
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 2008

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)

95-3540776
(I.R.S. Employer
Identification No.)

**One Amgen Center Drive,
Thousand Oaks, California**
(Address of principal executive offices)

91320-1799
(Zip Code)

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

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

Indicate by check mark whether the registrant 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 Accelerated filer Non-accelerated filer 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 May 5, 2008, the registrant had 1,088,696,087 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.

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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)

	Three Months Ended	
	March 31,	
	2008	2007
Revenues:		
Product sales	\$ 3,537	\$ 3,565
Other revenues	76	122
Total revenues	<u>3,613</u>	<u>3,687</u>
Operating expenses:		
Cost of sales (excludes amortization of acquired intangible assets presented below)	546	592
Research and development	694	851
Selling, general and administrative	874	770
Amortization of acquired intangible assets	74	74
Other	10	—
Total operating expenses	<u>2,198</u>	<u>2,287</u>
Operating income	1,415	1,400
Interest and other income and (expense), net	22	(6)
Income before income taxes	1,437	1,394
Provision for income taxes	301	283
Net income	<u>\$ 1,136</u>	<u>\$ 1,111</u>
Earnings per share:		
Basic	\$ 1.04	\$ 0.95
Diluted	\$ 1.04	\$ 0.94
Shares used in calculation of earnings per share:		
Basic	1,089	1,167
Diluted	1,092	1,177

See accompanying notes.

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

	<u>March 31,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,324	\$ 2,024
Marketable securities	4,323	5,127
Trade receivables, net	2,224	2,101
Inventories	2,091	2,091
Other current assets	1,565	1,698
Total current assets	14,527	13,041
Property, plant and equipment, net	5,949	5,941
Intangible assets, net	3,271	3,332
Goodwill	11,347	11,240
Other assets	1,034	1,085
	<u>\$36,128</u>	<u>\$ 34,639</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 522	\$ 378
Accrued liabilities	3,432	3,801
Current portion of other long-term debt	2,000	2,000
Total current liabilities	5,954	6,179
Deferred tax liabilities	381	480
Convertible notes	5,080	5,080
Other long-term debt	4,097	4,097
Other non-current liabilities	1,529	934
Contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750 shares authorized; outstanding - 1,088 shares in 2008 and 1,087 shares in 2007	25,088	24,976
Accumulated deficit	(6,031)	(7,160)
Accumulated other comprehensive income	30	53
Total stockholders' equity	19,087	17,869
	<u>\$36,128</u>	<u>\$ 34,639</u>

See accompanying notes.

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

	Three Months Ended	
	March 31,	
	2008	2007
Cash flows from operating activities:		
Net income	\$ 1,136	\$ 1,111
Depreciation and amortization	266	244
Other items, net	16	193
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(93)	(33)
Inventories	18	(201)
Other assets	35	(7)
Accounts payable	118	46
Accrued income taxes	112	(270)
Deferred revenue	297	—
Other accrued liabilities	(323)	(190)
Net cash provided by operating activities	<u>1,582</u>	<u>893</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(170)	(325)
Cash paid for acquisition, net of cash acquired	(48)	—
Purchases of marketable securities	(1,468)	(1,191)
Proceeds from sales of marketable securities	2,126	2,296
Proceeds from maturities of marketable securities	208	135
Other	49	12
Net cash provided by investing activities	<u>697</u>	<u>927</u>
Cash flows from financing activities:		
Net proceeds from issuance of common stock in connection with equity award programs	28	138
Repurchases of common stock	—	(537)
Repayment of debt	—	(1,702)
Other	(7)	65
Net cash provided by (used in) financing activities	<u>21</u>	<u>(2,036)</u>
Increase (decrease) in cash and cash equivalents	2,300	(216)
Cash and cash equivalents at beginning of period	2,024	1,283
Cash and cash equivalents at end of period	<u>\$ 4,324</u>	<u>\$ 1,067</u>

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2008
(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 months ended March 31, 2008 and 2007 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, 2007.

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 accounting principles generally accepted in the United States ("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.

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. Inventories consisted of the following (in millions):

	<u>March 31, 2008</u>	<u>December 31, 2007</u>
Raw materials	\$ 176	\$ 173
Work in process	1,217	1,246
Finished goods	698	672
	<u>\$ 2,091</u>	<u>\$ 2,091</u>

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Goodwill

Goodwill principally relates to the acquisition of Immunex Corporation (“Immunex”). The increase over the balance at December 31, 2007 is related to the goodwill associated with our acquisition of the remaining 51% ownership interest of Dompé Biotec, S.p.A (“Dompé”) on January 4, 2008 (see Note 7, “Acquisition” for further discussion). We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

Fair value measurement

The Company adopted the provisions of the Financial Accounting Standards Board’s (“FASB’s”) Statement of Financial Accounting Standards (“SFAS”) No. 157, “Fair Value Measurements” (“SFAS 157”), effective January 1, 2008, for its financial assets and liabilities. The FASB delayed the effective date of SFAS 157 until January 1, 2009, with respect to the fair value measurement requirements for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is 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 SFAS 157 did not have a material impact on the Company’s consolidated financial statements.

In determining the fair value of its financial assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes a hierarchy for inputs used in measuring fair value 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 input that is significant to the overall fair value measurement.

The Company’s available-for-sale securities, substantially all of which are fixed income investments, are comprised of U.S. Treasury securities, obligations of U.S. government agencies, money market funds, corporate debt securities, other interest bearing securities and publicly traded equity investments. U.S. Treasury securities, money market funds and publicly traded equity investments are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. Obligations of U.S. government agencies, corporate debt securities and other interest bearing securities are valued using

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

quoted market prices of recent transactions or are benchmarked to transactions of very similar securities. When observable price quotations are not available, cash flow models are used to incorporate benchmark yields and issuer spreads. Obligations of U.S. government agencies, corporate debt securities and other interest bearing securities are categorized in Level 2.

Derivatives 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 table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2008 (in millions):

	Fair value measurement at reporting date using:			Balance as of March 31, 2008
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
Assets:				
Available-for-sale securities	\$ 4,513	\$ 3,975	\$ —	\$ 8,488
Derivatives	—	123	—	123
Total	<u>\$ 4,513</u>	<u>\$ 4,098</u>	<u>\$ —</u>	<u>\$ 8,611</u>
Liabilities:				
Derivatives	\$ —	\$ 118	\$ —	\$ 118
Total	<u>\$ —</u>	<u>\$ 118</u>	<u>\$ —</u>	<u>\$ 118</u>

There were no remeasurements to fair value during the three months ended March 31, 2008 of financial assets and liabilities that are not measured at fair value on a recurring basis.

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 provisions for estimated rebates, wholesaler chargebacks, discounts and other incentives (collectively "sales incentives") and returns. Taxes assessed by government authorities on the sales of the Company's products, primarily in Europe, are excluded from revenues.

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.), 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

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 and amortization of technology used in R&D with alternative future uses. R&D expenses consist of internal R&D costs, costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of Kirin-Amgen Inc. ("KA"), and costs 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. R&D collaborations resulting in a net payment or reimbursement of R&D costs are recognized as the obligation has been incurred or we become entitled to the cost recovery.

Selling, general and administrative costs

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

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 and 2013 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.

Our 2011 Convertible Notes and 2013 Convertible Notes are considered Instrument C securities as defined by Emerging Issues Task Force ("EITF") Issue No. 90-19 "Convertible Bonds with Issuer Option to Settle for Cash upon Conversion." Therefore, only the shares of common stock potentially issueable with respect to the excess of the notes' conversion value over their principal amount, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the three months ended March 31, 2008 and 2007, the conversion values for our convertible notes were less than the related principal amounts and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Three months ended March 31,	
	2008	2007
Income (Numerator):		
Net income for basic and diluted EPS	\$ 1,136	\$ 1,111
Shares (Denominator):		
Weighted-average shares for basic EPS	1,089	1,167
Effect of Dilutive Securities	3	10
Weighted-average shares for diluted EPS	1,092	1,177
Basic EPS	\$ 1.04	\$ 0.95
Diluted EPS	\$ 1.04	\$ 0.94

Recent accounting pronouncements

In December 2007, the FASB issued SFAS No. 141(R), “*Business Combinations*” (“SFAS 141(R)”) and SFAS No. 160, “*Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51*” (“SFAS 160”). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing at the acquisition date the fair value of acquired in-process research and development (“IPR&D”), and testing for impairment and writing down these assets, if necessary, in subsequent periods during their development. These new standards will be applied prospectively for business combinations that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively.

In December 2007, the FASB ratified EITF No. 07-1, “*Accounting for Collaborative Agreements*” (“EITF 07-1”). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company has entered into regarding development and commercialization of products and product candidates. EITF 07-1 is effective for the Company as of January 1, 2009, and its adoption is not expected to have a material impact on our consolidated results of operations or financial position.

2. Restructuring

On August 15, 2007, we announced a plan to restructure 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. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoietic stimulating agent (“ESA”) products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. Our ESA products have and will continue to face current and future regulatory and reimbursement challenges, including the potential for further revisions to product labels and loss of or restrictions on reimbursement coverage. In addition, the restructuring plan is also, to a lesser degree, the result of various challenges facing certain of our other products.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Through March 31, 2008, we have completed a majority of the actions included in our restructuring plan and expect that all remaining actions will be substantially completed in 2008. Key components of our restructuring plan include: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases for certain R&D facilities that will not be used in our operations. We currently estimate that \$775 million to \$825 million of restructuring charges will be incurred in connection with these actions, of which \$751 million has been incurred through March 31, 2008. Such cost estimates and amounts incurred to date are net of amounts recoverable from our co-promotion partner, Wyeth.

The following table summarizes the charges (credits) recorded during the three months ended March 31, 2008 related to the restructuring plan by type of activity (in millions):

	<u>Separation costs</u>	<u>Asset impairments</u>	<u>Other</u>	<u>Total</u>
Cost of sales (excluding amortization of intangible assets)	\$ —	\$ 1	\$—	\$ 1
Research and development	2	—	—	2
Selling, general and administrative	—	—	(1)	(1)
Other	4	2	4	10
	<u>\$ 6</u>	<u>\$ 3</u>	<u>\$ 3</u>	<u>\$ 12</u>

As noted above, since the inception of our restructuring plan through March 31, 2008, we have incurred \$751 million of the estimated \$775 million to \$825 million of charges expected to be incurred. The charges incurred through March 31, 2008 include \$184 million of separation costs, \$411 million of asset impairments, \$148 million of accelerated depreciation and \$8 million of other charges, which primarily include \$123 million of loss accruals for leases offset by \$115 million of cost recoveries from Wyeth.

The following table summarizes the charges and spending relating to the restructuring plan (in millions):

	<u>Separation costs</u>	<u>Other</u>	<u>Total</u>
Restructuring reserves as of January 1, 2008	\$ 97	\$102	\$199
Expense	6	4	10
Payments	(78)	(4)	(82)
Restructuring reserves as of March 31, 2008	<u>\$ 25</u>	<u>\$102</u>	<u>\$127</u>

The Company records restructuring activities in accordance with SFAS 88, *Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*, SFAS 144, *Accounting for the Impairment and Disposal of Long-Lived Assets* and SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. 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 months ended March 31, 2008 and 2007, our share of KA’s profits was \$14 million and \$7 million, respectively. At March 31, 2008 and December 31, 2007, the carrying value of our equity method investment in KA was \$306 million and \$292 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 certain of these products under the brand names Aranesp[®], Neulasta[®], NEUPOGEN[®] and EPOGEN[®], respectively. KA receives royalty income from us, as well as 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 months ended March 31, 2008 and 2007, KA earned royalties from us of \$75 million and \$85 million, respectively. These amounts are included in “Cost of sales (excludes amortization of acquired intangible assets)” in the Condensed Consolidated Statements of Income. At March 31, 2008, KA owed us \$6 million, which was included in “Other current assets” in the Condensed Consolidated Balance Sheets. At December 31, 2007, we owed KA \$91 million, which was included in “Accrued liabilities” in the Condensed Consolidated Balance Sheets.

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 months ended March 31, 2008 and 2007, we earned revenues from KA of \$32 million and \$56 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.

4. Income taxes

The effective tax rate for the three months ended March 31, 2008 is different from the statutory 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.

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 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.

During the three months ended March 31, 2008, the gross amount of our unrecognized tax benefits (“UTBs”) increased approximately \$100 million as a result of tax positions taken during the current year, and decreased approximately \$185 million, net, related to tax positions taken in prior years, primarily as a result of an agreement with the Internal Revenue Service related to certain transfer pricing positions for the years 2005 and 2006. The majority of our UTBs at March 31, 2008, if recognized, would affect our effective tax rate.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of March 31, 2008 and December 31, 2007 (in millions):

	March 31, 2008	December 31, 2007
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$ 2,500	\$ 2,500
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	2,500
Floating rate notes due 2008 (2008 Floating Rate Notes)	2,000	2,000
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	999	999
6.375% notes due 2037 (2037 Notes)	899	899
Other	180	180
Total borrowings	11,177	11,177
Less current portion	2,000	2,000
Total non-current debt	\$ 9,177	\$ 9,177

On April 17, 2008, we filed a shelf registration statement with the Securities and Exchange Commission ("SEC"), which replaced our previous \$1.0 billion shelf registration statement, which allows us to issue an unspecified amount of debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or depository shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depository shares. Under this registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance.

In May 2008, we increased our commercial paper program by \$1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of \$2.5 billion. We also have a \$2.5 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper backup, which matures in November 2012. No amounts were outstanding under the commercial paper program or credit facility as of March 31, 2008.

6. Stockholders' equity*Stock repurchase programs*

A summary of activity under our stock repurchase programs for the three months ended March 31, 2008 and 2007 is as follows (in millions):

	2008		2007	
	Shares	Dollars	Shares	Dollars
First quarter	—	\$ —	8.8	\$ 537

As of March 31, 2008, \$6.4 billion was available for stock repurchases under the \$5.0 billion repurchase authorization received from the Board of Directors in July 2007 and amounts remaining from the Board of Director's previous authorization in December 2006. 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.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Acquisition

On January 4, 2008, we completed the acquisition of Dompé, a privately held company that marketed certain of our products in Italy. This cash acquisition was accounted for as a business combination. The purchase price was approximately \$162 million, which included the carrying value of our existing 49% ownership in Dompé. The purchase price paid was preliminarily allocated to net assets acquired of approximately \$55 million based on their estimated fair values at the acquisition date and the excess of the purchase price over the fair values of net assets acquired of approximately \$107 million was assigned to goodwill. The results of Dompé's operations have been included in the condensed consolidated financial statements commencing January 4, 2008. Pro forma results of operations for the three months ended March 31, 2008 assuming the acquisition of Dompé had taken place at the beginning of 2008 would not differ significantly from the actual reported results.

8. 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. In accordance with SFAS 5, "Accounting for Contingencies," 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, 2007 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 Litigation

On March 7, 2008, the Track II defendants reached a tentative class settlement of the in the federal Multi-District Litigation proceeding ("the MDL Proceeding"), captioned In Re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456 pending in the Massachusetts District Court, which was subsequently amended on April 3, 2008. The tentative Track II settlement relates to claims against numerous defendants including Abbott Laboratories, Inc., Amgen Inc., Aventis Pharmaceuticals Inc., Hoechst Marion Roussel, Baxter Healthcare Corp., Baxter International Inc., Bayer Corporation, Dey, Inc., Fujisawa Healthcare, Inc., Fujisawa USA, Inc., Immunex Corporation, Pharmacia Corporation, Pharmacia & Upjohn LLC (f/k/a Pharmacia & Upjohn, Inc.), Sicom, Inc., Gensia, Inc., Gensia Sicom Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., and ZLB Behring, L.L.C. A hearing before the Massachusetts District Court was held on April 9, 2008, following which the Massachusetts District Court docketed its preliminary approval of the proposed settlement and scheduled a fairness hearing for December 16, 2008.

Johnson & Johnson Matters

Arbitration/Demand for Separate BLA

In March 2008, Ortho Biotech Products, L.P., Ortho Biotech Inc., and Ortho-McNeil Pharmaceutical (each a wholly owned subsidiary of Johnson & Johnson, collectively, "Ortho") and Amgen reached an agreement in principle resolving the claims raised in the arbitration demand.

Ortho Biotech Spillover Arbitration

Ortho Biotech Products, L.P. and Amgen are currently engaged in a joint review of the matters raised in Ortho's demand and have temporarily stayed the arbitration proceedings to pursue this review.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Roche Matters

Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al (“Roche”)

On February 29, 2008, the U.S. District Court for the District of Massachusetts (the “Court”) entered an Order making a preliminary ruling that the jury’s verdict will stand in all respects and that the parties’ post-trial motions are denied. The Order also preliminarily enjoined Roche, for the life of the patents-in-suit, from infringing the claims of the patents-in-suit found to have been infringed. The February 29, 2008 Order also notified the parties that the Court might modify the preliminary injunction to impose a royalty on Roche along with other conditions in lieu of an injunction. On April 2, 2008, the Court denied Roche’s request for a second extension of time to appeal the preliminary injunction or, in the alternative to modify the injunction to impose a royalty in lieu of the preliminary injunction. On April 9, 2008, Roche filed a Notice of Appeal of the preliminary injunction. Still pending before the Court is Amgen’s motion requesting a permanent injunction upon entry of final judgment that would prevent Roche from commercializing MIRCERA® in the United States during the term of Amgen’s patents which have been found to be infringed by Roche. Roche in turn has requested the Massachusetts District Court’s impose a royalty on future sales of MIRCERA® in the United States in lieu of a permanent injunction.

U.S. International Trade Commission (“ITC”)

On March 19, 2008, the United States Court of Appeals for the Federal Circuit issued a ruling on Amgen’s appeal reversing the ITC’s dismissal of the investigation on jurisdictional grounds and remanding the case for further proceeding to determine if infringement has occurred or will occur and to provide a remedy, if appropriate.

Amgen Inc., et al. v. Ariad Pharmaceuticals, Inc. (“Ariad”)

On January 31, 2008, Ariad agreed to dismiss with prejudice its claims of infringement with respect to U.S. Patent Nos. 6,150,090 and 5,804,374 for any of Amgen’s activities as of the date of the dismissal. The United States District Court for the district of Delaware (the “Delaware District Court”) granted the dismissal with prejudice on February 1, 2008. Both parties filed dispositive motions on April 25, 2008. The Delaware District Court will hold a hearing on the motions on June 19, 2008.

Federal Derivative Litigation – Rosenblum v. Sharer et al

On May 1, 2008, plaintiff in Rosenblum v. Sharer et al filed an amended complaint which removes Dennis Fenton as a defendant and also eliminates the claims for insider selling by defendants. Defendants’ response to the amended complaint is currently due on June 3, 2008.

State Derivative Litigation – Larson v. Sharer et al

In the three state shareholder derivative cases consolidated into one action captioned *Larson v. Sharer et al*, an amended consolidated complaint was filed on March 13, 2008, adding Anthony Gringeri as a defendant and removing the causes of action for insider selling and misappropriation of information, violation of California Corporations Code Section 25402, and violation of California Corporations Code Section 25403. Defendants’ demurrers and alternative motion to stay this action were filed on April 14, 2008, and are currently scheduled for hearing on June 10, 2008 in the Superior Court of the State of California, Ventura County.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ERISA Litigation

On February 1, 2008, the plaintiffs in the ERISA class action lawsuit of *Harris v. Amgen Inc. et al* appealed the decision by the U.S. District Court for the Central District of California to dismiss the claims by both plaintiffs Harris and Ramos to the U.S. Court of Appeals for the 9th Circuit.

Third-party Payors Litigation

On April 8, 2008, the Judicial Panel on Multi-District Litigation granted plaintiffs' motion in the United Food & Commercial Workers Central Pennsylvania and Regional Health & Welfare Fund v. Amgen Inc. to centralize the five third-party payor lawsuits into one multi-district litigation ("MDL") case for the purpose of consolidated pretrial proceedings and the five cases are being transferred back to the U.S. District Court for the Central District of California. The cases will be transferred back to the home jurisdictions if and when they are set for trial.

Other

On April 4, 2008, the Attorney General for the State of Louisiana filed a Notice of Dismissal Without Prejudice for the lawsuit filed against Amgen on January 14, 2008 in the Civil District Court for the Parish of Orleans, State of Louisiana.

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those discussed above. 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 consolidated results of operations, financial position or cash flows.

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." 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 Amgen's business. 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, 2007.

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. Aranesp[®] and EPOGEN[®] stimulate the production of red blood cells to treat anemia and belong to a class of drugs referred to as erythropoiesis-stimulating agents, or 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[®], which are used in supportive cancer care, selectively stimulate the production of neutrophils, one type of white blood cell that helps the body fight infections. ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. ENBREL blocks the biologic activity of tumor necrosis factor ("TNF") by inhibiting TNF, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis and psoriasis. For each of the three months ended March 31, 2008 and 2007, our principal products represented 95% of total worldwide product sales. Our international product sales consist principally of European sales of Aranesp[®], Neulasta[®] and NEUPOGEN[®]. International product sales represented approximately 21% and 19% of total product sales for the three months ended March 31, 2008 and 2007, respectively. For additional information about our principal products, their

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approved indications and where they are marketed, see “*Item 1. Business – Principal products*” in Part I of our Annual Report on Form 10-K for the year ended December 31, 2007.

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. Most patients receiving our principal products for approved indications are covered by either government or private payer health care programs. The reimbursement environment is also evolving with greater emphasis on cost containment. Therefore, sales of our principal products are 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. Further, safety signals or adverse events or results from clinical trials or 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 for our approved products or may result in additional regulatory requirements, such as requiring risk management activities and/or additional or more extensive clinical trials as part of postmarketing commitments (“PMCs”) or a pharmacovigilance program, and may negatively impact worldwide reimbursement for our products.

Total product sales for the three months ended March 31, 2008 decreased 1%, principally due to a decline in U.S. Aranesp[®] sales, which was substantially offset by an increase in ENBREL sales. In particular, for the three months ended March 31, 2008, U.S. Aranesp[®] sales declined \$249 million, or 38%, reflecting the negative impact on demand, primarily in the supportive cancer care setting, of ongoing regulatory and reimbursement developments that were principally realized in the second half of 2007. Sales of ENBREL increased \$221 million, or 30%, for the three months ended March 31, 2008. This increase includes an initial wholesaler inventory stocking of approximately \$120 million resulting from the shift to a wholesaler distribution model. During the three months ended March 31, 2008, ENBREL’s distribution model was converted from primarily being drop shipped directly to pharmacies to a wholesaler distribution model similar to our other products. The increase in ENBREL’s sales also reflects higher demand due to increases in both patients and average net sales price.

Certain of our products, principally our marketed ESA products, face various challenges resulting from regulatory and reimbursement developments. Late in 2006 and throughout 2007, adverse safety results involving ESA products were observed in various studies that were performed by us and by others (including our licensees or independent investigators) that explored the use of ESAs in settings different from those outlined in the FDA approved label, including targeting higher hemoglobin (“Hb”) levels and/or use in non-approved patient populations. The results of these studies culminated in significant regulatory and reimbursement developments affecting the class of ESA products, including Aranesp[®] and EPOGEN[®]. For example, in February 2007, following the reported results from our Anemia of Cancer phase 3 study (the “AoC 103 study”), the United States Pharmacopoeia Dispensing Information (“USP DI”) Drug Reference Guides removed Aranesp[®] for use in the treatment of AoC. Thereafter, Aranesp[®] use in AoC decreased significantly. In addition, during 2007, we had ongoing discussions with the FDA and other regulatory authorities and meetings with certain of the FDA’s advisory panels, namely the Oncologic Drugs Advisory Committee (“ODAC”), the Cardiovascular-Renal Drug Advisory Committee (“CRDAC”) and the Drug Safety and Risk Management Advisory Committee (“DSaRMAC”), regarding the administration of our ESA products in certain settings. These adverse safety results involving ESA products in various studies and related discussions with regulatory authorities led to several key regulatory and reimbursement developments, including safety-related revisions to ESA product labels in the United States in March and November 2007. Further, in July 2007, the Centers for Medicare and Medicaid Services (“CMS”) issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the “Decision Memorandum”). The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia (“CIA”) with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice,

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for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy. These developments have had a material adverse impact on sales of our marketed ESA products, in particular Aranesp[®] sales in the U.S. supportive cancer care setting. Furthermore, our ESA products continue to face future challenges, including those described below under “*ESA Developments*” and also the potential for further revisions to product labels and changes to reimbursement. In addition, increased competition, including additional approved indications for existing products, has and will continue to present challenges to certain of our products.

As a result of the challenges facing certain of our products and, in particular, the regulatory and reimbursement developments involving our marketed ESA products that began in 2007 and their resulting impact on our operations, on August 15, 2007, we announced a plan to restructure 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. Through March 31, 2008, we have completed a majority of the actions included in our restructuring plan and expect that all remaining actions will be substantially completed in 2008. Key components of our restructuring plan include: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases for certain R&D facilities that will not be used in our operations. We currently anticipate that we will incur approximately \$775 million to \$825 million of restructuring charges in connection with these actions, of which \$751 million has been incurred through March 31, 2008.

The following is a discussion of select key developments affecting our business that occurred in 2008 and should be read in conjunction with “*Item 1. Business – Key Developments*” in Part I of our Annual Report on Form 10-K for the year ended December 31, 2007.

ESA Developments

- On January 1, 2008, the CMS’ revisions to its Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (“EMP”) became effective which require a 50% reduction in Medicare reimbursement if a patient’s Hb is above 13 grams per deciliter (“g/dL”) for three or more consecutive months. In addition, the EMP reduces 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. We believe that the EMP implementation in January 2008 has significantly impacted physician behavior resulting in declines in dosing trends, however we believe that the pronounced dose declines, which have been observed in the quarter of implementation, will moderate in subsequent quarters, as has been observed with prior years’ EMP changes.
- On March 13, 2008, the FDA held a follow-up ODAC panel meeting to discuss cumulative data, including recent study results, on the risks of ESAs when used in the oncology setting. Responding to questions posed by the FDA, the ODAC members discussed (i) continuing to allow the marketing of ESAs for use in the treatment of anemia due to concomitant cancer chemotherapy, (ii) restricting the use of ESAs to only patients with small cell lung cancer, (iii) including a statement that ESA use is not indicated for patients receiving potentially curative treatments, (iv) including a statement that ESA use is not indicated for patients with breast and/or head and neck cancers, (v) requiring the implementation of an informed consent/patient agreement for the treatment of CIA and (vi) restricting the distribution system for oncology patients receiving ESAs. The ODAC is an advisory committee of external experts who advise the FDA about the safety and efficacy of drug products for use in treating cancer patients. 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. We are in ongoing discussions with the FDA and, in connection with the available safety data, including the data and study results discussed at the ODAC, the FDA has asked us to (i) propose additional safety-related changes to the labeling for Aranesp[®] and EPOGEN[®], (ii) develop a proposed risk evaluation and mitigation strategy (“REMS”) for Aranesp[®] and

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EPOGEN® and (iii) conduct clinical trials to determine the effects of Aranesp® and EPOGEN® on survival and tumor outcomes. We are in the process of preparing the submissions responsive to the FDA's recent requests.

- On March 7, 2008, we announced that the FDA approved updated safety information, including an updated boxed warning in the labeling information for the class of ESAs, including Aranesp® and EPOGEN®. The updated boxed warning states that ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers when dosed to a target Hb of greater than or equal to 12 g/dL. In the "Increased Mortality and/or Tumor Progression" warning section of the updated labeling, the interim results of the Preoperative Epirubicin Paclitaxel Aranesp® ("PREPARE") study in neo-adjuvant breast cancer were added as well as follow up data from the Gynecologic Oncology Group study ("GOG-191 study") in cervical cancer.
- On March 5, 2008, we announced that the European Commission reached its decision to amend the prescribing information ("PI") for the class of ESAs, including Aranesp®, based on the positive opinion from the European Committee for Medicinal Products for Human Use ("CHMP") in January 2008. This includes stipulating a uniform target Hb range of 10 g/dL to 12 g/dL with guidance to avoid sustained Hb levels above 12 g/dL. In addition, on May 6, 2008, we announced that the CHMP has requested that we and other ESA marketing authorization holders participate in a closed meeting of the Scientific Advisory Group on Oncology ("SAG-O") on May 15, 2008. The marketing authorization holders have been asked to provide an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients. These data include previously disclosed interim results from the PREPARE study in neoadjuvant breast cancer therapy; follow-up data from the GOG-191 study in cervical cancer, which were published in the February 2008 issue of Gynecologic Oncology; and the February 2008 meta-analysis by Bennett et al, which was published in the Journal of the American Medical Association. Scientific Advisory Groups ("SAGs") are created by the CHMP to deliver answers, on a consultative basis, to specific questions addressed to them by the CHMP. The CHMP, while taking into account the position expressed by the SAG, remains responsible for its final opinion.

Other Regulatory Developments

- On March 17, 2008, we and Wyeth Pharmaceuticals, a division of Wyeth, announced updates to the FDA approved PI for ENBREL in which the U.S. PI now contains a boxed warning relating to the risk of infections, including tuberculosis. This information now in the boxed warning includes additional language regarding screening and monitoring patients for tuberculosis, including patients who tested negative for latent tuberculosis infection.
- On May 1, 2008, we announced that the FDA has asked us to participate in a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee ("DODAC") on June 18, 2008 to review data supporting the supplemental biologic license application ("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.
- On March 12, 2008, the ODAC voted unanimously that the data from our two phase 3 clinical studies evaluating Nplate™ (Romiplostim) for the treatment of thrombocytopenia in immune (idiopathic) thrombocytopenic purpura ("ITP"), which met both primary and secondary endpoints, supports a positive risk/benefit profile for Nplate™. The FDA has required us to submit a REMS as part of our BLA for Nplate™, which extended its Prescription Drug User Fee Act ("PDUFA") date

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from April 23, 2008 to July 23, 2008. As noted above, the ODAC 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 December 2007, Vectibix[®] (panitumumab) was granted a conditional marketing authorization by the European Commission for the treatment of metastatic carcinoma of the colon or rectum after failure of standard chemotherapy and was launched in several European countries in the first quarter of 2008.

