of such audit. Any audit conducted under this Agreement, the Expansion Agreement or the relevant Ivory supply agreement between Amgen and GSK will be considered an audit conducted under all such agreements. For the purposes of this Section 3.14.4 (Manufacturing), the following will give GSK the right to conduct a For Cause Audit: [\*]. The JSC will review events that may give rise to the right to conduct a For Cause Audit if so requested by either Party.

#### 4. COLLABORATION ACTIVITIES – PERFORMANCE STANDARDS

- 4.1. <u>Collaborative Activities</u>. Activities to be undertaken by the Parties hereunder will be conducted in a collaborative manner as determined by the committee or team overseeing such activities, and in accordance with the terms and conditions of this Agreement, as applicable.
- 4.2. <u>Diligence and Performance Standards</u>. Subject to the decisions made by and oversight of the teams and committees established hereunder, each Party will use, and will assure that each of its Affiliates use, Commercially Reasonable Efforts in the performance of its and their activities hereunder. Each Party will conduct, and ensure that each of its Affiliates conduct, all of its and their activities with respect to the promotion and commercialization of Ivory in the Collaboration Scope in accordance with this Agreement, the Brand Plan, applicable Country Plans, accepted national and international pharmaceutical industry codes of practices in and for the Collaboration Territory, and all Applicable Law. Amgen will conduct, and ensure that each of its Affiliates may agree in writing that GSK or its Affiliates will conduct any activities with respect to the manufacture, distribution or development of Ivory in the Collaboration Scope, then GSK will conduct, and ensure

that each of its Affiliates conduct), all of its and their activities with respect to the manufacture, distribution and development of Ivory in the Collaboration Scope in accordance with this Agreement and all Applicable Law including GMP and GDP. The Parties will provide each other with all reasonably requested cooperation to enable each of them to comply with Applicable Law and accepted national and international pharmaceutical industry codes of practices, including permitting each Party to verify the other Party's compliance therewith.

- 4.3. <u>Detailing Activities</u>. Each Party's sales representatives will conduct the Detailing activities under this Agreement in accordance with the relevant codes of practice established by the Party employing such representative, and nothing herein will be interpreted to require lower standards of conduct with respect to such sales representatives than those required in the codes of practice established by the Party employing such representatives. In addition:
  - 4.3.1. *Minimum Sales Activities.* Each Country Team will determine, in accordance with the Brand Plan, and will set forth in the applicable Country Plan, the number of: (i) primary care sales representatives to be provided by GSK for Detailing Ivory and a minimum number of Details to be conducted by such sales representatives, and (ii) specialty care sales representatives to be provided by Amgen for Detailing Ivory and a minimum number of Details to be conducted by Amgen. The minimums will be subject to periodic adjustments by the applicable Country Team (subject to approval by the JSC). Unless otherwise determined by the JSC or the relevant Country Team, GSK will Detail at least those primary care prescribers who in the aggregate are expected to prescribe [\*] of PMO prescriptions in such country (provided, however, that in [\*] GSK will Detail no less than [\*], and at least [\*] of GSK's Details of Ivory in the Collaboration Territory will be First Position Details; provided, that the [\*], unless otherwise determined by the relevant Country Team). The Parties will not Detail Ivory in the Collaboration Scope except as expressly set forth in the Brand Plan (including with respect to Detailing only to those types of healthcare professionals as set forth in the Brand Plan) and the applicable Country Plan and GSK will not promote or Detail Ivory outside the Collaboration Scope. Notwithstanding the foregoing, the Parties agree that to achieve the maximum effect of increasing prescribing preferences of Ivory, the JSC or JBT may determine that there will be sales representatives of each Party that are solely dedicated to Detailing Ivory in the Collaboration Scope, and that, [\*].
  - 4.3.2. *Sales Force Minimum.* Each Party will only use its employees to perform sales activities under this Agreement, including as sales representatives and sales managers, and will not utilize a contract sales organization to fulfill its obligations to Detail Ivory in the Collaboration Scope. Each sales representative of GSK that will Detail Ivory and each sales manager for Ivory of GSK will have comparable educational qualifications and experience as Amgen requires for its own sales representatives and sales managers for Ivory; provided, that if GSK requires stricter standards applicable to its sales representatives pursuant to its codes of practice, then those additional standards will also apply

to GSK's sales representatives. All sales representatives of each Party will have, prior to being assigned to Detail Ivory, at least [\*] of prior experience promoting and Detailing pharmaceutical products in [\*] to being assigned to Detail Ivory and will have received appropriate training on proper marketing and sales techniques to be used in promoting pharmaceutical products in accordance with all Applicable Law and applicable national and international pharmaceutical industry codes of practices. [\*]. All sales representatives and sales managers for Ivory of each Party will be subject to a reasonable proficiency examination relevant to Ivory (subject to Applicable Law).

- 4.3.3. *Sales Force Incentive Compensation* Unless otherwise agreed by the Parties, the Parties will provide for incentive compensation for their respective sales representatives Detailing Ivory that is consistent with incentive compensation for successful, first-in-class novel therapeutics at a similar stage in commercialization. In particular, such incentive compensation plans will be structured to ensure that Ivory's weighting is such that the following percentages of total incentive compensation paid to each member of such sales force during each calendar year during the Term will be as follows: [\*].
- 4.4. <u>Violation of Laws.</u> Each Party will promptly notify the other Party of any violation of Applicable Law by its personnel with respect to the conduct of activities in the Collaboration Scope under this Agreement. Upon request of the non-notifying Party, the notifying Party will promptly confer with the non-notifying Party regarding any such violation and will promptly take remedial and/or preventative action as may be reasonably required by the JSC with respect thereto. The JSC will have the right to require the removal of any personnel that materially violates Applicable Law or applicable national or international pharmaceutical industry codes of practices from performing activities contemplated under this Agreement with respect to Ivory in the Collaboration Scope.
- 4.5. <u>Use of Affiliates and Third Party Contractors</u>. GSK will perform the Designated GSK Activities itself or through a wholly-owned Affiliate, and any proposed use of a Third Party to conduct Designated GSK Activities will be subject to Amgen's prior written consent, such consent not to be unreasonably withheld. Amgen will perform the Designated Amgen Activities itself or through a wholly-owned Affiliate; provided, that if Amgen wishes to engage a Third Party to conduct Designated Amgen Activities of material strategic importance to the Collaboration Scope, then the applicable Country Team or JSC will discuss the allocation of such Designated Amgen Activities it has, prior to the Effective Date, arranged to have performed by Third Parties. The obligations of GSK and Amgen herein also apply to their respective Affiliates.
- 4.6. <u>Affiliates</u>. Each Party will be responsible for compliance by its respective Affiliates with this Agreement and will be responsible for all acts and omissions of such Affiliates as if committed or omitted by the applicable Party.
- 4.7. <u>Management of Personnel</u>. Each Party will have sole authority and responsibility for recruiting, hiring, managing, compensating (including paying for all benefits, wages,

special incentives, workers' compensation and employment taxes), disciplining, firing and otherwise controlling the personnel provided by such Party for performance of its obligations hereunder. Each Party will provide the day-to-day management of its sales representatives and other personnel, including furnishing administrative support, financial resources, equipment and supplies.

4.8. <u>COGS</u>. Amgen will supply Ivory for the Collaboration Scope in a manner consistent with its general corporate practice for supply. Amgen will not systematically supply Ivory for the Collaboration Scope from higher-priced Inventory Layers for the purpose of increasing costs chargeable within the Collaboration Scope. Currently, Amgen [\*] and Amgen promptly will inform the JSC if the foregoing supply structure changes.

# 5. UP-FRONT PAYMENT AND MILESTONES

- 5.1. <u>Payments by GSK</u>.
  - 5.1.1. *Up-Front Payment.* As partial consideration for the rights granted to GSK by Amgen pursuant to the terms of this Agreement, GSK will pay to Amgen a non-refundable, non-creditable payment equal to [\*] within ten (10) days after receipt of an invoice after the Effective Date from Amgen, payable by wire transfer of immediately available funds in accordance with wire transfer instructions of Amgen that will be provided in writing to GSK prior to the Effective Date.
  - 5.1.2. *Milestone Payment*. As partial consideration for the rights granted to GSK by Amgen under the terms of this Agreement, GSK will make a first non-refundable, non-creditable payment of [\*] to Amgen upon the [\*], and a second non-refundable, non-creditable payment of [\*] to Amgen upon [\*]. Amgen will provide GSK with prompt written notice upon achievement of the milestone. GSK will make the payment associated with the achieved milestone event within sixty (60) days of the date on which GSK receives an invoice from Amgen with respect to such milestone.
- 5.2. <u>Payment Method</u>. Payments pursuant to this Article 5 (Up-Front Payment and Milestones) will be made in accordance with the provisions of Article 7 (Payments).

#### 6. PROFIT/EXPENSE SHARING

- 6.1. <u>Sharing</u>. The Parties will share in profits and losses generated by Ivory in the Collaboration Scope as follows:
  - 6.1.1. *GSK Costs*: Within forty-five (45) days after the end of each calendar quarter GSK will provide Amgen a detailed, itemized report of the costs described in Sections 6.1.1.1 through 6.1.1.5 (collectively, "*GSK Costs*") incurred in such quarter in such format as designated by the JSC. Within five (5) days prior to the end of each calendar quarter GSK will provide Amgen an estimate of GSK Costs incurred and to be incurred in such quarter, and an estimate of GSK Costs to be incurred in the remaining quarters of such calendar year, in each case in such format as designated by the JSC.

- 6.1.1.1. Costs incurred by GSK or its Affiliates in performing activities allocated to GSK pursuant to Section 3.3 (Designated GSK Activities) or 3.1 (Allocation of Operational Responsibility) and not otherwise included in this Section 6.1.1 (GSK Costs);
- 6.1.1.2. Training costs incurred in accordance with Section 3.8 (Training);
- 6.1.1.3. GSK Sales Force Costs incurred in accordance with the Brand Plan and calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs).
- 6.1.1.4. Defense costs incurred within or materially related to the Collaboration Scope in accordance with Section 9.7 (Defense and Settlement of Third Party Claims of Infringement) or 13.5 (Defense of Third Party Claims) (but, in each case, not including defense costs incurred by GSK in fulfilling its obligations pursuant to Section 13.1 (Indemnity by GSK)), and enforcement (and cooperation) costs within or materially related to the Collaboration Scope incurred in accordance with Section 9.8 (Enforcement); and
- 6.1.1.5. Collaboration Losses.
- 6.1.2. *Amgen Costs*: Within forty-five (45) days of the end of each calendar quarter Amgen will provide GSK a detailed, itemized report of the costs described in Sections 6.1.2.1 through 6.1.2.13 (collectively "*Amgen Costs*") incurred in such format as designated by the JSC. Within five (5) days prior to the end of each calendar quarter Amgen will provide GSK an estimate of Amgen Costs incurred and to be incurred in such quarter, and an estimate of Amgen Costs to be incurred in the remaining quarters of such calendar year, in each case in such format as designated by the JSC. All Amgen Costs incurred on or after [\*] will be included in the profit/expense sharing provisions of this Article 6 (Profit/Expense Sharing).
  - 6.1.2.1. Costs incurred by Amgen or its Affiliates in performing activities allocated to Amgen pursuant to Section 3.4 (Designated Amgen Activities) or 3.1 (Allocation of Operational Responsibility) and not otherwise included in this Section 6.1.2 (Amgen Costs);
  - 6.1.2.2. Any amounts paid by Amgen to Third Parties for rights to manufacture, use or sell Ivory in or for the Collaboration Scope to the extent not already included in COGS [\*];
  - 6.1.2.3. Costs associated with obtaining, maintaining and renewing Regulatory Filings and Regulatory Approvals pertaining to Ivory;
  - 6.1.2.4. Training costs incurred in accordance with Section 3.8 (Training);
  - 6.1.2.5. Amgen Sales Force Costs incurred in accordance with the Brand Plan and calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs);
  - 6.1.2.6. COGS associated with Ivory Net Revenues;

- 6.1.2.7. [\*] of Qualified Amgen R&D Costs;
- 6.1.2.8. Collaboration Territory R&D Costs;
- 6.1.2.9. Standard Cost of any Samples of Ivory provided in the Collaboration Scope;
- 6.1.2.10. Costs associated with any recalls, returns and withdrawals of Ivory in the Collaboration Scope that are not attributable to Amgen's or its Affiliates' negligence or willful misconduct or Amgen's breach of this Agreement;
- 6.1.2.11. Defense costs incurred within or materially related to the Collaboration Scope in accordance with Section 9.7 (Defense and Settlement of Third Party Claims) or 13.5 (Defense of Third Party Claims) (but, in each case, not including defense costs incurred by Amgen in fulfilling its obligations pursuant to Section 13.2 (Indemnity by Amgen)) and enforcement (and cooperation) costs incurred in accordance with Section 9.8 (Enforcement) within or materially related to the Collaboration Scope;
- 6.1.2.12. Amgen's costs incurred in connection with Prosecution and Maintenance of Ivory Intellectual Property in accordance with Section 9.6 (Prosecution and Maintenance) within or materially related to the Collaboration Scope; and
- 6.1.2.13. Collaboration Losses (except as expressly provided in Section 6.5 (Collaboration Losses)).
- 6.1.3. *FTE Rate.* The FTE Rate used for calculation of costs pursuant to this Article 6 (Profit/Expense Sharing) with respect to any activity will be the relevant FTE Rate for the calendar quarter in which such activity was undertaken.
- 6.1.4. *Income Taxes*. For the avoidance of doubt, income and withholding taxes imposed on either of the Parties hereunder will not be included in cost sharing hereunder.
- 6.1.5. *Exchange Rate.* For purposes of calculating quarterly balancing payments as set forth in Section 6.1.9 (True-Up), Ivory Net Revenues, Amgen Costs and GSK Costs will be converted from local currency (if different from U.S. Dollars) to U.S. Dollars in accordance with Section 16.8 (Currency).
- 6.1.6. Budget and Overruns.
  - 6.1.6.1. <u>Preparation; Updating</u>. Promptly after the Country Teams prepare the Country Plans, the JSC will prepare the Collaboration Budget. On an annual basis, commencing with the Collaboration Budget for 2010, the JSC will prepare the Collaboration Budget for the following calendar year based upon the input of the Country Teams and JBT. The Parties agree that each Collaboration Budget covering a calendar year will be [\*] subject to mutual agreement of the CRC; provided, that if the CRC cannot mutually agree, then [\*] pursuant to Section 6.1.8 (Calculation of Profit (or Loss)). On an annual basis, commencing with the

Development Budget for 2010, the JDC will prepare a Development Budget for the following calendar year (or update the Initial Development Budget for the following year, as applicable). The Parties will promptly provide the JSC and JDC all reasonably requested information to facilitate the preparation or updating of each Collaboration Budget or Development Budget, as applicable, including detailed estimates of GSK Costs and Amgen Costs for the following calendar year.

- 6.1.6.2. <u>Overruns</u>. Each Party will provide prompt, written advance notice to the other Party if it becomes aware of any anticipated costs to be incurred by such Party in excess of the applicable Collaboration Budget or Development Budget. Unless otherwise agreed by the Parties in advance, in writing, costs reported by a Party pursuant to Section 6.1.1 (GSK Costs) or 6.1.2 (Amgen Costs) incurred in excess of [\*] of any aggregate amounts budgeted to be incurred by or on behalf of such Party for its activities for such calendar year in the then-current Collaboration Budget or Development Budget will not be included in the calculation of profit (or loss)); provided that GSK Costs and Amgen Costs in excess of such amount will be included in the calculation of profit (or loss) pursuant to Section 6.1.8 (Calculation of Profit (or Loss)) [\*].
- 6.1.7. *Ivory Net Revenues*. Within forty-five (45) days after the end of each calendar quarter, Amgen will provide GSK with a reasonably detailed report of Ivory Net Revenues for such calendar quarter.
- 6.1.8. *Calculation of Profit (or Loss).* The total profit (or loss) for a calendar quarter will be calculated by Amgen by first deducting from Ivory Net Revenues for such quarter a percentage of such Ivory Net Revenues equal to the Inventorship Margin, which will be paid to Amgen to reflect Amgen's inventorship of Ivory; and then deducting from the remaining Ivory Net Revenues the GSK Costs and Amgen Costs reported by the Parties pursuant to Sections 6.1.1 (GSK Costs) and 6.1.2 (Amgen Costs). The resulting amount will be the "*Collaboration Profit (Loss*)" for such quarter, which will be shared by the Parties equally.
- 6.1.9. *True-up.* Within ninety (90) days of the end of each calendar quarter, Amgen will calculate and provide to GSK a report of the Collaboration Profit (Loss) for such quarter, and a balancing payment will be made between the Parties such that each Party bears one half of the sum of GSK Costs and Amgen Costs, and each Party receives one half of Ivory Net Revenues, after deducting the amount allocated to Amgen under Section 6.1.8 (Calculation of Profit (or Loss)) above. The net paying Party will make a payment pursuant to this Section 6.1.9 (True-up). Payments pursuant to this Article 6 will be made in accordance with the provisions of Article 7.

6.1.10. *Calculation of Sales Force Costs.* Sales force FTE costs for each of the Parties will be determined by including in GSK Costs or Amgen Costs, as the case may be, a pro rata portion of each Party's sales representative's FTE Rate as follows:

(i) [\*] if such sales representative Details only Ivory with the approval of the JSC, (ii) [\*] if such sales representative Details two (2) products with Ivory as the First Position Detail or Details only Ivory without the approval of the JSC, (iii) [\*] if such sales representative Details two (2) products with Ivory as the Second Position Detail, (iv) [\*] if such sales representative Details three (3) or more products with Ivory as the Second Position Detail, (iv) [\*] if such sales representative Details three (3) or more products with Ivory as the Second Position Detail, and (v) [\*] if such sales representative Details three (3) or more products with Ivory as the Third Position Detail. For the avoidance of doubt, if a sales representative Details Ivory in more than one (1) position, then a pro rata share of the foregoing percentages, to be calculated based on the time spent by such sales representative on Detailing Ivory in each such position, will be included in GSK Costs or Amgen Costs, as the case may be. For periods in which sales representatives are performing activities in support of the collaboration but are not Detailing Ivory (e.g., during launch preparation or training), FTE costs will be calculated in accordance with Section 6.4 (Attribution of Costs).

- 6.2. <u>Example</u>. The Profit (Loss) True-up Schedule sets forth an example of calculation and true-up of the quarterly Collaboration Profit (Loss).
- 6.3. <u>Calculation of Net Revenues</u>. In calculating Ivory Net Revenues for the purposes of this Article 6 (Profit/Expense Sharing):
  - 6.3.1. *Free Products.* Any disposal of Ivory at no charge for, or use of Ivory without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same will not be included in Ivory Net Revenues.
  - 6.3.2. Bundled Products. Where Ivory is sold in a Bundle, then for the purposes of calculating the Ivory Net Revenues under this Agreement, such Ivory will be deemed to be sold for an amount equal to  $X \div (X + Y) \times Z$ , where: X is the average sales price during the applicable reporting period generally achieved for such dosage form of Ivory in the Collaboration Scope; Y is the sum of the average sales price during the applicable reporting the relevant dosage form included in the Bundle (excluding Ivory); and Z equals the price at which the Bundle was actually sold. In the event that Ivory or one or more of the other pharmaceutical products in the Bundle are not sold separately in the relevant dosage form, the Ivory Net Revenues from the sale of such Bundle will be reasonably allocated between Ivory and the other product(s) in such Bundle based upon their relative values and the JSC will determine an equitable fair market price to apply to such bundled Ivory. Notwithstanding the foregoing, Ivory will not be sold in a Bundle if such sale would violate Applicable Law.
- 6.4. <u>Attribution of Costs.</u> Unless otherwise set forth herein, for costs not specific to the Collaboration Scope or the activities to be performed hereunder (including FTE costs for personnel not solely devoted to Ivory in the Collaboration Scope (but not including sales force FTE costs for sales force Detailing Ivory, which will be calculated in accordance with Section 6.1.10 (Calculation of Sales Force Costs)), the portion of such

costs allocable to the collaboration may be determined based upon percent of effort, resource utilization or other reasonable measure, in each case calculated and allocated in accordance with the applicable Party's accounting procedures, consistently applied. For clarity, no particular cost will be allocated to the collaboration more than once.

6.5. <u>Collaboration Losses</u>. Each Party understands the risks attendant to the business of Ivory within the Collaboration Scope. Losses related to the Collaboration Scope that arise out of the development, manufacture, regulatory activities, commercialization or other exploitation of Ivory undertaken by or on behalf of a Party in the exercise of its rights or performance of its obligations under this Agreement in good faith (*"Collaboration Losses"*) will be charged to the Collaboration Profit (Loss); provided, that Collaboration Losses will not include Losses that are: [\*] will not be Collaboration Losses). If a Party becomes aware of a [\*] that would, if successful, result in a Collaboration Loss, such Party will inform the other Party of such [\*] as soon as reasonably practicable after it receives notice thereof. [\*].

### 7. PAYMENTS

- 7.1. <u>Appropriate Measure of Value.</u> Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including performance of various services, access to development and commercial expertise, clinical data and other financial and non-financial consideration and that the amount of the Inventorship Margin, and the ratio of profit and expense sharing set forth herein are intended to capture such value as an aggregate. Therefore the increase, decrease or lapse of any particular items or rights (including Patents), including allocation of operational responsibilities between the Parties, will not affect the amount of such payment, or the ratio of profit and expense sharing and the Parties agree that both the amount and duration of such payment or the ratio of profit and expense sharing are reasonable.
- 7.2. <u>No Other Compensation</u>. Other than as explicitly set forth (and as applicable) in this Agreement, neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other hereunder.
- 7.3. <u>Payment Method</u>. All payments made hereunder between the Parties will be made in U.S. Dollars except as set forth in Section 7.5 (Blocked Currency) or as otherwise agreed by the Parties. Each Party will pay all sums due hereunder by wire transfer, or electronic funds transfer (EFT) in immediately available funds. If the EFT option is chosen by Amgen or GSK, a completed electronic funds transfer form will be provided in a timeframe that facilitates timely payment. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments.
- 7.4. <u>Audits</u>. Each Party will keep complete and accurate records pertaining to the activities to be conducted hereunder in sufficient detail to permit the other Party (the "*Auditing Party*") to confirm the accuracy of all payments due hereunder, including the Tail Payments set forth in Section 14.11, and such records will be open (in such form as may be available or reasonably requested) to inspection for [\*] following the end of the period to which they pertain. The Auditing Party will have the right, at its own expense to have an independent, certified public accountant, selected by it, perform a review the

records of the other Party (the "Audited Party") applicable to amounts payable hereunder (including any records kept in the ordinary course of the Audited Party's business) upon reasonable notice, during regular business hours and under reasonable obligations of confidentiality. The report of such accountant will be made available to both Parties simultaneously, promptly upon its completion. The Auditing Party's right to perform an audit pertaining to any calendar year will expire [\*] after the end of such year and the books and records for any particular calendar year will only be subject to one (1) audit. Should an inspection pursuant to this Section 7.4 (Audits) lead to the discovery of a payment discrepancy, then the appropriate Party will pay to the other the amount of the discrepancy (plus, if the error was in favor of the Audited Party, interest accrued at the Contract Interest Rate, compounded annually from the day the relevant payment(s) were due). If a payment discrepancy was greater than [\*] of the correct amount for the audited period and the discrepancy was in favor of the Audited Party, then the Audited Party will pay the reasonable out-of-pocket cost of such inspection, but in no case will the costs of an audit pursuant to this Section 7.4 (Audits) be included in GSK Costs or Amgen Costs allocated to the collaboration. This Section 7.4 (Audits) does not apply to or include manufacturing audits or regulatory inspections.

- 7.5. <u>Blocked Currency</u>. If Applicable Law in the Collaboration Territory prevent the prompt remittance of any payments with respect to sales therein, the paying Party will have the right and option to make such payments by depositing the amount thereof in local currency to the other Party's account in a bank or depository in such country.
- 7.6. Withholding. If Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made pursuant to this Agreement, the paying Party will notify the other in writing of such payment or withholding requirements prior to making the payment and provide such assistance to the receiving Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in such Party's efforts to claim an exemption from or reduction of such Taxes. Each Party will withhold any Taxes required by law to be withheld from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes promptly following payment thereof. If Taxes are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. In the event that the governing tax authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding (or to additional withholding) for Taxes, and such Party (the *"Withholding Party"*) remits such withholding Taxes to the tax authority, the Withholding Party will have the right to offset such amount, including any interest and penalties that may be imposed thereon, against future payment obligations of the Withholding Party under this Agreement (or, at the option of the Withholding Party, the Withholding Party will have the right to invoice the other Party for such amount, and the other Party will pay such amount within sixty (60) days of the receipt of such invoice); provided however, that the Withholding Party may also pursue reimbursement by any other available remedy.
- 7.7. <u>VAT</u>. All payments due a Party pursuant to this Agreement will be paid exclusive of any VAT and other indirect Taxes (which, if applicable, will be payable by the paying

Party upon receipt of a valid VAT invoice). If such amounts of VAT are refunded by the applicable Governmental Authority or other fiscal authority subsequent to payment, the Party receiving such refund will transfer such amount to the paying Party within forty-five (45) days of receipt.

- 7.8. <u>Late Payment</u>. Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days such payment is delinquent. This Section 7.8 (Late Payment) will in no way limit any other remedies available to either Party.
- 7.9. <u>Change in Accounting Periods</u>. From time to time, either of the Parties may change its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other in writing of a change in its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the Parties will cooperate to determine a way to report and reconcile each Party's accounting periods so as to facilitate payments to be made hereunder.
- 8. [\*]

#### 9. INTELLECTUAL PROPERTY

- 9.1. <u>Invention Ownership</u>. Each Party will own all right, title, and interest in and to all Inventions that are made by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto (including in the case of GSK, GSK Inventions), and any Invention that is jointly made will be owned jointly by the Parties (each a "*Joint Invention*"). Inventorship will be determined according to United States Patent Law (without reference to any conflict of law principles).
- 9.2. <u>Copyright Ownership: Certain Confidential Information</u>. Except as set forth below, each Party will own all right, title, and interest in and to all Copyrights created pursuant to this Agreement that are authored by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto; provided that any Copyrights pertaining to Ivory (including any clinical trial protocols, investigator brochures and informed consent forms, and including the product labeling, package inserts, core data sheet and all marketing and promotional materials and including the Brand Book) will be owned solely by Amgen. The Parties will jointly own all right, title, and interest in and to all Copyrights that are authored by or on the behalf of the Parties jointly; provided that any Copyrights pertaining to Ivory will be owned solely by Amgen whether created jointly by the Parties or by either Party independent of the other Party. In addition, all Confidential Information to the extent pertaining to Ivory will be the Confidential Information of Amgen (and not of GSK), regardless of which Party created such information (and will not be subject to the exclusion under Section 11.1.1 or 11.1.4). Any Copyrights created by GSK or its Affiliates and specified in this Section 9.2 (Copyright Ownership) as being owned by Amgen will be considered a work for hire. To the extent any such Copyright is not considered a work for hire, GSK and/or such Affiliate will assign and does hereby assign to Amgen all of its right, title and interest in and to such Copyright and intellectual property rights therein and

thereto. Each Party will duly execute, acknowledge, and deliver to the other all such further papers, including assignments and applications for copyright registration or renewal, as may be reasonably requested and/or necessary to enable such other Party to publish or protect said Copyrights in any and all countries and to vest title to said Copyrights in such other Party (or its nominees, or its or their successor or assigns) in accordance with this Section 9.2 (Copyright Ownership), and will render such reasonable assistance, at such other Party's expense, as such other Party may reasonably require in any proceeding or litigation involving said Copyrights.