Licensing Developments

- In April 2008, we entered into a license agreement with Kyowa Hakko Kogyo Co., Limited (“Kyowa Hakko”), which provides us the exclusive rights to develop and commercialize Kyowa Hakko’s humanized monoclonal antibody KW-0761, which is in phase 1 clinical trials, worldwide, except in Japan, Korea, China and Taiwan. We initially acquired rights in all non-oncology indications and may elect to expand the license to include oncology at a later date. In connection with entering into the agreement, we recorded a R&D expense in April 2008 for the required \$100 million (approximately \$62 million, net of tax) up-front payment.

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 on-going clinical trials and trial initiation. These efforts will assist in allowing us to provide continued support of key activities including (i) current and future postmarketing studies, including those with respect to our ESA products, Aranesp[®] and EPOGEN[®]; (ii) regulatory affairs, safety and compliance functions; (iii) clinical studies to advance our late-stage pipeline; (iv) the advancement of earlier stage compounds and (v) research efforts in the core areas of oncology, inflammation, bone and metabolic disorders. Further, in order to continue advancing our expanding pipeline of product candidates and to assist in ensuring that patients around the world are able to benefit from our future products, we may seek partners to develop selected product candidates in our pipeline in certain countries and/or worldwide. We may also divest of certain less significant marketed products.

For the three months ended March 31, 2008, net income and diluted earnings per share were \$1.1 billion and \$1.04, respectively. As of March 31, 2008, cash, cash equivalents and marketable securities were \$8.6 billion, of which approximately \$4.5 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds are 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. Our total debt outstanding was \$11.2 billion as of March 31, 2008.

There are also many economic and industry-wide factors that affect our business generally and uniquely, 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; increasingly intense competition for marketed products and product candidates; 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, 2007 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.

Reimbursement

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. Generally, 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. Further, 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 safety labeling for our approved products and may negatively impact worldwide reimbursement for our products. On July 30, 2007, the CMS issued its Decision Memorandum and on January 14, 2008, issued changes to its Medicare National Coverage Determinations Manual, effective for claims with dates of service on or after July 30, 2007, with an implementation date of April 7, 2008. A discussion of the Decision Memorandum follows below. (See also “*Item 1A. Risk Factors — Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products 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.*”)

Most patients receiving Aranesp[®], Neulasta[®] and NEUPOGEN[®] for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare programs’ payment policies for drugs and biologicals are subject to various laws and regulations. Beginning in January 1, 2005 under the Medicare Prescription Drug Improvement and Modernization Act (the “MMA”), in the physician clinic setting and January 1, 2006, in the hospital outpatient and dialysis settings, Aranesp[®], Neulasta[®] and NEUPOGEN[®] have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its average sales price (“ASP”) (sometimes referred to as “ASP+6%”). Effective January 1, 2008, Medicare payment in the hospital outpatient setting reimburses each product at 105% of its ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product’s ASP is calculated on a quarterly basis and therefore 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 2008 will be based in part on certain historical sales and sales incentive data for Aranesp[®] from April 1, 2007 through March 31, 2008. CMS publishes the ASPs for products in advance of the quarter in which they go into effect.

In the United States, dialysis providers are primarily reimbursed for EPOGEN[®] by the federal government through the End Stage Renal Disease (“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. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN[®] and Aranesp[®], is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. Beginning in the third quarter of 2007, based on its ongoing assessment for payment of Part B drugs, CMS instituted a single payment limit for Epoetin alfa (EPOGEN[®] and PROCRI[®]) in all provider settings. Although we cannot predict the payment levels of EPOGEN[®] in future quarters or whether Medicare payments for dialysis drugs may be modified by future federal 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, dialysis facility 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

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prospectively and retroactively. 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 a revised Hematocrit Measurement Audit Program Memorandum (“HMA-PM”), a Medicare payment review mechanism used by CMS to monitor EPOGEN[®] and Aranesp[®] utilization and appropriate hematocrit outcomes of dialysis patients. This policy, 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 reduces the monthly dosing limits to 400,000 IUs of EPOGEN[®], from 500,000 IUs, and to 1,200 mcgs of Aranesp[®], from 1,500 mcgs. The implementation of the revised EMP and ESA label changes have 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. We believe that pronounced dose declines, which have been observed in the quarter of EMP implementation, will moderate in subsequent quarters, as has been observed with prior years’ EMP changes.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005, 2006 and 2007 were not significantly impacted by the reimbursement changes resulting from the MMA. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales in the future. For example, the MMA required a report to Congress and a demonstration project with regard to a bundled payment system for dialysis, including separately billable drugs and EPOGEN[®]. The report to Congress was issued on February 20, 2008, but the demonstration project, which was scheduled to start in January 2006, has been delayed with no announced start date. Bundling initiatives that have been implemented in other healthcare settings have resulted in lower utilization of services that had not previously been a part of the bundled payment. Because CMS is continuing to study bundled payments in the ESRD setting and legislation is possible, we cannot predict what impact a bundled payments system would have on sales of EPOGEN[®] or Aranesp[®] used in the treatment of persons receiving outpatient dialysis services.

In addition, in response to CMS considering and rejecting changes to the ASP calculation methodology for accounting for discounts in multi-product contracts in the 2007 Medicare Physician Fee Schedule Final Rule, MedPAC released its second Congressionally-mandated report on December 29, 2006 on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements “to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.” Under the ASP system, we allocate our discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Referencing a MedPAC December 2006 report, CMS proposed in the Medicare Physician Fee Schedule Proposed Rule for 2008 revising the methodology for calculating ASP to require the reallocation of price concessions of drugs sold under “bundled arrangements,” described by CMS in part as an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement. In the Medicare Physician Fee Schedule Final Rule for 2008, CMS stated that it was not finalizing the proposed regulatory change at this time, based on comments recommending a delay and raising concerns about the proposal. The agency also clarified that in the absence of specific guidance, manufacturers may continue to make “reasonable assumptions” in the calculation of ASP, consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices. The agency stated that it will continue to monitor this issue and may provide more specific guidance in the future. Related to this issue, CMS issued a final Medicaid rule on July 6, 2007 that covered a broad range of topics concerning the calculation and use of average manufacturing price (“AMP”) and best price as well as a definition for bundled sales under the Medicaid program. Although it has minor differences, the definition of “bundled sale” under this rule is essentially the same as what CMS proposed under the definition of “bundled arrangement” in

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the Medicare Physician Fee Schedule Proposed Rule for 2008 but which was not adopted for ASP reporting in the Final Rule for 2008. We continue in the process of evaluating what impact the final Medicaid rule will have on our business.

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 label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a national coverage analysis (“NCA”) which is generally CMS’ first step toward developing a national coverage determination (“NCD”). Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. On May 14, 2007, CMS issued the proposed NCD following a review of data and public comments submitted as part of the NCA, which under the MMA, was subject to a 30-day public comment period that ended 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. The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy.

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, based on our knowledge, although no private payers have implemented the Decision Memorandum to date, many private payers have implemented the restrictions included in the Decision Memorandum. Further, due to difficulties in administering a two-tier medical practice, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage.

In addition, the FDA held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. Although CMS has made no announcement of a nephrology focused NCA, any 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, would 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.

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Results of Operations

For the three months ended March 31, 2008 and 2007, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	Three months ended March 31,		Change
	2008	2007	
Aranesp®	\$ 761	\$ 1,020	(25)%
EPOGEN®	554	625	(11)%
Neulasta®/NEUPOGEN®	1,086	1,018	7%
ENBREL	951	730	30%
Sensipar®	133	105	27%
Vectibix®	34	51	(33)%
Other	18	16	13%
Total product sales	<u>\$ 3,537</u>	<u>\$ 3,565</u>	(1)%
Total U.S.	<u>\$ 2,788</u>	<u>\$ 2,884</u>	(3)%
Total International	749	681	10%
Total product sales	<u>\$ 3,537</u>	<u>\$ 3,565</u>	(1)%

Product sales are influenced by a number of factors, including demand, third-party reimbursement availability and policies, government programs, regulatory developments or guidelines, clinical trial outcomes, clinical practice, pricing strategies, wholesaler and end-user inventory management practices, patient population, fluctuations in foreign currency exchange rates, new product launches and indications, competitive products, product supply and acquisitions.

Total product sales for the three months ended March 31, 2008 decreased 1%, principally due to a decline in U.S. Aranesp® sales, which was substantially offset by an increase in ENBREL sales. In particular, for the three months ended March 31, 2008, U.S. Aranesp® sales declined \$249 million, or 38%, reflecting the negative impact on demand, primarily in the supportive cancer care setting, of ongoing regulatory and reimbursement developments that were principally realized in the second half of 2007. Sales of ENBREL increased \$221 million, or 30%, for the three months ended March 31, 2008, which includes an initial wholesaler inventory stocking of approximately \$120 million resulting from the shift to a wholesaler distribution model. During the three months ended March 31, 2008, ENBREL's distribution model was converted from primarily being drop shipped directly to pharmacies to a wholesaler distribution model similar to our other products. The increase in ENBREL sales in the first quarter of 2008 also reflects higher demand due to increases in both patients and average net sales price. Total international product sales for the three months ended March 31, 2008 increased 10% and were favorably impacted by \$72 million from foreign currency exchange rate changes. Excluding the favorable impact of foreign currency exchange rate changes, international product sales decreased 1% over the three months ended March 31, 2007.

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Aranesp®

For the three months ended March 31, 2008 and 2007, total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended March 31,		Change
	2008	2007	
Aranesp® - U.S.	\$ 405	\$ 654	(38)%
Aranesp® - International	356	366	(3)%
Total Aranesp®	<u>\$ 761</u>	<u>\$ 1,020</u>	(25)%

The decrease in U.S. Aranesp® sales for the three months ended March 31, 2008 reflects the negative impact on demand, primarily in the supportive cancer care setting, of physician conformance to ongoing regulatory and reimbursement developments, which were principally realized in the second half of 2007, and a slight decline in our segment share. This decrease in Aranesp® sales was partially offset by a slight benefit from a change in accounting estimates related to sales return reserves. The regulatory and reimbursement developments include in particular, (i) the CMS' Decision Memorandum issued in July 2007, which significantly restricted Medicare reimbursement for use of Aranesp® in CIA and which we believe has also negatively impacted Aranesp® use in CIA for patients covered by private insurance plans, (ii) the loss of Aranesp® for use in the treatment of AoC and (iii) the March 9, 2007 and November 8, 2007 product safety-related label changes in the United States. During the latter part of the three months ended December 31, 2007 and during the three months ended March 31, 2008, Aranesp® sales were relatively stable as we realized only a slight decrease in underlying demand.

The decrease in international Aranesp® sales for the three months ended March 31, 2008 principally reflects continued ESA dosing conservatism and pricing pressures in Europe, partially offset by changes in foreign currency exchange rates, which positively impacted sales by approximately \$35 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales for the three month period decreased 12%. Through March 31, 2008, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total international Aranesp® sales.

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

- regulatory developments, including those resulting from:
 - i product safety-related label changes occurring on March 7, 2008 in the United States for the class of ESAs, including Aranesp®, as a result of discussions with the FDA regarding safety data from the PREPARE and GOG-191 studies;
 - i pending additional product label changes in the United States for the class of ESAs, including Aranesp®, resulting from the ODAC meeting on March 13, 2008;
 - i product PI changes occurring on March 5, 2008 in Europe for the class of ESAs, including Aranesp®, by the European Commission and the potential for further changes resulting from additional regulatory review;
 - i outcome of the SAG-O meeting on May 15, 2008 to review an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients;

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- i future product label changes;
 - i risk management activities undertaken by us or required by the FDA or other regulatory authorities, including a REMS;
 - reimbursement developments, including those resulting from:
 - i government's and/or third-party payer's reaction to recent or future product label changes;
 - i current or future cost containment pressures by third-party payers, including governments and private insurance plans;
 - our ability to maintain segment share and differentiate Aranesp[®] from current and potential future competition, including through pricing strategies;
 - adverse events or results from clinical trials or studies 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 products;
 - an increasingly competitive environment of products or therapies, which have launched in certain countries outside of the United States, for example Roche's NeoRecormon[®] and peg-EPO product, MIRCERA[®], and Shire Pharmaceutical Group Plc's ("Shire's") erythropoietin product, Dynepo[®] (Epoetin delta), and biosimilar products that have been or are expected to be launched in the future; and
 - development of new treatments for cancer and future chemotherapy treatments. For example, those that are less myelosuppressive may require less Aranesp[®];
- any or all of which 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[®]

For the three months ended March 31, 2008 and 2007, total EPOGEN[®] sales were as follows (dollar amounts in millions):

	Three months ended March 31,		Change
	2008	2007	
EPOGEN [®] - U.S.	\$ 554	\$ 625	(11)%

The decrease in EPOGEN[®] sales for the three months ended March 31, 2008 was primarily driven by a reduction in dose/utilization due to ESA label changes and the CMS' revisions to its EMP, that became effective January 1, 2008, as well as unfavorable wholesaler inventory changes and unfavorable revised estimates of dialysis demand (primarily spillover) for prior quarters (see Note 1, "Summary of significant accounting policies – Product sales" to the Condensed Consolidated Financial Statements for further discussion).

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We believe that the EMP implementation in January 2008 has significantly impacted physician behavior resulting in declines in dosing trends, however we believe that the pronounced dose declines, which have been observed in the quarter of implementation, will moderate in subsequent quarters, as has been observed with prior years' EMP changes.

In addition to the 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:
 - i changes in healthcare providers' prescribing behavior resulting in dose declines due to the CMS' revisions to its EMP, which became effective January 1, 2008;
 - i the federal government's reaction to recent or future product label changes;
 - i changes in reimbursement rates or changes in the basis for reimbursement by the federal government;
- regulatory developments, including those resulting from:
 - i future product label changes;
 - i risk management activities undertaken by us or required by the FDA, including a REMS;
- 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 or studies 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;
- cost containment pressures from the federal government on healthcare providers;
- pricing strategies; and
- changes in future patient population growth or dose/utilization;

any or all of which 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.

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Neulasta®/NEUPOGEN®

For the three months ended March 31, 2008 and 2007, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended March 31,		Change
	2008	2007	
Neulasta® - U.S.	\$ 569	\$ 573	(1)%
NEUPOGEN® - U.S.	223	204	9%
U.S. Neulasta®/NEUPOGEN® - Total	792	777	2%
Neulasta® - International	187	146	28%
NEUPOGEN® - International	107	95	13%
International Neulasta®/NEUPOGEN® - Total	294	241	22%
Total Worldwide Neulasta®/NEUPOGEN®	\$ 1,086	\$ 1,018	7%

The increase in U.S. sales of Neulasta®/NEUPOGEN® for the three months ended March 31, 2008 was primarily driven by higher demand for Neulasta® primarily reflecting increases in average net sales price, partially offset by unfavorable wholesaler inventory changes. The increase in international Neulasta®/NEUPOGEN® sales for the three months ended March 31, 2008 reflects changes in foreign currency exchange rates, which positively impacted first quarter combined international sales by \$28 million, as well as increased demand driven by continued conversion from NEUPOGEN® to Neulasta®. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 10%.

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

- penetration of existing segments;
- competitive products or therapies, including biosimilar products that have been or may be approved in the European Union (“EU”) sometime in 2008 and be available shortly thereafter. For example, in February 2008, Teva Pharmaceuticals Industries Limited (“Teva”) received a positive opinion from the CHMP for its G-CSF biosimilar product, TevaGrastim®, and is expected to launch in the EU in the second quarter of 2008;
- reimbursement by third-party payers, including governments and private insurance plans;
- adverse events or results from clinical trials or studies performed by us or by others (including our licensees or independent investigators), which could expand 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 products;
- cost containment pressures from governments and private insurers on healthcare providers;
- our ability to minimize healthcare provider distraction from Neulasta®/NEUPOGEN® due to ESA issues;
- pricing strategies;

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- patient growth; and
- development of new treatments for cancer and future chemotherapy treatments. For example, those that are less myelosuppressive may require less Neulasta®/NEUPOGEN®, however, other future chemotherapy treatments that are more myelosuppressive, such as dose dense chemotherapy, could require more Neulasta®/NEUPOGEN®.

See “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

For the three months ended March 31, 2008 and 2007, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Three months ended March 31,		Change
	2008	2007	
ENBREL - U.S.	\$ 904	\$ 693	30%
ENBREL - International	47	37	27%
Total ENBREL	<u>\$ 951</u>	<u>\$ 730</u>	30%

ENBREL sales growth for the three months ended March 31, 2008 includes an initial wholesaler inventory stocking of approximately \$120 million resulting from the shift to a wholesaler distribution model in the first quarter of 2008. During the three months ended March 31, 2008, ENBREL’s distribution model was converted from primarily being drop shipped directly to pharmacies to a wholesaler distribution model similar to our other products. We believe that this estimated initial wholesaler inventory stocking is within the expected normal inventory range. The increase in ENBREL sales in the first quarter of 2008 also reflects higher demand due to increases in both patients and average net sales price. While ENBREL continued to maintain a leading position in both rheumatology and dermatology, the sales growth during the three months ended March 31, 2008 was affected by slight share declines in the United States in both segments versus the first quarter of 2007 due to increased competitive activity.

In addition to the factors mentioned in the “Product sales” section above, future worldwide ENBREL sales growth will be dependent, in part, on such factors as:

- the effects of competing products or therapies, which may include new indications for existing products and new competitive products coming to market, such as J&J’s CNTO 1275 (ustekinumab) and CNTO 148 (golimumab) and, in part, our ability to differentiate ENBREL based on its safety profile and efficacy;
- recent or future product label changes;
- risk management activities undertaken by us or required by the FDA or other regulatory authorities;
- growth in the rheumatology and dermatology segments;
- outcome of the DODAC meeting on June 18, 2008 to review data supporting the supplemental BLA submitted by us for the use of ENBREL in treating pediatric patients with chronic moderate to

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- severe plaque psoriasis, who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy;
- the availability, extent and access to reimbursement by government and third-party payers;
- adverse events or results from clinical trials or studies performed by us or by others (including our licensees or independent investigators), which could expand 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 products;
- cost containment pressures from governments and private insurers on healthcare providers;
- pricing strategies; and
- penetration of existing and new segments, including potential expanded indications.

See “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 for the three months ended March 31, 2008 and 2007 (dollar amounts in millions):

	Three months ended		Change
	March 31,		
	2008	2007	
Product sales	\$3,537	\$3,565	(1)%
Operating expenses:			
Cost of sales (excludes amortization of acquired intangible assets)	\$ 546	\$ 592	(8)%
% of product sales	15%	17%	
Research and development	\$ 694	\$ 851	(18)%
% of product sales	20%	24%	
Selling, general and administrative	\$ 874	\$ 770	14%
% of product sales	25%	22%	
Amortization of acquired intangible assets	\$ 74	\$ 74	0%
Other	\$ 10	\$ —	100%

Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see “Condensed Consolidated Statements of Income”), decreased 8% during the three months ended March 31, 2008 primarily driven by lower Aranesp[®] sales volume and reduced product scrap charges partially offset by a higher cost product mix attributable to increased ENBREL sales and a \$26 million write-off of a semi-completed manufacturing asset during the three months ended March 31, 2007.

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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 and amortization of technology used in R&D with alternative future uses. R&D expenses consist of internal R&D costs, costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of KA, and costs 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. R&D collaborations resulting in a net payment or reimbursement of R&D costs are recognized as the obligation has been incurred or we become entitled to the cost recovery.

R&D expenses decreased 18% for the three months ended March 31, 2008, which was primarily attributable to decreases of \$64 million in staff-related costs and other expense reductions principally resulting from the previously announced restructuring plan, \$36 million from cost recoveries derived from licensing transactions with Daiichi Sankyo Company, Limited and Takeda Pharmaceutical Company Limited (“Takeda”) in Japan and \$41 million of clinical trial costs. Clinical trial costs decreased as some of our large clinical trials completed enrollment and the significant costs associated with site initiation and patient enrollment are no longer being incurred.

Selling, general and administrative

SG&A expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel; outside marketing expenses; overhead and facilities costs and other general and administrative costs. For the three months ended March 31, 2008, the 14% increase in SG&A is primarily driven by higher Wyeth profit expense due to higher ENBREL sales, which accounted for approximately three quarters of the increase. For the three months ended March 31, 2008 and 2007, the Wyeth profit share expense as a percentage of total SG&A, was approximately one third and 30%, respectively.

Amortization of acquired intangible assets

Amortization of acquired intangible assets relates to the acquired product technology rights acquired in connection with the Immunex acquisition.

Other

As discussed in Note 2, “*Restructuring*” to the Condensed Consolidated Financial Statements, on August 15, 2007, we announced plans to restructure 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 a result of this restructuring plan, we recorded the following charges during the three months ended March 31, 2008: (i) staff separation costs of \$4 million, (ii) asset impairment charges of \$2 million and (iii) other charges of \$4 million.

Interest and other income and (expense), net

Interest and other income and (expense), net for the three months ended March 31, 2008 was \$22 million of income compared to \$6 million of expense for the three months ended March 31, 2007. This change is primarily due to the rebalancing of investments in our marketable securities portfolio which resulted in net realized gains of approximately \$30 million during the three months ended March 31, 2008 and the write-off of \$51 million of deferred financing and related costs in March 2007 resulting from the repayment of certain of our convertible debt, partially offset by the incremental interest expense of approximately \$53 million related to the \$4.0 billion of debt issued in May 2007.

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Income taxes

Our effective tax rate for the three months ended March 31, 2008 was 21.0%, compared with 20.3% for the same period last year. The increase in our effective tax rate for the three months ended March 31, 2008 compared to the three months ended March 31, 2007 was primarily due to the expiration of the federal research and experimentation tax credit (“R&E Credit”) on December 31, 2007, partially offset by a proportionate increase in the amount of foreign earnings intended to be invested indefinitely outside of the United States relative to total pretax income.

See Note 4, “*Income taxes*” to the Condensed Consolidated Financial Statements for further discussion.

Recent and proposed accounting pronouncements

In December 2007, the FASB issued SFAS No. 141(R), “*Business Combinations*” and SFAS No. 160, “*Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51*”. These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing at the acquisition date the fair value of acquired IPR&D, and testing for impairment and writing down these assets, if necessary, in subsequent periods during their development. These new standards will be applied prospectively for business combinations that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively.

In December 2007, the FASB ratified EITF No. 07-1, “*Accounting for Collaborative Agreements*”. EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements we have entered into regarding development and commercialization of products and product candidates. EITF 07-1 is effective for us as of January 1, 2009, and its adoption is not expected to have a material impact on our condensed consolidated results of operations or financial position.

In August 2007, the FASB exposed for public comment a proposed FASB Staff Position (“FSP”) that would change the method of accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion (“cash settled convertible debt securities”), which includes our convertible debt securities, and would require the proposed method to be retrospectively applied. During its March 2008 deliberations, the FASB affirmed the proposed method of accounting and decided to delay the effective date of the final FSP for calendar year end companies like us to the first quarter of 2009. The FASB currently indicates that it expects to take a final vote on and, if approved, issue the final FSP in the second quarter of 2008. Under this proposed method of accounting, the debt and equity components of our convertible debt securities would be bifurcated and accounted for separately in a manner that would result in recognizing interest on these securities at effective rates more comparable to what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities would be included in the paid-in-capital section of stockholders’ equity on our Consolidated Balance Sheet and, accordingly, the initial carrying values of these debt securities would be reduced. Our net income for financial reporting purposes would be reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amounts as additional non-cash interest expense. Therefore, if the FASB issues the final FSP to change the method of accounting for cash settled convertible debt securities as described above, it would have a material adverse impact on our past and future reported financial results. We cannot predict any other changes in GAAP that may be made which would affect accounting for convertible debt securities and which could have an adverse impact on our past or future reported financial results.

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Financial Condition, Liquidity and Capital Resources

The following table summarizes selected financial data (in millions):

	March 31, 2008	December 31, 2007
Cash, cash equivalents and marketable securities	\$ 8,647	\$ 7,151
Total assets	36,128	34,639
Current debt	2,000	2,000
Non-current debt	9,177	9,177
Stockholders' equity	19,087	17,869

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, as well as to support our stock repurchase programs and other business initiatives, including acquisitions and licensing activities. We have \$2.0 billion of floating rate notes due in November 2008 and we are currently exploring alternatives to refinance opportunistically.

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at March 31, 2008, approximately \$4.5 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds are 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.

Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of March 31, 2008 and December 31, 2007 (in millions):

	March 31, 2008	December 31, 2007
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$ 2,500	\$ 2,500
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	2,500
Floating rate notes due 2008 (2008 Floating Rate Notes)	2,000	2,000
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	999	999
6.375% notes due 2037 (2037 Notes)	899	899
Other	180	180
Total borrowings	11,177	11,177
Less current portion	2,000	2,000
Total non-current debt	\$ 9,177	\$ 9,177

On April 17, 2008, we filed a shelf registration statement with the SEC, which replaced our previous \$1.0 billion shelf registration statement, which allows us to issue an unspecified amount of debt securities, common stock, preferred stock, warrants to purchase debt securities, common stock, preferred stock or

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depository shares, rights to purchase common stock or preferred stock, securities purchase contracts, securities purchase units and depository shares. Under this registration statement, all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance.

In May 2008, we increased our commercial paper program by \$1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of \$2.5 billion. We also have a \$2.5 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper backup, which matures in November 2012. No amounts were outstanding under the commercial paper program or credit facility as of March 31, 2008.

Certain of our financing arrangements contain non-financial covenants and as of March 31, 2008 we were in compliance with all applicable covenants. None of our financing arrangements contain any financial covenants. Our outstanding convertible notes and our outstanding long-term notes are rated "A+" with a negative outlook by Standard & Poor's, "A2" under review for possible downgrade by Moody's Investors Service, Inc. and "A" with a stable outlook by Fitch, Inc.

See "*Recent and proposed accounting pronouncements*" for a discussion of potential future impacts to the accounting for our convertible debt.

Cash flows

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

	Three months ended March 31,	
	2008	2007
Net cash provided by operating activities	\$ 1,582	\$ 893
Net cash provided by investing activities	697	927
Net cash provided by (used in) financing activities	21	(2,036)

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 three months ended March 31, 2008 increased primarily due to a decrease in disbursements from the timing of payments in the normal course of business and the receipt of \$300 million for an upfront milestone payment related to our licensing agreement with Takeda, which is included in the "Changes in deferred revenue" in the Condensed Consolidated Statements of Cash Flows.

Investing

Capital expenditures totaled \$170 million during the three months ended March 31, 2008, compared with \$325 million during the same period last year. The capital expenditures during the three months ended March 31, 2008 were primarily associated with manufacturing capacity expansions in Puerto Rico and Fremont, other site developments and investment in our global enterprise resource planning ("ERP") system. The capital expenditures during the three months ended March 31, 2007 were primarily associated with manufacturing capacity expansions in Puerto Rico and other locations and investment in our global ERP system. We currently estimate 2008 spending on capital projects and equipment to be approximately \$900 million.

Financing

During the three months ended March 31, 2008, we did not repurchase any shares of our common stock. During the three months ended March 31, 2007, we repurchased 8.8 million shares of our common stock at a total cost of \$537 million. As of March 31, 2008, we had \$6.4 billion available for stock repurchases under the \$5.0 billion repurchase authorization received from the Board of Directors in July 2007 and amounts remaining from the Board of Director's previous authorization in December 2006. The manner of purchases, amounts 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. Repurchases under our stock repurchase programs reflect, in

part, our confidence in the long-term value of Amgen common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders.

For additional information regarding our stock repurchase program, see “*Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities*” in Part II herein.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock. Employee stock option exercises provided \$28 million and \$138 million of cash during the three months ended March 31, 2008 and 2007, 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.

On March 2, 2007, as a result of holders of substantially all of our outstanding 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we purchased \$2.3 billion aggregate principal amount, or the majority of the then outstanding convertible notes at their then-accreted value for \$1.7 billion in cash.

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 March 31, 2008.

Management determined that, as of March 31, 2008, 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 8, “Contingences” 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, 2007.

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 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 European Agency for the Evaluation of Medicinal Products (“EMA”) in European countries, 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 fail 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. On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (the “FDAAA”), 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 as the FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on distribution or use of a product. Failure to comply with the new requirements, if imposed on a sponsor by the FDA under the FDAAA, could result in significant civil monetary penalties. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

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 remains costly to maintain. With the occurrence of a

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number of high profile safety events with certain pharmaceutical products, regulatory authorities, and in particular the FDA, members of Congress, the U.S. Government Accountability Office (“GAO”), 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, we have received letters from both 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, promotions of our ESAs and other products, 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 changes could have a material or adverse effect on the use of our ESA products.

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 fewer treatments being approved by the FDA or other regulatory bodies, 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 (until additional clinical trials can be designed and completed), mandated PMCs, pharmacovigilance programs for approved products or 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 by therapeutic area, 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 payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.*”)

Certain specific labeling or label changes of 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 by regulatory agencies, the discovery of significant problems 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 performed by us or others. 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 2008, the labels of 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. We continue to be in discussion with the FDA to complete further revisions to our ESA labels. (See “– *The potential future labeling changes or risk management activities including those discussed at the March 13, 2008 ODAC meeting may adversely impact the use, sales and reimbursement of our ESAs.*”) On March 17, 2008, we and Wyeth announced updates to the FDA approved PI for ENBREL in which the U.S. PI now contains a boxed warning relating to the risk of infections, including tuberculosis. This information now in the boxed warning includes additional language regarding screening and monitoring patients for tuberculosis, including patients who tested negative for latent tuberculosis infection. Additionally, on May 1, 2008, we announced that the FDA has asked us to participate in a meeting of the DODAC on June 18, 2008 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. Although we cannot predict what action, if any, the FDA may take or require of us or what recommendations may arise from the DODAC meeting, a recommendation by the DODAC not to approve the new indication or any further revisions to the ENBREL label could have a negative impact on the use and sales of ENBREL. Additionally, the FDA previously instituted a class label change for the class of ESAs to add information about pure red cell aplasia (“PRCA”) to the adverse event profile section and for the boxed warning in the PI of the label described above. 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. Also in October 2007, we announced that we and the FDA

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adopted changes to the U.S. PI 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 metastatic colorectal cancer (“mCRC”). Vectibix[®] is not indicated for the first-line treatment of mCRC and the new safety information applies to an unapproved use of Vectibix[®].

In addition, 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 EMEA may impose risk management activities upon us at substantial costs 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, any of which could have a negative affect on our ability to launch the product candidate and could have a material adverse effect on sales of the affected products and on our business and results of operations. For example, the FDA required us to submit a REMS as part of the BLA for Nplate[™] which extended its PDUFA date from April 23 to July 23, 2008. Regulatory agencies such as the FDA could also require us to engage in risk management activities, including a REMS, which could modify or restrict our existing promotional activities, restrict or encumber the ability of healthcare providers to prescribe, dispense or use our products or limit patient access to our products. In addition to our ESA products, we have ongoing PMC studies for substantially all of our marketed products other than Sensipar[®]. 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 certain cancer indications. (See “– *The potential future labeling changes or risk management activities including those discussed at the March 13, 2008 ODAC meeting may adversely impact the use, sales and reimbursement of our ESAs.*”) Additionally, the 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. If results from mandated clinical trials as part of a PMC or pharmacovigilance program are negative or any risk management activities resulted in decreased use of our products, it 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 suggests 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. Although there have been no observable adverse event trends associated with the Neulasta[®] SureClick[™] pre-filled pen or with the reports of missing, detached or loose rubber caps on the needleless syringe packaged with the ENBREL vials, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends. Additionally, if other parties (including our licensees, such as J&J and Wyeth, or independent investigators) 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 imposed by regulators.

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

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or 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 resulted in revised safety 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 payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.” and “– Guidelines and recommendations published by various organizations can reduce the use of our products.”)

The potential future labeling changes or risk management activities including those discussed at the March 13, 2008 ODAC meeting may adversely impact the use, sales and reimbursement of our ESAs.

On March 9, 2007, based upon data from our AoC 103 Study, J&J’s Correction of Hemoglobin and Outcomes in Renal Insufficiency (“CHOIR”) study, and preliminary data from the third-party investigator Danish Head and Neck Cancer (“DAHANCA”) 10 Study, among others, the FDA approved updated safety information, including a boxed warning, in the PI for the class of ESAs, including Aranesp® and EPOGEN®. On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESA use in oncology. Responding to questions posed by the FDA, the ODAC recommended that more restrictions be added to ESA labels and that additional clinical trials be conducted by companies with currently approved ESAs, including us, although no specific restrictions or studies were recommended at the ODAC meeting. The committee is advisory and FDA officials are not bound to or limited by its recommendations. However, the FDA has commonly followed the recommendations of its advisory panels. The FDA also held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease.

On November 8, 2007, in recognition of the input from the May 2007 ODAC and September 2007 joint CRDAC/DSaRMAC meetings, we announced additional updates to the Aranesp® and EPOGEN®/PROCRI® package inserts which reflected ongoing interactions with the FDA regarding the safety and benefit/risk profile of ESAs. The changes to the ESA labels included modifications to the boxed warnings which included language with respect to renal failure which stated that “patients experienced greater risks for death and serious cardiovascular events when administered ESAs to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.” Additional language was also added to the INDICATIONS AND USAGE section, and the WARNINGS section and clarification of the Hb range for CRF patients was added in the DOSAGE AND ADMINISTRATION section. On March 7, 2008, we announced that the FDA approved updated safety information, including the boxed warning in the labeling information for the class of ESAs, including Aranesp® and EPOGEN®. The updated boxed warning states that ESAs shortened overall survival and/or time-to-tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid and cervical cancers when dosed to a target Hb of greater than or equal to 12 g/dL. In the “Increased Mortality and/or Tumor Progression” warning section of the updated labeling, the interim results of the PREPARE study in neo-adjuvant breast cancer were added as well as follow up data from the GOG-191 study in cervical cancer.

On March 13, 2008, the FDA held a follow-up ODAC panel meeting to discuss cumulative data, including recent study results, on the risks of ESAs when used in the oncology setting. Although not required, the FDA has and will likely continue to take into consideration the recommendations by the ODAC in its ongoing discussions with us regarding our ESAs. Responding to questions posed by the FDA, the fourteen ODAC members voted as follows:

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<u>FDA Questions to the Committee</u>	<u>Yes</u>	<u>No</u>	<u>Abstention</u>
Considering all the available data on the benefit and risks of ESAs in the treatment of anemia due to concomitant cancer chemotherapy, do you recommend that these products continue to be marketed for that indication?	13	1	
Should the current indication be modified to restrict use only to patients with small cell lung cancer?	6	8	
Should the current indication be modified to include a statement that ESA use is not indicated for patients receiving potentially curative treatments?	11	2	1
Should the current indication be modified to include a statement that ESA use is not indicated for patients with breast and/or head and neck cancers?	9	5	
Should the FDA require the implementation of an informed consent/patient agreement for the treatment of chemotherapy induced anemia?	8	5	1
Should the FDA mandate a restricted distribution system for oncology patients receiving ESAs?*	1	10	2

* Only thirteen votes cast.

We are in ongoing discussions with the FDA, and in connection with available safety data, including the data and study results discussed at the ODAC, the FDA has asked us to (i) propose additional safety-related changes to the labeling for Aranesp® and EPOGEN®, (ii) develop a proposed REMS for Aranesp® and EPOGEN® and (iii) conduct clinical trials to determine the effects of Aranesp® and EPOGEN® on survival and tumor outcomes. We are in the process of preparing the submissions responsive to the FDA's requests and although we cannot predict what final label revisions or risk management activities the FDA may require of us based upon the recommendations from the ODAC meeting, further revisions to the labels for Aranesp® and EPOGEN® and/or risk management activities 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. (See “– *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products 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 “– *Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.*”)

In addition, we continue to work with the FDA to finalize protocols for large placebo-controlled randomized studies that will formally evaluate overall survival and progression free survival endpoints in patients treated according to the U.S. approved package insert. The addition of these clinical trials to our pharmacovigilance program and any additional clinical trials required by the FDA could result in substantial additional expense, additional label restrictions, or the loss of regulatory approval for an approved indication and 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. (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.*”)

On March 5, 2008, we announced that the European Commission reached its decision to amend the PI for the class of ESAs, including Aranesp®, based on the positive opinion from the CHMP in January 2008, which was consistent with the EMEA's October 23, 2007 press release stipulating a 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. Following the March 13, 2008 ODAC, we have continued to share additional ESA safety data with the EMEA as it has become available. In addition, on May 6, 2008, we announced that the CHMP has requested that we and other ESA marketing authorization holders

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participate in a closed meeting of the SAG-O on May 15, 2008. The marketing authorization holders have been asked to provide an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients. These data include previously disclosed interim results from the PREPARE study in neoadjuvant breast cancer therapy; follow-up data from the GOG-191 study in cervical cancer, which were published in the February 2008 issue of Gynecologic Oncology; and the February 2008 meta-analysis by Bennett et al, which was published in the Journal of the American Medical Association. SAGs are created by the CHMP to deliver answers, on a consultative basis, to specific questions addressed to them by the CHMP. The CHMP, while taking into account the position expressed by the SAG, remains responsible for its final opinion. Should the CHMP and EMEA add additional safety labeling to the class of ESAs based upon the SAG-O meeting, the reimbursement, use and sales of Aranesp® in Europe could be materially adversely affected.

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 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, 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, China, India 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 (<http://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

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product candidates or additional indications for our currently approved products, or may render the product candidate commercially unfeasible or limit our ability to market existing products in certain therapeutic areas or at all. 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 diphosphate, we delayed our phase 3 trial in first-line non-small cell lung cancer (“NSCLC”), which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. 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 trial 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.

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. These efforts will assist in allowing us to provide continued support of key activities including (i) current and future postmarketing studies, including those with respect to our ESA products, Aranesp® and EPOGEN®; (ii) regulatory affairs, safety and compliance functions; (iii) clinical studies to advance our late-stage pipeline; (iv) the advancement of earlier stage compounds and (v) research efforts in the core areas of oncology, inflammation, bone and metabolic disorders. 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. We also partner certain portions and/or geographic regions of our pipeline to preserve opportunities that may result in sharing the positive economic results with another party. For example, in the first quarter of 2008 we completed a collaboration with Takeda for up to thirteen clinical molecules from our pipeline.

Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could 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. Generally, 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. Further, 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 safety labeling for our approved products and may negatively impact worldwide reimbursement for our products. On July 30, 2007, the CMS issued its Decision Memorandum and on January 14, 2008, issued changes to its Medicare National Coverage Determinations Manual, effective for claims with dates of service on or after July 30, 2007, with an implementation date of April 7, 2008. A 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 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.”)

Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare

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programs' payment policies for drugs and biologicals are subject to various laws and regulations. Beginning in January 1, 2005 under the MMA, in the physician clinic setting and January 1, 2006, in the hospital outpatient and dialysis settings, Aranesp[®], Neulasta[®] and NEUPOGEN[®] have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its ASP (sometimes referred to as "ASP+6%"). Effective January 1, 2008, Medicare payment in the hospital outpatient setting reimburses each product at 105% of its ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated on a quarterly basis and therefore 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 2008 will be based in part on certain historical sales and sales incentive data for Aranesp[®] from April 1, 2007 through March 31, 2008. CMS publishes the ASPs for products in advance of the quarter in which they go into effect.

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. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN[®] and Aranesp[®], is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. Beginning in the third quarter of 2007, based on its ongoing assessment for payment of Part B drugs, CMS instituted a single payment limit for Epoetin alfa (EPOGEN[®] and PROCRIT[®]) in all provider settings. Although we cannot predict the payment levels of EPOGEN[®] in future quarters or whether Medicare payments for dialysis drugs may be modified by future federal 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, dialysis facility 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. 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 a revised HMA-PM, a Medicare payment review mechanism used by CMS to monitor EPOGEN[®] and Aranesp[®] utilization and appropriate hematocrit outcomes of dialysis patients. This policy, 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 reduces the monthly dosing limits to 400,000 IUs of EPOGEN[®], from 500,000 IUs, and to 1,200 mcgs of Aranesp[®], from 1,500 mcgs. The implementation of the revised EMP and ESA label changes have 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. We believe that pronounced dose declines, which have been observed in the quarter of EMP implementation, will moderate in subsequent quarters, as has been observed with prior years' EMP changes. However, further reductions in utilization or declining doses of EPOGEN[®] as a result of the revised EMP will have a material adverse effect on the sales of EPOGEN[®] and our business and results of operations.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005, 2006 and 2007 were not significantly impacted by the reimbursement changes resulting from the MMA. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales in the future. For example, the MMA required a report to Congress and a demonstration project with regard to a bundled payment system for dialysis, including separately billable drugs and EPOGEN[®]. The report to Congress was issued on February 20, 2008, but the demonstration project, which was scheduled to start in January 2006, has been delayed with no announced start

date. Bundling initiatives that have been implemented in other healthcare settings have resulted in lower utilization of services that had not previously been a part of the bundled payment. Because CMS is continuing to study bundled payments in the ESRD setting and legislation is possible, we cannot predict what impact a bundled payments system would have on sales of EPOGEN® or Aranesp® used in the treatment of persons receiving outpatient dialysis services.

In addition, in response to CMS considering and rejecting changes to the ASP calculation methodology for accounting for discounts in multi-product contracts in the 2007 Medicare Physician Fee Schedule Final Rule, MedPAC released its second Congressionally-mandated report on December 29, 2006 on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements “to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug.” Under the ASP system, we allocate our discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Referencing a MedPAC December 2006 report, CMS proposed in the Medicare Physician Fee Schedule Proposed Rule for 2008 revising the methodology for calculating ASP to require the reallocation of price concessions of drugs sold under “bundled arrangements,” described by CMS in part as an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement. In the Medicare Physician Fee Schedule Final Rule for 2008, CMS stated that it was not finalizing the proposed regulatory change at this time, based on comments recommending a delay and raising concerns about the proposal. The agency also clarified that in the absence of specific guidance, manufacturers may continue to make “reasonable assumptions” in the calculation of ASP, consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices. The agency stated that it will continue to monitor this issue and may provide more specific guidance in the future. Related to this issue, CMS issued a final Medicaid rule on July 6, 2007 that covered a broad range of topics concerning the calculation and use of AMP and best price as well as a definition for bundled sales under the Medicaid program. Although it has minor differences, the definition of “bundled sale” under this rule is essentially the same as what CMS proposed under the definition of “bundled arrangement” in the Medicare Physician Fee Schedule Proposed Rule for 2008 but which was not adopted for ASP reporting in the Final Rule for 2008. We continue in the process of evaluating what impact the final Medicaid rule will have on our business.

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 label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a NCA which is generally CMS’ first step toward developing a NCD. Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. On May 14, 2007, CMS issued the proposed NCD following a review of data and public comments submitted as part of the NCA, which under the MMA, was subject to a 30-day public comment period that ended 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. The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy.

We believe this restriction on reimbursement of ESAs in the Decision Memorandum has had and may continue to have a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, based on our knowledge, although no private payers have implemented the Decision Memorandum to date, many private payers have implemented the restrictions

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included in the Decision Memorandum. Further, due to difficulties in administering a two-tier medical practice, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage. While we cannot fully predict the further impact of the Decision Memorandum on how, or under what circumstances, healthcare providers will prescribe or administer our ESAs, it had a significant impact to our business in 2007 and believe that it may continue to impact us in 2008.

In addition, the FDA held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. Although CMS has made no announcement of a nephrology focused NCA, any 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, would 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.

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 (“HCFA”), 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 labels and associated revisions in compendia, nearly all Medicare contractors dropped reimbursement for Aranesp[®] for anemia of cancer. (See “– *Guidelines and recommendations published by various organizations can reduce the use of our products.*”) Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, 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 product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our 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 prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude or delay 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. For example, with the October 23, 2007, jury verdict in the U.S. Federal District Court in Boston and the Court’s rulings on various pre-trial and post-trial motions, F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, “Roche”) was found to infringe a total of ten claims from

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four of Amgen's EPO patents. Roche filed a BLA with the FDA for their peg-EPO product and on November 14, 2007 the FDA approved MIRCERA[®] for the treatment of anemia associated with CRF including patients on dialysis and patients not on dialysis. We are now requesting the Court make permanent the preliminary injunction currently in place that prohibits Roche from commercializing its peg-EPO product in the United States in violation of our affirmed patent rights. On April 9, 2008, Roche appealed the preliminary injunction. This lawsuit is described in Note 10 "*Contingencies – Roche Matters*" to the Consolidated Financial Statements in our 2007 Form 10-K and are updated as required in subsequently filed Form 10-Qs. (See "*– Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.*") 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 patent term of product. If we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities; required to enter into third-party licenses for the infringed product or technology or required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

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 HCl, panitumumab and our other products and potential products. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet HCl and panitumumab products as EPOGEN[®] (Epoetin alfa), NEUPOGEN[®] (Filgrastim), Aranesp[®] (darbepoetin alfa), Neulasta[®] (pegfilgrastim), Enbrel[®] (etanercept), Sensipar[®]/Mimpara[®] (cinacalcet HCl) and Vectibix[®] (panitumumab), respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States.

We also have been granted or obtained rights to patents in Europe relating to erythropoietin; G-CSF; pegfilgrastim (pegylated G-CSF); etanercept; two relating to darbepoetin alfa; hyperglycosylated erythropoietic proteins; and cinacalcet HCl. 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 experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our recently announced restructuring plan.

As a result of recent developments and, in particular the regulatory and reimbursement changes to our marketed ESA products, on August 15, 2007, we announced a plan to restructure 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 the restructuring plan, we reduced staff, made changes to certain capital projects and closed certain production operations. As a result of our restructuring plan, we expect to reduce costs beginning in 2008. Our ability to achieve and maintain anticipated savings is dependent upon various future developments, some of which are beyond our control. We may also not realize or maintain, in full or in part, the anticipated benefits and savings from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve or maintain the anticipated savings or benefits to our business in the expected time frame or other unforeseen events occur, our business and results of operations may be adversely affected. Further, if we were to experience additional changes to our business, we may face further restructuring and/or reorganization activities in the future.

In addition, our reduction of staff was completed through a combination of a voluntary transition program and an involuntary reduction in force. In order to be successful and build our framework for future growth, we must continue to execute and deliver on our core business initiatives with fewer human resources

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and losses of intellectual capital. We must also attract, retain and motivate key employees including highly qualified management, scientific, manufacturing and sales and marketing personnel who are critical to our business. We may not be able to attract, retain or motivate qualified employees in the future and our inability to do so may adversely affect 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 payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could 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 August 30, 2007, the National Kidney Foundation (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 chronic kidney disease (“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™ Anemia Work Group recommended in their 2007 Update to the NKF-KDOQI™ 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. Like others in the nephrology community, we continue to monitor the impact the updated guidelines have had and will have on physician utilization and dosage of EPOGEN® and Aranesp®.
- The GAO issued a report on December 5, 2006 recommending that ESRD drugs and biologics, including EPOGEN®, be bundled into the Medicare dialysis composite payment rate. This recommendation is similar to the ones made by MedPAC and CMS. A day after the GAO report was released, the House Ways and Means Committee held a hearing that focused on EPOGEN®, including discussion of the delay in the MMA mandated bundled payment demonstration, and the GAO report and recommendation. Future Medicare reform legislation may require a bundled payment for all dialysis services, including but not limited to ESAs, other drugs and labs common in dialysis.
- On February 2, 2007, following the reported results from our AoC 103 Study, the USP DI Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, Aranesp® use in AoC decreased significantly throughout 2007.

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.

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

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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 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 diphosphate 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 three year 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 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 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*")

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of our products and limit our product sales.”; “– Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products 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 2007 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Litigation is inherently unpredictable, and the outcome can result in excessive verdicts 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.

The federal government, state governments and private payers are investigating, and many have filed actions against numerous pharmaceutical and biotechnology companies, including Amgen and Immunex, now a wholly owned subsidiary of ours, alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated average wholesale price (“AWP”), which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and other payers to healthcare providers who prescribed and administered those products. A number of these actions have been brought against us and/or Immunex. Additionally, a number of states have pending investigations regarding our Medicaid drug pricing practices and the U.S. Departments of Justice and Health and Human Services have requested that Immunex produce documents relating to pricing issues. Further, certain state government entity plaintiffs in some of these AWP cases are also alleging that companies, including ours, were not reporting their “best price” to the states under the Medicaid program. These cases and investigations are described in Note 10, “Contingencies – Average Wholesale Price Litigation” to the Consolidated Financial Statements in our 2007 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Other states and agencies could initiate investigations of our pricing practices. A decision adverse to our interests on these actions and/or investigations could result in substantial economic damages and 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.

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 been named as defendants in product liability actions for certain of our products.

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. For example, primarily as a result of various regulatory and reimbursement developments involving ESA products that began in 2007, our anemia product sales, in particular sales of Aranesp®, for 2007 were materially adversely impacted. 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. Further, primarily as a result of the various regulatory and reimbursement developments impacting ESA products, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. As of March 31, 2008, we have incurred approximately \$751 million of the current estimated \$775 million to \$825 million in charges in connection with this restructuring plan. Our operating results have and will continue to fluctuate and be adversely impacted as a result of these restructuring charges. (See “– *We may experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our recently announced restructuring plan.*”) In addition, in the event that the actual restructuring charges exceed our latest estimate, this may cause our operating results for a period to be below our expectations or projections. As a result of the above or other challenges, including the outcomes from the March 13, 2008 ODAC meeting and continuing label revisions to our ESAs, 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 statistical ratings organizations 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 March 31, 2008, the trading price of our common stock has ranged from a high of \$65.10 per share to a low of \$39.97 per share.

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

- adverse developments regarding the safety or efficacy of our products
- changes in the government’s or private payers’ reimbursement policies or prescribing guidelines for our products
- inability to maintain regulatory approval of marketed products or manufacturing facilities
- actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators
- business development or licensing activities
- product development or other business announcements by us or our competitors
- regulatory matters or actions, such as label changes or risk management activities
- 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 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

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- pronouncements and rule changes by applicable standards authorities that change the manner in which we account for certain transactions

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.

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 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 single-source unaffiliated third-party suppliers. Certain of these raw materials, medical devices and components are the proprietary products of these unaffiliated third-party suppliers and, in some cases, such proprietary products are specifically cited in our drug application with the FDA so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the FDA approved that other supplier. We would be unable to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party single-source 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 the FDA 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 an avian or pandemic flu outbreak, or otherwise
- failure to comply with our quality standards which results in quality 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 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 ("HSA"). We are also investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically-sourced raw materials as such raw materials may be subject to contamination and/or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. 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 biological sources and alternative manufacturing processes or our ability to gain

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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 effect 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.

We currently manufacture and market all our principal products, and we plan to manufacture and market many of our product candidates. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. (See “– *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products 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 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; Bothell, Washington and Juncos, Puerto Rico. (See “– *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.*”) Additionally, we currently use third-party contract manufacturers to produce or assist in the production of ENBREL and Sensipar[®]/Mimpara[®] and in the formulation, fill and finish of Vectibix[®] and plan to use contract manufacturers to produce a number of our late-stage product candidates. (See “– *We are dependent on third parties for a significant portion of our bulk supply and the formulation, fill and finish of ENBREL.*”) Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our facilities 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
- facility capacity of our facilities or those of our contract manufacturers
- facility contamination by microorganisms or viruses
- labor disputes or shortages, including the effects of an avian or pandemic flu outbreak
- compliance with regulatory requirements
- changes in forecasts of future demand
- timing and actual number of production runs
- 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 BI Pharma. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients, physicians may elect to prescribe competing therapeutics instead of our products, and sales of our products will be adversely affected, 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

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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 vast 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, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at appropriate production capacity over the next few years, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance. Key manufacturing projects include: (i) expansion of our existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate denosumab; (ii) construction, qualification and licensure of a new formulation and filling facility at our Puerto Rico site and (iii) expansion of our Fremont, California facility to support future product launches.

If regulatory authorities determine that we or our third-party contract manufacturers or 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 our third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and third-party service providers are subject to FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers and 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.

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. 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
- breakdown, failure or substandard performance of equipment
- improper installation or operation of equipment
- labor disputes or shortages, including the effects of an avian or 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

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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 could result in such losses adversely affecting our product sales and operating results materially. (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.”)

We are dependent on third parties for a significant portion of our bulk supply and the formulation, fill and finish of ENBREL.

Under a collaboration and global supply agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by our Rhode Island manufacturing facility, BI Pharma’s manufacturing facility in Germany and Wyeth’s manufacturing facility in Ireland. Our ENBREL supply forecasts rely on certain assumptions of how much ENBREL each of these manufacturing facilities is expected to produce. If any of these manufacturing facilities are unable to produce in accordance with our or Wyeth’s expectations, the worldwide supply of ENBREL could be adversely affected materially. In such cases, we may be required to allocate supply for Wyeth’s benefit. To the extent that there is a shortfall in worldwide production, our supply of ENBREL could be adversely affected. Additionally, the costs associated with a shortfall or failure in production of ENBREL would be borne by both parties.

We currently produce a substantial portion of the annual ENBREL supply at our Rhode Island manufacturing facility. However, we also depend on third parties for a significant portion of our ENBREL bulk supply as well as for some of the formulation, fill and finish of ENBREL that we manufacture. BI Pharma is our third-party contract manufacturer of ENBREL bulk drug; accordingly, our U.S. and Canadian supply of ENBREL is currently significantly dependent on BI Pharma’s production schedule for ENBREL. We would be unable to produce ENBREL in sufficient quantities to substantially offset shortages in BI Pharma’s scheduled production if BI Pharma or other third-party contract manufacturers used for the formulation, fill and finish of ENBREL bulk drug were to cease or interrupt production or services or otherwise fail to supply materials, products or services to us for any reason, including labor shortages or disputes, regulatory requirements or action or contamination of product lots or product recalls. 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 BI Pharma. We cannot guarantee that an alternative third-party contract manufacturer would be available on a timely basis or at all. This in turn could materially reduce our ability to satisfy demand for ENBREL, which could materially and adversely affect our operating results.

Among the factors that could affect our actual supply of ENBREL at any time include, without limitation, BI Pharma’s and our Rhode Island facility’s bulk drug production scheduling. For example, BI Pharma does not produce ENBREL continuously; rather, it produces the bulk drug substance through a series of periodic campaigns throughout the year. Our Rhode Island manufacturing facility is currently dedicated to ENBREL production. The amount of commercial inventory available to us at any time depends on a variety of factors, including the timing and actual number of BI Pharma’s production runs, the actual number of runs at our Rhode Island manufacturing facility, and, for either the Rhode Island or BI Pharma facilities, the level of production yields and success rates, the timing and outcome of product quality testing and the amount of formulation, fill and finish capacity. We are also dependent on third-parties for some formulation, fill and finish of ENBREL bulk drug substance manufactured at our Rhode Island facility. If third-party formulation, fill and finish manufacturers are unable to provide sufficient capacity or are otherwise unable to provide services to us, the supply of ENBREL could be adversely affected materially.

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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, ENBREL competes in certain circumstances with products marketed by J&J, Abbott Laboratories (“Abbott”), Biogen IDEC Inc., Genentech, Inc., Bristol-Myers Squibb Corporation, Novartis AG and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed, including J&J’s CNTO 1275 (ustekinumab). Additionally, on January 18, 2008, Abbott announced it had received approval from the FDA to market HUMIRA® as a treatment for adult patients with moderate to severe chronic plaque psoriasis. HUMIRA® will now compete with ENBREL in both the rheumatology and dermatology segments. While ENBREL continues to maintain a leading position in both rheumatology and dermatology, it has experienced and continues to experience share loss to competitors. Vectibix®, our oncology therapeutic in the United States and the EU to treat patients with mCRC, competes with Imclone’s Erbitux®. Additionally, Aranesp® competes or will potentially compete in the EU with:

Product	Company	Countries	Timing for Launch
EPREX®	J&J	EU	Launched in 1988
Neorecormon®	Roche	EU	Launched in 1993
Dynepo™	Shire	Germany, UK	Launched in 2007
Biosimilar Erythropoietin	Sandoz with co-marketers Hexal and Medice	Germany, UK Others	Launched in 2007 2008
Biosimilar Erythropoietin	Hospira/Stada	Germany, UK Others	2008 2008
peg-EPO/MIRCERA®	Roche	Germany, UK Netherlands, Austria, Sweden, Switzerland	Launched in 2007 2008

In addition, several companies are developing potentially competing therapies. For example, Affymax Inc./Takeda are co-developing, Hematide™, an erythropoietin mimetic for the treatment of anemia. 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 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.*”) 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.

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 other companies may receive approval for and market biosimilar or other products to compete with our products in the EU, presenting additional competition to our products. Although we cannot predict with certainty when the first G-CSF biosimilar products could appear on the market in the EU, with the February 21, 2008 positive opinion from the CHMP, we expect that the first biosimilar G-CSF product will be approved in the second quarter of 2008 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. For example, in February 2008, Teva received a positive opinion from the CHMP for its G-CSF biosimilar product, TevaGrastim®, which is expected to launch in the EU in the second quarter of 2008. We cannot predict to what extent the entry of biosimilar products or other competing products will impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU. Our inability to compete effectively could reduce sales which could have a material adverse effect on our results of operations.

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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, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In the United States, there currently is no legal approval pathway for the approval of BLAs for biosimilars. A number of events would need to occur before these products could enter the market, including passage of legislation by Congress to create a new approval pathway and, depending on the specific provisions of any such legislation, promulgation of associated regulations or guidance by the FDA. In 2007, several members of Congress expressed interest in the issue, a number of bills were introduced, the House of Representatives and the Senate held hearings on biosimilars, and the Senate Committee on HELP voted on legislation in June 2007. In 2008, additional legislation was introduced in the House of Representatives. To date, however, no final legislation has been considered or passed in either chamber of Congress. Given the continuing interest of Congress in the issue, it is possible but not likely that legislation on biosimilars will be finalized this year. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for issuance of regulations or guidance any final legislation would contain. Until such legislation is created, we cannot predict when biosimilars could appear in the United States.

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. Large pharmaceutical corporations may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do. 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 must build the framework for our future growth, and if we fail to execute on our initiatives our business could be adversely affected.

As a result of developments in 2007 and, in particular the regulatory and reimbursement changes to our ESA products, on August 15, 2007, we announced a plan to restructure 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. We face a number of risks, some of which we cannot completely control. For example:

- we will need to manage complexities associated with a large and geographically diverse organization
- we will need to manage and execute large, complex and global clinical trials
- we will need to significantly expand our sales and marketing resources to launch our late-stage product candidate, denosumab
- we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply

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- we have and continue to implement an ERP system to support our increasingly complex business and business processes and such implementation is costly and carries substantial operations risk, including loss of data or information, unanticipated increases in costs, disruption of operations or business interruption

Of course, there may be other risks and we cannot guarantee that we will be able to successfully manage these or other risks. If we fail to execute on our initiatives in these ways or others, such failure could result in a material adverse effect on our business and results of operations.

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 a 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, 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 Wyeth.

Under a co-promotion agreement, we and Wyeth market and sell ENBREL in the United States and Canada. A management committee comprised of an equal number of representatives from us and Wyeth is responsible for overseeing the marketing and sales of ENBREL including strategic planning, the approval of an annual marketing plan, product pricing and the establishment of a brand team. The brand team, with equal representation from us and Wyeth, 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 Wyeth fails to effectively deliver on its marketing commitments to us or if we and Wyeth fail to coordinate our efforts effectively, our sales of ENBREL may be adversely affected materially.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations.

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 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.”) 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

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potentially applicable foreign regulations and/or laws. If we 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.

The accounting method for our convertible debt securities may be subject to change.