- 9.3. <u>Joint Ownership</u>. Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property (including Copyrights) owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 9.3 (Joint Ownership) in a particular country within the Collaboration Territory.
- 9.4. <u>License Grant by Amgen</u>. Amgen hereby grants and causes its Affiliates to grant to GSK and its Affiliates during the Term a [\*] license to Ivory Intellectual Property solely to the extent necessary to Detail Ivory in the Collaboration Scope, conduct the Designated GSK Activities, and exercise and perform GSK's other rights and obligations under the terms of this Agreement.
- 9.5. <u>License Grant by GSK</u>. GSK hereby grants and causes its Affiliates to grant to Amgen and its Affiliates a [\*] license under all Know-How and Patents owned or controlled as of the Effective Date or during the Term (including GSK Inventions) by GSK or its Affiliates solely to use, make, have made, sell, offer for sale and import Ivory for all uses, and for performing Amgen's rights and obligations hereunder. Such license is sublicensable by Amgen or its Affiliates solely to Third Parties to whom Amgen or its Affiliates also grant a license to Know-How or Patents owned or controlled by Amgen claiming Ivory, its formulation or the use thereof; provided, that such sublicense will terminate no later than the date on which the license to the Third Party to Amgen Know-How or Patents described above terminates.
- 9.6. <u>Prosecution and Maintenance</u>. Subject to the provisions of Section 2.14 (Patent Coordinators), Amgen will control, itself or through outside counsel, and have final decision making authority (after consultation with GSK in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of the Patents and Product Trademarks within the Ivory Intellectual Property in the Collaboration Territory (the "*Ivory Patents and Trademarks*"), and with respect to preparation and filing for any patent term extensions or similar protections therefor. Through the Patent Coordinators: (i) Amgen will provide GSK with copies of and an opportunity to review and comment upon the text of the applications relating to the Ivory Patents and Trademarks at least [\*] before filing; provided, that if it is not reasonably practicable to provide such application in such [\*] period; (ii) Amgen will provide GSK with a copy of such application or a statement of intent to file such application in such [\*] period; (ii) Amgen will provide GSK with a copy of each

submission made to and document received from a patent authority, court or other tribunal regarding any Ivory Patent and Trademark reasonably promptly after making such filing or receiving such document, including a copy of each application for each Ivory Patent and Trademark as filed together with notice of its filing date and application number; (iii) Amgen will keep GSK advised of the status of all material communications, actual and prospective filings or submissions regarding the Ivory Patents and Trademarks, and will give GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) Amgen will consider in good faith GSK's comments on the communications, filings and submissions for the Ivory Patents and Trademarks. With respect to any filings or other materials provided to GSK under this Section 9.6 (Prosecution and Maintenance), Amgen will have the right to redact any manufacturing information and any information relating to any product other than Ivory from any such filings and materials.

- 9.7. Defense and Settlement of Third Party Claims of Infringement. If a Third Party asserts that Patents, Know-How or other rights owned or controlled by it are infringed by the activities hereunder of either of the Parties, then defense of such claim (an "*Infringement Claim*") will be managed in accordance with the provisions of Section 13.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators. If either Party seeks to initiate a nullification or revocation proceeding against any such Patents, Know-How or other rights in response to prospective or actual Third Party Claims of Infringement, the Parties will coordinate and cooperate in regard to such proceedings in accordance with the procedures set forth in Section 13.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party and Assisting Party and Assisting Party and Assisting Party and Party and Party Claims of Infringement, the Party Claims), with coordination and cooperate in regard to such proceedings in accordance with the procedures set forth in Section 13.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators.
- 9.8. Enforcement. Except as expressly set forth in this Section 9.7 (Enforcement), each Party will retain all its rights to control the enforcement of its own intellectual property. Amgen will have the sole right to enforce the Ivory Intellectual Property. GSK will reasonably assist Amgen with respect to any such enforcement in the Collaboration Territory, including, in the event that it is determined that the GSK is an indispensable Party to such action, by being named as a Party in such action, and cooperate in any such action at Amgen's request. Without limiting the foregoing, Amgen will keep GSK advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions (provided that Amgen will have the right to redact any manufacturing information and any information relating to any product other than Ivory from any such materials). All Recoveries will be retained by Amgen, but included in Ivory Net Revenues for the period in which such Recovery is made.
- 9.9. <u>Patent Term Extensions</u>. GSK will provide reasonable assistance to Amgen in connection with obtaining supplemental protection certificates for Patents within the Ivory Intellectual Property or otherwise licensed or assigned hereunder as determined by the Patent Coordinators. To the extent reasonably and legally required to obtain any such supplemental protection certificates in a particular country, GSK will make

available to Amgen copies of all necessary documentation to enable Amgen to use the same for the purpose of obtaining the supplemental protection certificates in such country.

9.10. <u>Employee Agreements</u>. Prior to beginning work relating to any aspect of the subject matter of this Agreement and/or being given access to Ivory Intellectual Property or Confidential Information of the other Party, each employee, consultant and/or agent of Amgen and GSK will have signed or will be bound to a commercially reasonable non-disclosure and/or invention assignment agreement. Each Party will be responsible for any compensation or payment to its employees, contractors or agents in connection with the invention of any patent right.

### 9.11. <u>Trademarks</u>.

- 9.11.1. Title. Amgen will own all right, title and interest in and to the Product Trademarks, and GSK agrees to assign and hereby assigns to Amgen all right title and interest that GSK has or may acquire in connection with the Product Trademarks. All goodwill arising out of the use of the Product Trademarks or otherwise related to Ivory will inure to the benefit of Amgen. GSK will not, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country; (ii) file, register or maintain any registrations for the Product Trademarks, or for any trademarks or trade names that are confusingly similar to any Product Trademark, in any country without the express prior written consent of Amgen, and such permitted registrations (if any) will be filed, registered or maintained by GSK in Amgen's name; or (iii) authorize or assist any Third Party to do the foregoing.
- 9.11.2. Required Use and Compliance.
  - 9.11.2.1. Promotional Materials for Ivory in the Collaboration Scope will display the Amgen Housemarks and the GSK Housemarks to the extent allowed by Applicable Law and in accordance with the Brand Plan. Except for the use of the Amgen Housemarks and the GSK Housemarks as may be expressly set forth in the Brand Plan, each Party will promote Ivory in the Collaboration Scope only under the Product Trademarks.
  - 9.11.2.2. GSK agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and/or the Amgen Housemarks by GSK is accompanied by an acknowledgement that the Product Trademarks and Amgen Housemarks are owned by Amgen; (ii) not use the Product Trademarks or Amgen Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Amgen therein; and (iii) not use any trademarks or trade names so resembling any of the Product Trademarks or Amgen Housemarks as to be likely to cause confusion or deception. Amgen agrees that it and its Affiliates will ensure that each use of the GSK Housemarks by Amgen is accompanied by an acknowledgement that the GSK Housemarks are owned by GSK.

### 9.11.3. Licenses.

- 9.11.3.1. **To GSK**. Amgen hereby grants to GSK [\*] license to use the Product Trademarks and Amgen Housemarks as set forth in the Promotional Materials and other materials provided to it by Amgen, solely to Detail Ivory in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement during the period that GSK has rights to Detail Ivory hereunder. GSK's right to use the Product Trademarks and the Amgen Housemarks will terminate, on a country-by-country basis, when GSK's rights to Detail Ivory in such country are terminated or expire. GSK will take all such steps as Amgen may reasonably request to give effect to the termination of the license to the Product Trademarks and Amgen Housemarks in such country and to record any documents that may be required to evidence the termination of such license.
- 9.11.3.2. **To Amgen**. GSK hereby grants to Amgen a [\*] license to use the GSK Housemarks as set forth in the Promotional Materials solely to Detail Ivory in the Collaboration Scope in accordance with the Brand Plan, Country Plans and this Agreement. Amgen's right to use the GSK Housemarks will terminate, on a country-by-country basis, when GSK's rights to promote Ivory in such country are terminated or expire; provided, that the license set forth in this Section 9.11.3.2 (To Amgen) will continue for a period of [\*] to permit Amgen to use and distribute its inventory of Promotional Materials containing GSK Housemarks in such country (or, where the on-hand inventory as of such termination or expiration of such Promotional Materials, but in no event longer than [\*]), in connection with Amgen's Detailing of Ivory. Amgen will take all such steps as GSK may reasonably request to give effect to the termination of the license to the Collaboration Housemarks in the applicable country and to record any documents that may be required to evidence the termination of such license.
- 9.11.4. *Respect of Trademarks*. GSK will not have, assert or acquire any right, title or interest in or to any of Product Trademarks or Amgen Housemarks or the goodwill pertaining thereto, and Amgen will not have, assert or acquire any right, title or interest in or to the GSK Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement.
- 9.11.5. *Infringement* Amgen will monitor the Product Trademarks against infringing uses within the Collaboration Scope. GSK will give Amgen prompt notice of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. Amgen will determine in its sole discretion what action, if any, to take in response to any such infringement or threatened infringement of any Product Trademark.

9.12. <u>Community Of Interest</u>. From time-to-time it may be desirable or beneficial to the Parties to share between each other and their respective outside counsel privileged and/or work product information with respect to certain Patents and/or Know-How related to Ivory, and legal matters relating thereto, and that they share a common interest in the prosecution, defense and enforcement of such Patents and Know-How, including such Patents and Know-How owned or controlled by Third Parties. Therefore, the Parties agree to execute the Joint Community Of Interest Privilege Agreement (attached hereto as the Privilege Agreement Schedule) concurrently with this Collaboration Agreement.

### 10. REGULATORY AND SAFETY

# 10.1. <u>Regulatory Matters</u>

- 10.1.1. *Regulatory Communication and Filings.* Amgen will use Commercially Reasonable Efforts to prepare, submit and maintain all Regulatory Filings and to obtain all Regulatory Approvals for Ivory in the Collaboration Scope, including making all Regulatory Filings necessary for the development of Ivory in accordance with the Development Plan. Amgen will use Commercially Reasonable Efforts with respect to all other regulatory matters regarding Ivory in the Collaboration Scope including pricing, reimbursement and health technology assessments. GSK will cooperate with Amgen, at its reasonable request, with respect to any regulatory matters related to Ivory in the Collaboration Scope. Amgen will provide GSK with copies of Regulatory Filings and material communications with Governmental Authorities in the Collaboration Scope prior to submission within a reasonable amount of time to allow GSK to review and comment on such Regulatory Filings and communications, but not less than five (5) days, and Amgen will consider all comments and proposed revisions from GSK in good faith prior to submission. Notwithstanding the foregoing, if exigent action is required with respect to such Regulatory Filing or material communication, and Amgen reasonably believes it is not practicable to provide such Regulatory Filing, communication or receipt of Regulatory Approval, Amgen will instead provide such filing or communication to GSK as soon as reasonably practicable. Amgen will consult with GSK regarding, and keep GSK informed of, the status of the preparation of all Regulatory Filings, Governmental Authority review of Regulatory Filings, and Regulatory Approvals made or obtained by it in the Collaboration Scope.
- 10.1.2. *Regulatory Meetings.* Amgen will consult with GSK reasonably in advance of the date of any anticipated meeting with a Governmental Authority in the Collaboration Scope and will consider in good faith any timely recommendations made by GSK in preparation for such meeting. Amgen will consider in good faith permitting GSK to attend particular meetings between Amgen and the applicable Governmental Authority that pertain to the Collaboration Scope. Where Amgen so agrees, it will request that the applicable Governmental Authority allow at least one (1) GSK representative to

attend, [\*] such meetings; provided, that the foregoing will not apply to [\*] only (such as interactions with EMEA rapporteurs). Amgen will timely inform GSK of any such meetings. [\*] with respect to any such meeting, and will not discuss the contents of any such meeting with any Governmental Authority except as required by Applicable Law or authorized by Amgen in writing.

- 10.1.3. GSK Obligations. Except as expressly provided in Section 10.1.1 (Regulatory Communications and Filings) GSK will cooperate with Amgen, at its request, with respect to any regulatory matters related to Ivory. GSK will not without the consent of Amgen or unless so required by Applicable Law (and then only pursuant to the terms of this Section 10.1.1 (Regulatory Communication and Filings)), correspond or communicate with any Governmental Authority, whether within the Collaboration Territory or otherwise, concerning Ivory or otherwise take any action with any Governmental Authority concerning any authorization or permission under which Ivory is sold or any application for the same. Furthermore, GSK will, immediately upon receipt of any communication from any Governmental Authority relating to Ivory, forward a copy (or written description, with respect to any oral communication) of the same to Amgen and respond to all inquiries by Amgen relating thereto. If GSK is advised by its counsel that it must communicate with any Governmental Authority with respect to Ivory or the activities under this Agreement, then GSK will so advise Amgen immediately and, if possible, provide to Amgen in advance for review a copy of any proposed written communication (or written description, with respect to any oral communication) with respect thereto. GSK will comply with any and all reasonable direction of Amgen concerning any meeting or written or oral communication with any Governmental Authority; provided, that GSK will not take direction of Amgen that GSK reasonably believes is not in compliance with Applicable Law. In addition to the foregoing: (i) unless required by Applicable Law, GSK will not disclose any information concerning any adverse drug experience to any Person or Governmental Authority without the prior consent of Amgen; (ii) GSK will utilize the global safety database maintained by Amgen as directed by Amgen from time-to-time; and (iii) Amgen will have the sole discretion to assess all adverse drug experiences and to determine whether any complaint or adverse drug experience must be reported to any Governmental Authority.
- 10.1.4. *Labeling and Packaging Materials*. Amgen will have sole authority and responsibility, and will use Commercially Reasonable Efforts to, seek and/or obtain any necessary governmental approvals of any labeling, package inserts or packaging for Ivory and Promotional Materials, and to determine whether the same requires governmental approval; provided, that Amgen will use Commercially Reasonable Efforts to obtain any Governmental Authority approval required to include the GSK Housemarks on the labeling, packaging and package inserts for Ivory in the Collaboration Scope within [\*] of the Effective Date. All filings and communications with Governmental Authorities in connection therewith will remain under the control of Amgen. No labeling, package inserts, or packaging for Ivory may be used or distributed by GSK

unless such labeling, package inserts or packaging has been approved in advance by Amgen. GSK will not modify or alter any labeling, package inserts or packaging for Ivory, without the express prior approval of such modification or alteration by Amgen. Amgen will provide GSK with prompt notice of, and copies of, any changes in the Ivory labeling, package inserts or packaging.

- 10.1.5. *Regulatory and Safety Information.* Each Party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Applicable Law with respect to Ivory, including reporting obligations of Amgen related to Ivory. Such assistance and actions will include, among other things, GSK keeping Amgen informed, commencing immediately upon notification of any action by, or notification or other information which it receives (directly or indirectly) from any Governmental Authority that: (i) raises any concerns regarding the safety or efficacy of Ivory; (ii) indicates or suggests a potential liability for either Party to Third Parties arising in connection with Ivory; or (iii) is reasonably likely to lead to a recall or market withdrawal of Ivory. Concurrently with entry into this Agreement, or promptly after the Effective Date of the Agreement, but not later than sixty (60) days thereafter, the Parties will enter into an agreement pertaining to safety, pharmacovigilance, product complaints and/or the like.
- 10.2. <u>Brand Security and Anti-Counterfeiting</u>. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto.

#### 10.3. Product Technical Complaints; Recalls; Returns.

- 10.3.1. *Product Technical Complaints* If GSK (including any GSK sales representative Detailing Ivory) becomes aware of any Product Technical Complaint (as defined below), GSK will submit a written report of such complaint to Amgen within one (1) business day of GSK so becoming aware (along with a sample of the Ivory product involved in the complaint, as soon as (and if) available). GSK will not take any other action in respect of any such complaint without the consent of Amgen unless otherwise required by Applicable Law. As used herein, *"Product Technical Complaint"* means: (i) any complaint that questions the purity, identity, potency or quality of Ivory, its packaging or labeling or the compliance of any batch of Ivory with Applicable Law; (ii) any complaint concerning Ivory being mistaken for, or Ivory's labeling being applied to, another article; (iii) any bacterial contamination or significant chemical, physical or other change or deterioration in Ivory; (iv) any failure of one (1) or more batches of Ivory to meet the specifications therefor in the applicable Regulatory Approval; or (v) any complaint or evidence of tampering with Ivory. Amgen will use Commercially Reasonable Efforts to address any such Product Technical Complaint with respect to Ivory in the Collaboration Scope.
- 10.3.2. *Recalls or Other Corrective Action.* Amgen will have the sole right to undertake, and will make all decisions with respect to, any recall, market withdrawals, field alerts or any other corrective action (including letters to

health care professionals) related to Ivory. At Amgen's request, GSK will provide reasonable assistance to Amgen in conducting such recall, market withdrawal or other corrective action in the Collaboration Territory. Without prejudice to Amgen's indemnity obligations pursuant to Section 13.2 (Indemnity by Amgen), Amgen will be under no liability whatsoever to compensate GSK or make any other payment to GSK based on any decision to recall, initiate a market withdrawal, issue a field alert or take any other corrective action with respect to Ivory, unless such action results from Amgen's failure to comply with the terms of this Agreement.

- 10.3.3. *Returns*. If any quantities of Ivory are returned to GSK, GSK will promptly notify Amgen and ship them to the facility designated by Amgen. GSK, at its option, may advise the customer who made the return that Ivory has been returned to Amgen, but will take no other steps in respect of any return without the consent of Amgen, except as may be expressly authorized by the relevant Country Team.
- 10.4. <u>Clinical Trial Register</u>. Amgen will use Commercially Reasonable Efforts to publish the results and/or summaries of clinical trials relating to Ivory in the Collaboration Scope on a clinical trial register maintained by it and the protocols of clinical trials relating to Ivory in the Collaboration Scope on www.ClinicalTrials.gov (or an equivalent register in the Collaboration Scope, or as otherwise required by Applicable Law or Amgen's policies). GSK will have the right to publish results and/or summaries [\*]. The Parties will cooperate to establish timelines and procedures for JDC review of publications and presentations.

### 11. CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

- 11.1. <u>Confidentiality; Exceptions</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [\*] thereafter, the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose any and all information or materials related to the activities contemplated hereunder and furnished to it by the other Party pursuant to this Agreement (or in the case of GSK, that is created by or on behalf of GSK and owned by Amgen pursuant to Section 9.2 (Copyright Ownership)) that is identified by the disclosing Party as confidential, proprietary or the like or that the receiving Party has reason to believe is confidential based upon its own similar information (collectively, "*Confidential Information*"). For clarity, GSK will have no right to and will not utilize any Confidential Information of Amgen for activities outside the Collaboration Scope or for activities related to products other than Ivory. Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information:
  - 11.1.1. was obtained or was already known by the receiving Party or its Affiliates without obligation of confidentiality as a result of disclosure from a Third Party that the receiving Party did not know was under an obligation of confidentiality to the disclosing Party with respect to such information;

- 11.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party through no act or omission of the receiving Party or its Affiliates in breach of this Agreement;
- 11.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement; or
- 11.1.4. was independently discovered or developed by the receiving Party or its Affiliates (without reference to or use of Confidential Information of the disclosing Party).
- 11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) as reasonably necessary in conducting the activities contemplated under this Agreement; (ii) with respect to Confidential Information generated in the course of the activities conducted hereunder, to the extent pertaining specifically to Ivory, for use by Amgen in connection with Ivory outside the Collaboration Scope or disclosure by Amgen to a partner, GSK or licensee for use with respect to Ivory outside the Collaboration Scope; (iii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for Ivory, or otherwise required by Applicable Law, provided that if a Party is required by Applicable Law to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing exceptions pursuant to this subsection (iii), will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iv) to advisors (including lawyers and accountants) on a need to know basis in support of the purposes of this Agreement, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; and (v) to the extent mutually agreed to by the Parties. Neither Party will disclose Confidential Information of the other Party to its personnel or to an Affiliate except to the extent such personnel or Affiliate needs to know such information for the performance of such Party's activities hereunder.
- 11.3. <u>Confidential Treatment of Terms and Conditions</u>. Neither Party will disclose the terms and conditions of this Agreement except that each Party has the right to disclose the terms and conditions of this Agreement under reasonable and customary obligations of confidentiality (but no less than equivalent obligations to those under which the disclosing Party would disclose its own confidential information of similar type): (i) if required by Applicable Law (including disclosure of a redacted version of this Agreement in a relevant SEC filing); (ii) to Governmental Authorities with authority over such Party that request to review this Agreement in connection with a review, audit or investigation of the operations of such Party by such authority (and provided

that review of the terms of this Agreement are reasonably pertinent to such review, audit or investigation); and (iii) to its attorneys and accountants in support of the purposes of this Agreement. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties will consult with one another concerning which terms of this Agreement will be requested to be redacted in any public disclosure of the Agreement, and in any event each Party will seek reasonable confidential treatment for any public disclosure by any such Governmental Authority.

- 11.4. <u>Press Releases</u>. Notwithstanding Section 11.3 (Confidential Treatment of Terms and Conditions), the Parties will issue a joint press release to announce the execution of this Agreement, which is attached hereto as the Press Release Schedule and is for use in responding to inquiries about the Agreement and will agree on the timing (in accordance with Applicable Law) and method for issuing such press release and any media briefings; thereafter, GSK and Amgen may each disclose to Third Parties (including media interviews and disclosures to financial analysts) the information contained in such press release (but only such information) without the need for further approval by the other, provided that such information is still accurate. Each Party will have the right to issue additional press releases and disclosures in regards to the terms of this Agreement only with the prior written consent of the other Party, such consent not to be unreasonably withheld (or as required to comply with Applicable Law). For any such proposed press release or disclosure, the disclosing Party will provide [\*] notice to the other Party and will reasonably consider the other Party's comments that are provided within [\*] after such notice, or such shorter notice and comment periods as are reasonably required under the circumstances but not less than [\*].
- 11.5. <u>Prior Agreement</u>. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated January 28, 2009, including any written requests thereunder (the *"Prior Agreement"*) with respect to information disclosed thereunder relating to Ivory and activities related thereto. All confidential information exchanged between the Parties under the Prior Agreement will be deemed Confidential Information of the disclosing Party disclosed hereunder and will be subject to the terms of this Agreement.
- 11.6. <u>Publications and Program Information</u>. Except as permitted pursuant to Section 10.4 (Clinical Trial Register), or as agreed by the JBT or JDC, Amgen will have the sole right to publish and make scientific presentations with respect to Ivory, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 11.4 (Press Releases) or make other public disclosures regarding Ivory (including with respect to its development, commercialization and regulatory matters), and GSK will not do so without Amgen's prior written consent. Amgen will keep the relevant committee or team informed of its general publication strategy and presentation calendar. In addition, Amgen will deliver to GSK a copy of any proposed written publication or outline of presentation with respect to Ivory in the Collaboration Scope in advance of submission for publication or presentation at least [\*] in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and GSK will have the right to: (i) require a delay in submission of not more than [\*] to enable patent applications protecting each Party's rights in such information to be filed;

and (ii) prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. Publications and presentations will be subject to policies established by the Patent Coordinators to ensure appropriate protection of intellectual property rights.

- 11.7. <u>Attorney-Client Privilege</u>. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the Applicable Law of any jurisdiction 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 may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.
- 11.8. <u>Injunctive Relief</u>. Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 11 (Confidentiality, Publications and Press Releases). In addition to all other remedies, a Party is entitled to seek specific performance and injunctive and other equitable relief (without the need to post a bond) as a remedy for any breach or threatened breach of this Article 11 (Confidentiality, Publications and Press Releases).
- 11.9. <u>Additional Permitted Disclosure</u>. [\*] will have the right to [\*] pursuant to [\*].

# 12. REPRESENTATIONS AND WARRANTIES

- 12.1. <u>Mutual Representations and Warranties</u>. Each of the Parties hereby represents and warrants, as of the Effective Date to the other Party as follows:
  - 12.1.1. It is duly organized and validly existing under the Applicable Law of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
  - 12.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement, and compliance with its terms and provisions, and the consummation of the transaction contemplated hereby, by such Party will not materially conflict, interfere or be inconsistent with, result in any material breach of or constitute a material default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor to its knowledge violate any Applicable Law. The person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

- 12.1.3. To its knowledge, no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority or under Applicable Law, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed concurrently herewith, or (except for Regulatory Approvals, licenses, clearances and the like necessary for the commercialization, research, development, manufacture, sales or marketing of pharmaceutical products and except for any required filing with the United States Securities and Exchange Commission) for the performance by it of its obligations under this Agreement;
- 12.1.4. It has not been debarred or the subject of debarment proceedings by any Governmental Authority;
- 12.1.5. To its knowledge it and its Affiliates have not violated any applicable anticorruption or anti-bribery law or regulation, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the regulations promulgated thereunder (collectively, "*Anticorruption Laws*");
- 12.1.6. It has established and maintains reasonable internal controls intended to ensure compliance with Anticorruption Laws, including reasonable reporting requirements; and
- 12.1.7. It has not granted any right to any Third Party relating to any intellectual property or proprietary right licensed, granted or assigned by it to the other Party hereunder that conflicts with the rights licensed, granted or assigned to the other Party hereunder.
- 12.2. <u>Amgen Representations and Warranties</u>. In addition to the representations and warranties set forth in Section 12.1 (Mutual Representations and Warranties) Amgen hereby represents and warrants to GSK that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [\*]
- 12.3. <u>Amgen Covenants</u>. Amgen hereby covenants to GSK that:

12.3.1. It will not [\*]

- 12.3.2. Amgen understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof.
- 12.4. <u>GSK Representations and Warranties</u>. In addition to the representations and warranties set forth in Section 12.1 (Mutual Representations and Warranties), GSK hereby represents and warrants to Amgen that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [\*]
- 12.5. <u>GSK Covenants</u>. GSK hereby covenants to Amgen that:
  - 12.5.1. GSK understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof; and

### 12.5.2. It will not [\*].

- 12.6. <u>Disclaimer of Warranties</u>. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS AND WARRANTIES), GSK AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, IVORY INTELLECTUAL PROPERTY, AMGEN HOUSEMARKS, GSK HOUSEMARKS, PRODUCT TRADEMARKS, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.
- 12.7. <u>Limitation of Liability</u>. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, OTHER THAN TO THE EXTENT RESULTING FROM A PARTY'S BREACH OF ARTICLE 8 [\*] OR SECTION 11.1 (Confidentiality; Exceptions), IN NO EVENT WILL GSK OR AMGEN BE LIABLE TO THE OTHER OR ANY OF THE OTHER'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE WILL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 13.1 (INDEMNITY BY GSK), SECTION 13.2 (INDEMNITY BY AMGEN) [\*].
- 12.8. <u>Covenants</u>. Each Party hereby covenants to the other Party that, during the Term:
  - 12.8.1. it will not grant any right to any Third Party relating to any intellectual property or proprietary right licensed or assigned by it to the other Party hereunder that conflicts with the rights granted to the other Party hereunder;
  - 12.8.2. it will not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency; and
  - 12.8.3. it will comply with all Applicable Law with respect to their performance of its rights, duties and obligations under this Agreement, including commercialization, manufacturing, research and development and regulatory activities.

### 13. INDEMNIFICATION AND INSURANCE

13.1. Indemnity by GSK. Subject to the remainder of this Article 13 (Indemnification), GSK will defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "Amgen

Indemnitees"), at GSK'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 or on behalf of any of the indemnitees until such time as the indemnification obligation is acknowledged and assumed hereunder with respect to the applicable claim) (collectively, "Losses") arising out of any Third Party Claims brought against any Amgen Indemnitee to the extent such Losses result from: [\*].

13.2. <u>Indemnity by Amgen</u>. Subject to the remainder of this Article 13 (Indemnification), Amgen will defend, indemnify, and hold harmless GSK, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "*GSK Indemnitees*"), at Amgen's cost and expense, from and against any and all Losses arising out of any Third Party Claims brought against any GSK Indemnitee to the extent such Losses: [\*].

13.3. [<u>\*</u>].

13.4. Claim for Indemnification. Whenever any Third Party Claim or Loss arises for which a GSK Indemnitee or an Amgen Indemnitee (the "Indemnified Party") may seek indemnification under this Article 13 (Indemnification), the Indemnified Party will promptly notify the other Party (the "Indemnifying Party") of the Third Party Claim or Loss and, when known, the facts constituting the basis for the Third Party Claim; provided 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) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party will have exclusive control of the defense and settlement of all Third Party Claims for which it is responsible for indemnification and will assume defense thereof at its own expense promptly upon notice of such Third Party Claim. The Indemnified Party will not settle or compromise any Third Party 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 will the Indemnifying Party settle any Third Party Claim without the prior written consent of the Indemnified Party if such settlement does not include a complete release from liability on such Third Party Claim or if such settlement would involve undertaking an obligation by the Indemnified Party other than the payment of money, would bind or impair the Indemnified Party, or includes any admission of wrongdoing by the Indemnified Party or that any intellectual property or proprietary right of the Indemnified Party is invalid or unenforceable. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information will be subject to Article 11 (Confidentiality, Publications and Press Releases). The Indemnifying Party will permit the Indemnified Party to participate in (but not to control) the Third Party Claim through counsel of its choosing to the extent it has the ability to do so (at the Indemnified Party's expense). 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 Third Party Claim if: (i) there are or may be legal defenses available to the Indemnified Party

that are different from or additional to those available to the Indemnifying Party; or (ii) in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between the Indemnified Party and Indemnifying Party that would make such separate representation advisable; 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.

13.5. Defense of Third Party Claims. Except as otherwise provided in Section 13.4 (Claim for Indemnification), each Party (such Party referred to as the "Defending Party") will have the sole right, but not the obligation, to defend against any Third Party Claims made against it with respect to its activities hereunder. Each Party will notify the other Party (the "Assisting Party") as promptly as practicable if any Third Party Claim is commenced or threatened against it, including any Infringement Claim or any [\*]. The Assisting Party will reasonably assist the Defending Party and cooperate in any such litigation at Defending Party's reasonable request (and the Defending Party will reimburse the Assisting Party's reasonable costs incurred in connection with such cooperation (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable)). The Defending Party will seek and reasonably consider, but is not obligated to follow, the Assisting Party's comments before determining the strategy for such matter. Without limiting the foregoing, the Defending Party will keep the Assisting Party advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide the Assisting Party copies of and an opportunity to review and comment on any such communications, filings and submissions; provided, that each Party will have the right to redact from any information disclosed to the other hereunder any information relating to a product other than Ivory or relating to the manufacture of Ivory. The Defending Party will control the defense and/or settlement of Third Party Claims at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) with counsel of its choice. The Assisting Party will have the right to participate in the defense and/or settlement of such Third Party Claim at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) with counsel of its choice. The Defending Party will not settle a Third Party Claim without the prior written consent of the other Party (such consent not to be unreasonably withheld), unless such settlement: [\*]. In the event that a Third Party Claim is brought against both of the Parties (a "Joint Claim"), then the Parties will determine whether to defend against such Joint Claim, which of the Parties should be the Defending Party or whether the Parties should jointly control such defense and the strategy for such defense. If the Parties determine that there will be one Defending Party for a Joint Claim, then the Assisting Party will have the right to participate in the defense of such Joint Claim through counsel, and at its own expense (subject to Section 6.1.1.4 and 6.1.2.11, to the extent applicable) of its choosing to the extent it has the ability to do so, and may control its own defense of the Joint Claim if there are or may be legal defenses available to the Assisting Party that are different from or additional to those available to the Defending Party, or in the reasonable opinion of counsel to the Assisting Party, a conflict or potential conflict exists between the Assisting Party and Defending Party that would make such separate representation advisable. In the case of an Infringement Claim, the coordination and cooperation set forth in this Section 13.5 (Defense of Third

Party Claims) will be accomplished via the Patent Coordinators. This Section 13.5 (Defense of Third Party Claims) will not apply to employment or similar personnel-related claims.

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

### 14. TERM AND TERMINATION

- 14.1. <u>Term</u>. This Agreement will become effective on the Effective Date and will terminate at the end of the Term unless and until sooner terminated pursuant to any provision of this Agreement.
- 14.2. <u>Termination for Breach</u>.
  - 14.2.1. In the event of a material breach of this Agreement, the non-breaching Party will have the right to terminate this Agreement (either as a whole or in the country or countries in which such breach occurred, at the terminating Party's option) by written notice to the breaching Party, which notice will specify the nature of such breach in reasonable detail. Such termination will become effective on the date specified in the notice (which will not be earlier than [\*] after the delivery thereof to the breaching Party or, in the case of a failure to pay amounts due hereunder, [\*]) unless, during the [\*] period after delivery of such notice to the breaching Party, the breaching Party has cured such breach to the reasonable satisfaction of the non-breaching Party.
  - 14.2.2. Notwithstanding the provisions of Section 14.2.1, the following will apply in the event of multiple breaches by the same Party: (i) in the event of [\*] material breaches of this Agreement by the same Party within a [\*] period, the non-breaching Party will have the right to terminate this Agreement by written notice to the breaching Party, which notice will specify the nature of such third breach in reasonable detail, effective (regardless of whether such third breach is cured) as of the date specified in such notice (which will not be earlier than [\*] from receipt thereof by the breaching Party), and (ii) if a Party commits at least [\*] material breaches of this Agreement and such breaches are with respect to the same obligation or activity hereunder, then the non-breaching Party will have the right, but not the obligation, to call a special meeting of the JDC with respect to development breaches or the JSC with respect to any other breach (a "*Special Meeting*"), by written notice to the breaching Party. Such notice will state with particularity the obligations that the non-breaching Party believes have not been satisfied and the basis for such belief. The Special Meeting will be convened within ten (10) business days of the breaching Party's receipt of such notice. At the Special Meeting, the JSC or JDC, as applicable, will discuss the non-breaching Party's concerns, the breaching Party's efforts in such area of concerns and any additional actions the breaching Party should take to alleviate

the non-breaching Party's concerns. The JSC or JDC, as applicable, will develop a plan describing the actions that the Parties reasonably believe the breaching Party should take to meet its applicable obligations under the Agreement (the "*Remediation Plan*"); provided, that the Remediation Plan may provide that the non-breaching Party will assume responsibility for such obligation or activity and the breaching Party will cooperate with the non-breaching Party to effect such transition to the non-breaching Party. The applicable Party will perform the actions described in such Remediation Plan in accordance with the timelines, if any, set forth therein. For the avoidance of doubt, if the nonbreaching Party chooses not to request a Special Meeting, then such Party may proceed in accordance with Section 14.2.1.

- 14.3. <u>Termination for Insolvency</u>. Either Party will have the right to terminate this Agreement immediately upon written notice, if: (i) the other Party becomes insolvent; (ii) the other Party files a petition in bankruptcy, or if an involuntary petition in bankruptcy is filed against the other Party and such involuntary petition is not dismissed within seventy-five (75) days and the other Party (a) fails to assume this Agreement in any such bankruptcy proceeding within thirty (30) days after filing or (b) assumes and assigns this Agreement to a Third Party, or (iii) a receiver or guardian has been appointed for the other Party who is not discharged within seventy-five (75) days after appointment.
- 14.4. <u>Early Termination by Amgen</u>. Amgen will have the right to terminate this Agreement by [\*], such termination to be effective no sooner than January 1, 2021 with respect to either: (i) all countries in the Collaboration Territory; or (ii) one, any or all of the Russian Federation, Mexico, Australia and/or New Zealand. In the event of any such termination, Amgen will pay GSK [\*].
- 14.5. <u>Termination Discussion</u>. If the sales of Ivory during any three (3) year period are less than [\*] of the total amount forecast for such period (as set forth in the Sales Forecast Schedule) (or if either Party reasonably determines that facts and circumstances pertaining at any time during the Term indicate a very high likelihood that the foregoing will occur, including by reason of label or other access limitations or safety events), then the Parties will meet and discuss whether it may be appropriate to terminate this Agreement, provided that no such termination will be effective unless expressly agreed in writing by the Parties.
- 14.6. <u>Valid Safety Issue</u>. Either Party may terminate this Agreement immediately upon written notice following either: [\*]. To be effective, such notice must be given no later than thirty (30) days following the notification by Amgen that such Valid Safety Issue has occurred.
- 14.7. <u>Failure to Supply</u>. GSK may terminate this Agreement on thirty (30) days prior written notice if Amgen is unable to supply for reasons other than Force Majeure, at least [\*] of the lower of: (i) the then-current monthly forecast requirements for Ivory in the Collaboration Scope as a whole; and (ii) the actual demand for Ivory in the Collaboration Scope as a whole, in each case for each of [\*]. To be effective, such notice must be given no later than thirty (30) days following the sooner of notification by Amgen or GSK otherwise becoming aware that such failure to supply has occurred.

- 14.8. <u>Termination for Challenge</u>. Either Party will have the right to terminate this Agreement by written notice to the other Party, if such other Party, its Affiliates or licensees bring or join any challenge to the validity or enforceability of (i) if Amgen is the challenging Party, any Know-How or Patents licensed to Amgen pursuant to Section 9.5 (License Grant by GSK) (including GSK Inventions); and (ii) if GSK is the challenging Party, any Ivory Intellectual Property (or any intellectual property corresponding to any such Ivory Intellectual Property outside the Collaboration Scope). Notwithstanding the foregoing, nothing in this Section 14.8 (Termination for Challenge) will either: (i) prevent either Party from asserting any defense or counterclaim in an action for infringement of intellectual property, brought against such Party or its Affiliates, or any Third Party that such Party or any of its Affiliates is obligated to indemnify, or responding in any other manner to such an action for infringement; or (ii) allow a Party to terminate this Agreement in the event the other Party asserts any such defense or counterclaim or otherwise responds in any such action for infringement.
- 14.9. <u>Effects of Expiration or Termination</u> Upon the expiration or termination of this Agreement for any reason, the following will apply:
  - 14.9.1. *Accrued Obligations*. Expiration or termination of this Agreement for any reason will not release either Party from any liability (including any payment obligations) that, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to activities prior to such expiration or termination.
  - 14.9.2. Promotion Rights; Licenses. Except as set forth in Section 14.10 (Transition), upon the expiration or termination of this Agreement: (i) GSK's right to promote Ivory in the Collaboration Scope will terminate; (ii) all licenses to GSK hereunder will terminate; and (iii) GSK will immediately cease all of its promotional and marketing activities for Ivory in the Collaboration Territory and discontinue all use of Amgen Housemarks and Product Trademarks. Amgen's right to use the GSK Housemarks pursuant to Section 9.11.3.2 will survive expiration or termination of the Agreement until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory in the Collaboration Territory that contain the GSK Housemarks have been depleted.
  - 14.9.3. *Product Data and Amgen Confidential Information.* GSK will promptly transfer to Amgen, at no cost, copies of all data, reports, records and materials in its possession or control that relate to Ivory (*"Product Data"*). Such Product Data will be in electronic form reasonably usable by Amgen and, if reasonably necessary in connection with Amgen's (or its designee's) further commercialization, development or exploitation of Ivory in the Collaboration Territory, will include original hardcopies or duplicate copies thereof, as required. In addition (without limiting Section 9.2 (Copyright Ownership; Certain Confidential Information), all Product Data generated by or under authority of [\*] hereunder during the term of the Agreement, that solely pertains to [\*], will be deemed Confidential Information of [\*] following termination of this Agreement. In addition, GSK will promptly return to Amgen, or destroy at Amgen's request, all relevant records and materials in GSK's possession or

control containing Confidential Information of Amgen (provided that GSK may keep: (i) copies of such records as may be required for GSK to comply with Applicable Law; and (ii) one copy of such Confidential Information of Amgen for archival purposes only; provided that, in each case, such copies are Segregated from any [\*]).

- 14.9.4. *Return of Samples and Materials.* GSK will promptly return to Amgen, or destroy at Amgen's request (and certify such destruction to Amgen), all Samples, Promotional Materials, sales training materials and any other documents, or materials primarily intended for use in commercialization of Ivory in the Collaboration Territory.
- 14.9.5. Assignment of Filings and Registrations. GSK will, at its own expense (other than with respect to any fee payable to the relevant Governmental Authority in connection with the relevant assignment, which will be borne by Amgen), assign to Amgen all Regulatory Filings and Regulatory Approvals in the Collaboration Territory related to Ivory that are in GSK's name (if any), and all trademark and copyright registrations related to Ivory (or to labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory) that are in GSK's name, if any. The foregoing is not meant to imply any right of GSK to own any filing or intellectual property except as may be expressly set forth herein or agreed in writing between the Parties.
- 14.9.6. *Survival*. Articles 5 (Up-Front Payments and Milestones) (with respect to periods prior to expiration or termination), 6 (Profit/Expense Sharing) (with respect to periods prior to expiration or termination), 7 (Payments) (with respect to periods prior to expiration or termination), 8 [\*] (only with respect to such continuing periods as expressly referenced in such Article), 13 (Indemnification and Insurance) (with respect to periods prior to expiration or termination), and 16 (Miscellaneous) and Sections 3.10 (Promotional Materials) (with respect to the termination of use of and destruction of existing Promotional Materials), 3.11 (Detailing Reports and Audit Rights) (with respect to periods prior to expiration or termination), 3.13 (Samples) (with respect to the return or destruction of Samples), 9.4 (License Grant by Amgen) (with respect to the transition period referenced in Section 14.10 (Transition)), 9.5 (License Grant by GSK), 9.8 (Enforcement) (with respect to periods prior to expiration or termination), 9.11.3 (Licenses) (with respect to the transition period referenced in Section 14.10 (Transition), 9.9 (Patent Term Extensions) (with respect to periods prior to expiration or termination), 9.11.3 (Licenses) (with respect to the transition period referenced in Section 14.10 (Transition), 11.2 (Authorized Disclosure), 11.3 (Confidential Treatment of Terms and Conditions), 11.7 (Attorney-Client Privilege), 11.8 (Injunctive Relief), 11.9 (Additional Permitted Disclosure), 14.8 (Effects of Expiration or Termination), and 14.10 (Transition), 14.11 (Tail Payments) will survive expiration or termination of this Agreement for any reason. Following any such expiration or termination, medical inquiries with respect to Ivory will be referred by GSK to Amgen in accordance with instructions provided by Amgen. Except as otherwise provided in this

Section 14.7 (Effects of Expiration or Termination), all rights and obligations of the Parties under this Agreement will terminate upon expiration or termination of this Agreement for any reason.

- 14.10. Transition. During all applicable notice periods prior to termination under Sections 14.1 (Termination for Breach), 14.3 (Termination for Insolvency), 14.4 (Early Termination by Amgen), 14.7 (Failure to Supply) and 16.9 (Force Majeure) (provided; that with respect to transition following termination pursuant to Section 16.9 (Force Majeure), the Party subject to such Force Majeure [\*] will not be liable for activities to the extent prevented from performing such activities due to the Force Majeure [\*] giving rise to such termination. GSK will continue to meet its obligations to promote Ivory within the Collaboration Scope, in accordance with the applicable Country Plan and this Agreement, unless otherwise requested by Amgen or agreed by the Parties. Except for termination pursuant to Section 14.4 (Early Termination by Amgen), during such period as the Parties determine is reasonably necessary (up to [\*]) following the effective date of such termination, GSK will undertake reasonable efforts to effect a smooth and orderly transition of all commercial activities and responsibilities of GSK under this Agreement to Amgen, as soon as reasonably possible, to enable Amgen to continue the promotion and commercialization of Ivory in the Collaboration Scope after termination. Notwithstanding the foregoing, the Parties will use reasonable efforts to effect the transition as quickly as possible within the time periods referenced above. For the avoidance of doubt, in the case of termination in accordance with Section 14.6 (Valid Safety Issue) GSK will have no obligation to Detail or commercialize Ivory, or take any other action that it reasonably believes presents a safety risk to patients (and GSK's decision to not take such action will not be subject to Amgen's final decision-making authority under Article 2 (Scope and Governance), but will carry out its other obligations pursuant to Section 14.8 (Effects of Expiration or Termination). During any transition period subsequent to the expiration or termination of this Agreement, Amgen will reimburse GSK's reasonable costs incurred at Amgen's request in connection with the transition of responsibilities for Ivory in the Collaboration Scope to Amgen.
- 14.11. <u>Tail Payments</u>. Upon expiration of the Term pursuant to Section 14.1 (Term) Amgen will make a tail payment to GSK in each of the two (2) years of the Tail Period (i.e., 2023 and 2024) (each, a *"Tail Payment"*). Such Tail Payments will be calculated as follows:
  - 14.11.1. No later than March 1, 2024, Amgen will pay GSK a Tail Payment in an amount equal to [\*].
  - 14.11.2. No later than March 1, 2025, Amgen will pay GSK a Tail Payment in an amount equal to [\*].
  - 14.11.3. "[\*]" means [\*] of that percentage that is determined by dividing an amount equal to [\*] by [\*]. If the [\*] equals zero (0) or a negative number, then GSK will not be entitled any Tail Payments pursuant to this Section 14.11 (Tail Payment).

- 14.11.4. An example of the calculation of the payment to be made pursuant to this Section 14.11 (Tail Payment) is set forth on the Tail Payment Schedule. The provisions of Article 7 will apply to the Tail Payments.
- 14.12. <u>No Limitation of Rights</u>. The rights provided in this Article 14 (Term and Termination) will be in addition and without prejudice to any other rights which the Parties may have with respect to any default or breach of the provisions of this Agreement. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies at equity or law will remain available to the Parties except as expressly agreed otherwise herein.

### 15. CHANGE OF CONTROL

- 15.1. <u>Change of Control of GSK</u>. GSK will give Amgen written notice within five (5) days after the public announcement or disclosure of, or if earlier the signing of any agreement for, a proposed Change of Control of GSK. In the event of the occurrence of, signing of an agreement for, or public announcement or disclosure of, any proposed Change of Control of GSK, Amgen will have the right to [\*].
- 15.2. <u>Change of Control of Amgen</u>. Amgen will give GSK written notice within five (5) days after the public announcement or disclosure of, or if earlier the signing of any agreement for, a proposed Change of Control of Amgen (a "*Change of Control Notice*"). In the event of the occurrence of a Change of Control of Amgen, if the entity acquiring ownership of Amgen is [\*] then GSK will have the right to [\*].

### 16. MISCELLANEOUS

- 16.1. <u>Affiliates</u>. Each Party will have the right to exercise its rights and perform its obligations hereunder through its Affiliates (including by licensing rights hereunder where such rights are held in the name of any such Affiliate); provided that such Party will be responsible for its Affiliates' performance hereunder.
- 16.2. <u>Arbitration</u>. In the event of any controversy or dispute arising out of or relating to any provision of this Agreement, the construction, validity or breach thereof, the Parties will try to settle the same amicably between themselves. If the Parties fail to settle such matter within thirty (30) days of it having arisen, such matter will be exclusively and finally resolved by binding arbitration under the [\*]. The place of the arbitration will be [\*] and the language of the arbitration will be English. In the event of a dispute involving the alleged breach of this Agreement, neither Party will have the right to terminate this Agreement until resolution of the dispute pursuant to this Section 16.2 (Arbitration), and any time period for cure will commence only after such resolution. Any disputed performance or suspended performance pending the resolution of a dispute involving the alleged breach of this Agreement that the arbitrator determines to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrator. The arbitration award will be final and binding upon both Parties and may be entered in any court of competent jurisdiction for enforcement. The arbitrators will have the power to grant monetary damages as well as injunctive or other specific relief. Notwithstanding the foregoing, each Party will have the right to seek, without establishment of the arbitral tribunal, injunctive or other provisional relief from a court of competent jurisdiction that may be

necessary to avoid irreparable harm or preserve the subject matter of a dispute. Each Party will bear its own costs and expenses and attorneys' fees, and the Party that does not prevail in the arbitration proceeding will pay the arbitrator's fees and any administrative fees of arbitration.

- 16.3. <u>Assignment</u>. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Applicable Law, general succession or otherwise) by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement, or rights and obligations hereunder, without prior written consent to any Affiliate, and Amgen may assign this Agreement without prior written consent in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Any assignment not in accordance with this Agreement will be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 16.4. <u>Choice of Law</u>. This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.
- 16.5. <u>Compliance with Applicable Law</u>. No Party will be required by this Agreement to take or omit to take any action in contravention of Applicable Law or applicable national and international pharmaceutical industry codes of practices.
- 16.6. <u>Construction</u>. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation". The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise: (i) a reference to a Party's costs includes both internal FTE costs at the FTE Rate and reasonable Third Party costs; (ii) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (iii) any reference herein to any person will be construed to include the person's permitted successors and assigns; (v) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; and (vi) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, will be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement has been executed in English, and the English version of this Agreement will control.

- 16.7. <u>Counterparts</u>. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 16.8. <u>Currency</u>. With respect to amounts required to be converted into another currency for calculation or payment, hereunder, such amounts will be converted using a rate of exchange which corresponds to the rate used for conversion between the relative currencies by whichever Party recorded the relevant receipt or expenditure, for the respective reporting period in its books and records that are maintained in accordance with GAAP or IFRS, as the case may be. If a Party is not required to perform such a currency conversion for its GAAP or IFRS reporting with respect to the applicable period, then for such period such Party will make such conversion using the rate of exchange which corresponds to the [\*] as published in the <u>Wall Street Journal</u>, <u>Eastern U.S. Edition</u> on the second to last business day of the calendar quarter (or such other publication as agreed-upon by the Parties) in which such receipt or expenditure was incurred.
- 16.9. <u>Entire Agreement</u>. 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 or contemporaneous negotiations, representations, agreements and understandings regarding the same. Nothing in this Agreements intended to modify, abrogate or eliminate those rights and obligations of the Parties expressly set forth in the Expansion Agreement.
- 16.10. <u>Force Majeure</u>. Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) to the extent such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest (*"Force Majeure"*); provided, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and provided, further that the affected Party uses its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with reasonable dispatch whenever such causes are removed. If the performance of any obligation or activity of either Party that is fundamental to the commercial success of Ivory in the Collaboration Scope is prevented by such Force Majeure event for a period of more than [\*], then either Party may terminate this Agreement upon [\*] written notice, unless such obligation is performed within such [\*] notice period. In addition, [\*].
- 16.11. <u>Further Assurances</u>. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 16.12. <u>Headings</u>. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

- 16.13. <u>No Set-Off</u>. Except as expressly set forth in Section 6.1.9 (True-Up), Section 7.6 (Withholding) or Section 7.7 (VAT), no Party will have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates), whether pursuant to this Agreement or otherwise.
- 16.14. <u>Notices</u>. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to Amgen:	Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 Attention: Corporate Secretary Telephone: 805-447-1000 Facsimile: [*]
If to GSK:	GlaxoSmithKline 709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939 USA Attention: Senior Vice President, Worldwide Business Development Telephone: [*] Facsimile: [*] With a copy to:
	GlaxoSmithKline 2301 Renaissance Boulevard Mailcode RN0220 King of Prussia, PA 19406-2772 USA Attention: Vice President and Associate General Counsel, Business Development Transactions Telephone: [*] Facsimile: [*]

Any such notice will be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 16.14 (Notices).

16.15. <u>Relationship of the Parties</u>. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon

one Party for the act or failure to act of the other Party. The Parties will operate their own businesses separately and independently and they will hold themselves out as, act as, and constitute independent contractors in all respects and not as principal and agent, partners or joint venturers. The Parties will each be responsible for fulfilling their own obligations under this Agreement, and they will not have control or responsibility over the actions of the other Party. The Parties will make and receive only such payments as are required under this Agreement for sales and services required hereunder, and will not share in, or participate in, the business operations of the other Party. Neither party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Each Party will file all necessary reports, statements, tax returns, information returns and any other filings with the FDA, the Securities and Exchange Commission, U.S. Internal Revenue Service, any regulatory authority or any other Governmental Authority on the basis that is consistent with the terms of this Section.

- 16.16. <u>Severability</u>. To the fullest extent permitted by Applicable Law, the Parties waive any provision of Applicable Law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect or to any extent, then in such respect and to such extent such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law, all other provisions of this Agreement shall remain in full force and effect and the Parties will use their commercially reasonable efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.
- 16.17. [\*]
- 16.18. <u>Third Party Beneficiaries</u>. Except as expressly provided with respect to Amgen Indemnitees or GSK Indemnities in Article 13 (Indemnification), there are no Third Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.
- 16.19. <u>Waivers and Modifications</u>. The failure of any Party to insist on the performance of any obligation hereunder will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement will be valid or effective unless in writing and signed by all Parties hereto.

\*\*\*\*\*\*

(Signature page follows)

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

### GLAXO GROUP LIMITED

By: /s/ PAUL WILLIAMSON

Name: Paul Williamson

Title: Edinburgh Pharmaceutical Industries Limited Corporate Director

### AMGEN INC.

By: /s/ ROBERT A. BRADWAY

Name: Robert A. Bradway

Title: Executive Vice President & Chief Financial Officer

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.

## **EXPANSION AGREEMENT**

## BY AND BETWEEN

# AMGEN INC.

### AND

# GLAXO GROUP LIMITED

#### **EXPANSION AGREEMENT**

This Expansion Agreement (this "*Agreement*") is entered into as of the 27<sup>th</sup> day of July, 2009 (the "*Effective Date*") by and between Amgen Inc., a Delaware corporation with a place of business at 1 Amgen Center Drive, Thousand Oaks, CA 91320 ("*Amgen*"), and Glaxo Group Limited, registered in England as company number 305979, doing business as "GlaxoSmithKline" and having its principal office at Glaxo Wellcome House, Berkley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom ("*GSK*"). Amgen and GSK are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties*".

#### RECITALS

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

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

WHEREAS, GSK desires to develop and commercialize Ivory in the Expansion Scope (as defined below) as set forth in more detail herein; and

WHEREAS, Amgen and GSK are entering into a Collaboration Agreement of even date herewith whereby the Parties will collaborate in the conduct of certain activities with respect to Ivory in certain countries in the Collaboration Territory (as defined below).

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

### 1. **DEFINITIONS**

- 1.1. *"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 Section 1.1, "control" means: (i) in the case of corporate entities, direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors; and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein (or, in each of (i) and (ii), if applicable, such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction).
- 1.2. "Alliance Manager" has the meaning set forth in Section 2.17 (Alliance Managers).
- 1.3. *"Amgen Housemarks"* means the corporate logo of Amgen, the trademark "Amgen" and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word "Amgen", or the trademark of an Affiliate of Amgen, and all intellectual property rights residing in the foregoing.