A convertible debt security providing for share and/or cash settlement of the conversion value and meeting specified requirements under EITF Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," including our outstanding convertible debt securities, is currently classified in its entirety as debt. No portion of the carrying value of such a security related to the conversion option indexed to our stock is classified as equity. In addition, interest expense is recognized at the stated coupon rate. The coupon rate of interest for convertible debt securities, including our convertible debt securities, is typically lower than what an issuer would be required to pay for nonconvertible debt with otherwise similar terms.

The EITF considered in 2007 whether the accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion ("cash settled convertible debt securities") should be changed, but was unable to reach a consensus and discontinued deliberations on this issue. Subsequently, in July 2007, the FASB voted unanimously to reconsider the current accounting for cash settled convertible debt securities, which includes our convertible debt securities. In August 2007, the FASB exposed for public comment a proposed FSP that would change the method of accounting for such securities and would require the proposed method to be retrospectively applied. During its March 2008 deliberations, the FASB affirmed the proposed method of accounting and decided to delay the effective date of the final FSP for calendar year end companies like us to the first quarter of 2009. The FASB currently indicates that it expects to take a final vote on and, if approved, issue the final FSP in the second quarter of 2008. Under this proposed method of accounting, the debt and equity components of our convertible debt securities would be bifurcated and accounted for separately in a manner that would result in recognizing interest on these securities at effective rates more comparable to what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities would be included in the paid-in-capital section of stockholders' equity on our Consolidated Balance Sheet and, accordingly, the initial carrying values of these debt securities would be reduced. Our net income for financial reporting purposes would be reduced by recognizing the accretion of the reduced carrying values of our convertible debt securities to their face amounts as additional non-cash interest expense. Therefore, if the FASB issues the final FSP to change the method of accounting for cash settled convertible debt securities as described above, it would have a material adverse impact on our past and future reported financial results.

We cannot predict any other changes in GAAP that may be made which would affect accounting for convertible debt securities and which could have an adverse impact on our past or future reported financial results.

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.

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Item 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

During the three months ended March 31, 2008, we had two outstanding stock repurchase programs. 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. Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of Amgen common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. A summary of our repurchase activity for the three months ended March 31, 2008 is as follows:

	<u>Total number of shares purchased</u>	<u>Average price paid per share</u>	<u>Total number of shares purchased as part of publicly announced programs</u>	<u>Maximum \$ value that may yet be purchased under the programs ⁽¹⁾</u>
January 1 - January 31	—	\$ —	—	\$ 6,439,425,117
February 1 - February 29	2,993	46.56	—	6,439,425,117
March 1 - March 31	35,158	45.48	—	6,439,425,117
	<u>38,151⁽²⁾</u>	45.56	<u>—⁽²⁾</u>	

⁽¹⁾ In December 2006, the Board of Directors authorized us to repurchase up to \$5.0 billion of common stock. In July 2007, the Board of Directors authorized us to repurchase up to an additional \$5.0 billion of common stock.

⁽²⁾ 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 5. OTHER INFORMATION

In May 2008, we increased our commercial paper program by \$1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of \$2.5 billion. We also have a \$2.5 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper backup, which matures in November 2012. No amounts were outstanding under the commercial paper program or credit facility as of March 31, 2008.

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)

Date: May 12, 2008

By: /s/ ROBERT A. BRADWAY
Robert A. Bradway
Executive Vice President
and Chief Financial Officer

AMGEN INC.
INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation (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	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 14, 2007). (Filed as an exhibit to Form 8-K filed on February 20, 2007 and incorporated herein by reference.)
3.5	Amendment to Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value \$.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.6	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.)
4.7	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.)
4.8	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	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.)
4.10	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 reference.)
4.11	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.)
4.12	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.)
4.13	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.)
4.14	Registration Rights Agreement, dated as of November 18, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (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)

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- 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 Registration Rights Agreement, dated as of February 17, 2006, among Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JPMorgan Securities Inc., Lehman Brothers Inc., Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
- 4.20 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.)
- 4.21 The instruments defining the rights of holders of the long-term debt securities of Abgenix, Inc. and its subsidiaries are omitted pursuant to section (b)(4)(iii)(A) of Item 601 of Regulation S-K. Amgen Inc. hereby agrees to furnish copies of these instruments to the Securities and Exchange Commission upon request.
- 4.22 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.)
- 4.23 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. Amended and Restated 1991 Equity Incentive Plan (As Amended and Restated December 5, 2005). (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.2+ Forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
- 10.3+ Amgen Inc. Amended and Restated Director Equity Incentive Program (As Amended and Restated December 10, 2007) and forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated Director Equity Incentive Program. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
- 10.4+ Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (As Amended and Restated December 5, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.5+ Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of December 5, 2005) and Forms of Stock Option Grant Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.6+ Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated April 1, 2006). (Filed as an exhibit to Form S-8 on April 3, 2006 and incorporated herein by reference.)
- 10.7+ Amgen Inc. Amended and Restated Employee Stock Purchase Plan. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
- 10.8+ First Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan (As Amended and Restated July 12, 2005). (Filed as an exhibit to Form 8-K on July 14, 2005 and

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incorporated herein by reference.)

- 10.9+ Second Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan (As Amended and Restated July 12, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
- 10.10+ Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 12, 2004 and incorporated herein by reference.)
- 10.11+ First Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 20, 2005 and incorporated herein by reference.)
- 10.12+ Second Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated July 1, 2006). (Filed as an exhibit to Form 8-K on May 16, 2006 and incorporated herein by reference.)
- 10.13+ Third Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2006 on February 28, 2007 and incorporated herein by reference.)
- 10.14+ Fourth Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
- 10.15+* Fifth Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005).
- 10.16+ Amgen Inc. Change of Control Severance Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 1998 on March 16, 1999 and incorporated herein by reference.)
- 10.17+ First Amendment to Amgen Inc. Change of Control Severance Plan (As Amended May 10, 2000). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
- 10.18+ Second Amendment to the Amgen Inc. Change in Control Severance Plan (As Amended October 16, 2001). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2001 on October 26, 2001 and incorporated herein by reference.)
- 10.19+ Third Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended January 1, 2004). (Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.)
- 10.20+ Fourth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended June 1, 2004). (Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.)
- 10.21+ Fifth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 6, 2004). (Filed as an exhibit to Form 8-K on December 9, 2004 and incorporated herein by reference.)
- 10.22+ Sixth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended May 10, 2006). (Filed as an exhibit to Form 8-K on May 16, 2006 and incorporated herein by reference.)
- 10.23+ Seventh Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended October 4, 2006). (Filed as exhibit to Form 8-K on October 6, 2006 and incorporated herein by reference.)
- 10.24+ Eighth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 15, 2006). (Filed as an exhibit to Form 10-K for the year ended December 31, 2006 on February 28, 2007 and incorporated herein by reference.)
- 10.25+ Amgen Inc. Executive Incentive Plan. (Filed as Annex G to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
- 10.26+ First Amendment to the Amgen Inc. Executive Incentive Plan (As Amended December 6, 2004). (Filed as an exhibit to Form 8-K on December 9, 2004 and incorporated herein by reference.)
- 10.27+ Amgen Inc. Executive Nonqualified Retirement Plan. (Filed as an exhibit to Form 10-K for the year ended December 31, 2001 on February 26, 2002 and incorporated herein by reference.)
- 10.28+ First Amendment to the Amgen Inc. Executive Nonqualified Retirement Plan. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
- 10.29+ Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2005). (Filed as an exhibit to Form 8-K on October 12, 2004 and incorporated herein by reference.)
- 10.30+ First Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 20, 2005 and incorporated

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herein by reference.)

- 10.31+ Second Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on November 22, 2005 and incorporated herein by reference.)
- 10.32+ Third Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2006 on February 28, 2007 and incorporated herein by reference.)
- 10.33+ Fourth Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
- 10.34+ Fifth Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
- 10.35+* Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated March 21, 2008) and form of Performance Unit Agreement.
- 10.36+ 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.)
- 10.37+ Agreement, dated March 2, 2001, between Amgen Inc. and Mr. George J. Morrow. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2001 on May 14, 2001 and incorporated herein by reference.)
- 10.38+ Agreement, dated March 2, 2001 between Amgen Inc. and Dr. Roger M. Perlmutter, M.D., Ph.D. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2001 on May 14, 2001 and incorporated herein by reference.)
- 10.39+ Agreement, dated May 2, 2001, between Amgen Inc. and Mr. Brian McNamee. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
- 10.40+ Restricted Stock Purchase Agreement, dated March 3, 2003, between Amgen Inc. and Brian M. McNamee. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2003 on July 30, 2003 and incorporated herein by reference.)
- 10.41+ Agreement, dated May 14, 2001, between Amgen Inc. and Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
- 10.42+ Promissory Note, dated June 27, 2001, of Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.)
- 10.43+ Amendment to Promissory Note, dated August 31, 2007 to Promissory Note, dated June 27, 2001, of Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
- 10.44+ Agreement, dated February 11, 2004, between Amgen Inc. and David J. Scott. (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
- 10.45 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.)
- 10.46 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.)
- 10.47 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.)
- 10.48 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

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- 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.)
- 10.49 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.)
- 10.50 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.)
- 10.51 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.)
- 10.52 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.)
- 10.53 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.)
- 10.54 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.)
- 10.55 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.)
- 10.56 G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
- 10.57 Enbrel[®] Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated as of November 5, 1998 (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Annual Report on Form 10-K for the year ended December 31, 1998 on March 23, 1998 and incorporated herein by reference.)
- 10.58 Amendment No. 1 to the Enbrel[®] Supply Agreement, dated June 27, 2000, among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Form 10-Q for the quarter ended June 30, 2000 on August 11, 2000 and incorporated herein by reference.)
- 10.59 Amendment No. 2 to the Enbrel[®] Supply Agreement, dated June 3, 2002, among Immunex Corporation, Wyeth (formerly known as American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
- 10.60 Amendment No. 3 to the Enbrel[®] Supply Agreement, dated December 18, 2002, among Immunex Corporation, Wyeth (formerly, "American Home Products Corporation") and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2002 on March 10, 2003 and incorporated herein by reference.)

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- 10.61 Amendment No. 4 to the Enbrel® Supply Agreement, dated May 21, 2004, among Immunex Corporation, Wyeth (formerly, “American Home Products Corporation”) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
- 10.62 Amendment No. 5 to the Enbrel® Supply Agreement, dated August 30, 2005, among Immunex Corporation, Wyeth (formerly, “American Home Products Corporation”) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2005 on November 9, 2005 and incorporated herein by reference.)
- 10.63 Amendment No. 6 to the Enbrel® Supply Agreement, dated November 27, 2007, among Immunex Corporation, Wyeth (formerly, “American Home Products Corporation”) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom) (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
- 10.64 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.)
- 10.65 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 Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
- 10.66 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.)
- 10.67 Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective as of April 20, 2004, by and among Wyeth, Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Form S-4/A on June 29, 2004 and incorporated herein by reference.)
- 10.68 Amendment No. 3 to Amended and Restated Promotion Agreement, effective as of January 1, 2005, by and among Wyeth, Amgen Inc. and 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.)
- 10.69 Purchase Agreement, dated as of November 15, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representatives of the several initial purchasers. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 10.70 Purchase Agreement, dated as of February 14, 2006, among Amgen Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JP Morgan Securities, Inc., Lehman Brothers Inc, Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
- 10.71 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.)
- 10.72 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.)
- 10.73 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.)
- 10.74 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.)

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10.75	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.)
10.76	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 herein by reference.)
10.77	Purchase Agreement, dated February 16, 2006, between Amgen Inc. and Citigroup Global Markets Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.78	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.)
10.79	Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.80	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information 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.)
10.81	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.)
10.82*	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).
10.83*	License Agreement for motesanib diphosphate between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom).
10.84*	Supply Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom).
10.85*	Sale and Purchase Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom).
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.

(* = 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.)

**FIFTH AMENDMENT TO THE
AMGEN INC. SUPPLEMENTAL RETIREMENT PLAN
AS AMENDED AND RESTATED EFFECTIVE JANUARY 1, 2005**

Section 2.7 of the Amgen Inc. Supplemental Retirement Plan (As Amended and Restated Effective January 1, 2005) (the "Plan") is hereby amended and restated, effective as of January 1, 2008, as follows:

2.7 Compensation has the same meaning as the term "Deferral Compensation" has under the Retirement Plan, except that, for purposes of this Plan, Compensation is not limited by the Salary Cap and includes amounts that are deferred into the NQDC.

To record this Amendment to the Plan as set forth herein, the Company has caused its authorized officer to execute this document this 18th day of March 2008.

AMGEN INC.

By: /s/ BRIAN MCNAMEE

Title: Senior Vice President, Human Resources

**AMENDED AND RESTATED AMGEN INC.
PERFORMANCE AWARD PROGRAM**
(Amended and Restated Effective March 21, 2008)

ARTICLE I

PURPOSE

The purpose of this document is to set forth the general terms and conditions applicable to the Performance Award Program (the "Program") established by the Compensation and Management Development Committee of the Board of Directors of Amgen Inc. (the "Company") pursuant to, and in implementation of, Section 10(d) of the Company's Amended and Restated 1991 Equity Incentive Plan, as amended (the "1991 Plan"). The Program is intended to carry out the purposes of the 1991 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, subject to the restrictions and other provisions of the Program and the 1991 Plan.

ARTICLE II

DEFINITIONS

Unless otherwise defined herein, capitalized terms used herein shall have the same definitions as such terms are defined in the 1991 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.

"Code" shall mean the Internal Revenue Code of 1986, as amended, together with the regulations and official guidance promulgated thereunder.

"Committee" shall mean the Compensation and Management Development Committee of the Board, appointed by the Board from among its members to administer the 1991 Plan in accordance with Section 2 thereof.

"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.

“Performance Period” 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.

“Performance Unit” 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.

“Permanent and Total Disability” 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.

“QDRO” shall mean a court order (i) that creates or recognizes the right of the spouse, former spouse or child (an “Alternate Payee”) of an individual who is granted an Award to an interest in such Award relating to marital property rights or support obligations and (ii) that the 1991 Plan administrator determines would be a “qualified domestic relations order,” as that term is defined in Section 414(p) of the Code and Section 206(d) of the Employee Retirement Income Security Act (“ERISA”), but for the fact that the 1991 Plan is not a plan described in Section 3(3) of ERISA.

“Retirement-Eligible” 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 Participants. 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 No Right to Participate. 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 Generally. 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 Section 2 of the 1991 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 Provisions Applicable to Section 162(m) Participants. 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 1991 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 Provisions Applicable to Participants in Foreign Jurisdictions. 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 of 1933, as amended, Securities Exchange Act of 1934, as amended, the Code, or any other securities or tax or other applicable law or regulation.

ARTICLE V

AWARD DETERMINATIONS

5.1 Award of Performance Units. 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 within the first ninety (90) days of such Performance Period, but in no event after 25 percent of the Performance Period has elapsed. Performance Units granted under the Program shall constitute stock bonuses under Sections 7 and 10(d) of the 1991 Plan.

5.2 Performance Requirements. The Committee shall approve the performance goals (collectively, the "Performance Goals") with respect to any of the business criteria permitted under Section 10(d) of the 1991 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 has elapsed.

ARTICLE VI

PAYMENT OF AWARDS

6.1 Form and Timing of Payment. 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 Tax Withholding. The Participant shall satisfy any federal, state and local tax withholding obligation relating to the payment of the Award by authorizing the Company to withhold from the shares of the Common Stock otherwise issuable to the Participant as a result of the vesting or the payment of the Award a number of shares having a fair market value less than or equal to the amount of the Company's required minimum statutory withholding for federal, state and local tax purposes, including any payroll taxes resulting from the vesting of the Performance Units. 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 1991 Plan. In addition, the Participant shall 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, no certificates representing the shares of Common Stock shall be delivered to a Participant unless and until he or she shall have paid to the Company the full amount of all federal, state and local tax withholding or other employment taxes applicable to him or her resulting from the payment of the Award.

ARTICLE VII

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, *provided*, that if (i) amounts payable under this Program are deemed to constitute "nonqualified deferred compensation," and (ii) a Participant is deemed to be a "specified employee" (within the meaning of Code Section 409A), then amounts payable under this Program shall not be paid until the later of (A) the payment date described in Article VI above, or (B) the date that is six months after the date of termination (or the date on which such Participant dies, if earlier), to the extent required by Code Section 409A. 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 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); provided however, that prior to termination of a Participant's employment with the Company or an Affiliate, such Participant signs a general release in a form provided by the Company.

(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, *provided*, that if (i) a Participant's employment terminates due to Permanent and Total Disability, (ii) amounts payable under this Program are deemed to constitute "nonqualified deferred compensation," and (iii) the Participant is deemed to be a "specified employee" (within the meaning of Code Section 409A), then amounts payable under this Program shall not be paid until the later of (A) the payment date described in Article VI above, or (B) the date that is six months after the date of termination (or the date on which such Participant dies, if earlier), to the extent required by Code Section 409A. 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, a Participant shall not be entitled to such full or prorated amount of such Participant's Award unless prior to a Participant's termination of employment due to such Participant's Permanent and Total Disability, such Participant signs a general release in a form provided by the Company.

(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 the Committee approves, based upon the recommendation of the Company's Chief Executive Officer which are based on valid business reasons, the payment of a prorated amount of the 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 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; provided however, that prior to termination of a

Participant's employment with the Company or an Affiliate, such Participant signs a general release in a form provided by the Company.

7.2 Termination of Employment After End of Performance Period. 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.

8.2 Change of Control After End of Performance Period. 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 Plan. The Program is subject to all the provisions of the 1991 Plan and its provisions are hereby made a part of the Program, including without limitation the provisions of Sections 7 and 10(d) thereof (relating to stock bonuses) and Section 11 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 1991 Plan. In the event of any conflict between the provisions of the Program and those of the 1991 Plan, the provisions of the 1991 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 1991 Plan.

9.2 Amendment and Termination. 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 No Contract for Employment. 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 Nontransferability. 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, (ii) by applicable laws of descent and distribution or (iii) to an Alternate Payee to the extent that a QDRO so provides. The assignment of an Award to an Alternate Payee pursuant to a QDRO shall not be treated as having caused a new grant. If an Award is assigned to an Alternate Payee, the Alternate Payee generally has the same rights as the Participant under the terms of the Program; *provided however*, that (i) the Award shall be subject to the same vesting terms as if the Award were still held by the Participant, and (ii) an Alternate Payee may not transfer an Award. In the event of the 1991 Plan administrator's receipt of a domestic relations order or other notice of adverse claim by an Alternate Payee of a Participant, transfer of the proceeds of such Award may be suspended. Such proceeds shall thereafter be transferred pursuant to the terms of a QDRO or other agreement between the Participant and Alternate Payee. A Participant's ability to receive payment of an Award may be barred if the 1991 Plan administrator receives a court order directing the 1991 Plan administrator not to make such payment.

9.5 Nature of Program. 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.

9.6 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.

PERFORMANCE UNIT AGREEMENT

_____, Amgen Inc. Grantee:

On this __ day of _____ (the "Grant Date"), Amgen Inc., a Delaware corporation (the "Company"), pursuant to its Performance Award Program (the "Program") which implements the Amended and Restated 1991 Equity Incentive Plan (the "Plan"), has granted to you, the grantee named above, _____ units (the "Performance Units") on the terms and conditions set forth in this Performance Unit Agreement (this "Agreement"), the Plan, 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 begin on __, 200_ and end on _____, 200_.

II. Value of Performance Units. The value of each Performance Unit is equal to a share of Common Stock.

III. Performance Goals. Up to 200% of the Performance Units shall be earned, depending on the extent to which the Company achieves objectively determinable performance goals established by the Compensation and Management Development Committee (the "Committee") pursuant to those certain Resolutions of the Compensation and Management Development Committee of the Board of Directors of Amgen Inc., adopted on _____, regarding the Performance Award Program (the "Resolutions"). The Performance Units earned shall be calculated in accordance with the Resolutions and the Program.

IV. Form and Timing of Payment. Subject to Section X and except as set forth in the Program, for any 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. Issuance of Certificates; Tax Withholding. All payments made pursuant to Section IV above shall be subject to withholding of all applicable taxes, based on the minimum statutory withholding rates for federal, state and local tax purposes, including any employment taxes resulting from the vesting of the Performance Units (the "Tax Obligations"). You hereby agree that you will satisfy the Tax Obligations resulting from the vesting of the Performance Units by authorizing, and you hereby authorize, the Company to withhold from the shares of Common Stock otherwise deliverable to you as a result of the vesting of the Performance Units in accordance herewith, a number of shares having a fair market value less than or equal to the Tax Obligations. 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. The number of shares of Common

Stock tendered by you pursuant to this subsection shall be determined by the Company and be valued at the fair market value of the Common Stock on the date the Tax Obligations arise. To the extent that the number of shares tendered by you pursuant to this subsection is insufficient to satisfy the Tax Obligations, you hereby authorize the Company to deduct from your compensation the additional amount necessary to fully satisfy the Tax Obligations. If the Company chooses not to deduct such amount from your compensation, you agree to pay the Company, in cash or by check, the additional amount necessary to fully satisfy the Tax Obligations. 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 Section IV above, no certificates representing the shares of Common Stock shall be delivered to you unless and until you have satisfied your obligations with respect to the full amount of all federal, state and local tax withholding or other employment taxes applicable to you resulting from the payment of the Performance Units earned.

VI. Nontransferability. 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, (ii) by applicable laws of descent and distribution or (iii) to an Alternate Payee to the extent that a QDRO so provides, as further described in the Program.

VII. No Contract for Employment. This Agreement is not an employment or service contract 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 of the Company to continue your employment or service with the Company.

VIII. Notices. Any notices provided for in this Agreement or the Plan shall be given in writing 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 Secretary of the Company.

IX. Resolutions, Plan and Program. 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 Sections 7 and 10(d) of the Plan (relating to stock bonuses) and Section 11 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.

X. No Compensation Deferral. The Performance Units are not intended to constitute “nonqualified deferred compensation” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (together with the regulations and official guidance promulgated thereunder, the “Code”). However, if at any time the Committee determines that the Performance Units may be subject to Section 409A, 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 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. Any such amendment to the Program may in the Committee’s sole discretion apply retroactively to this award of Performance Units.

XI. Provisions Applicable to Participants in Foreign Jurisdictions. Notwithstanding any provision of this Agreement or the Program to the contrary, if you are employed by the Company or its Affiliates outside the United States or are subject to the laws of any foreign jurisdiction, your award of Performance Units shall be subject to the following additional terms and conditions:

(a) the terms and conditions of your award of Performance Units are deemed modified to the extent necessary to comply with applicable foreign laws;

(b) if applicable, the effectiveness of your award of Performance 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 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 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 of 1933, as amended (the “Act”), Securities Exchange Act of 1934, as amended, 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 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 Act.

XII. Governing Law. This Agreement shall be construed and interpreted, and the rights of the parties shall be determined, in accordance with the laws of the State of Delaware, without regard to conflicts of law provisions thereof.

Very truly yours,
AMGEN INC.

By: _____
Name:
Title:

Accepted and Agreed,
this __ day of _____, 200_.

By: _____
Name:

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.

License Agreement
By and Between
Amgen Inc.
and
Takeda Pharmaceutical Company Limited
Dated
February 1, 2008

CONFIDENTIAL

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SCHEDULES

CONFIDENTIAL

License Agreement

Preamble

This License Agreement (this "*Agreement*") is entered into as of the 1st day of February, 2008 (the "*Effective Date*") by and between Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, U.S.A. ("*Amgen*"), and Takeda Pharmaceutical Company Limited, a Japanese corporation having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan ("*Licensee*"). Amgen and Licensee are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties*."

Recitals

WHEREAS, Amgen is a global biotechnology company that conducts pharmaceutical research, development, manufacturing and commercialization;

WHEREAS, Amgen is developing a number of products for the treatment of various diseases and conditions;

WHEREAS, Amgen's subsidiary, Amgen K.K., has previously conducted development activities in the Territory (as defined below);

WHEREAS, concurrently with the execution of this Agreement, the Parties are entering into the Sale and Purchase Agreement whereby Amgen shall sell, and Licensee shall purchase, all of the outstanding capital stock of Amgen K.K.;

WHEREAS, Licensee has existing development and commercialization capabilities in the Territory and will, subsequent to the closing of the transactions contemplated in the Sale and Purchase Agreement, have the additional development capabilities of Amgen K.K.;

WHEREAS, Amgen wishes to partner with Licensee, and Licensee wishes to partner with Amgen, in each case with respect to the development and commercialization of the Licensed Products in the Licensee Indications in the Territory (each as defined below) in accordance with the terms and conditions hereof;

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

1. DEFINITIONS

1.1. "*Affiliate*" shall mean any corporation or other entity which directly or indirectly controls, is controlled by or is under common control with a Party, for so long as such control exists. For the purposes of this Section 1.1 ("*Affiliate*"), "*control*" shall mean: (i) in the case of any corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for the election of directors thereof; or (ii) in the case of any non-corporate entity, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein.

1.2. "*Agreement*" shall have the meaning set forth in the Preamble.

- 1.3. “[*] Product” shall mean a [*] for which Amgen has the exclusive rights to develop and commercialize in North America, Europe and the Territory, and that is being developed for [*] and as its intended therapeutic mechanism of action targets the relevant receptor or ligand for such Distracting Product (as described on the Distracting Products Schedule).
- 1.4. “[*]” or “[*]” shall mean, with respect to a commercial presentation of a Licensed Product, the unit-volume-weighted average of: (a) the [*] for the [*] presentation during the Term pursuant to the relevant [*]; (b) the [*] for such presentation where Licensee [*] such presentation [*] in accordance with this Agreement and the relevant [*]; and (c) the [*] by Licensee to [*] engaged by Licensee in accordance with this Agreement that [*] to Licensee in accordance with this Agreement and the relevant [*] is calculated without reference to any payments associated with [*]. An example of calculation of the foregoing is set forth on the Royalty Calculation Schedule.
- 1.5. “Amgen” shall have the meaning set forth in the Preamble.
- 1.6. “Amgen Development Costs” shall mean Amgen’s (and its Affiliates’) fully-burdened, world-wide development costs [*] related to development of a Licensed Product, as more specifically set forth in the Development Costs Schedule.
- 1.7. “Amgen Development Data” shall mean the preclinical and clinical data generated by or on the behalf of Amgen or its Affiliates (both within and outside the Territory) in the course of its preclinical and clinical development of a Licensed Product, both before and after[*] of this Agreement.
- 1.8. “Amgen Indemnitees” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.9. “Amgen Indication” shall have the meaning set forth in Section 6.7.2 (Amgen Developed Indications).
- 1.10. “Amgen K.K.” shall mean Amgen Kabushiki Kaisha, a Japanese corporation.
- 1.11. “Annual Maximum” shall have the meaning set forth in Section 8.9.3 (Payment Caps).
- 1.12. “Bundle” shall mean a Licensed Product sold together with another pharmaceutical compound for a single price.
- 1.13. “[*]Quarter” shall mean a three-month period beginning on[*].
- 1.14. “[*]Year” shall mean a one-year period beginning on [*]and ending on[*].
- 1.15. “Change of Control” shall mean, with respect to Licensee, the occurrence of any of the following events: [*]
- 1.16. “Claims” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.17. “Collaboration” shall have the meaning set forth in Section 2.1 (Conduct of the Collaboration).
- 1.18. “Commercialization Committee” shall mean the committee established by the Parties to oversee and coordinate the commercialization of a particular Licensed Product in the Territory.

- 1.19. “*Confidential Information*” shall have the meaning set forth in Section 10.1 (Confidentiality; Exceptions).
- 1.20. “*Contract Interest Rate*” shall mean [*]% plus the [*] rate effective for the date [*], as published by The Wall Street Journal, Eastern U.S. Edition, on the date [*](or, if unavailable on such date, [*]on which such rate is available), or, if lower, the maximum rate permitted by Law.
- 1.21. “*Control*” shall mean, with respect to any Information or intellectual property, that the applicable Party owns or has a license to such Information or intellectual property and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense, or requiring any payment (whether or not then due and payable) under any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense.
- 1.22. “*Developed [*]*” shall mean a [*] having a [*] not consisting primarily of [*] that is either obtained through Licensee’s discovery research activities (whether exclusively internal or in collaboration with a Third Party) or where the rights to such [*] were controlled by a [*] at the time [*].
- 1.23. “*Development Committee*” shall mean the committee established by the Parties to oversee and coordinate the development of a particular Licensed Product in the Territory.
- 1.24. “*Distracting Product*”, with respect to each Licensed Product, shall have the meaning set forth on the Distracting Products Schedule.
- 1.25. “*Distracting Program*” shall mean the [*] or [*], in the Territory, of any Distracting Product. [*].
- 1.26. “*Distracting Transaction*” shall mean any transaction entered into by Licensee or its Affiliate after [*] whereby a Third Party that is engaged in a Distracting Program becomes an Affiliate of Licensee.
- 1.27. “*Distracting Transaction Affiliates*” shall mean those entities that are or would become Affiliates of Licensee by virtue of a Distracting Transaction.
- 1.28. “*Divest*” shall mean, with respect to any Distracting Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to such Distracting Program, including technology, Information, intellectual property and other assets materially relating thereto, to an independent Third Party, without the retention or reservation of any rights or interest (other than solely an economic interest) in such Distracting Program by the relevant Party or its Affiliates.
- 1.29. “*Effective Date*” shall have the meaning set forth in the Preamble.
- 1.30. “*Ex-Territory Distracting Affiliates*” shall mean those entities that are or would become Affiliates of Licensee by virtue of an Ex-Territory Distracting Transaction.
- 1.31. “*Ex-Territory Distracting Program*” shall mean any development, commercialization or manufacture of a Distracting Product intended for use or sale (or actually used or

sold) outside the Territory or intended for import (or actually imported) outside the Territory.