- 1.4. "Amgen Indemnitees" has the meaning set forth in Section 11.1 (Indemnity by GSK).
- 1.5. "Amgen's Patent Attorneys" means Amgen's in-house patent attorney, [\*], primarily responsible for patent matters with respect to Ivory in the Expansion Scope.
- 1.6. "Anticorruption Laws" has the meaning set forth in Section 10.1 (Mutual Representations and Warranties).
- 1.7. *"Applicable Law"* means, individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges or securities listing organizations, Governmental Authorities, courts, tribunals, agencies other than Governmental Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.
- 1.8. "Assisting Party" has the meaning set forth in Section 8.7 (Defense and Settlement of Third Party Claims).
- 1.9. "Audited Party" has the meaning set forth in Section 6.3 (Audits).
- 1.10. "Auditing Party" has the meaning set forth in Section 6.3 (Audits).
- 1.11. "Baseline" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.12. "Baseline Details" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.13. "Brand Book" means the Product Trademark usage and style guide for Ivory established and updated from time-to-time by Amgen.
- 1.14. "Buy-Out Date" has the meaning set forth in Section 12.8 (Amgen Termination Right).
- 1.15. "Change of Control" means: (i) the acquisition, directly or indirectly, by any person, entity or "group" (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*")) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding Voting Securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party and its Affiliates; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty percent (50%) or less of the surviving entity's voting power immediately after such consolidation, merger or reorganization.

- 1.16. "Change of Control Buyout Notice" has the meaning set forth in Section 12.5.2 (Later Change of Control of GSK).
- 1.17. "Change of Control Buyout Payment" has the meaning set forth in Section 12.5.2 (Later Change of Control of GSK).
- 1.18. "Claims" has the meaning set forth in Section 11.1 (Indemnity by GSK).
- 1.19. *"Collaboration Agreement"* means the Collaboration Agreement entered into between the Parties of even date herewith, pursuant to which Amgen grants GSK certain rights with respect to Ivory in the Collaboration Territory.
- 1.20. "Collaboration Scope" has the meaning of such term as defined in the Collaboration Agreement.
- 1.21. "Collaboration Territory" means the countries comprising the Collaboration Territory (as defined in the Collaboration Agreement).
- 1.22. "Commercially Reasonable Efforts" means, with respect to activities of a Party related to Ivory under this Agreement, the efforts and resources typically used by that Party (or, if a Party does not engage in that activity for other products or compounds, by biotechnology and/or pharmaceutical companies that are similar in size and financial resources to such Party) in the conduct of such activities with respect to products of comparable market potential, taking into account all relevant factors including, as applicable, stage of development, efficacy and safety relative to competitive products in the marketplace, actual or anticipated Governmental Authority approved labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost and likelihood of obtaining Regulatory Approval, and actual or projected profitability. For purposes of clarity, Commercially Reasonable Efforts will be determined on a market-by-market basis within the Expansion Territory, and it is anticipated that the level of effort may be different markets and may change over time, reflecting changes in the status of Ivory and the market(s) involved.
- 1.23. *"Contract Interest Rate"* means the [\*] effective for the date that payment was due, as published by <u>The Wall Street Journal</u>, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Applicable Law.
- 1.24. "Control Event" has the meaning set forth in Section 12.5.1 (Early Change of Control of GSK).
- 1.25. "Copyright" means all right, title, and interest in and to all copyrightable works and any copyright registration or corresponding legal right.
- 1.26. "Country Termination Notice" has the meaning set forth in Section 12.8 (Amgen Termination Right).
- 1.27. "Country Termination Payment" has the meaning set forth in Section 12.8 (Amgen Termination Right).
- 1.28. "Defending Party" has the meaning set forth in Section 8.7 (Defense and Settlement of Third Party Claims).

- 1.29. "*Designated Countries*" means those countries set forth on the Designated Countries Schedule, including any territory that becomes a part of any of these countries and any country of which any of these countries become a part.
- 1.30. "*Detail*" means an interactive face-to-face visit by a sales representative with a medical professional having prescribing authority or who is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings and/or other relevant characteristics of Ivory are discussed in an effort to increase prescribing preferences of Ivory for its approved uses. Activities conducted by medical support staff (such as medical science liaisons) will not constitute Details. 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 Ivory will not constitute Details. "*Detailing*" means the act of performing Details and to "*Detail*" mean to perform Details.
- 1.31. *"Development Budget"* means the budget applicable to the Development Plan.
- 1.32. "*Development Plan*" means, with respect to a country within the Expansion Territory, a plan established by the EDC covering: (i) the research and development of Ivory in the Expansion Scope in accordance with Section 5.1 (Development Activities); (ii) the preparation and submission of Regulatory Filings with respect thereto; and (iii) the obtaining, maintenance or expansion of Regulatory Approvals of Ivory in the Expansion Scope.
- 1.33. [\*]
- 1.34. [\*]
- 1.35. [\*]
- 1.36. [\*]
- 1.37. *"EMEA"* means the European Medicines Agency, and any successor agency thereto.
- 1.38. "Enforcement Action" has the meaning set forth in Section 8.8.1 (Amgen Sole Enforcement).
- 1.39. *"Excluded Territory"* means all countries of the world other than those countries included within the Reserved Territory, Expansion Territory or Collaboration Territory.
- 1.40. "Expansion Brand Plan" means the commercialization strategy and brand plan for Ivory in the Expansion Scope established by the ECC.
- 1.41. *"Expansion Commercialization Committee"* or *"ECC"* means the expansion commercialization committee described in Section 2.12 (Expansion Commercialization Committee).
- 1.42. *"Expansion Development Committee"* or *"EDC"* means the expansion development committee described in Section 2.13 (Expansion Development Committee).
- 1.43. "Expansion IP" has the meaning set forth in Section 8.6.1 (Primary Prosecution).

- 1.44. *"Expansion Operations Committee"* or *"EOC"* means the expansion operations committee described in Section 2.11 (Expansion Operations Committee).
- 1.45. "Expansion Review Committee" or "ERC" means the expansion review committee described in Section 2.9 (Expansion Review Committee).
- 1.46. *"Expansion Scope"* means the Field in the Expansion Territory.
- 1.47. "Expansion Steering Committee" or "ESC" means the expansion steering committee described in Section 2.10 (Expansion Steering Committee).
- 1.48. *"Expansion Territory"* means those countries moved from the Reserved Territory into the Expansion Territory by the ESC pursuant to Section 3.4 (Expansion Territory) and not removed from the Expansion Territory pursuant to Section 3.7 (Accession to EU), and for which this Agreement has not otherwise been terminated hereunder.
- 1.49. *"Field"* means the use of Ivory in humans for the treatment, palliation or prevention of any and all diseases and conditions.
- 1.50. *"Force Majeure"* has the meaning set forth in Section 13.10 (Force Majeure).
- 1.51. *"FTE"* means, with respect to a person, the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of 45.5 weeks or 1,820 hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
- 1.52. *"FTE Rate"* means [\*], increasing by [\*] of the then-current FTE Rate on January 1 of 2010 and each subsequent calendar year.
- 1.53. "*GAAP*" means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.
- 1.54. *"Governmental Authority"* means any government or supranational administrative agency, commission or other governmental or supranational authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental or supranational regulatory body.
- 1.55. *"GSK"* has the meaning set forth in the Preamble.
- 1.56. *"GSK Housemarks"* means the corporate logo of GSK, the trademark "GlaxoSmithKline" and any other related trademark, trade name or service mark (whether registered or unregistered) containing the word "GlaxoSmithKline" and intellectual property rights residing in the foregoing.
- 1.57. "GSK Indemnitees" has the meaning set forth in Section 11.2 (Indemnity by Amgen).
- 1.58. *"GSK Inventions"* means any Invention made solely by GSK or its Affiliates (and not jointly with Amgen or any of its Affiliates) during the Term in the course of performing the activities contemplated hereunder that relates substantially to the composition of matter, formulation or use of Ivory.

- 1.59. *"HTAs"* means health technology assessments.
- 1.60. "IFRS" means the then current International Financial Reporting Standards, consistently applied.
- 1.61. "Indemnified Party" has the meaning set forth in Section 11.4 (Claim for Indemnification).
- 1.62. "Indemnifying Party" has the meaning set forth in Section 11.4 (Claim for Indemnification).
- 1.63. "Infringement Claim" has the meaning set forth in Section 8.7 (Defense and Settlement of Third Party Claims).
- 1.64. *"Initial Countries"* means those countries set forth on the Initial Countries Schedule, including any territory that becomes a part of any of these countries and any country of which any of these countries become a part.
- 1.65. "Invention" means any idea, concept, discovery, invention, improvement or trade secret.
- 1.66. "ISS" means a clinical study or research study initiated and conducted by an individual not employed by a Party and not acting on behalf of a Party.
- 1.67. "Ivory" means [\*].
- 1.68. *"Ivory Intellectual Property"* means any Invention, Know-How, Patent, Product Trademark, trademark application, electronic media registrations (including domain names, usernames, websites, blogs and the like) or Copyright owned or controlled by Amgen or its Affiliates related to Ivory in the Expansion Scope.
- 1.69. "Ivory SKU" means a particular stock-keeping unit of Ivory supplied to GSK pursuant to the Supply Agreement.
- 1.70. [\*]
- 1.71. *"Know-How"* means all tangible and intangible techniques, information, technology, practices, trade secrets, Inventions (whether patentable or not), methods, processes, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological, manufacturing, and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, including works of authorship and copyrights.

- 1.72. "Launch Plan" has the meaning set forth in Section 3.3 (Launch Plans).
- 1.73. "Losses" has the meaning set forth in Section 11.1 (Indemnity by GSK).
- 1.74. "Manufacturing Filing Responsibilities" has the meaning set forth in Section 5.4.3 (Manufacturing Filings).
- 1.75. "Opt-In Date" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).

- 1.76. "Opt-In Notice" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.77. "Option" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.78. "*Option Exercise Year*" means, with respect to the applicable [\*], the twelve (12) month period following the date on which Amgen delivers the Opt-In Notice to GSK pursuant to Section 4.11 (Amgen Co-Promotion).
- 1.79. "*Patent Coordinator*" means those employees of each of the Parties appointed pursuant to Section 2.14 (Patent Coordinators) to serve as such Party's primary liaison with the other Party on matters relating to intellectual property as described in this Agreement.
- 1.80. *"Patents"* means the issued patents and pending patent applications (including certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, refilings, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and patent term extensions thereof, and all international or foreign counterparts of any of the foregoing (including supplemental protection certificates, patents of addition and the like).
- 1.81. "*Person*" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, "group" as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.
- 1.82. *"Phase IV Study"* means any clinical study initiated in a country within the Expansion Scope following the first Regulatory Approval for Ivory in such country for the indication being studied. Phase IV Studies may include epidemiological studies, modeling and pharmacoeconomic studies, ISS and post-marketing surveillance studies.
- 1.83. "Planned Details" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.84. *"Primary Countries"* means those countries set forth on the Primary Countries Schedule, including any territory that becomes a part of any of these countries and any country of which any of these countries become a part.
- 1.85. "Product Data" has the meaning set forth in Section 12.9.4 (Product Data and Amgen Confidential Information).
- 1.86. "*Product Trademarks*" means one (1) or more of the trademarks designated by Amgen for use by GSK in a country in the Expansion Territory from among those trademarks utilized by Amgen for Ivory outside the Expansion Territory, any other related trademark or service mark (whether registered or unregistered) containing such trademark and any other trademark or service mark (whether registered or unregistered) selected or authorized by Amgen for use on, with, or to refer to Ivory (other than Amgen Housemarks and GSK Housemarks, as applicable) in the Expansion Scope during the Term.

- 1.87. *"Promotional Materials"* means all sales representative training materials and all written, printed, graphic, electronic, audio or video sales, promotional or advertising materials relating to or used with respect to Ivory in the Expansion Scope, including journal advertisements, sales visual aids, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements, and sales reminder aids, and materials used for scientific exchange and disease state communications.
- 1.88. *"Prosecution and Maintenance"* means, the preparation, filing, prosecution and maintenance of patent applications and trademark applications, and maintenance of patents and trademarks, as well as re-examinations and reissues with respect to such patents and trademarks, together with the conduct of interferences and the defense of oppositions or similar proceedings with respect to such patent application, trademark application, patent or trademark; and *"Prosecute and Maintain"* has the correlative meaning.
- 1.89. *"Quality Agreement"* means the Quality Agreement to be entered into between the Parties (or Affiliates thereof) promptly after the Effective Date, to govern certain quality matters related to Ivory to be supplied under the Supply Agreement.
- 1.90. *"Recoveries"* means all monies received by Amgen or GSK (or any of their Affiliates) from a Third Party in connection with the final, non-appealable judgment (or judgment with respect to which the time period for appeal has expired), award or settlement of any enforcement with respect to any Ivory Intellectual Property, to the extent such judgment, award or settlement pertains to activities within the Expansion Scope.
- 1.91. "Reduction Amount" has the meaning set forth in Section 4.11 (Amgen Co-Promotion).
- 1.92. "*Regulatory Approval*" means a product-specific approval from a Governmental Authority necessary for the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory.
- 1.93. *"Regulatory Filing"* means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of Ivory. For the sake of clarity, *"Regulatory Filing"* does not include any submission with any Governmental Authority of adverse event reports, periodic safety reports, or other similar safety submissions (which submissions will be governed by the Safety Agreement).
- 1.94. "Remaining Interest" has the meaning set forth in Section 12.5.2 (Later Change of Control of GSK).
- 1.95. *"Reserved Territory"* means those Initial Countries which are included in the Reserved Territory in accordance with Section 3.2 (Reserved Territory). Any country that is removed from the Reserved Territory pursuant to the terms of this Agreement will cease to be a part of the Reserved Territory from that point forward.

- 1.97. [\*]
- 1.98. "*Safety Agreement*" means the Safety Agreement to be entered into by the Parties (or Affiliates thereof) promptly after the Effective Date pertaining to the handling of safety matters, pharmacovigilance matters, product complaints and/or the like with respect to Ivory.
- 1.99. "Segregate" means, with respect to two (2) programs: (i) [\*] (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Expansion Territory) [\*]; (ii) to ensure that personnel (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Expansion Territory) [\*]; (iii) to ensure that [\*] (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Expansion Territory) [\*]; (iii) to ensure that [\*] (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Expansion Territory) [\*]; 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 cooperate to enable the other Party to verify that such restrictions are in place and sufficient to achieve the foregoing. For clarity, [\*].
- 1.100. *"Supply Agreement"* means the Supply Agreement to be entered into by the Parties (or Affiliates thereof) promptly after the Effective Date, to address the supply of Ivory to GSK for the Expansion Territory. The Supply Agreement will be materially consistent with the terms set forth on the Supply Agreement Schedule, and will include supply pricing in accordance with the Supply Pricing Schedule.
- 1.101. "Taxes" means any tax, excise or duty, other than taxes upon income.
- 1.102. "Term" has the meaning set forth in Section 12.1 (Term).
- 1.103. "Third Party" means any Person that is not a Party, or an Affiliate of a Party.
- 1.104. *"Third Party Claim"* means any claim, action, lawsuit, or other proceeding brought by any Third Party. Third Party Claim includes any [\*] and any Infringement Claim.
- 1.105. "Unaddressed Inquiries" has the meaning set forth in Section 4.15 (Medical Inquiries and Product Inquiries).
- 1.106. *"VAT"* means the tax imposed by Council Directive 2006/112/EC of the European Community and any national legislation implementing that directive together with legislation supplemental thereto and in particular, in relation to the United Kingdom, the tax imposed by the Value Added Tax Act of 1994 or other tax of a similar nature imposed in other countries instead of or in addition to value added tax.
- 1.107. "Voting Securities" means securities entitled to be voted generally or in the election of directors of a Person.

<sup>1.96. [\*]</sup> 

1.108. "Withholding Party" has the meaning set forth in Section 6.4 (Withholding).

### 2. SCOPE AND GOVERNANCE

- 2.1. <u>Purpose of Collaboration</u>. The purpose of the collaboration is for GSK to develop and commercialize Ivory in the Expansion Scope, in accordance with the terms and conditions of this Agreement.
- 2.2. <u>Governance</u>. The collaboration hereunder will be governed by: (i) the ERC, which will be responsible for the resolution of issues within the collaboration that cannot be resolved by the ESC; (ii) the ESC, which will be responsible for oversight of the collaboration; (iii) the EOC, which will be responsible for overseeing supply for the Expansion Scope under the Supply Agreement and Quality Agreement, and for other manufacturing-related issues within the Expansion Scope (such as distribution, quality and release-testing); (iv) the ECC, which will be responsible for developing the Expansion Brand Plan for Ivory within the Expansion Scope; (v) the EDC, which will be responsible for regulatory matters within the Expansion Scope, establishing the Development Plan and discussing the activities to be conducted thereunder; and (vi) the Patent Coordinators, who will be responsible for intellectual property issues as set forth herein. All such committees and teams (the terms committee and team being used interchangeably herein) will be formed promptly following the Effective Date. Each such committee and team will oversee the activities undertaken by the Parties within the scope of authority of such committee or team, including monitoring progress against plans and outlining how Parties will collaborate in the conduct of such activities. It is expected that the committees will develop plans and strategies assigned to it in a collaborative manner and will serve as a forum for discussion of and input into such plans and strategies.
- 2.3. <u>Decision Making Standards</u>. The decisions made and actions taken by the ERC, ESC, ECC, EOC, EDC and Patent Coordinators will be made with the interests of both Parties (including the Parties' interests in the collaboration) (as presented to such committee or team) duly considered in good faith. Subject to the terms of this Agreement and Applicable Law, the decisions of such committees will be made in accordance with the discretion and business judgment of the members thereof.
- 2.4. <u>Membership</u>. Each of the ESC, EOC, ECC and EDC will be comprised of three (3) members appointed by Amgen and three (3) members appointed by GSK (or such other number of members as agreed in writing by the Parties). The ESC, EOC, ECC and EDC will each be led by two (2) co-chairs, one (1) appointed by each of the Parties. The ERC will be comprised of one (1) member appointed by each of the Parties, and such members initially will be the President, Emerging Markets (or his or her designee) for GSK and the Executive Vice President, Global Commercial Operations (or his or her designee) for Amgen. Each Party will ensure that the committee members appointed by it have the appropriate level of seniority and decision-making authority commensurate with the responsibilities of the committee to which they are appointed.

- 2.5. <u>Replacement of Members</u>. Each Party will have the right to replace its committee members by written notice to the other Party. In the event any committee member becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member will promptly appoint a replacement by written notice to the other Party.
- 2.6. <u>Establishment of Subcommittees</u>. Each committee will have the right to establish subcommittees or working teams with respect to issues within its area of responsibility as it sees fit.
- 2.7. <u>Efficiency in Meeting Planning</u>. The Parties will cooperate to achieve reasonable operational efficiencies in planning and conducting meetings of committees and teams hereunder (such as, for example, by scheduling meetings of committees with overlapping membership so as to minimize travel expense, by having one or more committee members participate in in-person meetings via video or teleconference and the like).
- 2.8. <u>No Authority to Amend or Modify</u>. Notwithstanding anything herein to the contrary, no committee will have any authority to amend, modify or waive compliance with this Agreement, the Supply Agreement, the Quality Agreement or the Safety Agreement.
- 2.9. <u>Expansion Review Committee</u>. The ERC will be responsible for resolving any issues within the collaboration that cannot be resolved by the ESC or EDC, as the case may be.
  - 2.9.1. *Meetings*. The ERC will meet as requested by the ESC or EDC to resolve unresolved collaboration issues, via teleconference or videoconference or otherwise, or as otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend ERC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. All ERC meetings must have all members in attendance.
  - 2.9.2. *Decision Making*. The ERC will make decisions by consensus with each Party having one (1) vote. In the event of a deadlock, the decision will be made by the member appointed to the ERC by Amgen; provided that: (i) the ERC will not have the right to [\*].
- 2.10. Expansion Steering Committee. The ESC will be responsible for overseeing the collaboration, including the commercialization of Ivory in the Expansion Scope generally. The ESC will be a forum for: (i) discussing commercialization strategy; (ii) reviewing, and approving Launch Plans, including updates thereof and changes thereto; (iii) reviewing, approving and updating the Expansion Brand Plan established by the ECC; (iv) developing and updating a rolling three (3) year Sales Forecast; (v) reviewing, approving and updating the supply forecast established by the EOC; (vi) reviewing and approving the pricing and access plan established by the ECC; (vii) keeping each of the Parties informed of conferences in the Expansion Territory as described in Section 4.6 (Conferences in Expansion

Territory) and attendees thereof, and (viii) discussing the schedule of significant near-term activities that will require Amgen to provide personnel and resource to allow Amgen reasonable time to plan for such resourcing in a manner that will not impede GSK's progress under this Agreement. On an ad hoc basis, the ESC may request special reports or briefings from the other committees. The ESC will conduct its activities in consultation and/or cooperation with the EDC with respect to those matters that such committees determine appropriate, including regulatory matters

- 2.10.1. *Meetings*. The ESC will meet quarterly in person, via teleconference or videoconference or otherwise (with at least two (2) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend ESC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the ESC as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All ESC meetings must have at least one (1) member appointed by each Party in attendance.
- 2.10.2. *Reporting.* Each Party will keep the ESC fully and promptly informed of progress and results of activities for which it is responsible or that it is permitted to conduct hereunder, through its members on the ESC and as otherwise provided herein. Each Party will fully and promptly inform the ESC with respect to its activities in the Expansion Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof. Once GSK obtains Regulatory Approval of Ivory in a country within the Expansion Territory, it will regularly update the ESC, on a country-by-country basis, with respect to (i) the number of sales representatives used to Detail Ivory and the number of Details performed, and (ii) any other information reasonably requested by the ESC.
- 2.10.3. *Decision Making*. The ESC will make decisions by consensus with each Party having one (1) vote. In the event of a deadlock on an issue, the decision will be made by the members of the ESC appointed by GSK if the issue is a commercialization matter, or by Amgen if the matter is any other matter; provided that the members appointed by either Party will have the right to require that such issue be escalated to the ERC for determination. Notwithstanding the foregoing, in the event of a decision on a matter that [\*].
- 2.11. <u>Expansion Operations Committee</u>. The EOC will be responsible for overseeing supply (in accordance with the Supply Agreement and the Quality Agreement), reviewing cost of goods of Ivory, preparing a draft supply forecast for approval by the ESC, and other operational issues within the Expansion Scope.

- 2.11.1. *Meetings*. The EOC will meet quarterly in person, via teleconference or videoconference or otherwise (with at least two (2) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European or global headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend EOC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the EOC as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All EOC meetings must have at least one (1) member appointed by each Party in attendance.
- 2.11.2. *Reporting.* Each Party will keep the EOC fully and promptly informed of progress and results of activities within the scope of responsibility of the EOC for which it is responsible or that it is permitted to conduct hereunder through its members on the EOC and as otherwise provided herein. Each Party will fully and promptly inform the EOC with respect to its activities in the Expansion Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof. Notwithstanding the foregoing, Amgen will have no obligation to provide proprietary manufacturing information to GSK through any committee or otherwise.
- 2.11.3. *Decision Making.* The EOC will make decisions by consensus with each Party having one (1) vote. In the event of a deadlock on an issue, the decision will be made by the members of the EOC appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the ESC for determination. Notwithstanding the foregoing, in the event of a decision on a matter that requires exigent action pursuant to Applicable Law or to prevent a material adverse effect on Ivory or a Party, the members of the EOC appointed by Amgen will have the right to make an interim decision pending ESC determination.
- 2.12. Expansion Commercialization Committee. The ECC will be responsible for developing specified plans and overseeing specified commercial activities relating to Ivory in the Expansion Scope. The ECC will be a forum for discussing, developing, and agreeing upon a draft Expansion Brand Plan for submission to the ESC for approval and reviewing the draft three (3) year sales forecast. The ECC's responsibilities will include: (i) cross-functional, collaborative development of the Expansion Brand Plan including strategies and tactics at the regional level; (ii) developing and updating a draft pricing and access plan for ESC approval; (iii) developing and updating core message elements; and (iv) discussing the schedule of significant near-term activities that will require Amgen to provide personnel and resource to allow Amgen reasonable time to plan for such resourcing in a manner that will not impede GSK's progress under this

Agreement. Based on the strategies approved by the ECC, GSK will prepare a draft Expansion Brand Plan and draft pricing and access plan for review and approval of the ECC. The ECC will then submit the draft Expansion Brand Plan and the draft pricing and access plan to the ESC for final approval.

- 2.12.1. *Meetings*. The ECC will meet quarterly in person, via teleconference or videoconference or otherwise (with at least two (2) meetings per calendar year being in person), or as otherwise agreed by the Parties. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend ECC meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the ECC as reasonably required to resolve particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All ECC meetings must have at least one (1) member appointed by each Party in attendance.
- 2.12.2. *Reporting.* Each Party will keep the ECC fully and promptly informed of progress and results of activities within the scope of responsibility of the ECC for which it is responsible or that it is permitted to conduct hereunder through its members on the ECC and as otherwise provided herein. Each Party will fully and promptly inform the ECC with respect to its activities in the Expansion Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.12.3. *Decision Making.* The ECC will make decisions by consensus with each Party having one vote. In the event of a deadlock on an issue, the decision will be made by the members of the ECC appointed by GSK, provided that the members appointed by either Party will have the right to require that such issue be escalated to the ESC for determination. Notwithstanding the foregoing, in the event of a decision on a matter [\*].
- 2.13. Expansion Development Committee. The EDC will be responsible for (i) establishing the Development Plans and Development Budgets, (ii) reviewing clinical protocols for studies to be conducted under the Development Plan, (iii) overseeing regulatory matters in the Expansion Scope and the conduct and progress of the activities set forth in the Development Plan, including the initial allocation of responsibility between the Parties and transfers of responsibility thereafter, (iv) discussing the schedule of significant near-term activities that will require Amgen to provide personnel and resource to allow Amgen reasonable time to plan for such resourcing in a manner that will not impede GSK's progress under this Agreement and (v) overseeing any recall, market withdrawal, field alert or any other corrective action (including letters to health care professionals) related to Ivory in the Expansion Scope. In addition to the foregoing, the EDC will discuss development to be undertaken by Amgen outside the Expansion Territory and in the Expansion Territory for the benefit of countries outside the

Expansion Territory, in each case to the extent either Party reasonably believes such development is reasonably likely to have a material benefit or a material adverse effect, in each case on Ivory within the Expansion Scope (and Amgen will provide summary information of Ivory development to be undertaken by Amgen in order to enable GSK to make such determination). The EDC will conduct its activities in consultation and/or cooperation with the ESC with respect to those matters as such committees determine appropriate, including regulatory matters.

- 2.13.1. *Meetings*. The EDC will meet quarterly in person, via teleconference or videoconference or otherwise (with at least one (1) meeting per calendar year being in person), or as otherwise agreed by the Parties. The Parties anticipate that the EDC may meet more frequently in the initial years of the Term. Any in-person meetings will be held on an alternating basis between GSK's and Amgen's European or global headquarters, unless otherwise agreed by the Parties. Each Party will be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend EDC meetings, but no Third Party personnel may attend unless otherwise agreed by the Parties. Each Party may also call for special meetings of the EDC as reasonably required to discuss particular matters requested by such Party by at least ten (10) business days prior written notice to the co-chair appointed by the other Party. All EDC meetings must have at least one (1) member appointed by each Party in attendance.
- 2.13.2. *Reporting.* Each Party will keep the EDC fully and promptly informed of progress and results of activities for which it is responsible or that it is permitted to conduct hereunder in accordance with the applicable Development Plan, through its members on the EDC and as otherwise provided herein. Each Party will provide copies of data and reports or other information from such activities to the EDC as requested by either Party. Each Party will fully and promptly inform the EDC with respect to its activities in the Expansion Scope undertaken pursuant to this Agreement as reasonably requested by any member thereof.
- 2.13.3. *Decision Making*. The EDC will make decisions by consensus with each Party having one vote. In the event of a deadlock on an issue, the decision will be made by the members of the EDC appointed by Amgen, provided that the members appointed by either Party will have the right to require that such issue be escalated to the ERC for determination. Notwithstanding the foregoing, in the event of a decision on a matter that [\*].
- 2.14. <u>Patent Coordinators</u>. The Parties will each appoint a Patent Coordinator promptly after the Effective Date of the Agreement. The Patent Coordinators will serve as the primary contacts and forum for discussion between the Parties with respect to intellectual property matters involving Ivory worldwide in the Field, and will cooperate with respect to the activities set forth in Article 8 (Intellectual Property). A [\*], in each case within the Expansion Scope or outside the Expansion Scope to

the extent such matter would be reasonably likely to have a material impact on the Expansion Scope. The Patent Coordinators will meet as often as agreed by them (and at least semi-annually if requested), via teleconference or videoconference or as otherwise agreed, to discuss matters arising out of the activities set forth in Article 8 (Intellectual Property). To the extent reasonably requested by either Patent Coordinator, the Patent Coordinators will solicit the involvement of more senior members of their respective legal departments (up to the most senior intellectual property attorney, where appropriate) with respect to critical issues. Each of the Patent Coordinators will consider comments and suggestions made by the other in good faith. Notwithstanding anything in this Agreement to the contrary, neither Patent Coordinator will have the obligation to disclose information to the extent prohibited by obligation of confidentiality or protective order, that would result in loss of attorney-client or other relevant legal privilege, that constitutes proprietary manufacturing information or where the other Party has an actual or potential conflict of interest with respect to such information (e.g., where sharing such information would be reasonably likely to provide the recipient with a commercial advantage with respect to a product competitive to Ivory that is being developed or commercialized by such Party).

- 2.15. <u>Internal Governance</u>. The Parties acknowledge that the committee and decision-making structure set forth herein is without prejudice to, and does not supplant, the Parties' internal decision-making structures.
- 2.16. <u>Right to Terminate Participation</u>. Amgen will have the right to terminate its participation in any or all of the committees contemplated pursuant to this Article 2 (Scope and Governance) by ninety (90) days prior written notice to GSK. In the event of such termination, matters subject to the collaboration and oversight of the relevant committees will be dealt with directly between Amgen and GSK. All information that was to be provided by a Party to a committee that has been terminated will instead be provided (in the same time frames as previously required) directly to the other Party. With respect to any matter under the purview of the terminated committee(s) that was subject to a final determination by Amgen's or GSK's committee members, such matter will instead be subject to the final determination of Amgen or GSK, respectively.
- 2.17. <u>Alliance Managers</u>. Promptly after the Effective Date, each Party will appoint a person who will oversee interactions between the Parties between meetings of the committees established hereunder (each, an *"Alliance Manager"*). Unless otherwise agreed by the Parties, the Alliance Managers will attend all meetings of the ESC and will have the right to attend all meetings of the EDC, EOC and ECC, as non-voting participants at such meetings. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

### 3. EXCLUSIVITY; LAUNCH PLANS

3.1. <u>Exclusivity</u>. Amgen will not, itself, through its Affiliates or any other entity which is controlled by Amgen, commercialize Ivory in the Reserved Territory for a period of [\*] after [\*], except through GSK pursuant to this Agreement. For purposes of this Section 3.1 (Reserved Territory), "control" means the possession

solely by Amgen or its Affiliates, of the power to direct or cause the direction of management and policies of an entity, whether through the ownership of Voting Securities, by contract or otherwise. Notwithstanding the foregoing, Amgen will have the right to conduct research, development and manufacturing in the Reserved Territory, but will not sell or offer for sale Ivory for commercial use in the Reserved Territory except to GSK or its Affiliates and as may be required by Applicable Law in connection with clinical development in the Reserved Territory.

- 3.2. <u>Reserved Territory</u>. Within [\*] of the Effective Date, GSK will inform the ESC which of the Initial Countries will be included in the Reserved Territory (which will at least include the Primary Countries). Any Initial Countries that are not included in the Reserved Territory at the expiration of such [\*] period will be deemed part of the Excluded Territory.
- 3.3. Launch Plans. GSK will prepare and provide to the ESC a launch plan ("Launch Plan") for each of the Designated Countries, Argentina and Colombia no later than [\*]. GSK will prepare and provide to the ESC Launch Plans for each of the remaining Primary Countries within [\*] after the Effective Date. GSK will prepare and provide to the ESC Launch Plans for each of the remaining countries in the Reserved Territory within [\*] of the Effective Date. The Launch Plan for each country will set forth in reasonable detail GSK's plan to develop, register and commercialize Ivory in the applicable country through the first three (3) full calendar years after commercial launch in such country, including (i) all development and clinical studies to be conducted, (ii) the information and portions of Regulatory Filings outside the Expansion Territory to be used for seeking Regulatory Approval in such country, (iii) supply forecasts, (iv) commercial strategy and forecasts, (v) proposed pricing, (vi) the anticipated timeline of development, filing, Regulatory Approval and launch, (vii) estimated resources and budget for the planned activities, (viii) any Third Parties proposed to be used in the development and/or commercialization, (ix) an outline of regulatory and supply requirements for obtaining Regulatory Approval, including a plan for which of the Parties will be the lead with respect to communications with the applicable Governmental Authority, (x) an access and reimbursement assessment (e.g., public/private reimbursement, formulary requirements, etc.), (xi) a distribution plan, (xii) a risk mitigation plan, (xiii) a plan for any required technology transfer to Governmental Authorities, including which Party will be responsible for transfer and the resource required for such transfer, (xiv) with respect to Launch Plans for the Designated Countries, GSK's operational and financial commitments with respect to Ivory as described in Section 4.1 (GSK Activities), and (xv) any other information that GSK reasonably believes it requires from Amgen to obtain Regulatory Approval of Ivory in the Expansion Scope. In addition, GSK will promptly provide any other information reasonably requested by the ESC to assist in the evaluation of the Launch Plan in accordance with Section 3.4 (Expansion Territory).
- 3.4. <u>Expansion Territory</u>. Promptly following receipt of a Launch Plan, the ESC will meet to discuss the Launch Plan and to evaluate the risks and benefits of

commercialization of Ivory in the applicable country in accordance with such Launch Plan. The ESC will consult with the EDC to take into consideration the development required to obtain Regulatory Approval of Ivory in the applicable country when evaluating risks and benefits. The ESC may request revisions to the Launch Plan. Promptly following the evaluation of the Launch Plan, the ESC will determine whether to move a country from the Reserved Territory into the Expansion Territory, and if it is so determined, then the [\*]. It is the Parties' current anticipation that [\*] Ivory in the Expansion Scope. For the avoidance of doubt, the members of the ESC from both Parties are required to unanimously agree to (i) approve a Launch Plan, (ii) make any material amendments to the Launch Plan after approval thereof and prior to the establishment of the applicable Expansion Brand Plan, Development Plan or supply requirements in accordance with Section 3.5 (Establishment of Plans) and (iii) move a country from the Reserved Territory into the Expansion Territory. If unanimous agreement is not reached, then such decision may be escalated to the ERC; provided, that if the members of the ERC do not agree to move a country from the Reserved Territory into the Expansion Territory and be subject to the provisions of this Agreement applicable to the Reserved Territory, including Section 3.1 (Exclusivity). Any country remaining in the Reserved Territory [\*] after [\*] will cease to be included in the Reserved Territory, and will be deemed to be included in the Excluded Territory at such time, unless otherwise expressly agreed in advance by the Parties in writing.

- 3.5. <u>Establishment of Plans</u>. Promptly following the movement of a country from the Reserved Territory into the Expansion Territory, (i) the ECC will meet to discuss, develop and agree upon an access and reimbursement plan for the applicable country and to discuss, develop and agree upon the Expansion Brand Plan (if one has not been developed as of such time) or the applicability of, including any changes to, the Expansion Brand Plan with respect to the applicable country, (ii) the EDC will meet to discuss, develop and agree upon a Development Plan for Ivory in the applicable country, and (iii) the EOC will meet to discuss and agree upon the supply requirements for the applicable country, in each case based substantially on the approved Launch Plan; provided, that Amgen cannot obligate [\*]. The ECC and EDC will determine, and include in the Expansion Brand Plan or Development Plan, as applicable, what reasonable materials with respect to Ivory in the Collaboration Scope (such as training materials, promotional materials and development documents) that GSK will require in order to conduct its activities under this Agreement, and Amgen will provide such materials as the Parties agree. On an annual basis, and more often as requested by the ESC, the ESC will review and update the planned activities with respect to Ivory for each country in the Expansion Territory, informed by the Expansion Brand Plan, and other activities of the ECC, EDC and EOC.
- 3.6. <u>Removal of Countries</u>. If GSK does not obtain Regulatory Approval to market Ivory in a given country of the Expansion Territory within [\*], then in each case the EDC will meet to discuss the reasons for not obtaining Regulatory Approval of Ivory in such country in accordance with the foregoing timelines. Such discussion by the EDC will include consideration of any delays caused by

Amgen's failure to timely review or provide materials hereunder necessary for GSK's progress in such country and other circumstances outside of GSK's reasonable control. If requested, GSK will prepare a detailed written plan for such EDC meeting (including detailed timelines and a date by which it expects to obtain Regulatory Approval) of the activities that GSK has undertaken, is undertaking and will undertake to obtain Regulatory Approval for Ivory in the Expansion Scope as soon as reasonably practicable in the applicable country. If GSK believes that it will not obtain Regulatory Approval in a country in the Expansion Territory in accordance with the foregoing timelines, then it will promptly notify the EDC thereof and provide to the EDC any information it reasonably requests with respect thereto.

3.7. <u>Accession to EU</u>. Any country within the Reserved Territory or Expansion Territory that accedes to the European Union after the Effective Date will become part of the Collaboration Territory pursuant to the Collaboration Agreement and will no longer be part of the Reserved Territory or Expansion Territory.

### 4. COLLABORATION ACTIVITIES

- 4.1. <u>GSK Activities</u>. Except as otherwise set forth herein, including Section 4.11 (Amgen Co-Promotion), GSK will have sole responsibility for the conduct of all commercialization activities within the Expansion Scope, including providing sales force representatives for Detailing Ivory within the Expansion Scope, pricing Ivory (including with respect to trade, quantity or other discounts), determining the launch conditions and terms of sale for Ivory, distribution, taking orders for and returns of Ivory, issuing credits for Ivory, selling Ivory and booking sales of Ivory, in each case within the Expansion Scope. GSK is solely responsible for all costs associated with its activities in the Expansion Scope. GSK will only commercialize Ivory in the Expansion Scope in accordance with the applicable Launch Plan, Expansion Brand Plan and this Agreement. GSK will not commercialize Ivory outside the Expansion Scope. In each [\*], unless prohibited by Applicable Law, on an ongoing basis throughout the period commencing [\*], GSK will: [\*].
- 4.2. <u>Amgen Activities</u>. Amgen will have sole responsibility for maintaining the global safety database and core data sheet for Ivory, and for manufacturing Ivory for the Expansion Territory in accordance with the Supply Agreement, Quality Agreement, the direction of the EOC and this Agreement. In addition, Amgen will have the sole right to perform activities with respect to Ivory outside the Expansion Scope and GSK will not promote or conduct any activities hereunder with respect to Ivory outside the Expansion Scope. GSK will not interact with key opinion leaders located outside the Expansion Territory with respect to Ivory, except as may be agreed in advance in writing by the Parties.
- 4.3. <u>Diligence and Performance Standards</u>. Subject to the decisions made by and oversight of the committees established hereunder, each Party will use, and will assure that each of its Affiliates use, Commercially Reasonable Efforts in the performance of its and their activities hereunder. GSK will conduct, and ensure that each of its Affiliates conduct, all of its and their activities with respect to the

registration and development of Ivory for the Expansion Scope in accordance with this Agreement, the Development Plans, the direction of the EDC, the Quality Agreement, the Safety Agreement and all Applicable Law, and with respect to the promotion and commercialization of Ivory in accordance with this Agreement, the Expansion Brand Plan, accepted national and international pharmaceutical industry codes of practices in and for the Expansion Territory, and all Applicable Law. Amgen will conduct, and ensure that each of its Affiliates conduct, all of its and their activities with respect to the manufacture and development (including making any Regulatory Filings) of Ivory for the Expansion Scope in accordance with this Agreement, the Development Plans, the direction of the EDC or EOC, as applicable, the Supply Agreement, Quality Agreement and all Applicable Law. The Parties will provide each other with all reasonably requested cooperation to enable each of them to comply with Applicable Law and accepted national and international pharmaceutical industry codes of practices, including permitting each Party to verify the other Party's compliance therewith. Notwithstanding the foregoing, GSK's sales force representatives will conduct the commercialization activities under this Agreement in accordance with the relevant codes of practice established by GSK, and nothing herein will be interpreted to require lower standards of conduct with respect to such sales force representatives than those required in GSK's codes of practice. In evaluating whether a Party has used or is using Commercially Reasonable Efforts, consideration will be given to the impact of any requests of or delays caused by the other Party and the impact of any final decisions made by the other Party within its final decision-making authority. If GSK reasonably determines that the [\*] for a country would make [\*], considering the relevant [\*] and other relevant factors, and the Parties are unable to reach agreement, after discussion, on an adjustment to [\*] for such country that would make commercialization of Ivory in such country [\*], then GSK will promptly notify Amgen thereof and Amgen will have the right to terminate this Agreement with respect to such country pursuant to Section 12.6 (Termination for Withdrawal or Stoppage).

4.4. <u>Use of Affiliates and Third Party Contractors</u>. GSK will perform its activities hereunder itself or through a wholly-owned Affiliate, unless otherwise provided in the approved Launch Plan. Amgen will perform any development and commercial activities hereunder for the Expansion Scope itself or through a wholly-owned Affiliate, unless otherwise provided in the Launch Plan. If GSK or Amgen decides to use a Third Party to conduct any such activity under this Agreement, and it was not set forth in the approved Launch Plan, then the use of such Third Party will be subject to the other Party's prior written consent. Notwithstanding the foregoing. GSK may use Third Party contractors for distribution operations and logistics for Ivory without Amgen's prior written consent (but with prior notice to and consultation with Amgen), provided that such Third Party contractors hereunder with this Agreement and will be responsible for the acts and omissions of such Third Parties as if committed or omitted by the

applicable Party. The obligations of GSK and Amgen herein also apply to their respective Affiliates. Each Party will be responsible for compliance by its respective Affiliates with this Agreement and will be responsible for all acts and omissions of such Affiliates as if committed or omitted by the applicable Party.

- 4.5. <u>Violation of Laws</u>. Each Party will promptly notify the other Party of any violation of Applicable Law by its personnel with respect to the conduct of activities in the Expansion Scope under this Agreement. Upon request of the non-notifying Party, the notifying Party will promptly confer with the non-notifying Party regarding any such violation and will promptly take remedial and/or preventative action as may be reasonably required by the ESC with respect thereto. The ESC will have the right to require the removal of any personnel that materially violates Applicable Law or applicable national or international pharmaceutical industry codes of practices from performing activities contemplated under this Agreement with respect to Ivory in the Expansion Scope.
- 4.6. <u>Conferences in Expansion Territory</u>. GSK will lead participation in any conferences or meetings located within the Expansion Territory that are not reasonably expected to have [\*] and Amgen will have the right to participate in any such conference or meeting with respect to Ivory at its own cost, and subject to GSK's reasonable direction. Amgen will lead participation in any conferences or meetings located within the Expansion Territory that are reasonably expected to have [\*], and GSK will have the right to participate in any such conference or meeting with respect to Ivory at its own cost, and subject to Amgen's reasonable direction.
- 4.7. <u>Brand Security and Anti-Counterfeiting</u>. The Parties will establish contacts for communication regarding brand security issues and will each reasonably cooperate with the other with respect thereto.
- 4.8. <u>Sales and Pricing</u>. GSK will make and book all sales of Ivory in the Expansion Scope. To the extent permitted by Applicable Law, the [\*], to the extent permitted by Applicable Law, [\*]. For the avoidance of doubt, the Parties will not [\*] and GSK will be solely responsible for setting the price and other commercial terms for Ivory in the Expansion Scope.
- 4.9. <u>Management of Personnel</u>. Each Party will have sole authority and responsibility for recruiting, hiring, managing, compensating (including paying for all benefits, wages, special incentives, workers' compensation and employment taxes), disciplining, firing and otherwise controlling the personnel provided by such Party for performance of its obligations hereunder. Each Party will provide the day-to-day management of its sales force representatives and other personnel utilized hereunder, including furnishing administrative support, financial resources, equipment and supplies.
- 4.10. <u>Provision of Information</u>. During the Term, upon request, the Parties will reasonably cooperate to exchange information that is reasonably necessary for the activities to be conducted hereunder. Notwithstanding the foregoing, neither Party will have an obligation to provide information relating to any product other than Ivory. Notwithstanding the foregoing, Amgen will have no obligation to provide proprietary manufacturing information to GSK.

### 4.11. <u>Amgen Co-Promotion</u>.

Option. On a [\*] basis, commencing on [\*] in such [\*] (the "Opt-In Date"), Amgen will have the option, but not the obligation, to provide 4.11.1. additional Details in an amount up to [\*] of the total Planned Details for Ivory in such [\*] (the "Option") and to maintain that percentage of Planned Details during the Term. "Planned Details" means, for the Option Exercise Year, the number of Details that are then-planned to be performed by GSK for Ivory in the applicable [\*] in the Option Exercise Year (or, if there is no "then-planned" number of Details for the full Option Exercise Year as of the date of the delivery of the Opt-In Notice, it will be the actual number of Details performed by GSK for Ivory in the applicable [\*] in the Option Exercise Year) (such then-planned or actual number of Details, as applicable, the "Baseline Details"), and for subsequent years to the Option Exercise Year means the greater of the Baseline Details for the applicable [\*] or the number of Details agreed by the ECC to be provided by GSK for Ivory in the applicable [\*] for the applicable year. For each co-promotion year, the ECC will establish a planned number of Details by GSK for Ivory in the applicable [\*], consistent with the Expansion Brand Plan. Amgen will exercise the Option by delivering [\*] prior written notice and such notice will indicate the percentage of Planned Details Amgen desires to conduct in the applicable [\*] (the "Opt-In Notice"). In addition, beginning on the Opt-In Date, at Amgen's request, Amgen and GSK will cooperate to increase Amgen's commercial operational responsibility for activities related to Ivory in such [\*]. Promptly after delivery of the Opt-In Notice, the ECC will meet to discuss amending the then-current Expansion Brand Plan for the applicable [\*] to include (a) the specific Detailing responsibilities of Amgen, and (b) alignment between the Parties in the conduct of their commercial activities in such [\*]. The ECC will also agree on a baseline sales forecast for Ivory in the [\*] (the "Baseline"), which will be based upon the expected sales forecast for the Option Exercise Year (which, if not a calendar year, will be a twelve (12) month period comprising a portion of each of two calendar years) in the then-current Expansion Brand Plan; provided, that if the Party's respective members of the ECC cannot mutually agree that the then-current Expansion Brand Plan forecast or an alternative forecast is an appropriate Baseline, then the Baseline will be an amount equal to [\*]. Amgen's sales representatives will use Commercially Reasonable Efforts to Detail Ivory in each such [\*] and will perform such Details in accordance with the applicable Expansion Brand Plan, this Agreement, accepted national and international pharmaceutical industry codes of practices in and for the Expansion Territory, and all Applicable Law. The allocation of operational responsibility for commercialization activities hereunder as well as the conduct of such activities by the Parties will be subject to comprehensive discussion by the

ECC and ESC, as applicable, where each Party will consider the input of the other with respect to the conduct of such activities. The commercial activities will be allocated between the Parties taking into consideration all relevant factors, including the capabilities of each Party to deliver the highest quality product in the most cost-effective manner, without duplication of efforts between the Parties. Amgen may terminate or reduce its co-promotion activities under this Section 12.8.1 (Option) in any [\*] on no less than [\*] prior written notice, unless otherwise agreed by the Parties; provided, that if Amgen opts to terminate or reduce its co-promotion activities in a [\*], it will not have the right to resume or increase such activities in such [\*] thereafter, without GSK's prior consent.

- 4.11.2. Costs. GSK will reimburse Amgen for costs incurred by Amgen in connection with its Detailing of Ivory after exercise of the Option, and the conduct of transitioned activities, in each case at rates equal to [\*], as provided in this Section 4.11 (Amgen Co-Promotion). If GSK performs less Details in the applicable [\*] in a year than the Planned Details for such year (such number of Details not performed, the "*Reduction Amount*"), then GSK will reimburse Amgen in full for costs incurred by Amgen in connection with Amgen's Detailing in such [\*] for such year, at rates equal to [\*], to the extent the Reduction Amount of Details are performed by Amgen. For (i) all Amgen Details of Ivory in the [\*] in a particular year in excess of the Reduction Amount, if applicable to such year, and (ii) all Amgen Details of Ivory in the [\*] in a particular year in connection with such Detailing at rates equal to [\*], but only to the extent that [\*]. The Parties will discuss a process to calculate and pay any such available reimbursement on a quarterly basis. Subject to the foregoing, such costs will be reimbursed on a calendar quarterly basis, within sixty (60) days of receipt of an invoice and supporting documentation therefor. Notwithstanding the foregoing, beginning with the [\*] of the date on which the Opt-In Notice is delivered to GSK, GSK will reimburse Amgen in full for costs incurred by Amgen in connection with its Detailing of Ivory in the applicable [\*] at rates equal to [\*].
- 4.12. <u>Training</u>. In addition to any training materials agreed to be provided in the approved Expansion Brand Plan for a country, the ECC will discuss what training materials related to the marketing and sale of Ivory outside the Expansion Scope would be useful for GSK to use for training its sales force representatives with respect to Ivory in the Expansion Scope. Amgen will provide to GSK any such training materials that the Parties mutually agree will be provided, at Amgen's expense. GSK will use the training materials provided by Amgen to train GSK's sales representatives with respect to the marketing and sale of Ivory in the Expansion Scope; provided that, if GSK deems it necessary, GSK may develop additional training materials for the marketing and sale of Ivory in the Expansion Scope. Any such new training materials will be subject to prior review and approval of Amgen, such approval not to be unreasonably withheld. GSK will be

solely responsible for the training of its sales representatives in the Expansion Scope and for providing refreshment of such training from time to time as appropriate, and will conduct such training in accordance with Applicable Law and applicable national and international pharmaceutical industry codes of practices. Amgen will own all right, title and interest in the training materials developed hereunder (except with respect to GSK Housemarks contained therein).

### 4.13. <u>Information Concerning Ivory</u>.

- 4.13.1. *Public Statements.* GSK will ensure that no claims or representations in respect of Ivory or the characteristics thereof are made by or on behalf of it or its Affiliates (by sales force members or otherwise) that have not been approved by Amgen or which do not represent an accurate summary or explanation of the labeling of Ivory.
- 4.13.2. *Ownership.* GSK will not represent to any Third Party that it has any proprietary or property right or interest in Ivory (or the Product Trademarks or any Patents claiming or covering Ivory or its manufacture, use or sale), except for the rights expressly granted to GSK hereunder. Furthermore, GSK acknowledges that it does not have any right, title or interest in Ivory or the Product Trademarks.

#### 4.14. <u>Promotional Materials</u>.

4.14.1. Development. In addition to any Promotional Materials agreed to be provided in the approved Launch Plan for a country, the ECC will discuss what promotional materials related to the promotion and sale of Ivory outside the Expansion Scope would be useful for GSK to use with respect to the promotion and sale of Ivory in the Expansion Scope. Amgen will provide to GSK copies of the Brand Book, standard language document and any marketing messaging templates and samples of promotional, scientific exchange and disease state materials that the Parties mutually agree will be provided, at Amgen's expense. GSK will be responsible for any further development of Promotional Materials, including the costs thereof. If GSK proposes to develop Promotional Materials that are inconsistent with the written content or messaging of the materials provided by Amgen in accordance with this Section 4.14.1 (Development), GSK will provide to Amgen for approval copies of any such proposed inconsistent Promotional Materials and GSK will specify all aspects that are inconsistent with the materials provided by Amgen. Amgen will respond to any such requests for approval within [\*] (commencing as of receipt of an English translation, if requested or provided). If Promotional Materials are not in English, GSK will also provide Amgen, at Amgen's expense). If Amgen ceases to use any particular promotional material outside the Expansion Scope because it believes such material may no longer be accurate or appropriate for use, GSK will cease use of any such corresponding Promotional Material for the Expansion Scope (or the Parties will agree upon appropriate modifications to the Promotional Material) upon notice from Amgen.

- 4.14.2. *Ownership.* Amgen will own all right, title and interest in and to any and all Promotional Materials directed to Ivory including applicable Copyrights and Product Trademarks (except with respect to any GSK Housemark included in any Promotional Materials), and GSK will execute all documents and take all actions as are reasonably requested by Amgen to vest such title in Amgen. GSK will provide to Amgen a copy of all Promotional Materials; provided, that GSK will not be required to provide such Promotional Materials in advance of their use if they are consistent with the materials provided by Amgen to GSK under Section 4.14.1 (Development).
- 4.15. <u>Medical Inquiries and Product Inquiries</u>. Amgen will provide GSK with responses for medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Ivory. GSK will respond to inquiries addressed by the responses provided by Amgen only in accordance with such responses. Amgen will provide to GSK contact details to allow GSK to obtain information to address questions for which GSK and its sales representatives have not received prepared answers or which are not answered by then existing Ivory information provided by Amgen (including with respect to technical information such as identification, ingredients or stability/storage) (collectively *"Unaddressed Inquiries"*). GSK will respond to any Unaddressed Inquiries only in accordance with the information provided by Amgen.
- 4.16. <u>Supply</u>. GSK will obtain supply of Ivory exclusively from Amgen or its designee and in accordance with the Supply Agreement. GSK will take reasonable steps (including as may be reasonably requested by Amgen) to ensure Ivory sold by it is not used outside the Expansion Territory. GSK will pay to Amgen the pricing set forth in the Supply Pricing Schedule for the supply of Ivory under the Supply Agreement. If GSK believes that the supply price set forth in the Supply Pricing Schedule would make commercialization of Ivory in a particular country in the Expansion Scope not commercially viable, considering the relevant commercial situation in such country, including anticipated pricing and reimbursement of Ivory, competitive landscape, product penetration, long term sales growth and other relevant factors, GSK may request that the ESC consider an adjustment to the supply price for such country that would make commercialization of Ivory in such country commercially viable. Upon such request, the ESC will consider in good faith whether such an adjustment is appropriate for such country and for how long, and GSK will provide to the ESC all reasonably requested information for it to evaluate the requested adjustment. Any actual adjustment to the supply price for a country will require mutual written agreement of the Parties.
- 4.17. <u>Other Agreements</u>. Promptly following the Effective Date, GSK and Amgen (or Affiliates of such entities) will complete the negotiation of, and enter into, the Supply Agreement, Quality Agreement and Safety Agreement.