- 1.32. “*Ex-Territory Distracting Transaction*” shall mean any transaction entered into by Licensee or its Affiliate after [*] whereby a Third Party that is engaged in an Ex-Territory Distracting Program becomes an Affiliate of Licensee.
- 1.33. “*Federal Court*” shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).
- 1.34. “*First Commercial Sale*” shall mean the first sale of a Licensed Product following Regulatory Approval by or on the behalf of Licensee, its Affiliate or sublicensees.
- 1.35. “*Force Majeure*” shall have the meaning set forth in Section 16.8 (Force Majeure).
- 1.36. “*FTE*” shall mean the equivalent of the work of one employee full time for one year (consisting of at least a total of [*] weeks or [*] hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
- 1.37. “*FTE Rate*” shall mean [*] per full-time employee per year (as of [*]), increasing by [*]% of the then-current FTE Rate on [*].
- 1.38. “*GAAP*” shall mean either Japanese or U.S. generally accepted accounting principles, consistently applied, as used by a Party to record the relevant transaction.
- 1.39. “*Governmental Authority*” shall mean any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.
- 1.40. “*Indemnified Party*” shall have the meaning set forth in Section 13.2 (Claim for Indemnification).
- 1.41. “*Indemnifying Party*” shall have the meaning set forth in Section 13.2 (Claim for Indemnification).
- 1.42. “*Information*” shall mean all tangible and intangible techniques, information, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms.
- 1.43. “*Initiation*” of a clinical trial or to “*Initiate*” a clinical trial shall mean the first dosing of a human subject with a Licensed Product in such trial.
- 1.44. “*Joint Patents*” shall mean any invention, patent or patent application jointly owned by the Parties pursuant to Section 9.1 (Ownership).
- 1.45. “*Key Event*” shall have the meaning set forth in Section 6.2 (Key Event Time Frames).
- 1.46. “*Law*” shall mean, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

- 1.47. “*Licensed Amgen Know-How*” shall mean Information in Amgen’s (or its Affiliate’s) possession and Control, as of [*] or thereafter during the Term, that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Licensee Indications in the Territory. Licensed Amgen Know-How shall include Amgen Development Data that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Licensee Indications in the Territory. Licensed Amgen Know-How does not include Amgen manufacturing information. Licensed Amgen Know-How shall include Information known to the employees of Amgen K.K. as of the date of the consummation of the transactions contemplated in the Sale and Purchase Agreement that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Licensee Indications in the Territory.
- 1.48. “*Licensed Amgen Patents*” shall mean those patents and patent applications set forth on the Licensed Amgen Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional application thereof, [*] For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.49. “*Licensed Amgen Trademarks*” shall mean any trademark rights Controlled by Amgen in the Territory on or after [*] and corresponding to any trademarks adopted by Amgen for use with a Licensed Product in a Licensee Indication outside the Territory (not including any corporate or house marks, and not including any such marks to the extent such marks would conflict with any right of any Third Party inside the Territory).
- 1.50. “*Licensed Licensee Know-How*” shall mean Information in Licensee’s (or its Affiliate’s) possession and Control, as of [*] or thereafter during the Term, that is reasonably necessary for Amgen to develop, manufacture or commercialize a Licensed Product within or outside the Territory in any indication. Licensed Licensee Know-How shall include Licensee Development Data that is reasonably necessary for Amgen to develop, manufacture or commercialize a Licensed Product within or outside the Territory in any indication.
- 1.51. “*Licensed Licensee Patents*” shall mean those patents and patent applications owned or Controlled by Licensee or its Affiliate (including an interest in a patent or Joint Patent pursuant to Section 9.1 (Ownership))[*] For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.52. “*Licensed Licensee Trademarks*” shall mean any trademarks adopted by Licensee for use with a Licensed Product in the Territory in the Licensee Indications (not including any corporate or house marks).
- 1.53. “*Licensed Product*” shall mean any one of the pharmaceutical products listed on the Licensed Products Schedule.
- 1.54. “*Licensee*” shall have the meaning set forth in the Preamble.

- 1.55. “*Licensee Assumed Item*” shall have the meaning set forth in Section 9.2.1.2 (Licensee Secondary Prosecution).
- 1.56. “*Licensee Development Data*” shall mean the preclinical and clinical data generated by or on behalf of Licensee or its Affiliates in the course of its preclinical (if any) and clinical development of a Licensed Product, on or after [*].
- 1.57. “*Licensee Indemnitees*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.58. “*Licensee Indications*” shall mean with respect to each Licensed Product, the treatment, palliation, prevention or prophylaxis of disease in humans with respect only to: (i) those specific indications (e.g., third-line metastatic colorectal cancer) that, as of [*], are the subject of clinical development by Amgen or for which Amgen has received Regulatory Approval with respect to such Licensed Product outside the Territory; and (ii) any other specific indications that are added with respect to such Licensed Product pursuant to Section 6.7 (Additional Indications). For the avoidance of doubt, Licensee Indications does not include Amgen Indications.
- 1.59. “*Licensee Product*” shall have the meaning set forth in Section 3.9 (Right of First Discussion).
- 1.60. “*Losses*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.61. “*MHLW*” shall mean the Japanese Ministry of Health, Labour and Welfare, and any successor agency thereto.
- 1.62. “*Net Sales*” shall mean with respect to a given period, the gross invoiced sales price for a Licensed Product sold by or on behalf of Licensee, its Affiliates or licensees hereunder to Third Parties (not including Licensee’s Affiliates, unless and to the extent such Affiliate is the end-user of such a Licensed Product) during such period (plus any additional consideration received by Licensee, its Affiliates or licensees with respect to such Licensed Product sold), less the total of the following charges or expenses, as determined in accordance with GAAP:
- 1.62.1. Trade, cash, prompt payment and quantity discounts;
 - 1.62.2. Returns, allowances, rebates, chargebacks and payments to government agencies;
 - 1.62.3. Retroactive price reductions;
 - 1.62.4. 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;
 - 1.62.5. Credits and allowances for product replacement, whether cash or trade; and
 - 1.62.6. Non-recoverable sales taxes, excise taxes, tariffs and duties (excluding taxes when assessed on income derived from sales);
- in each case, to the extent related to sales of a Licensed Product in a Licensee Indication in the Territory and actually given.

- 1.63. “*Ongoing Studies*” shall mean those clinical studies that are being undertaken by Amgen as of [*] utilizing Amgen K.K. in the Territory, including those set forth on the Ongoing Studies Schedule.
- 1.64. “*Party/Parties*” shall have the meaning set forth in the Preamble.
- 1.65. “*Patent Matters*” shall have the meaning set forth in Section 9.2.1.1 (Amgen Primary Prosecution).
- 1.66. “*Phase I Trial*” shall mean, with respect to the United States, any human clinical trial, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required under 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.67. “*Phase II Trial*” shall mean, with respect to the United States, any human clinical trial conducted in the specific patient population with the disease or condition of interest intended to be studied in a Phase III Trial for the purposes of preliminary assessment of safety and efficacy in the indication being studied, and selection of the dose regimen(s) to be studied in a Phase III Trial, as described under 21 C.F.R. §312.21(b), and that, if the defined end-points are met, is sufficient to allow the Initiation of a Phase III Trial in the indication being studied, or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.68. “*Phase III Trial*” shall mean, with respect to the United States, any human clinical trial, that, if the defined end-points are met, is intended to be a pivotal trial for obtaining Regulatory Approval in the indication being studied or to otherwise establish safety and efficacy in patients with the indication being studied for purposes of filing for Regulatory Approval with the United States Food and Drug Administration (or its successor) as required under 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical study. In the event that a human clinical trial that would otherwise meet the definition of a Phase II Trial would, if the defined end-points are met, be sufficient to obtain Regulatory Approval in the indication being studied then, for the purposes of this Agreement, such trial shall be considered a Phase III Trial.
- 1.69. “*Pricing Approval*” with respect to a Licensed Product in the Territory shall mean initial assignment, and any subsequent amendments thereto from time to time, of a Japanese National Health Insurance drug price for such Licensed Product.
- 1.70. “*Prior Agreement*” shall have the meaning set forth in Section 10.6 (Prior Agreement).
- 1.71. “[*]” shall mean: (i) with respect to a Licensed Product for which [*] outside the Territory, that Amgen, its Affiliates, and other licensees have [*] related to North America and Europe for a [*]; and (ii) with respect to a Licensed Product for which [*] outside the Territory, Amgen, its Affiliates, and other licensees have [*] such Licensed Product outside the Territory.
- 1.72. “[*]” shall mean, with respect to a Licensed Product, that (i) a [*] has continued for at least [*] with respect to such Licensed Product; and (ii) Amgen, its Affiliates and licensees have not [*] such Licensed Product will be [*].

- 1.73. “*Publishing Party*” shall have the meaning set forth in Section 10.7.3 (Oversight and Review).
- 1.74. “*Quarterly Maximum*” shall have the meaning set forth in Section 8.9.4 (Maximum Payments).
- 1.75. “*Reasonably Diligent Efforts*” shall mean, with respect to Licensee and a particular Licensed Product, the application of a level of resources, efforts and urgency to develop and commercialize such Licensed Product consistent with Licensee’s practices in pursuing the development and commercialization of its other high-value pharmaceutical products in light of its characteristic features, target indication, competitiveness and sales volume, but in no event less than the high professional standards and level commonly applied by other pharmaceutical companies to their high-value pharmaceutical products. [*].
- 1.76. “*Recall*” means a “recall” (as per Article 70 of the Japanese Pharmaceutical Affairs Law) or “market withdrawal” (as per Article 77-4-3 of the Japanese Pharmaceutical Affairs Law) of a Licensed Product or any lots thereof.
- 1.77. “*Recoveries*” shall mean all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party in connection with the final judgment, award or settlement of any enforcement with respect to any Licensed Amgen Patent, Licensed Amgen Trademark, Licensed Amgen Know-How, Licensed Licensee Know-How, Licensed Licensee Trademark or Joint Patent, each of the foregoing with respect to Licensed Products in Licensee Indications in the Territory.
- 1.78. “*Regulatory Approval*” shall mean the product-specific approvals from Governmental Authorities necessary for the distribution and sale of a Licensed Product.
- 1.79. “*Regulatory Filing*” shall mean any filing with any Governmental Authority with respect to the development, marketing, commercialization or reimbursement of a Licensed Product.
- 1.80. “*Reviewing Party*” shall have the meaning set forth in Section 10.7.3 (Oversight and Review).
- 1.81. “*Secondary Publication*” shall have the meaning set forth in Section 10.7.1 (In Territory).
- 1.82. “*Sites*” shall have the meaning set forth in Section 4.15 (Transition of Ongoing Studies).
- 1.83. “*SOPs*” shall have the meaning set forth in Section 4.13 (Recalls).
- 1.84. “*SPC*” shall mean any patent term extension or related extension of rights, including supplementary protection certificates and similar rights.
- 1.85. “*State Court*” shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).
- 1.86. “*Steering Committee*” shall mean the committee established by the Parties to oversee and coordinate their activities hereunder, and to ensure appropriate communication and oversight by the Parties.

- 1.87. “*Sale and Purchase Agreement*” shall mean that certain Sale and Purchase Agreement between the Parties dated as of the date hereof.
- 1.88. “*Taxes*” shall mean any tax, excise or duty, other than taxes upon income.
- 1.89. “*Term*” shall mean the period beginning on [*] and ending upon the termination of this Agreement pursuant to Article 14 (Term and Termination).
- 1.90. “*Termination Date*” shall have the meaning set forth in Section 14.3.1 (General).
- 1.91. “*Territory*” shall mean Japan.
- 1.92. “*Territory IP*” shall have the meaning set forth in Section 9.4.1 (In Territory).
- 1.93. “*Territory Patents and Trademarks*” shall have the meaning set forth in Section 9.2.1.1 ([*]).
- 1.94. “*Third Party*” shall mean any entity other than a Party or an Affiliate of a Party.
- 1.95. “*Transition Period*” shall have the meaning set forth in Section 14.5 (Transition Period).
- 1.96. “*VAT*” shall mean any value added tax.
- 1.97. “*Vectibix*” shall mean Amgen’s proprietary anti-EGFr monoclonal antibody known in the U.S. as Vectibix™ .

2. COLLABORATION SCOPE AND GOVERNANCE

- 2.1. Conduct of the Collaboration. The Parties shall cooperate to develop and commercialize the Licensed Products in the Licensee Indications in the Territory, in accordance with the terms and conditions of this Agreement (the “*Collaboration*”).
- 2.2. Ex-Territory Activities. The Parties acknowledge that no rights are granted hereunder to Licensee with respect to any country outside the Territory. Licensee shall not research, develop, manufacture or commercialize any Licensed Product outside the Territory without the express prior written consent of Amgen. Amgen shall have the sole right to research, develop, manufacture and commercialize the Licensed Products outside the Territory.
- 2.3. Governance. The Collaboration shall be governed by a Steering Committee, which shall oversee the activities of the Parties hereunder generally, and by a Development Committee and a Commercialization Committee for each Licensed Product, which shall coordinate and oversee the development and commercialization, respectively, of Licensed Products in the Territory. The Steering Committee and each Development Committee shall be formed promptly following [*]. Each Commercialization Committee shall be formed promptly following [*] for Licensed Products which have already Initiated one or more Phase III Trials in the Territory. For all other Licensed Products, the relevant Commercialization Committee shall be formed promptly following Initiation of the first Phase III Trial in the Territory for such Licensed Product.
- 2.4. Membership. Unless otherwise agreed by the Parties, each of the Development and Commercialization Committees shall be comprised of [*] members appointed by

Amgen, and [*] members appointed by Licensee. Each such committee shall be led by [*] co-chairs, [*] appointed by each of the Parties. Unless otherwise mutually agreed by the Parties, the Steering Committee shall be comprised of [*] member appointed by Amgen and [*] member appointed by Licensee. Each of the committees shall have the right to delegate any of its responsibilities to one or more subcommittees as it determines appropriate.

- 2.5. Replacement of Members. Each Party shall have the right to replace its committee members or co-chairs by written notice to the other Party. In the event any committee member or co-chair becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member shall promptly appoint a replacement by written notice to the other Party.
- 2.6. Input from other Personnel. Any committee member shall have the right to solicit input or assistance from any other personnel of the Party that appointed such member.
- 2.7. No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, no committee shall have any authority to amend, modify or waive compliance with this Agreement.
- 2.8. Steering Committee. The Steering Committee shall be responsible for overseeing the Parties' conduct of the Collaboration generally, and for ensuring an appropriate level of oversight of the Collaboration.
 - 2.8.1. Meetings. The Steering Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meeting per [*] Year being in person), or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Steering Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the member appointed by the other Party. All Steering Committee meetings must have the member appointed by each Party in attendance.
 - 2.8.2. Reporting. Each Party shall keep the Steering Committee 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 member on the Steering Committee and as otherwise provided herein. Each Party shall fully inform the Steering Committee with respect to all relevant facts and activities regarding any Licensed Product reasonably requested by any member thereof.
 - 2.8.3. Decision Making. The Steering Committee shall make decisions by consensus.
- 2.9. Development Committee. With respect to each Licensed Product in the Territory, the applicable Development Committee shall be responsible for:
 - (i) reviewing and approving development plans (and changes thereto) prior to adoption of such plans (or changes) by Licensee; (ii) providing for communication and discussion between the

Parties to optimize the efficacy and safety of the development of the applicable Licensed Product in the Territory; (iii) reviewing and monitoring the activities and progress against the development plans, including site enrollment, patient enrollment, progress of trials and data received; (iv) communicating with the applicable Commercialization Committee(s) regarding the interrelationship between development activities and potential commercialization; and (v) communicating with the Parties regarding all of the foregoing.

- 2.9.1. *Meetings.* Each Development Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meetings per [*] Year being in person), more frequently as may be required by ongoing development activities, or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Development Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the co-chair appointed by the other Party. All committee meetings must have at least [*] member appointed by each Party in attendance.
- 2.9.2. *Reporting.* Each Party shall keep the relevant Development Committee fully and promptly informed of progress and results of development activities for which it is responsible or that it is permitted to conduct hereunder through its members on such Development Committee and as otherwise provided herein, including by promptly providing copies of all clinical data and results for Licensed Products as reasonably requested by the other Party. Each Party shall fully inform the applicable Development Committee with respect to all relevant facts and activities regarding any Licensed Product development matter reasonably requested by any member thereof. At least [*] days prior to the first meeting of each Development Committee of each [*] Quarter, each Party shall deliver to such Development Committee a written summary of development activities conducted hereunder and material clinical data and results received by each such Party since the last such report, in each case with respect to the applicable Licensed Product(s).
- 2.9.3. *Development Plans.* At least [*] days prior to the first meeting of each Development Committee of each [*] Year, Licensee shall provide each such Development Committee a copy of its proposed development plan for the relevant Licensed Product in the Territory for the next [*] for the Development Committee's review, comment and approval. In addition, should Licensee seek to make material changes to an approved development plan, then at least [*] days prior to the next meeting of the relevant Development Committee it shall provide the Development Committee any proposed changes to the previously approved development plan for the Development Committee's approval.

- 2.9.4. *Decision Making.* Each Development Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event the Development Committee fails to reach consensus, the committee [*] determination unless [*] reasonably likely to [*] on Amgen's [*] Licensed Product [*], in which case the committee [*]determination.
- 2.10. Commercialization Committee. With respect to each Licensed Product in the Territory, the applicable Commercialization Committee shall be responsible for: (i) reviewing and approving commercialization plans (and changes thereto) prior to adoption of such plans (or changes) by Licensee; (ii) communicating with the applicable Development Committee(s) regarding the interrelationship between development activities and potential commercialization; (iii) reviewing and monitoring the activities and progress against the commercialization plans; (iv) establishing appropriate processes for coordinating review of promotional materials to ensure compliance with Law and industry best practices; (v) overseeing the trademark and publication strategies; and (vi) communicating with the Parties regarding all of the foregoing.
- 2.10.1. *Meetings.* Each Commercialization Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meetings per [*] Year being in person), more frequently as may be required by ongoing commercialization activities, or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Commercialization Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the co-chair appointed by the other Party. All committee meetings must have at least [*] member appointed by each Party in attendance.
- 2.10.2. *Reporting.* Each Party shall keep the relevant Commercialization Committee fully and promptly informed of progress and results of commercialization activities in the Territory for which it is responsible or that it is permitted to conduct hereunder through its members on the Commercialization Committee and as otherwise provided herein. Each Party shall fully inform the Commercialization Committee with respect to all relevant facts and activities regarding any Licensed Product commercialization matter reasonably requested by any member thereof. For each Commercialization Committee, at least [*] days prior to the first Commercialization Committee meeting of each [*] Quarter, each Party shall deliver to the Commercialization Committee a written summary of commercialization activities conducted hereunder by each such Party since the last such report.
- 2.10.3. *Commercialization Plans.* At least [*] days prior to the first meeting of each Commercialization Committee of each [*] Year, Licensee shall provide each such Commercialization Committee a copy of its proposed commercialization

plan for the relevant Licensed Product in the Territory for the next [*] for the Commercialization Committee's review, comment and approval (either by indication or for all indications for which it is responsible in the Territory). In addition, should Licensee seek to make material changes to an approved commercialization plan, then at least [*] days prior to the next meeting of the relevant Commercialization Committee it shall provide the Commercialization Committee any proposed changes to the previously approved commercialization plan for the Commercialization Committee's approval.

- 2.10.4. *Decision Making.* Each Commercialization Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event a committee fails to reach consensus, the committee [*] determination unless [*] reasonably likely to [*] on Amgen's [*] of the applicable Licensed Product [*], in which case the committee [*] determination.
- 2.10.5. Right to Terminate Participation. Amgen shall have the right to terminate its participation in any or all of the committees contemplated pursuant to this Article 2 (Collaboration Scope and Governance) by [*] days prior written notice to Licensee. In the event of such termination, matters subject to the collaboration and oversight of the relevant Committees shall be dealt with directly between Amgen and Licensee. All information that was to be provided by a Party to a committee that has been terminated shall instead provide such information (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 Licensee's committee members, such matter shall instead be subject to the final determination of Amgen or Licensee, respectively.

3. GRANT OF LICENSE

- 3.1. Licensed Amgen Patents. Amgen hereby grants Licensee an exclusive right and license under the Licensed Amgen Patents during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell Licensed Products only in the Licensee Indications in the Territory. Such license (and such exclusivity) is only with respect to the Licensed Products in the Licensee Indications in the Territory. Such license shall include the right to sublicense only as set forth in Section 3.5 (Licensee Sublicensing).
- 3.2. Licensed Amgen Know-How. Amgen hereby grants Licensee an exclusive right and license during the Term, subject to the terms and conditions hereof, to utilize the Licensed Amgen Know-How solely for the purpose of supporting its development, commercialization, use and sale of Licensed Products only in the Licensee Indications in the Territory. Such license (and such exclusivity) is only with respect to the Licensed Products in the Licensee Indications in the Territory. Such license shall include the right to sublicense only as set forth in Section 3.5 (Licensee Sublicensing).
- 3.3. [*]. In addition to the rights granted to Licensee pursuant to Sections 3.1 (Licensed Amgen Patents) and 3.2 (Licensed Amgen Know-How), Amgen hereby grants Licensee [*] during the Term under certain [*], subject to the terms and conditions hereof, solely

to develop, commercialize, use and sell Licensed Products only in the Licensee Indications in the Territory. The [*] with respect to each Licensed Product are detailed on the [*] and shall be subject to the restrictions and conditions set forth therein. Such [*] shall include the right to [*] only as set forth in [*], and further subject to the restrictions and conditions set forth on [*]. Specific [*] with respect to the [*] are set forth on the [*]. Licensee (and any of its permitted sublicensees) shall comply with all such obligations. In addition, Licensee shall take any other reasonable steps requested by Amgen to ensure compliance with the [*] (including providing [*]). At Amgen's request, Licensee shall cooperate with Amgen to secure for Licensee some or all [*] from the [*] (including by [*]), provided, however, that Licensee shall not be required to [*] than those set forth on [*]. At such time as Licensee has [*] with respect to any [*] hereunder, the [*] pursuant to this Agreement [*].

- 3.4. Licensed Licensee Know-How and Patents. Licensee hereby grants Amgen [*] right and license, subject to the terms and conditions hereof, under the Licensed Licensee Know-How and Licensed Licensee Patents solely for the purpose of the development, commercialization, manufacture, use and sale of Licensed Products outside the Territory (and within the Territory, in any Amgen Indications) for all uses, and inside and outside the Territory, for performing its obligations hereunder, including any supply obligations with respect to Licensed Products. Such license shall include the right to sublicense [*] provided, however, that: (i) any sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Licensee; (ii) Amgen shall be responsible for any disclosure of the Confidential Information of Licensee by such sublicensee in violation of the provisions of Article 10 (Confidentiality and Publications); (iii) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; and (iv) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions.
- 3.5. Licensee Sublicensing. Licensee shall have the right to sublicense the rights granted it hereunder only with Amgen's prior written consent, which Amgen may withhold or condition in its sole discretion. Any permitted sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Amgen and Licensee shall be responsible for any disclosure of the Confidential Information of Amgen by such sublicensee in violation of the provisions of Article 10 (Confidentiality and Publications). In addition, such written agreement shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed, and Licensee shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. No sublicense shall operate to excuse Licensee's compliance with its obligations hereunder. Licensee shall have the right to distribute a Licensed Product in the Territory through reputable distributors.
- 3.6. Provision of Know-How. Following [*], the Parties shall cooperate to establish procedures for the provision of Licensed Amgen Know-How to Licensee and Licensed Licensee Know-How to Amgen. During the Term, Amgen shall use reasonable efforts to provide all material Licensed Amgen Know-How to Licensee, and Licensee shall use reasonable efforts to provide all material Licensed Licensee Know-How to Amgen. In any event, each of the Parties shall provide to the other any Licensed Amgen Know-

How or Licensed Licensee Know-How (respectively) as the other Party shall reasonably request. Notwithstanding the foregoing, Amgen shall have no obligation to provide manufacturing information to Licensee and neither Party shall have an obligation to provide information relating to any product other than the Licensed Products.

3.7. Trademarks.

3.7.1. *Grant to Licensee.* Amgen hereby grants Licensee [*] (except as otherwise expressly set forth herein (such exception to include Amgen's co-promotion rights pursuant to Section 5.2 (Amgen Co-Promotion Right) and the transition period described in Section 14.5 (Transition Period))) right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell a Licensed Product in the Territory in the Licensee Indications under the same Licensed Amgen Trademarks as used by Amgen for such Licensed Product in the corresponding indications outside the Territory. Such license shall include the right to sublicense only as set forth in Section 3.5 (Licensee Sublicensing). The Parties acknowledge that the use of the Licensed Amgen Trademarks in the Territory may have commercial value to Licensee, and that Licensee shall have the right to commercialize a Licensed Product in the Licensee Indications in the Territory under the same Licensed Amgen Trademarks as utilized for such Licensed Product in such indications by Amgen outside the Territory. Should the Parties desire that a different trademark be used for Licensee Indications in the Territory, or if additional trademarks to those used outside the Territory are otherwise required, the Parties shall consult and agree upon an additional or replacement trademark (or trademarks). In addition, if the manufacture of Licensed Product for Licensee for use in the Territory materially varies from the manufacture of Licensed Product for Amgen or its Affiliates for use outside the Territory, then upon request of Amgen the Parties shall consult and agree upon a replacement trademark (or trademarks). Upon Amgen's request, Licensee shall include an Amgen trademark designated by Amgen to Licensee in writing (e.g., "Amgen") on all packaging, labeling, promotional and marketing materials for the applicable Licensed Product in equal prominence to those of Licensee. Amgen hereby grants Licensee a non-exclusive right and license, with the right to sublicense only as set forth in Section 3.5 (Licensee Sublicensing), during the Term, subject to the terms and conditions hereof, to use such marks solely for such purpose.

3.7.2. *Grant to Amgen.* Licensee hereby grants Amgen [*] right and license during the Term to use Licensed Licensee Trademarks in connection with Amgen's activities pursuant to Section 5.2 (Amgen Co-Promotion Right). Upon any termination or expiration of this Agreement (in its entirety or with respect to a particular Licensed Product in accordance with Section 14.2.3 (Specific Product Termination)), such license shall become perpetual, and shall include the right to use the relevant Licensed Licensee Trademarks (and the associated goodwill) in connection with the relevant Licensed Product(s) in all indications and both within and outside the Territory or, at Licensee's option, Licensee shall have the right to assign at no charge to Amgen the relevant Licensed Licensee Trademarks (and the associated goodwill).

- 3.8. Trademark Quality Standards. Each Party shall (i) maintain such reasonable quality standards for the Licensed Amgen Trademarks (with respect to Licensee) or the Licensed Licensee Trademarks (with respect to Amgen) as it maintains for its own trademarks of a similar nature and shall comply with the other Party's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time); (ii) not use any Licensed Amgen Trademark (with respect to Licensee) or Licensed Licensee Trademark (with respect to Amgen) in a manner that suggests any connection with any product other than a Licensed Product or any service; and (iii) not use or display the Licensed Amgen Trademarks (with respect to Licensee) or the Licensed Licensee Trademarks (with respect to Amgen) in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any Licensed Amgen Trademark (with respect to Licensee) or Licensed Licensee Trademark (with respect to Amgen), the Parties shall agree upon a guideline for use of such trademarks, including the review procedure and timing. From time to time, upon request by a Party, the other Party shall provide copies of the usage of the Licensed Amgen Trademarks (with respect to Licensee) or Licensed Licensee Trademarks (with respect to Amgen) used in the marketing or promotion of a Licensed Product in order to review such usage. Amgen agrees that it shall not seek to register or obtain ownership rights in any Licensed Licensee Trademark (or confusingly similar trademark) and Licensee agrees that it shall not seek to register or obtain ownership rights in any Licensed Amgen Trademark or any trademark used by Amgen in connection with a Licensed Product outside the Territory in any indication (or confusingly similar trademark to any of the foregoing).
- 3.9. Right of First Discussion. Licensee agrees that Amgen shall have a right of first discussion with respect to any Distracting Product contemplated to be outlicensed by Licensee or its Affiliate, or rights to which are contemplated to be sold or transferred to a Third Party, or for which Licensee or its Affiliate seeks a development and/or commercialization collaborator (a "*Licensee Product*") for North America or Europe (or any portion thereof). Should Licensee determine to seek a licensee or collaborator in such territory for a Licensee Product, it shall give prompt written notice to Amgen thereof, and shall provide Amgen any information reasonably requested by Amgen to allow Amgen to determine its potential interest in such Licensee Product. Should Amgen, within [*] days of receipt of such notice and information, notify Licensee in writing that Amgen is interested in pursuing a potential license or collaboration, then Licensee and Amgen shall discuss such a potential transaction in good faith, and Licensee shall not discuss a potential license or collaboration with respect to such Licensee Product with any Third Party until at least [*] days after initiation of such good-faith discussions. No such license or collaboration shall be effective or binding on either Party unless and until set forth in a definitive written agreement duly executed by the Parties.
- 3.10. Retained Rights and Limitations. No rights are granted to Licensee hereunder to Licensed Amgen Patents, Licensed Amgen Know-How or Licensed Amgen Trademarks outside the Licensee Indications, or outside the Territory. No rights are granted to Licensee hereunder to make or have made a Licensed Product or any other product. No rights are granted to Licensee hereunder to import or export a Licensed Product

manufactured by Amgen or its licensee. No rights are granted herein to Licensee to control the research, development or commercialization of a Licensed Product outside the Territory. No rights to either Party's patents, trademarks or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved.

- 3.11. [*]. Amgen shall have the right to [*] to the Collaboration as [*] by written notice to Licensee, such notice to be given within [*]. As of the date of such notice, [*] shall be considered [*] hereunder for all purposes. Promptly following such [*], Licensee shall [*] Amgen any [*] that would have been required hereunder [*] as a [*] (including pursuant to [*] and shall reimburse to Amgen any reasonable costs incurred by Amgen with respect to [*] in the Territory subsequent to [*] (including costs of [*] in the Territory). In the event Amgen does not so [*] within the [*], then Amgen shall [*]of the [*] Licensee pursuant to Section [*]. Any such [*] shall be [*] within [*] days of the end of such [*] period.