## 5. DEVELOPMENT, REGULATORY AND SAFETY

- 5.1. <u>Development Activities</u>. All development activities within the Expansion Territory conducted for the purpose of the collaboration hereunder will be performed in accordance with this Agreement, the applicable Development Plan and Development Budget, including Phase IV Studies, generation of health economics information, and approval of requests to perform ISS. For the avoidance of doubt, Amgen will have the right to conduct research and development activities for Ivory in the Expansion Territory for purposes other than the collaboration hereunder, and to conduct all regulatory activities related thereto.
  - 5.1.1. *Updates.* The Development Plans and Development Budgets established by the EDC in accordance with Section 3.5 (Establishment of Plans) will be reviewed and updated by the EDC on an annual basis; provided, that if GSK believes development activities in addition to those contained in the applicable Development Plan are required or advisable with respect to the commercialization of Ivory in any country within the Expansion Territory, it will have the right to propose such activities (together with a reasonably detailed description thereof) to the EDC at any time. The EDC will meet to discuss such proposal, and GSK will provide to the EDC any information reasonably requested to facilitate evaluation of the proposal. The EDC may determine that: (i) Amgen will conduct such proposed development activity; (ii) GSK will conduct such proposed development activity; or (iii) the development activity will not be conducted.
  - 5.1.2. *Conduct of Development.* The Parties will reasonably cooperate in the conduct of the activities set forth in the applicable Development Plan, including the preparation of protocols and the development of documents therefor in accordance with Section 5.1.4 (Development Documents). GSK will not knowingly provide or sell Ivory to Third Parties to conduct development activities unless set forth in the Development Plan.
  - 5.1.3. *Development Data.* Each Party will solely own all data generated in its development activities conducted hereunder for the Expansion Scope, and such data will be subject to the license from GSK to Amgen under Section 8.5 (License Grant by GSK) or from Amgen to GSK under Section 8.4 (License Grant by Amgen), as applicable. GSK will not use any such data that is specific to Ivory, whether licensed or owned, for any purpose except with respect to Ivory in the exercise of its rights and performance of its obligations hereunder.
  - 5.1.4. Development Documents.
    - 5.1.4.1. <u>Development</u>. In addition to any development documents agreed to be provided in the approved Launch Plan for a country, the EDC will discuss what development documents related to the development of Ivory outside the Expansion Scope would be useful for GSK to use with respect to the development of Ivory in the Expansion Scope. Amgen will provide to GSK any such

development documents that the Parties mutually agree will be provided, at Amgen's expense. The Parties will reasonably cooperate in the development of relevant documents for the development of Ivory in the Expansion Scope as required by the applicable Development Plan; provided, that GSK will be responsible for the production of development documents to be used by it in the Expansion Scope, including the costs thereof. If GSK proposes development documents that are inconsistent with the written content or messaging of the materials provided by Amgen in accordance with this Section 5.1.4.1 (Development), GSK will provide to Amgen for approval copies of any such proposed inconsistent development documents and GSK will specify all aspects that are inconsistent with the materials provided by Amgen. Amgen will respond to any such requests for approval within [\*] (commencing as of receipt of an English translation, if requested or provided). If any such development documents are not in English, GSK will also provide one upon request of Amgen, at Amgen's expense). If Amgen ceases to use any development documents outside the Expansion Scope because it believes such materials may no longer be accurate or appropriate for use, GSK will cease use of any such corresponding development documents for the Expansion Scope (or the Parties will agree upon appropriate modifications to the development documents) upon notice from Amgen.

- 5.1.4.2. <u>Ownership</u>. Amgen will own all right, title and interest in and to any and all development documents directed to Ivory including applicable Copyrights and Product Trademarks (except with respect to any GSK Housemark included in any development documents), and GSK will execute all documents and take all actions as are reasonably requested by Amgen to vest such title in Amgen. GSK will provide to Amgen a copy of all development documents used in the Expansion Scope; provided, that GSK will not be required to provide such development documents in advance of their use if they are consistent with the materials provided by Amgen to GSK under Section 5.1.4.1 (Development).
- 5.1.5. *Development Costs.* GSK will reimburse Amgen for costs (including FTE costs) actually incurred by Amgen in connection with its conduct under the Development Plans in accordance with the applicable Development Budget. Such costs will be reimbursed on a calendar quarterly basis, within sixty (60) days of receipt of an invoice and supporting documentation therefor. Amgen will provide prompt, written advance notice to GSK if it becomes aware of any anticipated costs in excess of the applicable Development Budget. Unless otherwise agreed by the Parties in advance, in writing, costs reported by Amgen incurred in excess of [\*]

of any aggregate amounts budgeted to be incurred by or on behalf of Amgen for its activities for a calendar quarter in the then-current Development Budget will not be reimbursed by GSK as described above. If Amgen conducts development activities in accordance with a Development Plan, and GSK notifies Amgen in writing that GSK desires to cease such activities, Amgen can elect to continue such activities at its own cost or to cease such activities as soon as reasonably practicable, in accordance with Applicable Law and accepted national and international pharmaceutical industry codes of practices in and for the Expansion Territory, and GSK will pay for all cancellation and winddown costs associated therewith.

# 5.2. <u>Regulatory Filings</u>.

- 5.2.1. *Preparation of Filings*. Unless otherwise set forth in the applicable Launch Plan or Development Plan, GSK will have operational responsibility for the preparation and submission of all Regulatory Filings for Ivory in the Expansion Scope. The EDC will discuss what Regulatory Filings, if any, related to Ivory outside the Expansion Scope would be useful for GSK to use with respect to the registration of Ivory in the Expansion Scope. Amgen will provide to GSK any such Regulatory Filings that the Parties mutually agree will be provided, at Amgen's expense. GSK will use such Regulatory Filings solely in preparing Regulatory Filings for Ivory in the Expansion Scope.
- 5.2.2. Amgen Review and Comment. GSK will provide to Amgen a draft copy of any Regulatory Filing in the Expansion Territory (and any Regulatory Filing relating to manufacturing made by GSK in accordance with Section 5.4 (Manufacturing Matters)) and provide no less than [\*] (where the Regulatory Filing only contains data that has been previously approved by Amgen or utilized by Amgen in regulatory filings outside the Expansion Territory) and no less than [\*] (where the Regulatory Filing provided by Amgen, in a manner that may reasonably be deemed to alter the material message or content of the data, or where the Regulatory Filing contains data not previously utilized by Amgen in Regulatory Filings outside the Expansion Territory) for Amgen to review prior to filing it with a Governmental Authority. For any such Regulatory Filings that are not in English, GSK will provide an English translation thereof if one has been or will be prepared for GSK's own purposes (and if not, will provide one upon request of Amgen, at Amgen's expense). GSK will consult with and make all changes requested by Amgen with respect to Regulatory Filings in the Expansion Territory, to the extent reasonably practicable (subject to the other provisions of this Agreement), and will delete information specified by Amgen where Amgen believes the relevant Governmental Agency may not have adequate provisions to protect the confidentiality of such information. Upon request of Amgen, GSK will promptly provide to Amgen a copy of any Regulatory Filing submitted in the Expansion Territory.

- 5.2.3. *Regulatory Approvals.* Unless otherwise set forth in the applicable Launch Plan or Development Plan, GSK will hold in its name (or the name of its Affiliate) all Regulatory Filings for Regulatory Approval and Regulatory Approvals for commercialization of Ivory in the Expansion Scope. For the sake of clarity, Amgen may hold in its own name any Regulatory Filings or Regulatory Approvals with respect to the development or manufacture of Ivory in the Expansion Scope. GSK will provide to Amgen a copy of any Regulatory Approvals are not in English, GSK will also provide an English translation thereof if one has been or will be prepared for GSK's own purposes (and if not, will provide one upon request of Amgen, at Amgen's expense). Upon the request of either Party, the other Party will provide a right of reference and access to Regulatory Filings (and any Regulatory Filing relating to manufacturing made by GSK in accordance with Section 5.4.2 (Manufacturing Information)) or Regulatory Approvals for Ivory in the Expansion Territory. Amgen will provide such right of reference and access to GSK with respect to Regulatory Filings and Regulatory Approvals for Ivory outside the Expansion Territory, in each case as reasonably necessary for GSK's commercialization of Ivory in the Expansion Scope.
- 5.2.4. *Prescribing Information, Label and Core Data Sheet.* Notwithstanding anything herein to the contrary, GSK will ensure that the Ivory prescribing information, product label and core data sheet in the Expansion Scope are consistent with Amgen's prescribing information, core data sheet and product label in the applicable country of origin for Ivory provided by Amgen for the Expansion Scope. GSK will not permit any change to such prescribing information, label or core data sheet without Amgen's prior written consent, and will make any change thereto instructed by Amgen (or request such change, where approval of a Governmental Authority is required by Applicable Law). This Section 5.2 (Regulatory Filings) does not apply to any submission to any Governmental Authority of adverse event reports, periodic safety reports, or other similar safety submissions, which submissions will be governed by the Safety Agreement.
- 5.2.5. *Costs.* Except as may expressly be set forth herein to the contrary, GSK will be solely responsible for all costs associated with preparing, translating and submitting Regulatory Filings, and obtaining and maintaining Regulatory Approvals, in the Expansion Scope, including registration fees. Notwithstanding the foregoing, if GSK reasonably requires Amgen to provide information already in Amgen's possession to enable GSK to prepare Regulatory Filings for the Expansion Scope, then Amgen will be solely responsible for its own costs associated therewith.

#### 5.3. <u>Regulatory Communications</u>.

- 5.3.1. *GSK Responsibility*. Except as expressly set forth herein (including Section 5.4.3 (Manufacturing Filings) and Section 5.1 (Development Activities)) or as set forth in the Safety Agreement, GSK will have responsibility, at its sole cost, for all correspondence and for any official communication with Governmental Authorities (except as Amgen may be required by Applicable Law or a Governmental Authority to communicate) regarding Ivory in the Expansion Scope. GSK will promptly file any updates or changes to Regulatory Filings and Regulatory Approvals as reasonably directed by Amgen.
- 5.3.2. Amgen Review and Comment. Except as set forth in the Safety Agreement and without prejudice to the time periods relevant to review of Regulatory Filings pursuant to Section 5.2 (Regulatory Filings), GSK will supply to Amgen a copy of: (i) all material correspondence and communications (including a written description, with respect to any oral communication) with any Governmental Authority with respect to Ivory at least [\*] prior to provision of such correspondence or communication to such Governmental Authority (or as promptly as possible where exigent circumstances make such provision impractical); and (ii) all such material correspondence and communications received from any Governmental Authority with respect to Ivory within [\*] after receipt of any such correspondence. Materials provided pursuant to Section 5.2 (Regulatory Filings) need not be re-provided pursuant to this Section 5.3 (Regulatory Communications) unless changed. Where correspondence or communications are not in English, GSK will also provide an English translation if one has been or will be prepared for GSK's own purposes (and if not, will provide one upon request of Amgen, at Amgen's expense), but will not be required to do so within the [\*] period set forth above. To the extent reasonably practicable (subject to the other provisions of this Agreement), GSK will comply with Amgen's comments concerning any meeting or written or oral communication with any Governmental Authority. Amgen will reasonably cooperate with GSK in responding to any inquiry made by a Governmental Authority in the Expansion Scope.
- 5.3.3. *Regulatory Meetings.* Amgen will be entitled to [\*] any discussions between GSK and any Governmental Authority relating to Ivory at Amgen's own expense, and GSK will give Amgen [\*] prior written notice thereof (or prompt written notice, if [\*] notice is impractical); provided, that the foregoing will not apply to informal meetings or teleconferences that are unscheduled or intended by the Governmental Authority to be between it and GSK representatives only, and in such case, GSK will thereafter provide Amgen prompt written notice of such communication with a summary of the discussion. If GSK communicates with any Governmental Authority in a manner that is inconsistent with the regulatory strategy agreed by the EDC or communications of Amgen outside the Expansion Scope and disclosed to GSK, and such

communication has not been approved by the EDC, then Amgen will have the right to [\*] for Ivory in the Expansion Scope [\*] if permitted by such Governmental Authority.

#### 5.4. <u>Manufacturing Matters</u>.

- 5.4.1. *Initial Responsibility.* Unless otherwise provided in the applicable Launch Plan or Development Plan, GSK will have operational responsibility for all correspondence and for any official communication with Governmental Authorities regarding manufacturing of Ivory in the Expansion Scope (except as Amgen may be required by Applicable Law or a Governmental Authority to communicate). Amgen will have the option to transfer operational responsibility from GSK to Amgen for some or all correspondence and for specified official communication (except as GSK may be required by Applicable Law or a Governmental Authority to communicate) upon approval of the EDC, in circumstances where Amgen reasonably believes it is advisable to protect its confidential information. If Amgen desires to transfer such operational responsibility from GSK to Amgen, Amgen will first notify the EDC and the EDC will discuss the risks and benefits of such transfer, including potential impact to GSK's existing relationships with the applicable Governmental Authority with respect to Ivory, potential disruption to Ivory development, registration or commercialization, and coordination with respect to regulatory communications to the applicable Governmental Authority. The EDC will then determine whether to approve such transfer of operational responsibility and, if it does so approve, GSK may escalate such issue to the ERC in accordance with Section 2.13.3 (Decision-Making) if it chooses. With respect to any such correspondence and communication, each Party will promptly provide the other with copies of material written correspondence as reasonably necessary to permit GSK to comply with its relevant regulatory obligations or as reasonably requested by Amgen (provided that Amgen will not be required to disclose proprietary or competitively sensitive information).
- 5.4.2. *Manufacturing Information*. Upon GSK's request, Amgen will reasonably cooperate with GSK to make and provide copies of any direct communications by Amgen either to or from the Governmental Authorities having jurisdiction in the Expansion Territory regarding the manufacture of Ivory by Amgen for supply to GSK; provided, that Amgen's obligation to provide GSK with manufacturing and process information is limited to the circumstance where the information is reasonably required for GSK to carry out its commercialization responsibilities, or access to such information only to the extent required by Such Applicable Law or Governmental Authority or to the extent reasonably required to carry out its commercialization responsibilities hereunder and will only permit access to those of its employees who need

to know for such purposes. Amgen will also have the right to instead provide any such manufacturing information directly to the relevant Governmental Authority (including by provision of a drug master file) if such provision will satisfy such requirement. Notwithstanding anything herein to the contrary, Amgen will not be required to provide to GSK nor to allow GSK to access (except a right of reference as set forth in this Section 5.4.2 (Manufacturing Information) to the extent necessary), including with respect to Regulatory Filings, Amgen's manufacturing information with respect to Ivory or any sections of any Regulatory Filing related thereto or to provide information relating to any product other than Ivory.

- 5.4.3. *Manufacturing Filings*. Unless otherwise set forth in the applicable Launch Plan or Development Plan, GSK will have operational responsibility for the preparation and submission of all Regulatory Filings required to be filed with any Governmental Authority in the Expansion Territory with respect to the manufacture of Ivory provided to GSK by Amgen (including with respect to the use of any contract manufacturer to produce Ivory on Amgen's behalf) (the foregoing *"Manufacturing Filing Responsibilities"*). The EDC will have the right to transfer operational responsibility for some or all Manufacturing Filing Responsibilities from GSK to Amgen (except as GSK may be required by Applicable Law or a Governmental Authority to communicate). In the event of any such transfer, the Parties will cooperate to transition the relevant Manufacturing Filing Responsibilities to Amgen and Amgen thereafter will be responsible for the relevant Manufacturing Filing Responsibilities at its sole cost. Each Party will provide the other any cooperation reasonably requested in connection with any such filings.
- 5.5. <u>Health Technology Assessments</u>. The EDC will oversee the generation of all data for HTAs for GSK's use in Regulatory Filings for Ivory within the Expansion Scope. Upon GSK's reasonable request, Amgen will provide to GSK HTA data or methodology for generating HTA data so GSK can generate such data as agreed by the EDC. GSK will use such methodology and any such HTA data solely for use in preparing Regulatory Filings necessary to support pricing and reimbursement filings for Ivory in the countries in the Expansion Territory for which the EDC approves such use. GSK will only permit access to any such methodology solely to those of its employees who need to know for the intended purpose. Prior to implementation, GSK will submit to the EDC for discussion a draft of the overall HTA strategy as part of the access and reimbursement plan, which will align with the strategic intent and design of Amgen's positioning of Ivory and cost effectiveness strategy for Ivory unless otherwise agreed by the EDC. GSK will provide to Amgen for approval copies of any proposed HTAs in the Expansion Territory. Amgen will respond to any such requests for approval within [\*] (where such data has been previously approved or utilized by Amgen for HTAs outside the Expansion Territory) prior to submitting it to a Governmental Authority

(commencing as of receipt of an English translation, if requested or provided). If an HTA is not in English, GSK will also provide Amgen with an English translation if one has been or will be prepared for GSK's own purposes (and if not, GSK will provide one upon request of Amgen, at Amgen's expense).

5.6. <u>Labeling and Packaging Materials</u>. Notwithstanding anything herein to the contrary, GSK will not agree with any Governmental Authority on any product label (i.e., physical sticker), package inserts or packaging with respect to Ivory without the prior written consent of the EDC; provided, that the EDC will not unreasonably withhold consent if the product label, package inserts or packaging is consistent with the regulatory strategy provided in the approved Launch Plan or Development Plan for the applicable country. No product label, package inserts, or packaging for Ivory may be used or distributed by GSK if any of them are inconsistent with the regulatory strategy provided in the applicable country without the prior approval of the EDC. GSK will not modify or alter any product label, package inserts or packaging for Ivory, without the prior approval of such modification or alteration by the EDC, and will make any changes to any labeling, package inserts or packaging for Ivory directed to be made by the EDC (to the extent permitted by Applicable Law).

# 5.7. <u>Product Technical Complaints; Recalls; Returns</u>.

- 5.7.1. *Product Technical Complaints*. Complaints with respect to Ivory in the Expansion Scope will be handled in accordance with the Quality Agreement.
- 5.7.2. *Recalls or Other Corrective Action.* If either Party proposes to the EDC to initiate a recall, market withdrawal, field alert or other corrective action with respect to Ivory in the Expansion Territory, the EDC will promptly meet to consider such proposed action and will discuss the implementation of any such corrective actions. The Party requiring such action will bear all costs with respect to the conduct of such action and the other Party will reasonably cooperate therewith. The conduct of any recall, market withdrawal, field alert or other corrective action with respect to Ivory in the Expansion Scope will be handled in accordance with the Quality Agreement.
- 5.7.3. *Returns*. If any quantities of Ivory are returned to GSK from GSK's customers, GSK will destroy such quantities and maintain appropriate, auditable documentation with respect thereto.

# 6. PAYMENTS

6.1. <u>Support Costs</u>. On a calendar quarterly basis, GSK will reimburse Amgen for all costs actually incurred in such quarter by Amgen or its Affiliates, including internal costs at the FTE Rate, for activities conducted in support of the Expansion Scope and not otherwise included in the price of supply under the Supply Agreement, reimbursed as set forth in Section 5.1.5 (Development Costs), or Section 4.11.2 (Costs). Such costs will include only those costs that are

incurred by Amgen or its Affiliates in connection with discrete activities that are incremental to Amgen's activities for its own purposes and are requested by GSK to support GSK's efforts to develop, obtain Regulatory Approval of or commercialize Ivory in the Expansion Scope (such as analytical technology transfer to Governmental Authorities). For the avoidance of doubt, reimbursement of costs under this Section 6.1 (Support Costs) does not include costs incurred by Amgen or its Affiliates (i) to provide to GSK information already in its possession that is reasonably necessary for GSK to develop, obtain Regulatory Approval for or commercialize Ivory in the Expansion Scope (such as the transfer of development documents or Regulatory Approvals used by Amgen outside the Expansion Scope), or (ii) to conduct activities that are not required to be performed by Amgen but that Amgen has requested it be permitted to perform. The appropriate attribution of such costs to the Expansion Scope may be determined based upon percent of effort, resource utilization or other reasonable measure.

- 6.2. <u>Payment Method</u>. All payments made hereunder between the Parties will be made in U.S. Dollars, except as otherwise agreed by the Parties. Each Party will pay all sums due hereunder by wire transfer, or electronic funds transfer (EFT) in immediately available funds. If the EFT option is chosen by Amgen or GSK, a completed electronic funds transfer form will be provided in a timeframe that facilitates timely payment. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments.
- 6.3. Audits. Each Party will keep complete and accurate records pertaining to the activities to be conducted hereunder in sufficient detail to permit the other Party (the "*Auditing Party*") to confirm the accuracy of all payments due hereunder, and such records will be open (in such form as may be available or reasonably requested) to inspection for [\*] following the end of the period to which they pertain. The Auditing Party will have the right, at its own expense to have an independent, certified public accountant, selected by it, perform a review the records of the other Party (the "*Audited Party*") applicable to amounts payable hereunder (including any records kept in the ordinary course of the Audited Party's business) upon no less than sixty (60) days' notice, during regular business hours and under reasonable obligations of confidentiality. The report of such accountant will be made available to both Parties simultaneously, promptly upon its completion. The Auditing Party's right to perform an audit pertaining to any calendar year will expire [\*] after the end of such year and the books and records for any particular calendar year will only be subject to one (1) audit. Should an inspection pursuant to this Section 6.3 (Audits) lead to the discovery of a payment discrepancy, then the appropriate Party will pay to the other the amount of the discrepancy (plus, if the error was in favor of the Audited Party, interest accrued at the Contract Interest Rate, compounded annually from the day the relevant payment(s) were due). If a payment discrepancy was greater than [\*] of the correct amount for the audited period and the discrepancy was in favor of the Audited Party will pay the reasonable out-of-pocket cost of such inspection. This Section 6.3 (Audits) does not apply to or include manufacturing audits or regulatory inspections.

- 6.4. <u>Withholding</u>. If Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made pursuant to this Agreement, the paying Party will notify the other in writing of such payment or withholding requirements prior to making the payment and provide such assistance to the receiving Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in such Party's efforts to claim an exemption from or reduction of such Taxes. Each Party will withhold any Taxes required by Applicable Law to be withheld from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes promptly following payment thereof. If Taxes are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid. In the event that the governing tax authority retroactively determines that a payment made by a Party to the other pursuant to this Agreement should have been subject to withholding (or to additional withholding) for Taxes, and such Party (the *"Withholding Party"*) remits such withholding Taxes to the tax authority, the Withholding Party will have the right to offset such amount, including any interest and penalties that may be imposed thereon, against future payment obligations of the Withholding Party under this Agreement; provided however, that the Withholding Party may also pursue reimbursement by any other available remedy.
- 6.5. <u>VAT</u>. All payments due a Party pursuant to this Agreement will be paid exclusive of any VAT and other indirect Taxes (which, if applicable, will be payable by the paying Party upon receipt of a valid VAT invoice). If such amounts of VAT are refunded by the applicable Governmental Authority or other fiscal authority subsequent to payment, the Party receiving such refund will transfer such amount to the paying Party within forty-five (45) days of receipt.
- 6.6. <u>Late Payment</u>. Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days such payment is delinquent. This Section 6.6 (Late Payment) will in no way limit any other remedies available to either Party.
- 6.7. <u>Change in Accounting Periods</u>. From time to time, either of the Parties may change its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other in writing of a change in its accounting and financial reporting practices from calendar quarters and calendar years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the Parties will cooperate to determine a way to report and reconcile each Party's accounting periods so as to facilitate payments to be made hereunder.

#### 7. [\*]

# 8. INTELLECTUAL PROPERTY

- 8.1. <u>Invention Ownership</u>. Each Party will own all right, title, and interest in and to all Inventions that are made by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto. Any Invention that is jointly made will be owned jointly by the Parties (each a "*Joint Invention*"). Inventorship will be determined according to United States Patent law (without reference to any conflict of law principles).
- 8.2. Copyright Ownership; Certain Confidential Information. Except as set forth below, each Party will own all right, title, and interest in and to all Copyrights created pursuant to this Agreement that are authored by or on behalf of such Party, solely or independent of the other Party, and all intellectual property rights related thereto; provided, that any Copyrights pertaining to Ivory (including any clinical trial protocols, investigator brochures and informed consent forms, and the product labeling, package inserts, core data sheet and all marketing and Promotional Materials and the Brand Book) will be owned solely by Amgen. The Parties will jointly own all right, title, and interest in and to all Copyrights that are authored by or on the behalf of the Parties jointly; provided, that any Copyrights pertaining to Ivory will be owned solely by Amgen whether created jointly by the Parties or by either Party independent of the other Party. In addition, all Confidential Information to the extent pertaining to Ivory will be the Confidential Information of Amgen (and not of GSK), regardless of which Party created such information (and will not be subject to the exclusion under Section 9.1.1 or 9.1.4). Any Copyrights created by GSK or its Affiliates and specified in this Section 8.2 (Copyright Ownership; Certain Confidential Information) as being owned by Amgen will be considered a work for hire. To the extent any such Copyright is not considered a work for hire, GSK and/or such Affiliate will assign and does hereby assign to Amgen all of its right, title and interest in and to such Copyright and intellectual property rights therein and thereto. Each Party will duly execute, acknowledge, and deliver to the other all such further papers, including assignments and applications for copyright registration or renewal, as may be reasonably requested and/or necessary to enable such other Party to publish or protect said Copyrights in any and all countries and to vest title to said Copyrights in such other Party (or its nominees, or its or their successor or assigns) in accordance with this Section 8.2 (Copyright Ownership; Certain Confidential Information), and will render such reasonable assistance, at such other Party's expense, as such other Party may reasonably require in any proceeding or litigation involving said Copyrights.
- 8.3. <u>Joint Ownership</u>. Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property (including Copyrights) owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require such approval, consent or accounting. Each Party agrees to

cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to Section 8.1 (Invention Ownership), Section 8.2 (Copyright Ownership; Certain Confidential Information) and this Section 8.3 (Joint Ownership) in a particular country in the Expansion Territory.

- 8.4. <u>License Grant by Amgen</u>. Amgen hereby grants and causes its Affiliates to grant to GSK and its Affiliates during the Term an [\*] license to Ivory Intellectual Property solely to the extent necessary to develop, use, sell, offer for sale and import Ivory in the Expansion Scope, and otherwise exercise and perform GSK's rights and obligations under the terms of this Agreement; subject to Amgen's retained rights to develop, use and import Ivory in the Expansion Scope for the benefit of countries outside the Expansion Territory and to exercise and perform its rights and obligations under the terms of this Agreement.
- 8.5. <u>License Grant by GSK</u>. GSK hereby grants and causes its Affiliates to grant to Amgen and its Affiliates a [\*] license under all Know-How and Patents owned or controlled as of the Effective Date or during the Term (including GSK Inventions) by GSK or its Affiliates solely to develop, use, make, have made, sell, offer for sale and import of Ivory [\*], and for performing Amgen's rights and obligations hereunder. Such license is sublicensable by Amgen or its Affiliates solely to Third Parties to whom Amgen or its Affiliates also grant a license to Know-How or Patents owned or controlled by Amgen or its Affiliates claiming Ivory, its formulation or the use thereof; provided, that such sublicense will terminate no later than the date on which the license to the Third Party to Amgen Know-How or Patents described above terminates.