4. DEVELOPMENT AND REGULATORY APPROVAL

- 4.1. Responsibility for Development in Licensee Indications. Licensee shall use its Reasonably Diligent Efforts to develop each Licensed Product in each Licensee Indication in the Territory. Such development shall be conducted in accordance with the then-current development plan approved by the Development Committee for such Licensed Product in such Licensee Indication. Licensee's responsibility with respect to Licensed Products in Licensee Indications in the Territory shall include: (a) filing for and seeking Regulatory Approval for Licensed Products in the Territory for a particular Licensee Indication in the name of Licensee from the relevant Governmental Authorities; (b) identifying and carrying out all major development tasks to be conducted prior to submission of filings for Regulatory Approval of a Licensed Product in the Territory for a particular Licensee Indication and any post-approval activities to be conducted for any such Licensed Product in such Licensee Indication; (c) identifying key development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (d) carrying out all aspects of all clinical trials necessary to obtain Regulatory Approval in the name of Licensee in the Territory for each Licensed Product in each Licensee Indication (including post-approval clinical studies) including, but not limited to, (i) designing study protocols; (ii) establishing/contracting with clinical trial sites, investigators and clinical research organizations, (iii) enrolling clinical trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing clinical trial results; (e) performing any other additional clinical research in support of the clinical development of each Licensed Product; (f) forecasting clinical manufacturing production requirements; and (g) reporting on study design, study outcome, other communications and regulatory filings to the appropriate Governmental Authority. Licensee shall be solely responsible for its costs incurred in its development of the Licensed Products.
- 4.2. Preclinical Development in Licensee Indications. Amgen shall have the first option to perform (itself or through a subcontractor) any preclinical research that is required in order to conduct development of a Licensed Product in one or more Licensee

Indications in the Territory in accordance with this Agreement. Licensee shall give Amgen prompt written notice upon becoming aware of any such requirement. Amgen shall, promptly following receipt of such notice, notify Licensee of whether or not Amgen intends to conduct such research or, instead, shall permit Licensee to do so. Should Amgen not elect to perform such research, then Licensee shall promptly and diligently conduct such research (itself or through a subcontractor). [*] Such research shall be conducted in accordance with a research plan to be agreed in writing by Amgen and Licensee. Notwithstanding the foregoing, should [*] is reasonably likely to [*] of a Licensed Product [*] then it shall notify [*] In such case, [*] Upon the request of either Party, the Parties shall [*] of such research.

- 4.3. [*] Should Licensee determine to [*] of such Licensed Product for the [*] (including with respect to [*] (e.g., [*] and including [*] Licensee shall give Amgen prompt prior written notice thereof. The Parties shall promptly meet to discuss [*]. Should Amgen agree in writing to permit the [*], the Parties shall agree on a course of action with respect to such [*] prior to undertaking any such [*] and Licensee shall conduct such [*] in accordance with any [*] by Amgen to [*] to Amgen's [*]. Should Amgen not so agree, then Licensee shall not [*]. Upon the request of either Party, the Parties shall meet to discuss [*]
- 4.4. Development in Combination. Licensee shall not, without Amgen's prior express written consent, conduct any development of a Licensed Product in combination with any other pharmaceutical product, unless and only to the extent that Amgen is pursuing such development outside the Territory.
- 4.5. Development in Amgen Indications and Outside the Territory. Amgen shall have the sole right to manage and conduct the development of the Licensed Products inside the Territory in any Amgen Indications and outside the Territory in all indications. The foregoing is without prejudice to Licensee's payment obligations pursuant to Section 8.9 (Development Cost Sharing).
- 4.6. Global Development. The Parties acknowledge that it may be in their mutual interests to integrate Licensee's development of a Licensed Product within the Territory into Amgen's global development plan for such Licensed Product for a particular Licensee Indication. The Parties agree to discuss in good faith where it may be appropriate to so integrate such development, and the relevant cost-sharing that will be applicable thereto. The Parties further acknowledge the mutual desire to progress Licensed Products in an effort to provide meaningful therapies to patients. While each Party acknowledges that the Licensed Products are of a developmental nature and that there is no guarantee that any or all Licensed Products will ultimately provide such benefits, the Parties express their current desire to seek to progress the Licensed Products as is reasonably prudent, in accordance with this Agreement, to provide data that can inform the Parties of the development potential of the Licensed Products.
- 4.7. Sharing of Regulatory Filings. Licensee will disclose to Amgen a draft copy of any Regulatory Filing in the Territory (and any regulatory filing relating to manufacturing made by Licensee in accordance with Section 7.4 (Responsibility for Regulatory Filings with Respect to Manufacturing)) no less than [*] days prior to filing it with a Governmental Authority. Licensee will consider in good faith any comments made by

Amgen with respect to such filings. Where documents are not in English, Licensee shall also provide an English summary. Licensee shall maintain a database which contains all clinical trial data accumulated from all clinical trials of a Licensed Product conducted by, on behalf of, or with the support of Licensee in the Territory (in a computer readable format as reasonably specified by Amgen). Upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings (and any regulatory filing relating to manufacturing made by Licensee in accordance with Section 7.4 (Responsibility for Regulatory Filings with Respect to Manufacturing)) or Regulatory Approvals for a Licensed Product in the Territory, and Amgen shall provide the same such right of reference to Licensee with respect to such Regulatory Filings and Regulatory Approvals outside the Territory, in each case as reasonably necessary for the requesting Party's development or commercialization of such Licensed Product as permitted hereunder (or, with respect to Amgen, manufacture of such Licensed Product). Notwithstanding the foregoing, Amgen shall not be required to provide to Licensee nor to allow Licensee to access (but shall provide a right of reference as set forth in Section 4.12.3 (Amgen Cooperation – Manufacturing Information) to the extent necessary) Amgen's manufacturing information with respect to a Licensed Product or any sections of any Regulatory Filing related thereto and neither Party shall have an obligation to provide information relating to any product other than a Licensed Product.

4.8. Quality Agreement. Promptly following [*], the quality assurance departments of Amgen and Licensee will develop and agree upon a quality agreement governing the quality and specifications of clinical Licensed Products (or, should Amgen so determine, separate quality agreements for each Licensed Product or subgroups of Licensed Products) to be supplied hereunder (with commercial product handled separately through the supply agreement to be entered into pursuant to Section 7.3 (Supply) or one or more additional quality agreements) including with respect to product quality and product complaints (to the extent not covered in a separate safety agreement entered into pursuant to Section 4.10 (Safety Agreement)) with respect to Licensed Products. The quality agreement will be documented in writing, and routinely updated by mutual written agreement of the Parties.

4.9. Transfer of Regulatory Filing. Promptly after [*], Amgen shall transfer to Licensee all Regulatory Filings in the Territory with respect to each Licensed Product. Licensee shall not transfer title in, fail to maintain or otherwise attempt in any manner to dispose of any Regulatory Filings or Regulatory Approvals or other governmental licenses, approvals or certificates for any Licensed Product in the Territory without the prior written approval of Amgen. Notwithstanding the foregoing, Amgen shall have no obligation to transfer any Regulatory Filing if effectuating such transfer may give rise to any material delay in, or make less likely, the receipt of any Regulatory Approval or might otherwise adversely affect any such Regulatory Filing. Should any such transfer be so delayed: (i) Amgen shall take steps reasonably necessary to provide Licensee the necessary access to such Regulatory Filing; and (ii) Amgen shall thereafter transfer such Regulatory Filing at such time as such delay or adverse effect is no longer likely to occur. In particular, the Parties shall discuss the appropriate timing for the transfer of Regulatory Filings related to Vectibix.

- 4.10. Safety Agreement. Promptly following [*], the safety departments of Amgen and Licensee will develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the Licensed Products sufficient to permit each Party, its Affiliates, permitted sublicensees and licensees to comply with Law, including, to the extent applicable, those obligations contained in U.S. Food and Drug Administration (or any successor agency) and MHLW regulations. The safety data exchange procedures will be documented in writing, and promptly updated if required by changes in Law or by agreement of the Parties.
- 4.11. Adverse Event Reporting. Each Party shall be responsible for reporting to the relevant Governmental Authorities all adverse events with respect to the Licensed Products (whether within or outside the Territory), to the extent required by and in accordance with Law. Each Party will ensure that its Affiliates, permitted sublicensees and licensees, as applicable, comply with all such reporting obligations. Each Party will designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events with respect to a Licensed Product.
- 4.12. Communications.
- 4.12.1. *Licensee Responsibility*. Licensee shall have exclusive responsibility for all correspondence and for any official communication (except as Amgen may be required by Law or a Governmental Authority to communicate) regarding the Licensed Products in Licensee Indications with applicable Governmental Authorities in the Territory (other than with respect to manufacturing) (but including with respect to any aspects of manufacturing for which Licensee has assumed responsibility as expressly provided in Section 7.4 (Responsibility for Regulatory Filings with Respect to Manufacturing)). Without prejudice to the time periods relevant to Regulatory Filings pursuant to Section 4.7 (Sharing of Regulatory Filings), Licensee will supply to Amgen a copy of: (i) all such correspondence and communications to any such Governmental Authority at least [*] days 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 correspondence and communications from any such Governmental Authority within [*] days after receipt of any such correspondence. Materials provided pursuant to Section 4.7 (Sharing of Regulatory Filings) need not be re-provided pursuant to this subsection 4.12.1 (Licensee Responsibility) unless changed. Where correspondence or communications are not in English, Licensee shall also provide an English summary. Licensee shall consider in good faith any comments or suggestions made by Amgen with respect to any such communication. Amgen shall reasonably cooperate with Licensee in responding to any inquiry made by a Governmental Authority in the Territory regarding a Licensed Product in Licensee Indications, and Licensee shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith. Amgen shall be entitled to observe and participate in any discussions between Licensee and any Governmental Authority relating to any Licensed Products, and Licensee shall give Amgen [*] days prior written notice

thereof (or prompt written notice, if [*] days notice is impractical). Should Licensee be unable to solicit Amgen's participation in any such discussion (as, for example, with respect to a call or visit to Licensee by such Governmental Authority without notice), then Licensee shall provide Amgen prompt written notice of such communication with a summary of the discussion.

4.12.2. *Amgen Responsibility.* Amgen shall have exclusive responsibility for all correspondence and for any official communication (except as Licensee may be required by Law or a Governmental Authority to communicate or as expressly provided in Section 4.12.1 (Licensee Responsibility)) regarding manufacture of the Licensed Products and regarding the Licensed Products inside the Territory in Amgen Indications and outside the Territory in all indications. With respect to correspondence and communication with Governmental Authorities relating to Licensed Products, Amgen shall use reasonable efforts to provide Licensee copies of material written correspondence as reasonably necessary to permit Licensee to comply with its relevant regulatory obligations (provided that Amgen shall not be required to disclose competitively sensitive information or manufacturing information).

4.12.3. *Amgen Cooperation – Manufacturing Information.* Upon Licensee's request, Amgen will reasonably cooperate with Licensee to make and provide copies of any direct communications by Amgen either to or from the Governmental Authorities having jurisdiction in the Territory regarding the manufacture of any Licensed Product by Amgen for supply to Licensee; provided, however, that Amgen's obligation to provide Licensee with manufacturing and process information is limited to the circumstance where the information is reasonably required for Licensee to carry out its development and commercialization responsibilities, or access to such information is required by Law or a Governmental Authority having jurisdiction in the Territory; but Licensee shall only be entitled to use such information to the extent required by such Law or Governmental Authority or to the extent reasonably required to carry out its development and commercialization responsibilities hereunder. Amgen shall 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 (in order to better protect the confidentiality of such information).

4.13. Recalls. The Parties shall exchange their internal standard operating procedures as to product recalls ("SOPs") reasonably promptly after [*] and thereafter reasonably promptly after such SOPs are approved or modified. If either Party becomes aware of information about quantities of a Licensed Product supplied by Amgen to Licensee which may not conform to the specifications for such Licensed Product then in effect, or for which there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, or for which a Licensed Product itself is or is likely to be the subject of a Recall in the Territory, it shall promptly so notify the other Party and the Party having the right to control such a Recall pursuant to Section 4.13.1 (Licensee Right) or 4.13.2 (Amgen Right) shall have the right to take immediate action with notice to the other Party when the regulatory timeframes or public safety considerations

so require. The Parties will meet (in person, by telephone or otherwise) to discuss the circumstances of any potential Recall and to consider appropriate courses of action, which courses of action with respect to a Recall shall be consistent with the internal SOP of the Party having the right to control such Recall pursuant to Section 4.13.1 (Licensee Right) or 4.13.2 (Amgen Right), and the other Party shall make available to the Party having the right to control such Recall all pertinent records which the Party having the right to control such Recall may reasonably request to assist in effecting any Recall (provided, however, Amgen shall be obligated to provide manufacturing information to Licensee only to the extent necessary for Licensee to conduct such Recall, and Amgen shall 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) as appropriate (in order to better protect the confidentiality of such information). In the event of an order of a Governmental Authority having jurisdiction in the Territory mandating a Recall, the Party having the right to control such a Recall pursuant to subsection 4.13.1 (Licensee Right) or 4.13.2 (Amgen Right) shall promptly comply with such order with written notice to the other Party.

4.13.1. *Licensee Right.* Licensee shall have the sole right to control a Recall of a Licensed Product in the Licensee Indications in the Territory. Licensee shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.13 (Recalls) for such periods as may be required by Law, but in any event for no less than [*]

4.13.2. *Amgen Right.* Amgen shall have the sole right to control a Recall of a Licensed Product inside the Territory in any Amgen Indication and outside the Territory in all indications. Amgen shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.13 (Recalls) for such periods as may be required by Law, but in any event for no less than [*]

4.14. Cooperation Generally. Subject to the oversight of the Development Committee, the Parties shall provide each other with any cooperation reasonably requested by the other with respect to the development of a Licensed Product in the Territory.

4.15. [*].

4.16. [*]. The Parties acknowledge that Amgen has ongoing [*] in the Territory with respect to certain [*] other than [*] which it may have previously performed through [*]. Licensee agrees that it shall provide Amgen any [*] reasonably requested by Amgen to [*] of such [*] to Amgen or its designee and to enable [*] with such [*]. Amgen shall [*] any [*] Licensee in providing [*].

4.17. [*]. Amgen will seek to promptly inform Licensee of any [*] and Amgen's [*], to the extent practicable. Upon request of Licensee, during the [*] day period following notice to Licensee of [*]:

4.17.1. *Discuss* [*]. Amgen will engage with Licensee in good faith discussion with respect to [*] necessary to [*] of the applicable [*]; and

4.17.2. *Discuss* [*]. In addition to the discussions set forth in Section 4.17.1 (*Discuss* [*]), in the event: (a) Amgen [*] develop a Licensed Product in [*]; (b) Amgen causes a [*] with respect to such Licensed Product due to [*] of an [*] that

Amgen intends to [*]; and (c) the applicable [*] is, as of the date of notice of [*] Licensed Product was [*] prior to the date of notice of [*], then, during such [*] day period, upon request of Licensee, the Parties shall also [*] with respect to [*] such [*] in the Territory.

Any [*] the Parties with respect to any of the foregoing shall be [*], and neither Party shall [*]. Notwithstanding the foregoing, if a [*] is initiated for [*] prior to [*] for such [*], then the rights set forth in [*] shall not apply, and if [*] the Agreement, neither the provisions of [*] or [*] shall apply.

4.18. Provision of Development Information. If Amgen [*] with [*] whereby Amgen [*] with respect to a Licensed Product in [*], such [*] will [*] whereby such [*] will [*] with [*] hereunder.

5. COMMERCIALIZATION

- 5.1. Operational Control in Licensee Indications. Licensee shall have operational responsibility for commercialization of the Licensed Products in the Territory in the Licensee Indications. Licensee shall commercialize the Licensed Products in all Licensee Indications in the Territory. Such commercialization shall be conducted in accordance with the then-current commercialization plan approved by the Commercialization Committee. Licensee shall promote and commercialize the Licensed Products using only professional and well-trained employees of Licensee, and shall not utilize a contract sales organization in connection with a Licensed Product without Amgen's prior written approval. Subject to the foregoing, with respect to Licensee Indications in the Territory, Licensee's responsibilities shall include: (a) determination of commercial strategies (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch and post-launch marketing and promotion, pricing and reimbursement and field sales force optimization); (b) determination of packaging and labeling (provided, however, that Amgen shall have the right to participate in any discussions with Governmental Authorities with respect to labeling in accordance with Section 4.12.1 (Licensee Responsibility)); (c) creation of promotional materials regarding the Licensed Products which are intended for distribution to Third Parties (including medical professionals) and to Licensee's sales force (subject to Section 3.8 (Trademark Quality Standards)); (d) determining and conducting promotion activities; and (e) conducting sales, distribution and medical affairs activities, including booking sales (i.e., recognizing all revenues), taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Licensee shall be solely responsible for its costs incurred in its commercialization of the Licensed Products.
- 5.2. Amgen Co-Promotion Right. Amgen shall have the right, on an indication-by-indication basis, upon [*] written notice to Licensee to co-promote each Licensed Product in one or more Licensee Indications in the Territory, from and [*] in the Territory. Licensee shall provide Amgen any information reasonably requested by

Amgen to allow Amgen to consider whether to exercise such right. Should Amgen elect to co-promote a Licensed Product in one or more Licensee Indications in the Territory, it may elect to provide up to [*]%) of the details for such indication, and Amgen's notice of exercise of its option shall specify the percentage of total details (up to such maximum) that Amgen desires to perform for such indication. The Parties shall cooperate to allocate details between them on an equitable basis in good faith, taking into account geography, settings, provider category and detailing position, as well as Amgen's sales force composition and strategic focus in the Territory so as not to unreasonably interfere with Licensee's commercialization activities hereunder. Licensee shall pay Amgen [*] (but not less than [*]). Amgen shall have the right to terminate its co-promotion activities by [*] days notice to Licensee, and the Parties shall cooperate to transition such activities to Licensee with a minimum of disruption. At the request of either Party, the Parties shall enter into a written agreement detailing the terms and conditions of such co-promotion effort.

- 5.3. Commercialization in Amgen Indications and Outside the Territory. Amgen shall be solely responsible for the commercialization of the Licensed Products inside the Territory in Amgen Indications and outside the Territory in all indications and, in each case, the costs thereof. Licensee shall have no rights with respect thereto.
- 5.4. Compliance with Laws, Regulations and Guidelines. Each Party agrees to comply with Law with respect to the development and commercialization of the Licensed Products in the Licensee Indications in the Territory. Neither Party shall be required to undertake any activity relating to the commercialization of a Licensed Product in the Territory that it believes, in good faith, may violate any Law.
- 5.5. Cooperation Generally. Subject to the oversight of the Commercialization Committee, the Parties shall cooperate generally with respect to the commercialization of the Licensed Products in the Licensee Indications in the Territory.

6. LICENSEE AND AMGEN INDICATIONS; ACTIVITIES OUTSIDE THE COLLABORATION

- 6.1. Reasonably Diligent Efforts. Licensee shall use Reasonably Diligent Efforts to develop, obtain Regulatory Approval for and commercialize each Licensed Product in each Licensee Indication in the Territory.
- 6.2. [*]. With respect to each of the [*], there shall be a [*] with respect to a particular Licensed Product in a given Licensee Indication would result in such [*] being [*] in the Territory no later than [*] with regard to the [*]; and, [*] with regard to the [*] and the [*], as the case may be, after the corresponding [*] (or its Affiliate or licensee) [*] with respect to the [*]. Should Licensee [*] with respect to a particular [*] during such time period, there shall [*] that Licensee [*] with respect to such Licensed Product, which [*] Licensee may [*] by [*] the [*] to [*] within: [*] with regard to [*]; and, [*] with regard to the [*] and the [*], as the case may be, of [*]. For the purposes of this Section 6.2 [*] achieved by [*] prior to [*] shall be [*]. For the purposes of this Section 6.2 [*] achieved by Amgen outside the Territory with respect to [*] prior to [*] provided by Amgen pursuant to [*] shall be deemed to have been [*].

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6.3. [*]. If Licensee [*] in accordance with Section [*] or [*] with respect to a Licensed Product, then Amgen [*]. If Licensee [*], then Amgen shall [*] with respect to such [*]. Should Amgen provide [*] to Licensee with respect to such Licensed Product, [*] with respect to such Licensed Product upon [*], or upon such earlier point as Amgen has specified by no less than [*] days written notice to Licensee. During such [*], Licensee shall [*] with respect to such Licensed Product [*].

6.4. [*].

6.5. [*].

6.6. [*].

6.7. Additional Indications.

6.7.1. *Licensee Proposed Indications.* Licensee shall develop and commercialize Licensed Products only in Licensee Indications. Should Licensee wish to develop or commercialize a Licensed Product in the Territory in an indication other than a Licensee Indication, it shall request Amgen's written approval thereof and the Parties shall discuss in good faith expansion of the definition of Licensee Indications to include such indication. Licensee shall provide Amgen any information reasonably requested by Amgen in order to allow Amgen to understand the circumstances and relevant factors with respect to such request. Amgen shall have the right to approve or reject the expansion of such definition in its sole discretion. Should Amgen agree in writing to expand the definition of Licensee Indication to include the newly proposed indication, then such indication shall, from such point forward, be a Licensee Indication. Should Amgen not so agree, then Licensee shall not develop or commercialize such Licensed Product in the indication so proposed. Any such approved development shall be subject to [*]

6.7.2. *Amgen Developed Indications.* Within [*] days after Amgen's written request with respect to a Licensed Product in a particular indication (other than a Licensee Indication) which is then subject to actual or planned clinical development by Amgen outside the Territory, Licensee shall inform Amgen in writing of whether or not it intends to develop and commercialize such Licensed Product in the Territory in such indication. Amgen shall provide Licensee with all information reasonably requested by Licensee reasonably necessary to enable

Licensee to make such determination. Should Licensee elect in writing to do so during such [*] day period, then such indication shall, from that point forward, be a Licensee Indication. Should Licensee notify Amgen that it does not intend to so develop and commercialize such Licensed Product for such indication (or fail to timely respond to Amgen's request), then such indication in the Territory shall become an "Amgen Indication" with respect to such Licensed Product, and Licensee shall have no rights hereunder with respect thereto. Amgen shall have the right to develop and commercialize, itself or through one or more Third Parties, the Licensed Products in the Territory in Amgen Indications, without restriction and without payment or obligation to Licensee.

7. MANUFACTURE AND SUPPLY

- 7.1. Manufacturing Rights. No rights are granted to Licensee hereunder to manufacture a Licensed Product or to obtain a Licensed Product from any entity other than Amgen or its designee. Licensee shall not manufacture a Licensed Product or obtain a Licensed Product from any entity other than Amgen or its designee, except as expressly provided in the Clinical Supply Schedule or a supply agreement separately entered into between the Parties.
- 7.2. Clinical Supply. Licensee shall obtain its requirements of Licensed Products (except for Vectibix, clinical supply for which is the subject of Section 7.3 (Supply)) for use in clinical development solely from Amgen or its designee, except to the extent expressly set forth on the Clinical Supply Schedule attached hereto. The terms for providing such clinical supply are set forth on the Clinical Supply Schedule. The Parties may determine to include in one or more commercial supply agreements to be entered into in accordance with Section 7.3 (Supply) with respect to Licensed Products provisions for clinical supply of such Licensed Products.
- 7.3. Supply. The Parties (or their Affiliates) will enter into a supply agreement for the clinical and commercial supply of Vectibix. The supply agreement is attached hereto as the Vectibix Supply Agreement Schedule and shall be entered into by the Parties concurrently with the execution of this Agreement. Following the initiation of the first Phase III Trial for a Licensed Product in the Territory, upon the request of either Party, the Parties shall negotiate in good faith a commercial supply agreement for commercial supply of such Licensed Product to Licensee for use in the Territory. The terms of such commercial supply agreement shall be materially consistent with the Supply Agreement Term Sheet Schedule attached hereto.
- 7.4. Responsibility for Regulatory Filings with Respect to Manufacturing. Amgen shall be solely responsible for the preparation and submission of all regulatory filings required to be filed with any Governmental Authority in the Territory with respect to the manufacture of a Licensed Product provided to Licensee by Amgen (including with respect to the use of any contract manufacturer to produce such Licensed Product on Amgen's behalf) (the foregoing "Manufacturing Filing Responsibilities"), except to the extent that either: (i) Licensee has assumed responsibility for aspects of manufacturing pursuant to the Clinical Supply Schedule, a supply agreement between the Parties or other agreement between the Parties; or (ii) Amgen has maintained manufacturing

responsibility but notifies Licensee that it wishes to transition Manufacturing Filing Responsibilities with respect to one or more Licensed Products to Licensee. In any of the foregoing cases, the Parties shall cooperate to transition the relevant Manufacturing Filing Responsibilities to Licensee and Licensee thereafter shall be solely responsible for the relevant Manufacturing Filing Responsibilities. Licensee shall provide Amgen any cooperation reasonably requested by Amgen in connection with any such filings, and Amgen shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Licensee in connection with such cooperation.

8. PAYMENT

- 8.1. License Payments by Licensee. In consideration of the rights granted by Amgen to Licensee hereunder, Licensee shall make the following payments to Amgen;
- 8.1.1. *License Fee*. Licensee shall pay Amgen a non-refundable, non-creditable license fee in the amount of \$200,000,000, within [*] days after [*].
- 8.1.2. *Development Milestone Payments*. Licensee shall pay Amgen the non-refundable, non-creditable development milestone payments as set forth on the Milestone Payments Schedule attached hereto, in each case within [*] days after the occurrence of the corresponding event with respect to each Licensed Product. Such milestone payments shall be payable for each Licensed Product. If a milestone payment becomes due for occurrence of a milestone event with respect to a given Licensed Product and Licensee has not paid a milestone payment listed prior in order to the milestone payment then due for such Licensed Product, then Licensee shall pay all such previously listed and unpaid milestone payments concurrently with payment of the milestone payment then due (regardless of whether or not the milestone event(s) corresponding to the previously unpaid milestone payment(s) has/have occurred with respect to such Licensed Product); provided that no milestone payments shall be due for milestone events that occurred prior to [*].
- 8.2. Royalty Payments. Licensee shall pay Amgen a royalty on Net Sales during the Term for each Licensed Product. Such royalty shall be equal to the greater of the following: (a) [*]% of Net Sales, [*]; and (b) [*]% of Net Sales. An example of calculation of the foregoing is set forth on the Royalty Calculation Schedule.
- 8.3. [*]. At such time as Licensee receives Pricing Approval in the Territory for a Licensed Product or from time-to-time thereafter as the Pricing Approval is amended, [*], given the Parties' [*] such Licensed Product for the Territory and the relevant [*] the Territory, that: (i) the [*] Licensed Product hereunder would be predominantly [*] (i.e. the [*] of Section [*]); and (ii) due to such [*] such Licensed Product by Licensee in the Territory would [*], then it shall have the right to [*] will provide [*] all reasonable supporting information requested by [*] to enable [*] to confirm [*] Licensed Product. Such [*] shall specify the total [*] and [*] at which [*] such Licensed Product [*] and [*] shall notify [*] in writing within [*] days of [*] as to whether [*] shall either: (a) [*] such Licensed Product to [*] set forth in [*]; or (b) [*] with respect to such Licensed Product, such [*] days following [*] of [*] providing for [*].

- 8.4. **[*] Not Included.** The payments to be made pursuant to Section 8.2 (Royalty Payments) do not include any amounts payable pursuant to Section 8.10 ([*]) hereof or pursuant to any section of the relevant supply agreement that provides for a pass-through of third-party payment obligations similar to Section 8.10 ([*]), each of which are separately due and payable without reference to amounts paid pursuant to such Section 8.2 (Royalty Payments).
- 8.5. **Appropriate Measure of Value.** Each of the Parties acknowledges that the value provided by the other hereunder is comprised of many related items, including intellectual property of various types, access to development and commercial expertise, clinical data and other financial and non-financial consideration and that the royalties set forth in Section 8.2 (Royalty Payments) are intended to capture such value as an aggregate. Therefore the increase, decrease or lapse of any particular items or rights shall not affect the amount of such royalty, and the Parties agree that both the amount and duration of the royalties set forth in this Article are reasonable.
- 8.6. **Calculation of Net Sales.** In calculating Net Sales:
- 8.6.1. **Free Products.** Any disposal of a Licensed Product at no charge for, or use of a Licensed Product without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales.
- 8.6.2. **Bundled Products.** Where a Licensed Product is sold in a Bundle, then for the purposes of calculating the Net Sales under this Agreement, such Licensed Product shall be deemed to be sold for an amount equal to $(X \div Y) \times Z$, where: X is the average sales price during the applicable reporting period generally achieved for such Licensed Product (or, should more than one Licensed Product be included in a Bundle with a product other than a Licensed Product, the sum of such average sales prices for the included Licensed Products) in the Territory; Y is the sum of the average sales price during the applicable reporting period generally achieved in the Territory, when sold alone, by each pharmaceutical product included in the Bundle; and Z equals the price at which the Bundle was actually sold. In the event that a Licensed Product or one or more of the other pharmaceutical products in the Bundle are not sold separately, the Parties shall confer in good faith to determine an equitable fair market price to apply to such bundled Licensed Product.
- 8.7. **Reports.** Beginning with the [*] Quarter after the First Commercial Sale of a Licensed Product in the Territory and thereafter for each [*] Quarter until the expiration of Licensee's obligation to pay royalties hereunder, royalty payments and reports of the sale of each Licensed Product for each [*] Quarter will be calculated and delivered by Licensee to Amgen under this Agreement within [*] days after the end of each such [*] Quarter. Each payment of royalties will be accompanied by a report of Net Sales of each Licensed Product stating: (a) Net Sales of each Licensed Product (on a Licensed Product-by-Licensed Product basis) by or on behalf of Licensee, its Affiliates or licensees during the applicable [*] Quarter (detailed with gross invoiced amounts, deductions and Net Sales); and (b) a calculation of the royalty payment due from Licensee hereunder for such [*] Quarter. [*]. Reports will contain additional

information as reasonably requested by Amgen to enable it to comply with its obligations to its licensors.

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

8.9. Development Cost Sharing. In addition to the other payments referenced herein, Licensee shall pay to Amgen a share of Amgen Development Costs for [*]:

8.9.1. *Amounts*. Licensee’s share of Amgen Development Costs shall be as set forth in the below table, subject in each case to the maximum amounts described in Section 8.9.3 (Payment Caps):

<u>[*] Year</u>	<u>Licensee Share</u>
[*]	[*]%

8.9.2. [*]. From and after [*], Licensee shall pay to Amgen a share equal to [*]% of Amgen Development Costs relating to [*].

8.9.3. *Payment Caps*. Licensee’s payment obligations pursuant to this Section 8.9 (Development Cost Sharing) (such payment obligations “*Development Cost Payments*”), shall be subject to a maximum payment as set forth below for each [*] Year (each, an “*Annual Maximum*”). In the event that payment of a Development Cost Payment would result in payments to Amgen pursuant to such sections in excess of the Annual Maximum for the relevant [*] Year, then such Development Cost Payment shall be reduced so that the total Development Cost Payment to be paid by Licensee for such [*] Year shall equal the Annual Maximum for such [*] Year. Once the Annual Maximum is met for a given [*] Year, no further Development Cost Payment shall be payable by Licensee for such [*] Year. For the purposes of this Section 8.9.3 (Payment Caps), payments of Licensee’s share of Amgen Development Costs payable pursuant to Section 8.9 (Development Cost Sharing) shall apply against the Annual Maximum in the [*] Quarter for which such costs are invoiced, without reference to when such payments are actually paid or payable hereunder (but provided that such payments are subsequently actually paid). No excess payment obligation above the Annual Maximum for a particular [*] Year shall be carried forward to future periods. For the avoidance of doubt, Licensee’s payment obligations pursuant to Section 8.1.2 (Development Milestone Payments) shall not be subject to the Annual Maximum.

<u>[*] Year</u>	<u>Annual Maximum</u>
[*]	[*]
[*]	[*]
[*]	[*]

- 8.9.4. *Maximum Payments.* In addition to the Annual Maximum described in Section 8.9 (Payment Caps), Licensee’s payment obligation pursuant to this Section 8.9 (Development Cost Sharing) shall be subject to a quarterly maximum as described below. In the event the amount otherwise payable pursuant to this Section 8.9 (Development Cost Sharing) with respect to a [*] Quarter (“Q1”; “Q2”; “Q3” or “Q4”, as appropriate) would exceed: [*] (each, the “Quarterly Maximum”), then Licensee shall pay only such Quarterly Maximum for the applicable [*] Quarter. No excess payment obligation above the Annual Maximum for a particular [*] Year nor above the Quarterly Maximum for a particular [*] Quarter shall be carried forward to future periods.
- 8.9.5. *Reports.* Within [*] days after the end of each [*] Quarter, Amgen shall provide Licensee with a report specifying in reasonable detail the Amgen Development Costs incurred or paid by Amgen in such [*] Quarter, as well as any other costs for which Amgen is entitled reimbursement hereunder. Amgen Development Costs may be attributed by Amgen to either the [*] Quarter in which they are paid or incurred, but no amount shall be attributed to more than one [*] Quarter.
- 8.9.6. *Payments.* Licensee shall pay Amgen its share of Amgen Development Costs in accordance with Section 8.12 (Payment Method) within [*] days after receiving Amgen’s report pursuant to Section 8.9.5 (Reports).
- 8.9.7. *Example.* The Development Costs Example Schedule sets forth an example of the calculation of Licensee’s share of Amgen Development Costs.
- 8.10. [*]. In addition to the other amounts payable hereunder, Licensee shall pay Amgen with respect to the [*] in accordance with the timing set forth therein for such payments or, if not specified therein, in accordance with the same time periods set forth in this Agreement for a similar type of payment. Responsibility for amounts payable in connection with [*] hereunder shall be as follows. With respect to [*] apply based upon [*], each [*] of such [*] shall be calculated based upon their [*] during the applicable period. An example is set forth as the [*] in the [*]. For [*] payable upon the [*], each Party would [*] of such [*] equal to [*] of previously achieved [*] such [*] or a [*] of such [*] equal to [*] of [*] in the relevant [*] to which such [*] applies (if such [*] was based upon [*] in a given [*]). Examples are set forth as the [*] Example in the [*]. For [*] that are [*] (e.g. [*]), Licensee shall be responsible for [*] of [*]. For [*] based on [*] (e.g., [*]), the [*] to [*] shall be responsible for [*] of the payment(s) associated with [*]. Upon the other Party [*] the [*], it shall reimburse the Party that previously was obligated to pay such [*] for either: (i) [*] of the relevant [*], if Licensee initially was obligated to make such [*]; or (ii) [*] of the relevant [*], if Amgen initially was obligated to make such [*]. An example is set forth as the [*] in the [*].
- 8.11. Cost Reimbursement. Amgen shall invoice Licensee [*] with respect to costs to be reimbursed by Licensee hereunder including pursuant to Section 4.15 [*] and Section 9.2.1.1 ([*]). Licensee shall pay such invoices within [*] days of receipt.
- 8.12. Payment Method. All payments made hereunder between the Parties shall be made in U.S. Dollars except as set forth in Section 8.14 (Blocked Currency). Licensee shall pay all sums due hereunder by check, wire transfer, or electronic funds transfer (EFT) in

immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.16 (Withholding) and Section 8.17 (VAT)).

- 8.13. Audits. Licensee shall keep complete and accurate records pertaining to the development and sale of the Licensed Products in the Territory in sufficient detail to permit Amgen to confirm the accuracy of all payments due hereunder, and such records shall be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 8.13 (Audits)) to inspection for [*] following the end of the period to which they pertain. Amgen shall have the right, at its own expense, to have an independent, certified public accountant, selected by it review the records of Licensee upon reasonable notice and during regular business hours. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. Amgen's audit rights with respect to any [*] Year shall expire [*] after the end of such year and the books and records for any particular [*] Year shall only be subject to one (1) audit. Should the inspection lead to the discovery of a discrepancy to Amgen's detriment, then Licensee shall pay to Amgen the amount of the discrepancy plus interest accrued at the Contract Interest Rate, compounded daily from the day the relevant payment(s) were due. Should the inspection lead to the discovery of a discrepancy to Licensee's detriment, then Amgen shall pay to Licensee the amount of the discrepancy without interest. Amgen shall pay the full cost of the inspection unless the discrepancy is to the Amgen's detriment and is greater than [*]%) of the amount actually paid for the audited period, in which case Licensee shall pay the cost of such inspection.
- 8.14. Blocked Currency. If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, Licensee shall have the right and option to make such payments by depositing the amount thereof in local currency to Amgen's account in a bank or depository designated by Amgen in the Territory.
- 8.15. Taxes. All Taxes levied on account of a payment made by Licensee to Amgen pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 8.16 (Withholding).
- 8.16. Withholding. In the event that Law requires Licensee to pay or withhold Taxes with respect to any payment to be made by Licensee pursuant to this Agreement, Licensee shall notify Amgen in writing of such payment or withholding requirements prior to making the payment to Amgen and provide such assistance to Amgen, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in Amgen's efforts to claim an exemption from or reduction of such Taxes. Licensee will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish Amgen with proof of payment of such Taxes within [*] days following payment thereof. If Taxes are paid to a tax authority, Licensee shall provide such assistance to Amgen as is reasonably

required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

- 8.17. VAT. All payments due Amgen from Licensee pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by Licensee upon receipt of a valid VAT invoice).
- 8.18. Late Payment. Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate, compounded daily, calculated on the number of days such payment is delinquent. This Section 8.18 (Late Payment) shall in no way limit any other remedies available to either Party.
- 8.19. Third Party Royalties. Except as expressly set forth in Sections 8.16 (Withholding) and 8.17 (VAT), neither Party shall have the right to make any deduction from amounts otherwise payable pursuant to this Agreement on account of any royalty or other amount payable to any Third Party.

9. INTELLECTUAL PROPERTY

- 9.1. Ownership. Except to the extent expressly specified to the contrary in this Agreement: (i) each Party shall retain and own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party; (ii) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created jointly by the Parties pursuant to the Collaboration and, subject to the provisions of this Agreement (including those licenses granted pursuant to Article 3 (Grant of License)), neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit, license or assign such intellectual property rights; and (iii) inventorship and authorship of any invention or work of authorship conceived or created by either Party, or jointly by the Parties pursuant to the Collaboration, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the United States (without reference to any conflict of law principles).
- 9.2. Prosecution and Maintenance.
 - 9.2.1. *In Territory*.
 - 9.2.1.1. [*] shall control, itself or through outside counsel reasonably acceptable to [*] and directed by [*] the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) (the foregoing collectively “*Patent Matters*”) with respect to [*] as well as preparation and filing for any [*]
 - 9.2.1.2. [*] it shall give [*] reasonable notice thereof [*] and continue the prosecution or maintenance of such patent, trademark or application [*] control Patent Matters with respect to such patent, trademark or application within the [*] in accordance with this Section 9.2.1.2 [*] shall

control, itself or through outside counsel reasonably acceptable to [*] and directed by [*] as well as preparation and filing for any [*].

9.2.2. [*] shall control and be [*] responsible for all Patent Matters with respect to its patent rights, trademark rights and other intellectual property [*], at its sole cost and expense. [*] shall control and be solely responsible for Patent Matters with respect to [*]

9.3. Defense and Settlement of Third Party Claims. If a [*] that a [*] by the [*], [*] shall have the sole right to [*] at its sole cost. [*] shall reasonably [*] at [*] request, and [*] shall [*] in connection therewith. Subject to such [*] may [*] any [*] pursuant to this Section 9.3 (Defense and Settlement of Third Party Claims), with [*] at its sole cost. [*] shall seek and reasonably consider [*] before [*] for such matter. Without limiting the foregoing, [*] shall keep [*] of all [*] regarding such [*], and shall provide [*] of and an [*] to [*] on any such [*] and [*]. [*] (provided that, should such [*] be reasonably necessary for [*] shall endeavor to provide such [*] to the relevant [*] or with similar [*], or otherwise make available such [*] as reasonably necessary to [*] shall not [*] hereunder without [*]. [*] shall keep [*] of all [*] this Section 9.3 (Defense and Settlement of Third Party Claims). In the event [*] becomes engaged in: [*] and, in each such case, such [*] of the other Party: [*] use reasonable efforts to [*] in such [*] (and then so [*]).

9.4. Enforcement.

9.4.1. *In Territory.* Each Party shall promptly notify the other Party in writing if it reasonably believes that any [*] are infringed or misappropriated by a Third Party in the Territory.

9.4.1.1. [*] shall reasonably [*] at [*] request [*] in connection therewith), and [*] shall seek and reasonably [*] before [*] within the Territory and outside the Territory so as to[*]

9.4.1.2. [*]. [*] shall seek and reasonably [*] shall keep [*] of all [*] and shall provide [*] of and an [*] (provided that [*] shall have the [*] and any [*]).

9.4.2. [*]. [*] shall have the [*] right [*] its patent rights, trademark rights and other intellectual properties, and the Joint Patents [*] and [*] any such matters [*]

9.5. Allocation of Recoveries. All Recoveries shall [*]. Any Recoveries that are [*] shall be allocated [*] shall have the [*] right to [*] with respect to the [*] of any [*]. After any termination or expiration of this Agreement, [*] shall have [*].

9.6. Patent Term Extensions. Each Party shall provide reasonable assistance to the other Party in connection with obtaining SPCs for Licensed Amgen Patents consistent with the rights of the other Party to control such matters as specified in Section 9.2 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such SPC in a particular country, each Party shall make available to the other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the SPC in such country.

- 9.7. Employee Agreements. Prior to [*] relating to [*] and/or [*], each [*], shall have [*] pursuant to which each such person [*], as appropriate, substantially including: [*]. It is understood and agreed that any [*] and that the [*] shall be sufficient to [*] Each Party shall [*].
- 9.8. Patent Marking. Licensed Products marketed and sold by or on the behalf of Licensee hereunder shall be marked with appropriate patent numbers or indicia of Licensed Amgen Patents, to the extent permitted by Law in the Territory.

10. CONFIDENTIALITY AND PUBLICATIONS

- 10.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "*Confidential Information*") (including information known by the employees of Amgen KK and/or materials in the possession of Amgen KK prior to the consummation of the transactions contemplated in the Sale and Purchase Agreement, which shall be considered the Confidential Information of Amgen). Licensee shall have no right to and shall not utilize any Confidential Information of Amgen for activities outside the Territory (including, with respect to the research, development or commercialization of any Distracting Product outside the Territory). For clarity, Confidential Information of a Party shall include, without limitation, all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:
- 10.1.1. was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;
 - 10.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
 - 10.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
 - 10.1.4. was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence prepared contemporaneously with such independent development; or

- 10.1.5. was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.
- 10.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, and (b) to the extent such disclosure is reasonably necessary or useful in conducting development under this Agreement; (ii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for a Licensed Product, or otherwise required by Law, provided, however, that if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it shall, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; or (iv) to the extent mutually agreed to by the Parties.
- 10.3. Use of Confidential Information and Amgen Data with Distracting Programs. Licensee acknowledges the value of Confidential Information and other data provided by Amgen hereunder and agrees that it shall not utilize any such information to benefit Licensee programs or products other than the Licensed Products.
- 10.3.1. *Ex-Territory Distracting Program.* If Licensee or its Affiliate engages, after [*], in an Ex-Territory Distracting Program (including under a license or collaboration agreement with a Third Party that contemplates Licensee or its Affiliate engaging in or supporting an Ex-Territory Distracting Program), it shall provide Amgen with prompt written notice describing in reasonable detail, to the extent permitted by Law and without disclosing any proprietary information of the Ex-Territory Distracting Program, the Ex-Territory Distracting Program and its focus.
- 10.3.2. *Ex-Territory Distracting Transaction.* In the event that Licensee enters into or agrees with a Third Party to enter into an Ex-Territory Distracting Transaction then it shall provide prompt written notice to Amgen, specifying the identity of the actual or potential Ex-Territory Distracting Affiliate(s) and describing in

reasonable detail, to the extent permitted by Law and without disclosing any proprietary information of the Ex-Territory Distracting Program, the Ex-Territory Distracting Program and its focus.

10.3.3. *Protection of Amgen Information.* In the event that Licensee or its Affiliate engages in an Ex-Territory Distracting Program as set forth in Section 10.3.1 (Ex-Territory Distracting Program) or enters into an Ex-Territory Distracting Transaction, then Licensee shall hold separate such Ex-Territory Distracting Program (including ensuring that no personnel working on the Collaboration work on an Ex-Territory Distracting Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working on the Ex-Territory Distracting Program (and vice versa)), and the Parties shall promptly meet to agree upon policies and procedures to be implemented to safeguard Amgen's Confidential Information and data related to the relevant Licensed Product from misuse. Until such time as the Parties have so agreed, Amgen shall have the right to suspend provision of Confidential Information and data (including Amgen Development Data) to Licensee hereunder with respect to the applicable Licensed Product.

10.4. [*]. From time to time, upon [*] reasonable request, [*] shall [*] relating to the foregoing, and will [*] the foregoing.

Without prejudice to the foregoing, within twenty (20) business days of the Effective Date, Licensee shall submit to Amgen the [*] this Section 10.4 [*]. If Amgen has any particular comments or suggestions thereon, Amgen and Licensee will finalize the said [*] through good faith discussion.

10.5. Terms and Conditions Confidential. Neither Party shall disclose the terms and conditions of this Agreement except as may be required by Law. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Notwithstanding the foregoing, the Parties shall agree upon and release a mutual press release to announce the execution of this Agreement in the form attached hereto as the Press Release Schedule for use in responding to inquiries about the Agreement; thereafter, Licensee and Amgen may each disclose to Third Parties the information contained in such press release without the need for further approval by the other. Each Party shall additionally have the right to issue additional press releases in regards to this Agreement and/or the Licensed Products with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [*] days' notice to the other Party and reasonably considering comments provided by such other Party within [*] days after such notice).

10.6. Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated [*] as amended and supplemented, including any written requests thereunder, (the "*Prior Agreement*") with respect to information disclosed

thereunder relating to the Licensed Products and the research and development related thereto. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Agreement.

10.7. Publications.

- 10.7.1. *In Territory.* Except as set forth in Section 10.7.2 (Other Publications), Licensee shall have the [*] right to publish with respect to Licensed Products in Licensee Indications in publications based in the Territory and to make scientific presentations on Licensed Products in Licensee Indications within the Territory. Except as set forth in Section 10.7.2 (Other Publications), Amgen shall have the [*] right to publish with respect to Licensed Products in Amgen Indications in publications based in the Territory, and with respect to Licensed Products in all indications in publications based outside the Territory and to make scientific presentations on Licensed Products in Amgen Indications inside the Territory, and with respect to Licensed Products in all indications outside the Territory. Any proposed publication by Licensee [*], any proposed publication by Amgen [*], any publication by Licensee [*] of [*], and any publication by Amgen [*] (each such publication a “[*] Publication”) shall be [*] the [*] to Sections 10.7.2 (Other Publications) and 10.7.3 (Oversight and Review).
- 10.7.2. *Other Publications.* The Parties shall regularly consult and confer with respect to a global publication plan for a Licensed Product, with the understanding that Licensee shall have primary responsibility for shaping and determining the publication plan with respect to the Territory, and Amgen shall have sole responsibility for shaping and determining the publication plan outside the Territory, but with the understanding that the Parties may agree it is in their mutual scientific and/or commercial interest to allow a Party to publish or present a Secondary Publication. [*]
- 10.7.3. *Oversight and Review.* Except as required by Law or court order, with respect to any publication or presentation concerning the activities to be conducted in the Territory hereunder with respect to a Licensed Product, including studies or clinical trials carried out by a Party under this Agreement, or any Secondary Publication, the Party desiring to publish or present any such publication or presentation (the “Publishing Party”): (i) shall transmit to the other Party (the “Reviewing Party”) for review and comment a copy of the proposed publication or presentation, at least [*] days prior to the submission of the proposed publication or presentation to a Third Party; (ii) shall postpone the publication or presentation for up to an additional [*] days upon request by the Reviewing Party in order to allow the consideration of appropriate patent applications or other protection to be filed on information contained in the publication or presentation; (iii) upon request of the Reviewing Party, shall remove all Confidential Information of the Reviewing Party from the information intended to be published or presented; and (iv) shall consider all reasonable comments made by the Reviewing Party to the proposed publication or presentation. [*].

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

11. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

- 11.1.1. As of [*], it is duly organized and validly existing under the Laws of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
- 11.1.2. As of [*], this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of [*] violate any Law; and the person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;
- 11.1.3. To its knowledge, as of [*] no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or shall be necessary for, or in connection with, the entering into of this Agreement or the transaction contemplated by this Agreement, or (except for MHLW or other regulatory approvals, licenses, clearances and the like necessary for the 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;
- 11.1.4. [*];
- 11.1.5. As of [*], it has not been debarred or the subject of debarment proceedings by any Governmental Authority;

- 11.1.6. It has not granted as of [*] any right to any Third Party relating to any patent, trademark or other proprietary right that conflicts with the rights granted to the other Party hereunder;
 - 11.1.7. As of [*], it has not knowingly used 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 Governmental Authority;
 - 11.1.8. It has carried out its activities materially in accordance with Law (including relevant Laws relating to economic sanctions and bribery); and
 - 11.1.9. It has not knowingly misappropriated any trade secret(s) of a Third Party in connection with the performance of its activities hereunder.
- 11.2. Amgen Representations and Warranties. Amgen hereby represents that, as of [*]:
- 11.2.1. Amgen has provided Licensee with [*] with respect to the Licensed Products, and has [*] information relating to [*] that are [*] relevant Licensed Product [*] provided to Licensee;
 - 11.2.2. Amgen has disclosed to Licensee [*] as set forth on the [*] Schedule, and has [*] Licensee with [*] that are [*] Licensed Product [*];
 - 11.2.3. The [*] Schedule sets forth a list that, to the best of Amgen's knowledge, is materially true and complete of all [*] with respect to the [*] and corresponding [*] outside the Territory, and of [*] of the [*] or corresponding [*] outside the Territory; and
 - 11.2.4. Except as referenced on the [*] Schedule, to the best of Amgen's knowledge Amgen has not [*] which [*] that the [*] in the Territory [*] of such [*], or which [*] that the [*] of an [*] of [*], which [*] to an [*] in the Territory.
- 11.3. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 11 (Representations, Warranties and Covenants), LICENSEE AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, THE LICENSED AMGEN PATENTS, LICENSED AMGEN TRADEMARKS, LICENSED AMGEN KNOW-HOW, LICENSED LICENSEE PATENTS, LICENSED LICENSEE TRADEMARKS, LICENSED LICENSEE KNOW-HOW, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.
- 11.4. Covenants. Each of the Parties hereby covenants to the other Party as follows:
- 11.4.1. It shall 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 Governmental Authority;

- 11.4.2. It shall carry out its activities hereunder in compliance with Law (including relevant Laws relating to economic sanctions and bribery);
- 11.4.3. It shall not misappropriate any trade secret(s) of a Third Party in connection with the performance of its activities hereunder; and
- 11.4.4. It shall not grant any right to any Third Party that conflicts with the rights granted to the other Party hereunder.

12. LIMITATIONS OF LIABILITY; INSURANCE

- 12.1. Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 12.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 13 (Indemnification), (ii) breach of Section 4.4 (Development in Combination), 10.1 (Confidentiality; Exceptions), 10.2 (Authorized Disclosure), or (iii) gross negligence or intentional misconduct of a Party.
- 12.2. Insurance. During the Term and for [*] thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry in the Territory (or reasonable self-insurance sufficient to provide materially the same level and type of protection).

13. INDEMNIFICATION

- 13.1. Indemnity. Subject to the remainder of this Article 13 (Indemnification), Licensee shall defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees and agents (collectively, "*Amgen Indemnitees*"), at Licensee's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees incurred by any Amgen Indemnitees until such time as Licensee has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) (collectively, "*Losses*") arising out of any claim, action, lawsuit, or other proceeding (other than a shareholder derivative suit or like action) (collectively, "*Claims*") brought against any Amgen Indemnitee, by a Third Party to the extent such Losses result from (i) the negligence or willful misconduct of Licensee, its Affiliates or agents in performing under this Agreement, (ii) a breach by Licensee of this Agreement, including any failure of Licensee's representations or warranties in Section 11.1 to be true, or (iii) Licensee's, its Affiliate's or its licensee's (other than Amgen, its Affiliates or its licensees) development or commercialization of a Licensed Product but excluding such Losses to the extent they arise from (y) or (z) below. Subject to the remainder of this Article 13

(Indemnification), Amgen shall defend, indemnify, and hold harmless Licensee, its Affiliates, and their respective directors, officers, employees and agents (collectively, “*Licensee Indemnitees*”), at Amgen’s cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys’ fees incurred by any Licensee Indemnitees until such time as Amgen has acknowledged and assumed its indemnification obligation hereunder with respect to the applicable Claim) arising out of any Claim brought against any Licensee Indemnitee, by a Third Party to the extent such Losses result from (y) the negligence or willful misconduct of Amgen, or its Affiliates or agents in performing under this Agreement, or (z) a breach by Amgen of this Agreement, including any failure of Amgen’s representations or warranties in Section 11.1 (Mutual Representations and Warranties) to be true, but excluding such Losses to the extent they arise from (i), (ii), or (iii) above. The indemnification obligations of this Article 13 shall not apply to commercial supply obligations or the obligations under the Vectibix supply agreement to be entered into concurrently herewith; any indemnification obligations related to commercial supply (or clinical supply of Vectibix) shall be handled under the supply agreements to be entered into pursuant to Section 7.3 (Supply).

- 13.2. Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Licensee Indemnitee or an Amgen Indemnitee (the “*Indemnified Party*”) may seek indemnification under this Article 13 (Indemnification), the Indemnified Party shall promptly notify the other Party (the “*Indemnifying Party*”) of the Claim or Loss and, when known, the facts constituting the basis for the Claim; provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 13.2 (Claim for Indemnification) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense. The Indemnified Party shall not settle or compromise any Claim by a Third Party for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party’s expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Article 10 (Confidentiality and Publications).

14. TERM AND TERMINATION

14.1. Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect until terminated in accordance with this Article 14 (Term and Termination).

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

14.2.1. *Termination for Breach*. If either Party believes that the other Party or its Affiliate is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. In such written notice, the noticing Party shall identify the actions or conduct that such Party would consider to be an acceptable cure of such material breach (if curable). If the breaching Party (or its Affiliate) fails to cure such material breach within [*] days after the receipt of such notice (or [*] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [*] days after the end of such cure period and effective upon delivery;

14.2.2. *Termination for Challenge*. Amgen shall have the right to terminate this Agreement by written notice to Licensee should Licensee, its Affiliate or its or their licensee bring or join any challenge to the validity or enforceability of any Licensed Amgen Patent or Licensed Amgen Trademark;

14.2.3. *Specific Product Termination*. This Agreement may terminate with respect to a particular Licensed Product in accordance with Section 6.3 (Termination), Section 8.3 ([*]), Section 14.2.5 [*] or Section 15.1 (Change of Control);

14.2.4. *All Product Termination*. This Agreement shall automatically terminate upon any termination of this Agreement with respect to all Licensed Products in accordance with Section 6.3 [*] or Section 15.1 (Change of Control); and

14.2.5. [*]. In the event a [*] Licensed Product [*] of the [*] it would [*] Licensee to [*], then Licensee shall [*] that [*] in the Territory until such time as [*] Licensed Product [*]. Similarly, if a [*] occurs for a Licensed Product [*], and in [*] it would not [*], then Licensee shall [*], upon [*] (provided, however, that during such [*]; Amgen shall [*]. For clarity, Licensee shall not have the right to [*] under this Section 14.2.5 [*] if the reason for the [*], as the case may be, is [*] and does not [*].

14.3. Effect of Termination. Expiration or termination of this Agreement (whether as a whole, or with respect to a particular Licensed Product) shall have the following effects with regard to the relevant Licensed Product(s):

14.3.1. *General*. In the event of any termination or expiration of this Agreement [*]. Any termination or expiration of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled. Upon termination or expiration of this Agreement, [*]

14.3.2. *Development Cost Share*. In the event of termination by [*] under Sections [*] pursuant to [*] with respect to [*] shall survive. In the event of termination by [*] or by [*] shall continue to [*] pursuant to [*] only with respect to [*] attributable to [*]

14.4. **Additional Surviving Provisions.** In addition and without prejudice to the provisions of Section 14.3 (Effect of Termination), in the event of any expiration or termination of this Agreement the following provisions shall survive: Articles 10 (Confidentiality and Publications) (except with respect to Section 10.7 (Publications)); 12 (Limitations of Liability; Insurance); 13 (Indemnification); 14 (Term and Termination) and 16 (Miscellaneous); and Sections 3.4 (Licensed Licensee Know-How and Patents); 6.6 ([*]) ([*]); 8.1.1 (License Fee); 8.1.2 (Development Milestone Payments) (with respect to milestones reached prior to such expiration or termination); 8.2 (Royalty Payments) through 8.8 (No Wrongful Reductions) (inclusive) (with respect to sales made prior to such expiration or termination); 8.10 ([*])(with respect to amounts incurred prior to such expiration or termination); 8.11 (Cost Reimbursement) through 8.19 (Third Party Royalties) (inclusive); 9.1 (Ownership); 9.5 (Allocation of Recoveries) (with respect to periods prior to termination); and 11.3 (Disclaimer of Warranties).

14.5. **Transition Period.** During the twelve (12) month period [*] pursuant to Section [*] (Termination) or another provision of this Agreement, ([*]) (the "Transition Period"), the Parties shall[*] and, if applicable, manufacture of,[*] Licensee shall take all actions [*] to facilitate [*], and the Parties shall [*] expeditiously and as reasonably necessary to [*] in the Territory. The Parties shall each be responsible for [*] provided that, in the event of [*] Amgen shall [*]

15. CHANGE OF CONTROL

15.1. **Change of Control.** Licensee shall give Amgen written notice within [*] days after the public announcement or disclosure of any proposed Change of Control of Licensee. In the event of the occurrence of any Change of Control of Licensee: (i) [*] and, (ii) Amgen shall have the right to [*]. Upon such notice: Amgen shall have the right, by written notice to Licensee, to [*] Licensed Products in [*]. In such case, Licensee shall [*], subject to [*]. In particular: (a) Amgen shall [*] Licensed Products, and shall [*]; (b) Amgen shall [*] with respect to such Licensed Products; (c) Amgen shall [*] all [*] Licensed Products, and the sole right to [*] relating to such Licensed Products; and (d) Amgen shall [*] Licensed Products in the Territory. In addition, should the Change of Control of Licensee result in Licensee becoming an Affiliate of a Party that is [*], then, without prejudice to Sections 6.4 ([*]) through 6.6 ([*]) (inclusive), Amgen shall have the right to [*]. In addition, should such Change of Control involve [*], Amgen shall have the right to [*] written notice to Licensee, such notice to be given not later than [*].

16. MISCELLANEOUS

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

16.2. **Assignment.** Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by Licensee without the prior written consent of Amgen. Amgen may assign

this Agreement, and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Amgen shall have the right to assign its rights and delegate its obligations under this Agreement with respect to one or more Licensed Products to a Party or Parties to which Amgen licenses or transfers rights with respect to such product(s) outside the Territory. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

- 16.3. Choice of Law. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of California without regard to its conflicts of law provisions.
- 16.4. Construction. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person shall be construed to include the person’s permitted successors and assigns, (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.
- 16.5. Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 16.6. Currency. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, such Net Sales invoiced or expenses incurred shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by whichever of Licensee or Amgen (or an Affiliate of one of them) recorded such

receipt or expenditure, for the respective reporting period, related to recording such Net Sales or expenses in its books and records that are maintained in accordance with GAAP. If a Party is not required to perform such currency conversion for its GAAP reporting with respect to the applicable period, then for such period such Party shall convert its amounts received and expenses incurred into U.S. Dollars using a rate of exchange which corresponds to [*] buying rate as published in the Wall Street Journal, Eastern U.S. Edition on [*] day of the [*] Quarter (or such other publication as agreed-upon by the Parties). Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.