#### 8.6. <u>Prosecution and Maintenance</u>.

8.6.1. *Primary Prosecution*. Amgen will control, by itself or through outside counsel reasonably acceptable to GSK and directed by Amgen, and have final decision making authority (after consultation between the Patent Coordinators in accordance with the terms and conditions of this Agreement) and [\*] with respect to the Prosecution and Maintenance of Patents and Product Trademarks within Ivory Intellectual Property, in each case solely in the Reserved Territory and Expansion Territory (collectively, the "*Expansion IP*"), and with respect to the preparation and filing for any patent term extensions or similar protections therefor. Through the Patent Coordinators: (i) Amgen will provide GSK with copies of and an opportunity to review and comment upon the text of the applications relating to the Expansion IP at least [\*] before filing; provided, that if it is not reasonably practicable to provide such application in such [\*] period, then Amgen will provide either a draft copy of such application or a statement of intent to file such application in such [\*] period; (ii) Amgen will provide GSK with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Expansion IP reasonably promptly after making such filing or receiving such document, including a copy of each application for each Product Trademark and Patent within the Expansion IP as filed together with notice of its filing date and application number; (iii) Amgen will keep

GSK advised of the status of all material communications, actual and prospective filings or submissions regarding the Expansion IP, and will give GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (iv) Amgen will consider in good faith GSK's comments on the communications, filings and submissions for the Expansion IP. With respect to any filings or other materials provided to GSK under this Section 8.6 (Prosecution and Maintenance), Amgen will have the right to redact any manufacturing information and any information relating to any product other than Ivory from any such filings and materials.

Secondary Prosecution. If Amgen proposes to abandon or fail to maintain any Patent, Product Trademark or application within the 8.6.2. Expansion IP, or if Amgen proposes to offer GSK the right to control Prosecution and Maintenance of any Patent, Product Trademark or application within the Expansion IP, Amgen will give GSK reasonable notice thereof (with sufficient time for GSK to assume control thereof and continue the Prosecution and Maintenance of such Patent, trademark or application) and thereafter GSK may, upon prompt written notice to Amgen (delivered in no event later than [\*] after receipt of Amgen's notice), control Prosecution and Maintenance and defense with respect to such Patent or trademark within the Expansion IP thereafter in accordance with this Section 8.6.2 (Secondary Prosecution) (any Patent, trademark or application so assumed, an "Assumed Item"). In such case, GSK will control, by itself or through outside counsel reasonably acceptable to the Parties and directed by GSK, and have final decision making authority (after consultation between the Patent Coordinators in accordance with the terms and conditions of this Agreement) with respect to the Prosecution and Maintenance of Assumed Items in the Expansion Territory, [\*], and with respect to the preparation and filing for any patent term extensions or similar protections therefor. Through the Patent Coordinators, GSK will (i) provide Amgen with copies of and an opportunity to review and comment upon the text of the applications relating to the Assumed Items at least [\*] before filing; provided, that if it is not reasonably practicable to provide such application in such [\*] period, then GSK will provide either a draft copy of such application or a statement of intent to file such application in such [\*] period; (ii) provide Amgen with a copy of each submission made to and document received from a patent authority regarding any Assumed Items reasonably promptly after making such filing or receiving such document, including a copy of each application for each item within the Assumed Items as filed together with notice of its filing date and application number; (iii) keep Amgen advised of the status of all material communications, actual and prospective filings or submissions regarding the Assumed Items, and will 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) reasonably consider in good faith Amgen's comments on the communications, filings and submissions for the Assumed Items. Notwithstanding the foregoing, GSK will not Prosecute and Maintain any Assumed Item, and will not do so in any manner, that Amgen believes would be reasonably likely to have a material adverse effect on Ivory or intellectual property related to Ivory, and Amgen will have control and final decision-making authority over any such matter; provided, that if Amgen makes a final decision in accordance with this sentence, then Amgen will reimburse GSK for costs incurred in connection with GSK's implementation of such decision; and provided, further that GSK is not obligated to take action pursuant to such Amgen decision, but if GSK elects not to take a required action then at Amgen's request GSK will reasonably cooperate to take such action (including, if necessary, transitioning the requisite rights for such purpose) as reasonably necessary to enable Amgen to take the required action. If GSK proposes to abandon or fails to maintain any Assumed Item, or if GSK proposes to offer Amgen the right to control Prosecution and Maintenance of any Assumed Item, GSK will give Amgen reasonable notice thereof (with sufficient time for Amgen to assume control thereof and continue the Prosecution and Maintenance of such Assumed Item) and thereafter Amgen may, upon prompt written notice to GSK (delivered in no event later than [\*] after receipt of GSK's notice) and at Amgen's sole cost, control Prosecution and Maintenance and defense with respect to such Assumed Item thereafter in accordance with Section 8.6.1 (Primary Prosecution).

- 8.7. Defense and Settlement of Third Party Claims. If a Third Party asserts that Patents, Know-How or other rights owned or controlled by it are infringed by the activities hereunder of either of the Parties (an "*Infringement Claim*"), then defense of such Infringement Claim or the conduct of such proceedings will be managed in accordance with the provisions of Section 11.5 (Defense of Third Party Claims), with coordination and cooperation between the Defending Party and Assisting Party occurring via the Patent Coordinators. If either Party seeks to initiate a nullification or revocation proceeding against any such Patents, Know-How or other rights in response to prospective or actual Third Party Claims of Infringement, the Parties will coordinate and cooperate in regard to such proceedings in accordance with the procedures set forth in Section 11.5 (Defense of Third Party Claims), with coordinators.
- 8.8. <u>Enforcement</u>. Except as expressly set forth in this Section 8.8 (Enforcement), each Party will retain all its rights to control the enforcement of its own intellectual property.
  - 8.8.1. *Amgen Sole Enforcement*. Amgen will have the sole right, but not the obligation, to bring an action to enforce the Ivory Intellectual Property against any actual, alleged or threatened infringement or misappropriation by Third Parties (an *"Enforcement Action"*) in the Reserved Territory, at

Amgen's sole cost. In the event Amgen elects to bring and prosecute such Enforcement Action, GSK will reasonably assist Amgen and cooperate in any such Enforcement Action at Amgen's request (and Amgen will reimburse all reasonable, documented, out-of-pocket expenses incurred by GSK in connection therewith), and Amgen will seek and reasonably consider GSK's comments before determining the strategy via the Patent Coordinators. Without limiting the foregoing, Amgen will keep GSK advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions (provided that Amgen will have the right to redact any Amgen manufacturing information and any information relating to any product other than Ivory from any such materials).

- 8.8.2. *Amgen Primary Enforcement.* Amgen will have the first right, but not the obligation, to bring an Enforcement Action in the Expansion Territory, at Amgen's sole cost. In the event Amgen elects to bring and prosecute such Enforcement Action, GSK will reasonably assist Amgen and cooperate in any such Enforcement Action at Amgen's request (and Amgen will reimburse all reasonable, documented, out-of-pocket expenses incurred by GSK in connection therewith), and Amgen will seek and reasonably consider GSK's comments before determining the strategy via the Patent Coordinators. Without limiting the foregoing, Amgen will keep GSK advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide GSK copies of and an opportunity to review and comment on any such material communications, filings and submissions (provided that Amgen will have the right to redact any Amgen manufacturing information and any information relating to any product other than Ivory from any such materials). Amgen will not settle, or consent to any judgment in, any action under this Section 8.8.2 (Amgen Primary Enforcement), without GSK's prior written consent, not to be unreasonably withheld or delayed.
- 8.8.3. *GSK Secondary Enforcement*. In the event Amgen does not commence an Enforcement Action in accordance with Section 8.8.2 (Amgen Primary Enforcement), or otherwise take action to abate any alleged material infringement or misappropriation of any Ivory Intellectual Property within [\*] after GSK requests Amgen to do so in writing (or, if later, within [\*] after such action can viably be brought by Applicable Law (as, for example, in the case of expiration of a clinical trial exemption to patent infringement)), GSK will be entitled to bring and prosecute such Enforcement Action in the Expansion Territory at GSK's sole cost and Amgen will cooperate with GSK at GSK's request (and GSK will reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith). If GSK elects to bring and prosecute such Enforcement Action, then GSK will seek and reasonably consider Amgen's comments before determining the strategy via the Patent Coordinators. Without limiting the foregoing, GSK will keep Amgen

advised of all material communications, actual and prospective filings or submissions regarding such Enforcement Action, and will provide Amgen copies of and an opportunity to review and comment on any such material communications, filings and submissions. Notwithstanding the foregoing, GSK will not commence or maintain an Enforcement Action or settlement under this Section 8.8.3 (GSK Secondary Enforcement), and will not conduct any such enforcement or settlement in a manner, that Amgen believes would be reasonably likely to have a material adverse effect on Ivory Intellectual Property or intellectual property related to Ivory; and Amgen will have control and final decision-making authority over any such matter; provided, that if Amgen makes a final decision in accordance with this sentence, then Amgen will reimburse GSK for costs incurred in connection with GSK's implementation of such decision; and provided, further that GSK will reasonably cooperate to take action pursuant to such Amgen decision, but if GSK elects not to take a required action then at Amgen's request GSK will reasonably cooperate to take such action (including, if necessary, transitioning the requisite rights for such purpose) as reasonably necessary to enable Amgen to take the required action.

- 8.8.4. *Recoveries.* All Recoveries obtained under an action brought by Amgen under Section 8.8.1 (Amgen Sole Enforcement) or Section 8.8.2 (Amgen Primary Enforcement) will be retained solely by Amgen. All Recoveries obtained under an action brought by GSK under Section 8.8.3 (GSK Secondary Enforcement) will be retained solely by GSK.
- 8.8.5. *Joining an Action*. For any enforcement action under Section 8.8.1 (Amgen Sole Enforcement), 8.8.2 (Amgen Primary Enforcement) or 8.8.3 (GSK Secondary Enforcement), if the non-enforcing Party is an indispensable party to such action or reasonably necessary to be joined in such action to enable enforcement, it will cooperate to join such action at the enforcing Party's request (and the requesting Party will reimburse all reasonable, documented, out-of-pocket expenses incurred by the joining Party in connection therewith), but the enforcing Party will continue to control the action pursuant to Section 8.8.1 (Amgen Sole Enforcement), 8.8.2 (Amgen Primary Enforcement) or 8.8.3 (GSK Secondary Enforcement), as applicable.
- 8.9. <u>Patent Term Extensions</u>. GSK will provide reasonable assistance to Amgen in connection with obtaining supplemental protection certificates for Patents within the Ivory Intellectual Property or otherwise licensed or assigned hereunder as determined by the Patent Coordinators. To the extent reasonably and legally required to obtain any such supplemental protection certificates in a particular country, GSK will make available to Amgen copies of all necessary documentation to enable Amgen to use the same for the purpose of obtaining the supplemental protection certificates in such country.
- 8.10. <u>Employee Agreements</u>. Prior to beginning work relating to any aspect of the subject matter of this Agreement and/or being given access to Ivory Intellectual Property or Confidential Information of the other Party, each employee, consultant

and/or agent of Amgen and GSK will have signed or will be bound to a commercially reasonable non-disclosure and/or invention assignment agreement. Each Party will be responsible for any compensation or payment to its employees, contractors or agents in connection with the invention of any patent right.

# 8.11. <u>Trademarks</u>.

- 8.11.1. *Title*. Amgen will own all right, title and interest in and to the Product Trademarks, and GSK agrees to assign and hereby assigns to Amgen all right title and interest that GSK has or may acquire in connection with the Product Trademarks. All goodwill arising out of the use of the Product Trademarks or otherwise related to Ivory will inure to the benefit of Amgen. GSK will not, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country; (ii) file, register or maintain any registrations for the Product Trademarks, or for any trademarks or trade names that are confusingly similar to any Product Trademark, in any country without the express prior written consent of Amgen, and such permitted registrations (if any) will be filed, registered or maintained by GSK in Amgen's name; or (iii) authorize or assist any Third Party to do the foregoing.
- 8.11.2. Required Use and Compliance.
  - 8.11.2.1. Except as may be otherwise requested by Amgen, Promotional Materials for Ivory in the Expansion Scope will display only the GSK Housemarks to the extent allowed by Applicable Law. To the extent requested by Amgen and permitted by Applicable Law, GSK will include a specified Amgen Housemark on Promotional Materials. If requested by Amgen prior to submission of an application for Regulatory Approval to market Ivory in a country in the Expansion Scope, GSK will promote Ivory in each indication in such country within the Expansion Scope only under the same Product Trademark utilized by Amgen for such indication outside the Expansion Territory, unless otherwise agreed by the Parties. If promotion under such Product Trademark is not permitted by Applicable Law in a particular country within the Expansion Territory, then the Parties will agree on an alternate trademark for use therein.
  - 8.11.2.2. GSK agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and/or the Amgen Housemarks by GSK is accompanied by an acknowledgement that the Product Trademarks and Amgen Housemarks are owned by Amgen; (ii) not use the Product Trademarks or Amgen Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Amgen therein; and (iii) not use any trademarks or trade names so resembling any of the Product Trademarks or Amgen Housemarks are to be likely to cause confusion or deception.

## 8.11.3. Trademark Licenses.

- 8.11.3.1. <u>To GSK</u>. Amgen hereby grants to GSK a [\*] license to use the Product Trademarks and Amgen Housemarks as set forth in the Promotional Materials and other materials provided to it by Amgen, solely to market and promote Ivory in the Expansion Scope in accordance with the Expansion Brand Plan, applicable Launch Plan and this Agreement during the period that GSK has rights to promote Ivory hereunder. GSK's right to use the Product Trademarks and the Amgen Housemarks will terminate, on a country-by-country basis, when GSK's rights to promote Ivory in such country are terminated or expire hereunder. GSK will take all such steps as Amgen may reasonably request to give effect to the termination of the license to the Product Trademarks and Amgen Housemarks in such country and to record any documents that may be required to evidence the termination of such license.
- 8.11.3.2. <u>To Amgen</u>. If Amgen exercises its Option pursuant to Section 4.11.1 (Option), then GSK hereby grants to Amgen a [\*] license to use the GSK Housemarks as set forth in the Promotional Materials solely to Detail Ivory in the Expansion Scope in accordance with the Expansion Brand Plan and this Agreement. Amgen's right to use the GSK Housemarks will terminate, on a country-by-country basis, when GSK's rights to promote Ivory in such country are terminated or expire; provided, that the license set forth in this Section 8.11.3.2 (To Amgen) will continue for a period of [\*] to permit Amgen to use and distribute its inventory of Promotional Materials containing GSK Housemarks returned to Amgen in accordance with Section 12.9.5 (Return of Materials) in such country (or, where the on-hand inventory as of such termination or expiration of such Promotional Materials, but in no event longer than [\*]), in connection with Amgen's Detailing of Ivory. Amgen will take all such steps as GSK may reasonably request to give effect to the termination of the license to the Collaboration Housemarks in the applicable country and to record any documents that may be required to evidence the termination of such license.
- 8.11.4. *Respect of Trademarks*. GSK will not have, assert or acquire any right, title or interest in or to any of Product Trademarks or Amgen Housemarks or the goodwill pertaining thereto, and Amgen will not have, assert or acquire any right, title or interest in or to the GSK Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement.
- 8.11.5. *Infringement*. Amgen will monitor the Product Trademarks for infringing uses within the Expansion Scope consistent with its monitoring of product

trademarks for its other products. Each Party will give the other prompt notice of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. Amgen will determine in its sole discretion what action, if any, to take in response to any such infringement or threatened infringement of any Product Trademark.

8.12. <u>Community Of Interest</u>. From time to time it may be desirable or beneficial to the Parties to share between each other and their respective outside counsel privileged and/or work product information with respect to certain Patents and/or Know-How related to Ivory, and legal matters relating thereto, and that they share a common interest in the prosecution, defense and enforcement of such Patents and Know-How, including such Patents and Know-How owned or controlled by Third Parties. Therefore, the Parties agree to execute the Joint Community Of Interest Privilege Agreement (attached hereto as the Privilege Agreement Schedule) concurrently with this Agreement.

#### 9. CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

- 9.1. <u>Confidentiality; Exceptions</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [\*] thereafter, the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose any and all information or materials related to the activities contemplated hereunder and furnished to it by the other Party pursuant to this Agreement (or in the case of GSK, that is created by or on the behalf of GSK and owned by Amgen pursuant to Section 8.2 (Copyright Ownership; Certain Confidential Information) or Section 5.1.3 (Development Data)) that is identified by the disclosing Party as confidential *Information*"). For clarity, GSK will have no right to and will not utilize any Confidential Information of Amgen for activities outside the Expansion Scope or for activities related to products other than Ivory. Notwithstanding the foregoing, Confidential Information will not include any information to the extent that it can be established by written documentation by the receiving Party that such information:
  - 9.1.1. was obtained or was already known by the receiving Party or its Affiliates without obligation of confidentiality as a result of disclosure from a Third Party that the receiving Party did not know was under an obligation of confidentiality to the disclosing Party with respect to such information;
  - 9.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party through no act or omission of the receiving Party or its Affiliates in breach of this Agreement;
  - 9.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement; or

- 9.1.4. was independently discovered or developed by the receiving Party or its Affiliates (without reference to or use of Confidential Information of the disclosing Party).
- 9.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) as reasonably necessary in conducting the activities contemplated under this Agreement; (ii) with respect to Confidential Information generated in the course of the activities conducted hereunder, to the extent pertaining specifically to Ivory, for use by Amgen in connection with Ivory outside the Expansion Scope or disclosure by Amgen to a partner, GSK or licensee for use with respect to Ivory outside the Expansion Scope; (iii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting Patent, Copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for Ivory, or otherwise required by Applicable Law, provided, however, that if a Party is required by Applicable Law to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing exceptions pursuant to this subsection (iii), will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iv) to advisors (including lawyers and accountants) on a need to know basis in support of the purposes of this Agreement, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; and (v) to the extent mutually agreed to by the Parties. Neither Party will disclose Confidential Information of the other Party to its personnel or to an Affiliate except to the extent such personnel or Affiliate needs to know such information for the performance of such Party's activities hereunder.
- 9.3. <u>Confidential Treatment of Terms and Conditions</u>. Neither Party will disclose the terms and conditions of this Agreement, except that each Party has the right to disclose the terms and conditions of this Agreement under reasonable and customary obligations of confidentiality (but no less than equivalent obligations to those terms under which the disclosing Party would disclose its own confidential information of similar type): (i) if required by Applicable Law; (ii) to Governmental Authorities with authority over such Party that request to review this Agreement in connection with a review, audit or investigation of the operations of such Party by such authority (and provided that review of the terms of this Agreement are reasonably pertinent to such review, audit or investigation); and (iii) to its attorneys and accountants in support of the purposes of this Agreement. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties will consult with one another

concerning which terms of this Agreement will be requested to be redacted in any public disclosure of the Agreement, and in any event each Party will seek reasonable confidential treatment for any public disclosure by any such Governmental Authority.

- 9.4. <u>Press Releases</u>. Notwithstanding Section 9.3 (Confidential Treatment of Terms and Conditions), the Parties will issue a joint press release to announce the execution of this Agreement, which is attached hereto as the Press Release Schedule and is for use in responding to inquiries about the Agreement and will agree on the timing in accordance with Applicable Law and method for issuing such press release and any media briefings; thereafter, GSK and Amgen may each disclose to Third Parties (including media interviews and disclosures to financial analysts) the information contained in such press release (but only such information) without the need for further approval by the other, provided that such information is still accurate. Each Party will have the right to issue additional press releases and disclosures in regards to the terms of this Agreement only with the prior written consent of the other Party, such consent not to be unreasonably withheld (or as required to comply with any Applicable Law). For any such proposed press release or disclosure, the disclosing Party will provide [\*] notice to the other Party and will reasonably consider the other Party's comments that are provided within [\*] after such notice, or such shorter notice and comment periods as are reasonably required under the circumstances but not less than [\*].
- 9.5. <u>Publications and Program Information</u>. The EDC will oversee publications, presentations and public disclosures with respect to Ivory in the Expansion Scope. GSK will have the right to publish with respect to Ivory and to make scientific presentations with respect to Ivory, in each case within the Expansion Scope, subject to Section 4.6 (Conferences in the Expansion Territory) and approval of the EDC. All publications and presentations in the Expansion Scope must be consistent with the publication strategy established by the EDC. GSK may publish the results and summaries of clinical studies with respect to Ivory for the Expansion Scope on clinical trial registries maintained by GSK or its Affiliates, provided that: (i) [\*]. The Parties will cooperate to establish timelines and procedures for EDC review of publications and presentations, and publications and presentations in the Expansion Scope will be subject to policies established by the Patent Coordinators to ensure appropriate protection of intellectual property rights.
- 9.6. <u>Attorney-Client Privilege</u> Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the Applicable Law of any jurisdiction 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 may become joint defendants in proceedings to which the information covered by such protections and

privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

- 9.7. <u>Injunctive Relief</u>. Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9 (Confidentiality, Publications and Press Releases). In addition to all other remedies, a Party is entitled to seek specific performance and injunctive and other equitable relief (without the need to post a bond) as a remedy for any breach or threatened breach of this Article 9 (Confidentiality, Publications and Press Releases).
- 9.8. <u>Additional Permitted Disclosure</u>. [\*] will have the right to [\*] pursuant to [\*].

## 10. REPRESENTATIONS AND WARRANTIES

- 10.1. <u>Mutual Representations and Warranties</u>. Each of the Parties hereby represents and warrants, as of the Effective Date, to the other Party as follows:
  - 10.1.1. It is duly organized and validly existing under the Applicable Law of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
  - 10.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement, and compliance with its terms and provisions, and the consummation of the transaction contemplated hereby, by such Party will not conflict, interfere or be inconsistent with, result in any breach of or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor to its knowledge violate any Applicable Law. The person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action.
  - 10.1.3. To its knowledge, no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority or under Applicable Law, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed concurrently herewith, or (except for Regulatory Approvals, licenses, clearances and the like necessary for the commercialization, research, development, manufacture, sales or marketing of pharmaceutical products and except for any required filing with the United States Securities and Exchange Commission) for the performance by it of its obligations under this Agreement;
  - 10.1.4. It has not been debarred or the subject of debarment proceedings by any Governmental Authority;

- 10.1.5. To its knowledge it and its Affiliates have not violated any applicable anticorruption or anti-bribery law or regulation, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the regulations promulgated thereunder (collectively, "*Anticorruption Laws*");
- 10.1.6. It has established and maintains reasonable internal controls intended to ensure compliance with Anticorruption Laws, including reasonable reporting requirements; and
- 10.1.7. It has not granted any right to any Third Party relating to any intellectual property or proprietary right licensed or granted by it to the other Party hereunder that conflicts with the rights licensed or granted to the other Party hereunder.
- 10.2. <u>Amgen Representations and Warranties</u>. In addition to the representations and warranties set forth in Section 10.1 (Mutual Representations and Warranties), Amgen hereby represents and warrants to GSK that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [\*]
- 10.3. <u>Amgen Covenants</u>. Amgen hereby covenants to GSK that:
  - 10.3.1. It will not [\*]; and
  - 10.3.2. Amgen understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof.
- 10.4. <u>GSK Representations and Warranties</u>. In addition to the representations and warranties set forth in Section 10.1 (Mutual Representations and Warranties), GSK hereby represents and warrants to Amgen that, except as would not be expected to have a material adverse effect on the activities of the Parties hereunder, as a whole, as of the Effective Date: [\*]
- 10.5. <u>GSK Covenants</u>. GSK hereby covenants to Amgen that:
  - 10.5.1. GSK understands its rights and obligations under this Agreement, and has and will at all times during the Term maintain sufficient resources to fully and diligently perform its obligations hereunder in accordance with the terms and provisions hereof; and
  - 10.5.2. It will not [\*].
- 10.6. <u>Disclaimer of Warranties</u>. EXCEPT AS SET FORTH IN THIS ARTICLE 10 (REPRESENTATIONS AND WARRANTIES), GSK AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, IVORY INTELLECTUAL PROPERTY, AMGEN HOUSEMARKS, GSK HOUSEMARKS, PRODUCT TRADEMARKS, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

- 10.7. <u>Limitation of Liability</u>. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, OTHER THAN TO THE EXTENT RESULTING FROM A BREACH OF ARTICLE 7 [\*] OR SECTION 9.1 (CONFIDENTIALITY; EXCEPTIONS), IN NO EVENT WILL GSK OR AMGEN BE LIABLE TO THE OTHER OR ANY OF THE OTHER'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE WILL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 11.1 (INDEMNITY BY GSK), SECTION 11.2 (INDEMNITY BY AMGEN), [\*].
- 10.8. <u>Acknowledgment</u>. The Parties agree that neither Party is making any representation hereunder with respect to the prospects of Ivory, including that Ivory will achieve any particular clinical or commercial results or will obtain Regulatory Approval(s) in any country(ies) within the Expansion Territory. Each Party understands and assumes hereunder the risks attendant to the business of developing, manufacturing, seeking to obtain Regulatory Approvals and access and reimbursement for, and commercializing Ivory, a human therapeutic product. Such risks include negative clinical results, adverse safety events, denial or delay of Regulatory Approvals, limited or restricted product labeling, no or limited access or reimbursement, product liability claims, supply failures or shortages, loss of exclusivity protections, and claims of misappropriation or infringement of intellectual property. Except with respect to a breach of this Agreement or to the extent a Loss is subject to indemnification pursuant to Section 11.1 (Indemnity by GSK), 11.2 (Indemnity by Amgen) [\*], it is intended that each Party will bear its respective Losses related to the Expansion Scope that arise out of the development, manufacture, regulatory activities, commercialization or other exploitation of Ivory undertaken by or on behalf of a Party in good faith.
- 10.9. <u>Covenants</u>. Each Party hereby covenants to the other Party that, during the Term:
  - 10.9.1. It will not grant any right to any Third Party relating to any intellectual property or proprietary right licensed or assigned by it to the other Party hereunder that conflicts with the rights granted to the other Party hereunder;
  - 10.9.2. It will not knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency; and

10.9.3. It will comply with all Applicable Law with respect to their performance of its rights, duties and obligations under this Agreement, including commercialization, manufacturing, research and development and regulatory activities.

### 11. INDEMNIFICATION AND INSURANCE

- 11.1. <u>Indemnity by GSK</u>. Subject to the remainder of this Article 11 (Indemnification), GSK will defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, agents and representatives (collectively, "*Amgen Indemnitees*"), at GSK'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 or on behalf of any of the indemnitees until such time as the indemnification obligation is acknowledged and assumed hereunder with respect to the applicable 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: [\*].
- 11.2. Indemnity by Amgen. Subject to the remainder of this Article 11 (Indemnification), Amgen will defend, indemnify, and hold harmless GSK, its Affiliates, and their respective directors, officers, employees and agents (collectively, "GSK Indemnitees"), at Amgen's cost and expense, from and against any and all Losses arising out of any Claims brought against any GSK Indemnitee by a Third Party to the extent such Losses result from: [\*]. Notwithstanding the foregoing, this Section 11.2 (Indemnity by Amgen) will not apply to any issues related to supply of Ivory by Amgen, which matters are subject to the Supply Agreement.
- 11.3. [\*].
- 11.4. <u>Claim for Indemnification</u>. Whenever any Third Party Claim or Loss arises for which a GSK Indemnitee or an Amgen Indemnitee (the "*Indemnified Party*") may seek indemnification under this Article 11 (Indemnification), the Indemnified Party will promptly notify the other Party (the "*Indemnifying Party*") of the Third Party Claim or Loss and, when known, the facts constituting the basis for the Third Party Claim; provided that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 11.4 (Claim for Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party claims for which it is responsible for indemnification and will assume defense thereof at its own expense promptly upon notice of such Third Party Claim. The Indemnified Party will not settle or compromise any Third Party 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 will the Indemnifying Party settle any Third Party Claim without the prior written consent of the Indemnified Party

if such settlement does not include a complete release from liability on such Third Party Claim or if such settlement would involve undertaking an obligation by the Indemnified Party other than the payment of money, would bind or impair the Indemnified Party, or includes any admission of wrongdoing by the Indemnified Party or that any intellectual property or proprietary right of the Indemnified Party is invalid or unenforceable. The Indemnifying Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information will be subject to Article 9 (Confidentiality, Publications and Press Releases). The Indemnifying Party will permit the Indemnified Party to participate in (but not to control) the Third Party Claim through counsel of its choosing to the extent it has the ability to do so (at the Indemnified Party's expense). Notwithstanding the foregoing, the Indemnified Party Claim if: (i) there are or may be legal defenses available to the Indemnified Party that are different from or additional to those available to the Indemnifying Party 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

11.5. Defense of Third Party Claims. Except as otherwise provided in Section 11.4 (Claim for Indemnification), each Party (such Party referred to as the *"Defending Party"*) will have the sole right, but not the obligation, to defend against any Third Party Claims made against it with respect to its activities hereunder. Each Party will notify the other Party (the *"Assisting Party"*) as promptly as practicable if any Third Party Claim is commenced or threatened against it, including any Infringement Claim or any [\*]. The Assisting Party will reasonably assist the Defending Party and cooperate in any such litigation at Defending Party's reasonable request (and the Defending Party will reimburse the Assisting Party's reasonable costs incurred in connection with such cooperation). The Defending Party will seek and reasonably consider, but is not obligated to follow, the Assisting Party's comments before determining the strategy for such matter. Without limiting the foregoing, the Defending Party will keep the Assisting Party advised of all material communications, actual and prospective filings or submissions regarding such action, and will provide the Assisting Party copies of and an opportunity to review and comment on any such communications, filings and submissions; provided, that each Party will have the right to redact from any information disclosed to the other hereunder any information relating to a product other than Ivory or relating to the manufacture of Ivory. The Defending Party will control the defense and/or settlement of Third Party Claims at its own expense with counsel of its choice. The Defending Party will have the right to participate in the defense and/or settlement of such Third Party Claim at its own expense with counsel of its choice. The Defending Party will not settle a Third

Party Claim without the prior written consent of the other Party (such consent not to be unreasonably withheld), unless such settlement: [\*]. In the event that a Third Party Claim is brought against both of the Parties (a "*Joint Claim*"), then the Parties will determine whether to defend against such Joint Claim, which of the Parties should be the Defending Party or whether the Parties should jointly control such defense and the strategy for such defense. If the Parties determine that there will be one Defending Party for a Joint Claim, then the Assisting Party will have the right to participate in the defense of such Joint Claim through counsel, and at its own expense of its choosing to the extent it has the ability to do so, and may control its own defense of the Joint Claim if there are or may be legal defenses available to the Assisting Party that are different from or additional to those available to the Defending Party that would make such separate representation advisable. In the case of an Infringement Claim, the coordination and cooperation set forth in this Section 11.5 (Defense of Third Party Claims) will be accomplished via the Patent Coordinators. This Section 11.5 (Defense of Third Party Claims) will be accomplished via the Patent Coordinators.

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

#### 12. TERM AND TERMINATION

12.1. <u>Term</u>. This Agreement will become effective on the Effective Date and, unless and until sooner terminated pursuant to any provision of this Agreement, will terminate [\*] following the Effective Date (the "*Term*"). If earlier, this Agreement will terminate upon such time as there are no countries remaining in either the Reserved Territory or the Expansion Territory. Upon request of either Party, the Parties will discuss a [\*] extension of the Term on the same terms as set forth herein. Any such extension of the Term will only be effective if expressly set forth in a written amendment hereto signed by each Party.

#### 12.2. <u>Termination for Breach</u>.

12.2.1. In the event of a material breach of this Agreement, the non-breaching Party will have the right to terminate this Agreement (either as a whole or in the country or countries with respect to which such breach occurred, at the terminating Party's option) by written notice to the breaching Party, which notice will specify the nature of such breach in reasonable detail. Such termination will become effective on the date specified in the notice (which will not be earlier than [\*] after the delivery thereof to the breaching Party or, in the case of a failure to pay amounts due hereunder, [\*]) unless, during the [\*] period after delivery of such notice to the breaching Party, the breaching Party has cured such breach to the reasonable satisfaction of the non-breaching Party.

- 12.2.2. Notwithstanding the provisions of Section 12.2.1, the following will apply in the event of multiple breaches by the same Party: (i) in the event of [\*] material breaches of this Agreement by the same Party within a [\*] period, the non-breaching Party will have the right to terminate this Agreement by written notice to the breaching Party, which notice will specify the nature of such third breach in reasonable detail, effective (regardless of whether such third breach is cured) as of the date specified in such notice (which will not be earlier than [\*] from receipt thereof by the breaching Party), and (ii) if a Party commits at least [\*] material breaches of this Agreement and such breaches are with respect to the same obligation or activity hereunder, then the non-breaching Party will have the right, but not the obligation, to call a special meeting of the EDC with respect to development breaches or the ESC with respect to any other breach (a "Special Meeting"), by written notice to the breaching Party. Such notice will state with particularity the obligations that the non-breaching Party believes have not been satisfied and the basis for such belief. The Special Meeting will be convened within ten (10) business days of the breaching Party's receipt of such notice. At the Special Meeting, the ESC or EDC, as applicable, will discuss the non-breaching Party's concerns, the breaching Party's efforts in such area of concerns and any additional actions the breaching Party should take to alleviate the non-breaching Party's concerns. The ESC or EDC, as applicable, will develop a plan describing the actions that the Parties reasonably believe the breaching Party should take to meet its applicable obligations under the Agreement (the "Remediation Plan"); provided, that the Remediation Plan may provide that the non-breaching Party will assume responsibility for such obligation or activity and the breaching Party will cooperate with the non-breaching Party to effect such transition to the non-breaching Party. The applicable Party will perform the actions described in such Remediation Plan in accordance with the timelines, if any, set forth therein. For the avoidance of doubt, if the non-breaching Party chooses not to request a Special Meeting, then such Party may proceed in accordance with Section 12.2.1.
- 12.3. <u>Termination for Insolvency</u>. Either Party will have the right to terminate this Agreement immediately upon written notice, if: (i) the other Party becomes insolvent; (ii) the other Party files a petition in bankruptcy, or if an involuntary petition in bankruptcy is filed against the other Party and such involuntary petition is not dismissed within seventy-five (75) days and the other Party (a) fails to assume this Agreement in any such bankruptcy proceeding within thirty (30) days after filing or (b) assumes and assigns this Agreement to a Third Party; or (iii) a receiver or guardian has been appointed for the other Party who is not discharged within seventy-five (75) days after appointment.

12.4. <u>Termination for Challenge</u>. A Party will have the right to terminate this Agreement by written notice to the other Party, if such other Party, its Affiliates or licensees bring or join any challenge to the validity or enforceability of (i) if Amgen is the challenging Party, any Know-How or Patents licensed to Amgen pursuant to Section 8.5 (License Grant by GSK) (including GSK Inventions); and (ii) if GSK is the challenging Party, any Ivory Intellectual Property (or any intellectual property corresponding to any such Ivory Intellectual Property outside the Expansion Scope). Notwithstanding the foregoing, nothing in this Section 12.4 (Termination for Challenge) will either: (i) prevent either Party from asserting any defense or counterclaim in an action for infringement of intellectual property, brought against such Party or its Affiliates, or any Third Party that such Party or any of its Affiliates is obligated to indemnify, or responding in any other manner to such an action for infringement; or (ii) allow a Party to terminate this Agreement in the event the other Party asserts any such defense or counterclaim or otherwise responds in any such action for infringement.

### 12.5. <u>Termination for Change of Control</u>.

- 12.5.1. *Early Change of Control of GSK*. GSK will give Amgen written notice within five (5) days after the public announcement or disclosure of, or if earlier the signing of any agreement for, a proposed Change of Control of GSK. In the event of the occurrence of, signing of an agreement for, or public announcement or disclosure of, any proposed Change of Control of GSK (a "*Control Event*") prior to the [\*] of the Effective Date, Amgen will have the right to [\*].
- 12.5.2. Later Change of Control of GSK. If a Control Event occurs on or after the [\*] of the Effective Date, Amgen will have the right to [\*].
- 12.5.3. Change of Control of Amgen. In the event of the occurrence of a Change of Control of Amgen, if [\*], then GSK will have the right to [\*].
- 12.6. <u>Termination for Withdrawal or Stoppage</u>. If (i) GSK decides to not sell Ivory in a country in the Expansion Scope, or (ii) after receipt of Regulatory Approval for Ivory in a country in the Expansion Scope GSK does not sell Ivory in such country, in either case for a period of [\*] for reasons other than Force Majeure, then in any such event GSK will promptly notify Amgen thereof in writing and Amgen will have the right to terminate this Agreement with respect to such country, on [\*] prior written notice; provided, that during the [\*] notice period, GSK may request that the Parties meet to discuss without obligation, whether, and under what conditions, GSK may be able to commence or continue selling Ivory in such country. Termination under this Section 12.6 (Termination for Withdrawal or Stoppage) is independent of any termination right under Section 12.2 (Termination for Breach) and the occurrence of an event in clause (i) or (ii) of this Section 12.6 (Termination for Withdrawal or Stoppage) will not necessarily constitute a breach hereunder or imply that a breach has occurred hereunder.
- 12.7. Termination for Convenience. GSK will have the right to terminate this Agreement (in its entirety, not on a country-by-country basis) upon [\*] prior

written notice; provided, that in no event will a termination under this Section 12.7 (Termination for Convenience) be effective prior to [\*] (even if notice is delivered more than [\*] prior thereto). Upon delivery of a valid termination notice in accordance with this Section 12.7 (Termination for Convenience), the Parties will discuss a plan to effect a smooth and orderly transition to Amgen of all activities and rights with respect to Ivory in the Expansion Scope and GSK will comply with all reasonable requests of Amgen in connection therewith. During the [\*] notice period, GSK will undertake reasonable efforts to effect such transition. On a country-by-country basis, during the [\*] notice period Amgen in its discretion may accelerate the termination of this Agreement with respect to a country or countries within the Expansion Territory, such that Amgen can take over activities and rights with respect to Ivory hereunder in countries in the Expansion Territory at different times during the notice period.

- 12.8. <u>Amgen Termination Right</u>.
  - 12.8.1. *Buy-Out.* Beginning on [\*] (the "*Buy-Out Date*"), Amgen will have the right, on a [\*] basis, to terminate this Agreement in such [\*] by at least [\*] prior written notice to GSK (a "*Country Termination Notice*"), such termination to be effective no sooner than the Buy-Out Date. During the Term, GSK will provide to Amgen all information reasonably requested by Amgen for it to evaluate and plan with respect to the potential exercise of its termination rights under this Section 12.8 (Amgen Termination Right). In the event of any such termination, Amgen will pay GSK [\*].
  - 12.8.2. *Buy-In Discussion*. In addition to Amgen's right to terminate under Section 12.8.1 (Buy-Out), beginning on the Buy-Out Date, either Party may request that the Parties meet and discuss, without any obligation, alternatives with respect to the commercialization of Ivory in the applicable [\*], which may include continuing to commercialize pursuant to this Agreement, increasing operational participation by Amgen under this Agreement, or entering into a joint venture with respect to such [\*] (with respect to Ivory or other products of the Parties). During the Term, GSK will provide to Amgen all information reasonably requested by Amgen for it to evaluate and plan with respect to the potential discussions described in this Section 12.8.2 (Buy-In Discussion).
- 12.9. Effects of Expiration or Termination. Upon the expiration or termination of this Agreement for any reason, the following will apply (to the Expansion Territory as a whole, if the entire Agreement is terminated, or only to the applicable country(ies) if the Agreement is terminated only with respect to a country or certain countries within the Expansion Territory):
  - 12.9.1. *Accrued Obligations*. Expiration or termination of this Agreement for any reason will not release either Party from any liability (including any payment obligations) that, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to activities prior to such expiration or termination.

- 12.9.2. *Transfer of Materials.* With respect to any terminated country within the Expansion Territory, upon Amgen's request, GSK will transfer to Amgen any inventory of and/or materials related to Ivory, and Amgen will reimburse GSK's acquisition or reasonable production costs thereof.
- 12.9.3. Promotion Rights; Licenses. Except as set forth in Section 12.10 (Transition), upon the expiration or termination of this Agreement: (i) GSK's right to further develop and commercialize Ivory in the Expansion Scope will terminate, (ii) all licenses to GSK hereunder will terminate, and (iii) GSK will immediately cease all of its commercialization and other activities for Ivory in the Expansion Scope and discontinue all use of Amgen Housemarks and Product Trademarks. Amgen will have the right to use the GSK Housemarks incorporated in Ivory materials until such time as any existing inventory of labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory in the Expansion Scope that contain the GSK Housemarks have been depleted.
- 12.9.4. *Product Data and Amgen Confidential Information.* GSK will promptly transfer to Amgen, at no cost, copies of all data, reports, records and materials in its possession or control that relate to Ivory ("*Product Data*"). Such Product Data will be in electronic form reasonably usable by Amgen and, if reasonably necessary in connection with Amgen's (or its designee's) further commercialization, development or exploitation of Ivory in the Expansion Territory, will include original hardcopies or duplicate copies thereof, as required. In addition (without limiting Section 8.2 (Copyright Ownership; Certain Confidential Information)), all Product Data generated by or under authority of [\*] hereunder during the term of the Agreement that solely pertains to [\*] following termination of this Agreement. In addition, GSK will promptly return to Amgen, or destroy at Amgen's request, all relevant records and materials in GSK's possession or control containing Confidential Information of Amgen (provided that GSK may keep: (i) such copies of such records as may be required for GSK to comply with Applicable Law; and (ii) one copy of such Confidential Information of Amgen, for archival purposes only, provided that, in each case, such copies are Segregated from any [\*]).
- 12.9.5. *Return of Materials*. GSK will promptly return to Amgen, or destroy at Amgen's request (and certify such destruction to Amgen), all Promotional Materials, sales training materials and any other documents, or materials primarily intended for use in commercialization of Ivory in the Expansion Territory.
- 12.9.6. Assignment of Filings and Registrations. Upon request of Amgen, GSK will, at its own expense (other than with respect to any fee payable to the relevant Governmental Authority in connection with the relevant assignment, which will be borne by Amgen), (i) assign to Amgen (or its designee) all Regulatory Filings and Regulatory Approvals in the Expansion Territory related to Ivory that are in GSK's name (if any) or

withdraw such Regulatory Filings or Regulatory Approvals or take such other action with respect thereto as directed by Amgen, and (ii) assign to Amgen (or its designee) all trademark and Copyright registrations related to Ivory (or to labeling, package inserts or outserts, monographs or packaging materials or Promotional Materials for Ivory) that are in GSK's name, if any. The foregoing is not meant to imply any right of GSK to own any filing or intellectual property except as may be expressly set forth herein or agreed in writing between the Parties. To the extent permitted by Applicable Law, until each requested Regulatory Filing and Regulatory Approval is assigned to Amgen (or its designee), GSK will hold such filing or approval for the benefit of Amgen and will take all action reasonably necessary or requested by Amgen to provide Amgen with the benefit thereof, including granting Amgen exclusive rights thereunder, providing Amgen with a right of reference and access to all such filings and approvals and notice of and an opportunity to participate in any interactions and correspondence with Governmental Authorities with respect to such filings and approvals.

- 12.9.7. Survival. Articles 6 (Payments) (with respect to periods prior to expiration or termination), 7 [\*] (only with respect to such continuing periods as expressly referenced in such Article), 11 (Indemnification and Insurance), 13 (Miscellaneous) and Sections 5.7 (Product Technical Complaints; Recalls; Returns) (only with respect to Ivory sold by GSK in the Expansion Scope prior to the termination), 5.1.5 (Development Costs) (only with respect to activities undertaken prior to termination), 6.1 (Support Costs) (only with respect to activities undertaken prior to termination), 8.3 (Joint Ownership), 8.4 (License Grant by Amgen) (only with respect to the transition period referenced in Section 12.10 (Transition)), 8.5 (License Grant by GSK), 8.11.3.1 (To GSK) (with respect to the transition period referenced in Section 12.10 (Transition)), 8.11.3.2 (To Amgen) (with respect to the sell-off period referenced therein), 9.1 (Confidentiality; Exceptions), 9.2 (Authorized Disclosure), 9.3 (Confidential Treatment of Terms and Conditions), 9.6 (Attorney-Client Privilege), 9.7 (Injunctive Relief), 12.9 (Effects of Expiration or Termination), 12.10 (Transition), and 12.11 (No Limitation of Rights) will survive expiration or termination of this Agreement for any reason. Following any such expiration or termination, medical inquiries with respect to Ivory will be referred by GSK to Amgen in accordance with instructions provided by Amgen. Except as otherwise provided in this Section 12.9 (Effects of Expiration or Termination), all rights and obligations of the Parties under this Agreement will terminate upon expiration or termination of this Agreement for any reason.
- 12.10. *Transition*. During all applicable notice periods prior to termination of this Agreement under Sections 12.2 (Termination for Breach), 12.3 (Termination for Insolvency), 12.4 (Termination for Challenge), 12.5 (Termination for Change of Control), 12.7 (Termination for Convenience) 12.8 (Amgen Termination Right) and 13.10 (Force Majeure) (provided, however, that with respect to transition

following termination pursuant to Section 13.10 (Force Majeure), the Party subject to such Force Majeure or [\*] will not be liable for activities under this Section 12.10 (Transition) to the extent prevented from performing such activities due to the Force Majeure or [\*] giving rise to such termination), GSK will continue to meet its obligations to promote Ivory within the Expansion Scope, in accordance with the Expansion Brand Plan and this Agreement, unless otherwise requested by Amgen. Except for termination pursuant to Section 12.8 (Amgen Termination Right), during such period as the Parties determine is reasonably necessary (up to [\*]) following the effective date of such termination, GSK will undertake reasonable efforts to effect a smooth and orderly transition of all commercial activities and responsibilities of GSK under this Agreement to Amgen, as soon as reasonably possible, to enable Amgen to continue the promotion and commercialization of Ivory in the Expansion Scope after termination. Notwithstanding the foregoing, the Parties will use reasonable efforts to effect the transition as quickly as possible within the time periods referenced above. For the avoidance of doubt, in the case of termination in accordance with Section 12.6 (Termination for Withdrawal or Stoppage) for a safety issue, GSK will have no obligation to Detail or commercialize Ivory, or take any other action that it reasonably believes presents a safety risk to patients, but will carry out its other obligations pursuant to Section 12.9 (Effects of Expiration or Termination). During the longer of any such notice period and a [\*] period following any termination of this Agreement, GSK will undertake reasonable efforts to effect a smooth and orderly transition of all commercial and other activities and responsibilities of GSK under this Agreement to Amgen, as soon as reasonably possible, to enable Amgen to continue the development, promotion and commercialization of Ivory in the Expansion Scope after termination. During any transition period subsequent to the expiration or termination of this Agreement, Amgen will reimburse GSK's reasonable costs incurred at Amgen's request in connection with the transition of responsibilities for Ivory in the Expansion Scope to Amgen. As the case may be, this Section 12.10 (Transition) will apply to the Expansion Territory as a whole if the entire Agreement is terminated, or only to the applicable country(ies) if the Agreement is terminated only with respect to a country or certain countries within the Expansion Territory.

12.11. *No Limitation of Rights*. The rights provided in this Article 12 (Term and Termination) will be in addition and without prejudice to any other rights which the Parties may have with respect to any default or breach of the provisions of this Agreement. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies at equity or law will remain available to the Parties except as expressly agreed otherwise herein.

#### 13. MISCELLANEOUS

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

- 13.2. <u>Arbitration</u>. In the event of any controversy or dispute arising out of or relating to any provision of this Agreement, the construction, validity or breach thereof, the Parties will try to settle the same amicably between themselves. If the Parties fail to settle such matter within thirty (30) days of it having arisen, such matter will be exclusively and finally resolved by binding arbitration under the [\*] selected in accordance with the Rules. The place of the arbitration will be [\*] and the language of the arbitration will be English. In the event of a dispute involving the alleged breach of this Agreement, neither Party will have the right to terminate this Agreement until resolution of the dispute pursuant to this Section 13.2 (Arbitration), and any time period for cure will commence only after such resolution. Any disputed performance or suspended performance pending the resolution of a dispute involving the alleged breach of this Agreement that the arbitrator determines to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrator. The arbitration award will be final and binding upon both Parties and may be entered in any court of competent jurisdiction for enforcement. The arbitrators will have the power to grant monetary damages as well as injunctive or other specific relief. Notwithstanding the foregoing, each Party will have the right to seek, without establishment of the arbitration proceeding will pay the arbitrators' fees and any administrative fees of arbitration.
- 13.3. <u>Assignment</u>. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Applicable Law, general succession or otherwise) by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement, or rights and obligations hereunder, without prior written consent to any Affiliate, and Amgen may assign this Agreement without prior written consent in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Any assignment not in accordance with this Agreement will be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 13.4. <u>Choice of Law</u>. This Agreement will be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its conflicts of law provisions. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.
- 13.5. <u>Compliance with Applicable Law</u>. No Party will be required by this Agreement to take or omit to take any action in contravention of Applicable Law or applicable national and international pharmaceutical industry codes of practices
- 13.6. <u>Construction</u>. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to

be followed by the phrase "without limitation". The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Applicable Law herein will be construed as referring to such Applicable Law as from time to time enacted, repealed or amended, (iii) any reference herein to any person will be construed to include the person's permitted successors and assigns, (iv) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections or Schedules, unless otherwise specifically provided, will be construed to refer to Articles, Sections or Schedules of this Agreement. This Agreement has been executed in English, and the English version of this Agreement will control.

- 13.7. <u>Counterparts</u>. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 13.8. <u>Currency</u>. With respect to amounts required to be converted into another currency for calculation or payment, hereunder, such amounts will be converted using a rate of exchange which corresponds to the rate used for conversion between the relative currencies by whichever Party recorded the relevant receipt or expenditure, for the respective reporting period in its books and records that are maintained in accordance with GAAP or IFRS, as the case may be. If a Party is not required to perform such a currency conversion for its GAAP or IFRS reporting with respect to the applicable period, then for such period such Party will make such conversion using the rate of exchange which corresponds to the [\*] as published in the <u>Wall Street Journal</u>, <u>Eastern U.S. Edition</u> on the second to last business day of the calendar quarter (or such other publication as agreed-upon by the Parties) in which such receipt or expenditure was incurred.
- 13.9. <u>Entire Agreement</u>. This Agreement, including the attached Schedules, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior or contemporaneous negotiations, representations, agreements and understandings regarding the same. Nothing in this Agreement is intended to modify, abrogate or eliminate those rights and obligations of the Parties expressly set forth in the Collaboration Agreement.
- 13.10. <u>Force Majeure</u>. Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) to the extent such delay or failure is due to causes beyond its reasonable

control, including acts of God, fires, floods, earthquakes, labor strikes, 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 uses its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with reasonable dispatch whenever such causes are removed. If the performance of any obligation or activity of either Party that is fundamental to the commercial success of Ivory in the Expansion Scope is prevented by such Force Majeure event for a period of more than [\*], then either Party may terminate this Agreement upon [\*] written notice, unless such obligation is performed within such [\*] notice period. In addition, [\*].

- 13.11. Further Assurances. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 13.12. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.
- 13.13. No Set-Off. Except as expressly set forth in Section 6.4 (Withholding) or Section 6.5 (VAT), no Party will have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates), whether pursuant to this Agreement or otherwise.
- 13.14. Notices. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

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

709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939 USA Attention: Senior Vice President, Worldwide Business Development Telephone: [\*] Facsimile: [\*]

With a copy to:

GlaxoSmithKline 2301 Renaissance Boulevard Mailcode RN0220 King of Prussia, PA 19406-2772 USA Attention: Vice President and Associate General Counsel, Business Development Transactions Telephone: [\*] Facsimile: [\*]

Any such notice will be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 13.14 (Notices).

- 13.15. <u>Relationship of the Parties</u>. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. The Parties will operate their own businesses separately and independently and they will hold themselves out as, act as, and constitute independent contractors in all respects and not as principal and agent, partners or joint venturers. Each Party will be responsible for fulfilling its own obligations under this Agreement, and it will not have control or responsibility over the actions of the other Party. The Parties will make and receive only such payments as are required under this Agreement for sales and services required hereunder, and will not share in, or participate in, the business operations of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Each Party will file all necessary reports, statements, tax returns, information returns and any other filings with the U.S. Food and Drug Administration, the Securities and Exchange Commission, U.S. Internal Revenue Service, any regulatory authority or any other Governmental Authority on a basis that is consistent with the terms of this Section 13.15 (Relationship of the Parties).
- 13.16. <u>Severability</u>. To the fullest extent permitted by Applicable Law, the Parties waive any provision of Applicable Law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect or to any extent, then in such respect and to such extent such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law, all other provisions of this Agreement shall

remain in full force and effect and the Parties will use their commercially reasonable efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

13.17. [\*]

- 13.18. <u>Third Party Beneficiaries</u>. Except as expressly provided with respect to Amgen Indemnitees or GSK Indemnities in Article 11 (Indemnification), there are no Third Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.
- 13.19. <u>Waivers and Modifications</u>. The failure of any Party to insist on the performance of any obligation hereunder will not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof will not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement will be valid or effective unless in writing and signed by all Parties hereto.

#### \*\*\*\*\*\*

(Signature page follows)

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

# GLAXO GROUP LIMITED

- By: /s/ PAUL WILLIAMSON
- Name: Paul Williamson
- Title: Edinburgh Pharmaceutical Industries Limited Corporate Director

# AMGEN INC.

By: /s/ ROBERT A. BRADWAY

Name: Robert A. Bradway

Title: Executive Vice President & Chief Financial Officer

## CERTIFICATIONS

I, Kevin W. Sharer, 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: November 6, 2009

/S/ KEVIN W. SHARER

Kevin W. Sharer Chairman of the Board, Chief Executive Officer and President

#### CERTIFICATIONS

- I, Robert A. Bradway, 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: November 6, 2009

/S/ ROBERT A. BRADWAY

Robert A. Bradway 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 September 30, 2009 (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.

Dated: November 6, 2009

/S/ KEVIN W. SHARER Kevin W. Sharer

Chairman of the Board, Chief Executive Officer and President

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

#### **Certification of Chief Financial Officer**

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2009 (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.

Dated: November 6, 2009

/S/ ROBERT A. BRADWAY

Robert A. Bradway 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.