- 16.7. Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same. The foregoing is without prejudice to the Parties' rights and obligations pursuant to the Sale and Purchase Agreement, License Agreement relating to AMG706, and the Vectibix Supply Agreement, each executed concurrently herewith.
- 16.8. Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest ("*Force Majeure*"); provided, however, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect) and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.
- 16.9. Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 16.10. Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.
- 16.11. Jurisdiction and Venue. Each Party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of California ("*State Court*") and the courts of the United States of America located in the State of California ("*Federal Court*"), for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth in Section 16.13 (Notices) (as such address may be changed by notice delivered pursuant to such section) shall be effective service of process for any action, suit or proceeding in the applicable Federal Court or State Court with respect to any matters to which it has submitted to jurisdiction in this Section 16.11

(Jurisdiction and Venue). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Federal Court or State Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of any transaction contemplated hereby shall be conducted in English. Notwithstanding the foregoing, either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction. Each Party irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. Except as may be expressly set forth to the contrary herein (including in Section 12.1 (Limitations of Liability) hereof), nothing in this Agreement shall serve to limit any remedy to which a Party might otherwise be entitled, at law or in equity.

16.12. No Set-Off. No Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

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

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

If to Licensee: Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome, Chuo-ku
Osaka 540-8645, Japan
Attention: General Manager, Global Licensing & Business Development
Telephone: [*]
Facsimile: [*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 16.13 (Notices).

16.14. Reimportation. Licensee shall undertake all steps necessary to prevent any Licensed Product provided to or made for or on behalf of Licensee for use or sale inside the Territory from being distributed or sold outside the Territory, except where Amgen and Licensee agree that the exporting person or entity is in possession of all regulatory

authorizations and intellectual property licenses necessary for such export, import and sale. Licensee shall notify Amgen if it becomes aware of the exportation of a Licensed Product from the Territory and discuss with Amgen the same.

- 16.15. Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Licensee and Amgen as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.
- 16.16. Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- 16.17. Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or Licensee Indemnities in Article 13 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.
- 16.18. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.

(Signature page follows)

CONFIDENTIAL

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

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Yasuhiko Yamanaka
Name: Yasuhiko Yamanaka
Title: Director
General Manager, Pharmaceutical Marketing Division

AMGEN INC.

By: /s/ Kevin W. Sharer
Name: Kevin W. Sharer
Title: Chairman of the Board,
CEO and President

CONFIDENTIAL

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.

License Agreement
By and Between
Amgen Inc.
and
Takeda Pharmaceutical Company Limited
Dated
February 1, 2008

CONFIDENTIAL

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SCHEDULES

CONFIDENTIAL

License Agreement

Preamble

This License Agreement (this “*Agreement*”) is entered into as of the 1st day of February, 2008 (the “*Effective Date*”) by and between Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (“*Amgen*”), and Takeda Pharmaceutical Company Limited, a Japanese corporation having its principal place of business at 1-1, Doshomachi 4-Chome, Chuo-ku, Osaka 540-8645, Japan (“*Licensee*”). Amgen and Licensee are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*.”

Recitals

WHEREAS, Amgen is a global biotechnology company that conducts pharmaceutical research, development, manufacturing and commercialization;

WHEREAS, Licensee is a global pharmaceutical company that conducts pharmaceutical research, development, manufacturing and commercialization;
and

WHEREAS, Amgen wishes to partner with Licensee, and Licensee wishes to partner with Amgen, in each case with respect to the worldwide development and commercialization of a product Amgen is developing that is referred to as AMG706 in the Indications (each as defined below), all in accordance with the terms and conditions hereof.

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

1 DEFINITIONS

- 1.1. “*Additional Indications*” shall mean, with respect to Licensed Product, any specific indications other than the NSCLC Indication that are mutually agreed upon by the Parties through the Development Committee pursuant to Section 6.6 (Additional Indications).
- 1.2. “*Affiliate*” shall mean any corporation, person or other entity which directly or indirectly controls, is controlled by or is under common control with a Party, for so long as such control exists. For the purposes of this Section 1.2 (“*Affiliate*”), “*control*” of a corporation or other entity shall mean: (i) in the case of any corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for the election of directors thereof; or (ii) in the case of any non-corporate entity, direct or indirect ownership of more than fifty percent (50%) of the equity or income interest therein.
- 1.3. “*Agreement*” shall have the meaning set forth in the Preamble.
- 1.4. “*Amgen*” shall have the meaning set forth in the Preamble.

- 1.5. “*Amgen Development Data*” shall mean the preclinical and clinical data generated by or on the behalf of Amgen or its Affiliates on a worldwide basis in the course of its preclinical and clinical development of Licensed Product in an Indication, both before and after [*] of this Agreement.
- 1.6. “*Amgen Indemnitees*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.7. “*Amgen Territory*” shall mean the United States, Canada and Mexico and their respective territories and possessions.
- 1.8. “*AMG706*” shall mean that certain small molecule known as motesanib diphosphate in clinical development as of [*].
- 1.9. “*Asia*” shall mean the following countries and their respective territories and possessions: [*] and [*].
- 1.10. “*Bundle*” shall mean the Licensed Product sold to an end-user together with another pharmaceutical compound for a single price.
- 1.11. “[*] *Quarter*” shall mean a three-month period beginning on [*].
- 1.12. “[*] *Year*” shall mean a one-year period beginning on [*] and ending on [*].
- 1.13. “*Change of Control*” shall mean, with respect to Licensee, the occurrence of any of the following events: [*].
- 1.14. “*Claims*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.15. “*Collaboration*” shall have the meaning set forth in Section 2.1 (Conduct of the Collaboration).
- 1.16. “*Commercialization Committee*” shall mean the committee established by the Parties to oversee and coordinate the commercialization of the Licensed Product pursuant to the Collaboration and shall have the responsibilities set forth in Section 2.10 (Commercialization Committee).
- 1.17. “*Commercialization Costs*” shall mean [*]. Commercialization Costs shall not include any of the foregoing costs in this Section 1.17 with respect to Japan.
- 1.18. “*Confidential Information*” shall have the meaning set forth in Section 10.1 (Confidentiality; Exceptions).
- 1.19. “*Contract Interest Rate*” shall mean [*] plus the [*] rate effective for the date [*] as published by The Wall Street Journal, Eastern U.S. Edition, on the [*] (or, if unavailable on such date, [*] on which such rate is available), or, if lower, the maximum rate permitted by Law.

- 1.20. “Control” shall mean, with respect to any Information or intellectual property, that the applicable Party owns or has a license to such Information or intellectual property and has the right to grant to the other Party access to and a license or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense or, with respect to Japan only, requiring any payment (whether or not then due and payable) under any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense.
- 1.21. “Cost of Goods Sold” shall mean the [*]. Cost of Goods Sold shall include [*] such activities. Cost of Goods Sold shall not include any of the foregoing costs in this Section 1.21 with respect to Japan.
- 1.22. “Cost of Sales” shall mean the sum of Cost of Goods Sold and [*].
- 1.23. “Development Committee” shall mean the committee established by the Parties to oversee and coordinate the development of the Licensed Product pursuant to the Collaboration and shall have the responsibilities set forth in Section 2.9 (Development Committee).
- 1.24. “Development Costs” shall mean [*]. Development Costs shall not include any of the foregoing costs in this Section 1.24 with respect to Japan.
- 1.25. “Development Plan” shall have the meaning set forth in Section 2.9.3 (Development Plans).
- 1.26. “Distracting Product” shall mean any [*].
- 1.27. “Distracting Product Commercial Conditions” shall have the meaning set forth in Section 6.3 (Addition of Distracting Products).
- 1.28. “Distracting Product Expiration Date” shall have the meaning set forth in Section 6.3 (Addition of Distracting Products).
- 1.29. “Distracting Program” shall mean the [*] by either Party of any Distracting Product.
- 1.30. “Distracting Transaction” shall mean any transaction entered into by a Party or its Affiliate after [*] whereby a Third Party that is engaged in a Distracting Program becomes an Affiliate of such Party prior to the Distracting Product Expiration Date.
- 1.31. “Distracting Transaction Affiliates” shall mean those entities that are or would become Affiliates of a Party by virtue of a Distracting Transaction.
- 1.32. “Distracting Transaction Party” shall have the meaning set forth in Section 6.4 (Distracting Transactions).

- 1.33. “*Divest*” shall mean, with respect to any Distracting Product or Distracting Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to the applicable Distracting Product, including technology and other intellectual property and other assets materially relating thereto, to an independent Third Party, without the retention or reservation of any rights, title or interest (other than solely an economic interest) in or to the applicable Distracting Product or Distracting Program by the relevant Party or its Affiliates.
- 1.34. “*Effective Date*” shall have the meaning set forth in the Preamble.
- 1.35. “*EMA*” shall mean the European Medicines Evaluation Agency or any successor agency thereof.
- 1.36. “*Europe*” shall mean the following countries and territories: [*].
- 1.37. “*FDA*” shall mean the United States Food and Drug Administration, and any successor agency thereto.
- 1.38. “*Federal Court*” shall have the meaning set forth in Section 15.12 (Jurisdiction and Venue).
- 1.39. “*First Commercial Sale*” shall mean with respect to a Party, the first sale of a Licensed Product following Regulatory Approval by or on the behalf of such Party or any of its Affiliates or licensees.
- 1.40. “*Force Majeure*” shall have the meaning set forth in Section 15.9 (Force Majeure).
- 1.41. “*FTE*” shall mean the equivalent of the work of one employee full time for one year (consisting of at least a total of [*] weeks or [*] hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
- 1.42. “*FTE Rate*” shall mean [*] per full-time employee per year (as of [*]), increasing by [*] of the then-current FTE Rate on [*].
- 1.43. “*GAAP*” shall mean either Japanese (with respect to Licensee) or U.S. (with respect to Amgen) generally accepted accounting principles, consistently applied, as used by a Party to record the relevant transaction.
- 1.44. “*Governmental Authority*” shall mean any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.
- 1.45. “*Gross Profit*” shall mean Net Sales of Licensed Product (excluding Net Sales in Japan) less the Cost of Sales for such Licensed Product, plus any Recoveries.

- 1.46. “*Indemnified Party*” shall have the meaning set forth in Section 13.2 (Claim for Indemnification).
- 1.47. “*Indemnifying Party*” shall have the meaning set forth in Section 13.2 (Claim for Indemnification).
- 1.48. “*Indications*” shall mean with respect to each Licensed Product, the treatment, palliation, prevention or prophylaxis of disease in humans with respect only to (i) the NSCLC Indication, and (ii) any Additional Indication.
- 1.49. “*Information*” shall mean all tangible and intangible techniques, information, technology, practices, trade secrets, inventions (whether patentable or not and whether or not reduced to practice), processes, methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms.
- 1.50. “*Initiation*” of a clinical trial or to “*Initiate*” a clinical trial shall mean the first dosing of a human subject with a Licensed Product in such trial.
- 1.51. “*Joint Loss(es)*” shall have the meaning set forth in Section 13.3 (Joint Losses).
- 1.52. “*Joint Patents*” shall mean any invention, patent or patent application jointly owned by the Parties pursuant to Section 9.1 (Ownership).
- 1.53. “*Joint Project Team*” shall mean the committee established by the Parties to coordinate the activities of the Parties hereunder and to establish and designate subcommittees as necessary to manage the activities of the Parties hereunder.
- 1.54. “*Law*” shall mean, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.
- 1.55. “*Licensed Amgen Know-How*” shall mean Information Controlled by Amgen (or its Affiliates), as of [*] or thereafter during the Term, that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Indications in the Licensee Territory. Licensed Amgen Know-How shall include Amgen Development Data that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Indications in the Licensee Territory. Except to the extent otherwise mutually agreed by the Parties in connection with any supply arrangement entered into pursuant to Section 7.3 (Commercial Supply), Licensed Amgen Know-How does not include Amgen manufacturing Information. Licensed Amgen Know-How shall include Information known to the employees of Amgen K.K., Amgen’s wholly-owned subsidiary that is being acquired by Licensee, as of the consummation of the transactions contemplated in that certain Sale and Purchase Agreement executed concurrently herewith that is reasonably necessary for Licensee to develop or commercialize a Licensed Product in the Indications in the Licensee Territory.

- 1.56. “*Licensed Amgen Patents*” shall mean those patents and patent applications set forth on the Licensed Amgen Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional applications thereof, [*]. For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.57. “*Licensed Amgen Trademarks*” shall mean any trademark rights Controlled by Amgen (or its Affiliates) in the Licensee Territory on or after [*] and corresponding to any trademarks adopted by Amgen for use with a Licensed Product in an Indication in the Amgen Territory (not including any corporate or house marks, and not including any marks to the extent such marks would conflict with any right of any Third Party inside the Licensee Territory).
- 1.58. “*Licensed Licensee Know-How*” shall mean Information Controlled by Licensee (or its Affiliates), as of [*] or thereafter during the Term, that is reasonably necessary for Amgen to develop, manufacture or commercialize a Licensed Product in the Territory in any Indication. Licensed Licensee Know-How shall include Licensee Development Data that is reasonably necessary for Amgen to develop, manufacture or commercialize a Licensed Product in the Territory in any Indication.
- 1.59. “*Licensed Licensee Patents*” shall mean those patents and patent applications Controlled by Licensee or its Affiliates (including an interest in a patent or Joint Patent pursuant to Section 9.1 (Ownership)) that [*]. For purposes of determining whether a patent application falls within this definition, a patent application shall be considered “infringed” if its pending claims would be infringed if issued as then currently set forth in the patent application.
- 1.60. “*Licensed Licensee Trademarks*” shall mean any trademarks adopted by Licensee for use with a Licensed Product in the Licensee Territory in the Indications (not including any corporate or house marks or Licensed Amgen Trademarks).
- 1.61. “*Licensed Product*” shall mean any pharmaceutical composition comprising [*].
- 1.62. “*Licensee*” shall have the meaning set forth in the Preamble.
- 1.63. “*Licensee Assumed Item*” shall have the meaning set forth in Section 9.2.1(ii) (Licensee Secondary Prosecution).
- 1.64. “*Licensee Development Data*” shall mean the preclinical and clinical data generated by or on behalf of Licensee or its Affiliates in the course of its preclinical (if any) and clinical development of a Licensed Product, on or after [*].
- 1.65. “*Licensee Indemnitees*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.66. “*Licensee Territory*” shall mean the entire world excluding the Amgen Territory.

- 1.67. “*Licensee Territory IP*” shall have the meaning set forth in Section 9.4.1 (In Licensee Territory).
- 1.68. “*Licensee Territory Patents and Trademarks*” shall have the meaning set forth in Section 9.2.1 (i) (Amgen Primary Prosecution).
- 1.69. “*Losses*” shall have the meaning set forth in Section 13.1 (Indemnity).
- 1.70. “*MHLW*” shall mean the Japanese Ministry of Health, Labour and Welfare, and any successor agency thereto.
- 1.71. “*Net Operating Profit*” shall mean, with respect to each Party, such Party’s share of Gross Profit less such Party’s share of Operating Expenses.
- 1.72. “*Net Sales*” shall mean with respect to a given period, the gross invoiced sales price for a Licensed Product sold by or on behalf of a Party, its Affiliates or licensees hereunder to Third Parties (not including such Party’s Affiliates, unless and to the extent such Affiliate is the end-user of such a Licensed Product) during such period, less the total of the following charges or expenses, as determined in accordance with GAAP:
- 1.72.1. Trade, cash, prompt payment and quantity discounts;
 - 1.72.2. Returns, allowances, rebates, chargebacks and payments to government agencies;
 - 1.72.3. Retroactive price reductions;
 - 1.72.4. 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;
 - 1.72.5. Credits and allowances for product replacement, whether cash or trade; and
 - 1.72.6. Non-recoverable sales taxes, excise taxes, tariffs and duties (excluding taxes when assessed on income derived from sales);
- in each case, to the extent related to sales of a Licensed Product in an Indication and actually given.
- 1.73. “*NSCLC Indication*” shall mean the treatment, palliation, prevention or prophylaxis of disease in humans with respect only to non-small cell lung cancer (NSCLC).
- 1.74. “*Ongoing Studies*” shall mean those clinical studies that are being undertaken by Amgen as of [*] with respect to the Licensed Product, including those set forth on the Ongoing Studies Schedule.
- 1.75. “*Operating Expenses*” shall mean [*]. Operating Expenses shall include Commercialization Costs and Other Collaboration Costs. Operating Expenses shall not include any of the foregoing costs in this Section 1.75 with respect to Japan.

- 1.76. “*Other Collaboration Costs*” shall mean [*]. Other Collaboration Costs shall not include any of the foregoing costs in this Section 1.76 with respect to Japan.
- 1.77. “*Party/Parties*” shall have the meaning set forth in the Preamble.
- 1.78. “*Patent Matters*” shall have the meaning set forth in Section 9.2.1(i) (Amgen Primary Prosecution).
- 1.79. “*Phase I Trial*” shall mean, with respect to the United States, any human clinical trial, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required under 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.80. “*Phase II Trial*” shall mean, with respect to the United States, any human clinical trial conducted in the specific patient population with the disease or condition of interest intended to be studied in a Phase III Trial for the purposes of preliminary assessment of safety and efficacy in the indication being studied, and selection of the dose regimen(s) to be studied in a Phase III Trial, as described under 21 C.F.R. §312.21(b), and that, if the defined end-points are met, is sufficient to allow the Initiation of a Phase III Trial in the indication being studied, or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.81. “*Phase III Trial*” shall mean, with respect to the United States, any human clinical trial, that, if the defined end-points are met, is intended to be a pivotal trial for obtaining Regulatory Approval in the indication being studied or to otherwise establish safety and efficacy in patients with the indication being studied for purposes of filing for Regulatory Approval with the FDA as required under 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.82. “*Prior Agreement*” shall have the meaning set forth in Section 10.4 (Prior Agreement).
- 1.83. “*Publishing Party*” shall have the meaning set forth in Section 10.5.2 (Oversight and Review).
- 1.84. “*Reasonably Diligent Efforts*” shall mean, with respect to a Party and a particular Licensed Product, the application of a level of resources, efforts and urgency to develop and commercialize such Licensed Product consistent with such Party’s practices in pursuing the development and commercialization of its other high-value pharmaceutical products in light of its characteristic features, target indication, competitiveness, sales volume and intellectual property situation, but in no event less than the high professional standards and level commonly applied by other pharmaceutical companies to their high-value pharmaceutical products. [*].
- 1.85. “*Recall*” means a “recall” or “market withdrawal” (each as defined per Section 7.3 of Title 21 (Food and Drugs) of the Code of Federal Regulations, or, with respect to a jurisdiction other than the United States, the equivalent regulations of the applicable Governmental Authority in such jurisdiction) of Licensed Product or any lots thereof.

- 1.86. “*Recoveries*” shall mean [*]. Recoveries shall not include any of the foregoing amounts in this Section 1.86 with respect to Japan.
- 1.87. “*Regulatory Approval*” shall mean, with respect to a country or territory, the product-specific approvals from a Governmental Authority necessary for the marketing, distribution and sale of a Licensed Product in such country or territory.
- 1.88. “*Regulatory Filing*” shall mean any filing with any Governmental Authority with respect to the development, marketing, commercialization or reimbursement of a Licensed Product.
- 1.89. “*Reviewing Party*” shall have the meaning set forth in Section 10.5.2 (Oversight and Review).
- 1.90. “*SOPs*” shall have the meaning set forth in Section 4.14 (Recalls).
- 1.91. “*SPC*” shall mean any patent term extension or related extension of rights, including supplementary protection certificates and similar rights.
- 1.92. “*State Court*” shall have the meaning set forth in Section 15.12 (Jurisdiction and Venue).
- 1.93. “*Steering Committee*” shall mean the committee established by the Parties to oversee and coordinate their activities hereunder, and to ensure appropriate communication and oversight by the Parties, as set forth in Section 2.7 (Steering Committee).
- 1.94. “*Taxes*” shall mean any tax, excise or duty, other than taxes upon income.
- 1.95. “*Term*” shall mean the period beginning on [*] and ending upon the termination of this Agreement pursuant to Article 14 (Term and Termination).
- 1.96. “*Termination Date*” shall have the meaning set forth in Section 14.3 (Effect of Termination).
- 1.97. “*Territory*” shall mean the entire world.
- 1.98. “*Third Party*” shall mean any entity other than a Party or an Affiliate of a Party.
- 1.99. “*Third Party Royalties*” shall mean [*]. Third Party Royalties shall not include any of the foregoing amounts in this Section 1.99 with respect to Japan.
- 1.100. “*Transition Period*” shall have the meaning set forth in Section 14.5 (Transition Period).
- 1.101. “*VAT*” shall mean any value added tax.

2 COLLABORATION SCOPE AND GOVERNANCE

- 2.1 Conduct of the Collaboration. The Parties shall cooperate to develop and commercialize the Licensed Product in the Indications in the Territory, in accordance with the terms and conditions of this Agreement (the “*Collaboration*”).
- 2.2 Governance. The Collaboration shall be governed by (i) a Steering Committee, which shall oversee the activities of the Parties hereunder generally, (ii) a Joint Project Team, which shall coordinate the activities of the Parties hereunder, and (iii) subcommittees of the Joint Project Team which shall be established by the Joint Project Team as necessary to manage the activities of the Parties hereunder. Two such subcommittees shall be those of the Development Committee and the Commercialization Committee, which shall oversee the development and commercialization of the Licensed Product hereunder, respectively. The Steering Committee, the Joint Project Team, the Development Committee and the Commercialization Committee shall be formed promptly following [*].
- 2.3 Membership. Unless otherwise mutually agreed by the Parties, the Joint Project Team, the Development Committee and the Commercialization Committee shall each be comprised of [*] members appointed by Amgen and [*] members appointed by Licensee. Each committee shall be led by [*] co-chairs, [*] appointed by each of the Parties. Unless otherwise mutually agreed by the Parties, the Steering Committee shall be comprised of [*] members appointed by Amgen and [*] member appointed by Licensee. The Joint Project Team shall have the right to delegate any of its responsibilities to one or more subcommittees as it determines appropriate.
- 2.4 Replacement of Members. Each Party shall have the right to replace its committee members or co-chairs by written notice to the other Party. In the event any committee member or co-chair becomes unwilling or unable to fulfill his or her duties hereunder, the Party that appointed such member shall promptly appoint a replacement by written notice to the other Party.
- 2.5 Input from other Personnel. Any committee member shall have the right to solicit input or assistance from any other personnel of the Party that appointed such member.
- 2.6 No Authority to Amend or Modify. Notwithstanding anything herein to the contrary, no committee shall have any authority to amend, modify or waive compliance with this Agreement.
- 2.7 Steering Committee. The Steering Committee shall be responsible for overseeing the Parties’ conduct of the Collaboration generally, and for ensuring an appropriate level of oversight of the Collaboration.
- 2.7.1 Meetings. The Steering Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meeting per [*] Year being in person), or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee’s and Amgen’s facilities, unless otherwise agreed by the Parties. As appropriate, other employee representatives

of the Parties may attend Steering Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the co-chair appointed by the other Party. All Steering Committee meetings must have at least [*] member appointed by each Party in attendance.

2.7.2. *Reporting.* The Joint Project Team shall keep the Steering Committee fully and promptly informed of progress and results of activities conducted by the Parties hereunder and shall fully inform the Steering Committee with respect to all relevant facts and activities reasonably requested by any member thereof regarding Licensed Product.

2.7.3. *Decision Making.* The Steering Committee shall make decisions by consensus. In the event the Steering Committee fails to reach consensus with respect to any matter that may [*], such matter shall be [*].

2.8 Joint Project Team. The Joint Project Team shall be responsible for overseeing and coordinating the overall plans of the Parties and resolving matters that are otherwise not resolved within the various subcommittees as may exist hereunder and for ensuring an appropriate level of communication between the Parties.

2.8.1. *Meetings.* The Joint Project Team shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meetings per [*] Year being in person), or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. As appropriate, other employee representatives of the Parties may attend Joint Project Team meetings as nonvoting participants, but no Third Party personnel may attend unless otherwise agreed by the Parties. All Joint Project Team meetings must have at least [*] member appointed by each Party in attendance.

2.8.2. *Reporting.* Each Party, through the members appointed by it on each subcommittee, shall keep the Joint Project Team fully and promptly informed of progress and results of activities for which each subcommittee is responsible. Each Party, through the members appointed by it on each subcommittee, shall fully inform the Joint Project Team with respect to all relevant facts and activities reasonably requested by any member thereof regarding any Licensed Product.

2.8.3. *Decision Making.* With respect to unresolved development matters, the Joint Project Team shall make decisions by consensus. In the event the Joint Project Team fails to reach consensus with respect to any such matter, and the Joint Project Team determines that it is appropriate to do so, such matter shall be escalated to the Steering Committee for resolution. With respect to unresolved commercialization matters, [*] shall make the final determination with respect to commercialization of Licensed Product in the Licensee Territory, and [*] shall

make the final determination with respect to commercialization of Licensed Product in the Amgen Territory.

- 2.9 Development Committee. With respect to each Licensed Product, the Development Committee shall be responsible for: (i) subject to Section 2.9.3 (Development Plans), reviewing and approving new development plans prior to adoption of such plans by a Party; (ii) reviewing and approving changes to development plans (including the AMG706 Development Plan) prior to adoption of such changes by a Party; (iii) providing for communication and discussion between the Parties to, as appropriate, coordinate the development activities of the Parties and to optimize the efficacy and safety of the development of the applicable Licensed Product; (iv) reviewing and monitoring the activities and progress of the Parties against the development plans, including site enrollment, patient enrollment, progress of trials and data received; (v) communicating with the Commercialization Committee regarding the interrelationship between development activities and potential commercialization; and (vi) communicating with the Joint Project Team regarding all of the foregoing.
- 2.9.1. *Meetings*. Each Development Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meetings per [*] Year being in person), more frequently as may be required by ongoing development activities, or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee's and Amgen's facilities, unless otherwise agreed by the Parties. As appropriate, other employee representatives of the Parties may attend Development Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the co-chair appointed by the other Party. All committee meetings must have at least [*] member appointed by each Party in attendance.
- 2.9.2. *Reporting*. Each Party shall keep the relevant Development Committee fully and promptly informed of progress and results of development activities for which it is responsible or that it is permitted to conduct hereunder through its members on such Development Committee and as otherwise provided herein, including by promptly providing copies of all clinical data and results for Licensed Product as reasonably requested by the other Party through the Development Committee. Each Party shall fully inform the applicable Development Committee with respect to all relevant facts and activities reasonably requested by any member thereof regarding any Licensed Product development matter. At least five (5) business days prior to the first meeting of each Development Committee of each Calendar Quarter, each Party shall deliver to such Development Committee a written summary of development activities conducted hereunder and material clinical data and results received by each such Party since the last such report, in each case with respect to the applicable Licensed Product(s).
- 2.9.3. *Development Plans*. The development plan and budget for development of AMG706 for the NSCLC Indication in the Territory and completion of the

Ongoing Studies has been mutually agreed upon by the Parties as of [*] and is attached hereto as the Development Plan Schedule (as amended by Agreement of the Development Committee from time to time, “*Development Plan*”). Should either Party seek to make changes to an approved Development Plan, then at least [*] days prior to the next meeting of the Development Committee, it shall provide the Development Committee any proposed changes to the previously approved Development Plan for the Development Committee’s review and approval (including approval for any Additional Indication).

2.9.4. *Decision Making.* The Development Committee shall make decisions by consensus. In the event the Development Committee fails to reach consensus with respect to any matter, such matter shall be [*].

2.10 Commercialization Committee. The Commercialization Committee shall be responsible for: (i) reviewing and approving global commercialization plans (and changes thereto) prior to adoption of such plans (or changes) by the Parties; (ii) communicating with the Development Committee regarding the interrelationship between development activities and potential commercialization; (iii) reviewing the commercialization activities of the Parties; (iv) overseeing the trademark and publication strategies; and (v) communicating with the Joint Project Team regarding all of the foregoing.

2.10.1. *Meetings.* The Commercialization Committee shall meet [*] in person, via teleconference or videoconference or otherwise (with at least [*] meetings per [*] Year being in person), or as otherwise agreed by the Parties. Any in-person meetings shall be held on an alternating basis between Licensee’s and Amgen’s facilities, unless otherwise agreed by the Parties. As appropriate, other employee representatives of the Parties may attend Commercialization Committee 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 as reasonably required to resolve particular matters requested by such Party by at least [*] days written notice to the co-chair appointed by the other Party. All committee meetings must have at least [*] member appointed by each Party in attendance.

2.10.2. *Reporting.* Each Party shall keep the Commercialization Committee fully and promptly informed of progress and results of commercialization activities in the territory for which it is responsible or that it is permitted to conduct hereunder through its members on the Commercialization Committee and as otherwise provided herein. Each Party shall fully inform the Commercialization Committee with respect to all relevant facts and activities reasonably requested by any member thereof regarding any Licensed Product commercialization matter. At least [*] days prior to the Commercialization Committee meeting of each [*] Quarter, each Party shall deliver to the Commercialization Committee a written summary of commercialization activities conducted hereunder by each such Party since the last such report.

- 2.10.3. *Commercialization Plans.* At least [*] days prior to the last meeting of the Commercialization Committee of each [*] Year (or such other time as mutually agreed), each Party shall provide the Commercialization Committee a copy of its proposed commercialization plan for the Licensed Product in such Party's respective territory under the Collaboration for the next [*] Year for the Commercialization Committee's review, comment and approval (either by Indication or for all Indications for which it is responsible in such Party's respective territory)). In addition, should a Party seek to make material changes to an approved commercialization plan, then at least [*] days prior to the next meeting of the Commercialization Committee it shall provide the Commercialization Committee any proposed changes to the previously approved commercialization plan for the Commercialization Committee's approval.
- 2.10.4. *Decision Making.* The Commercialization Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. Decisions with respect to day-to-day commercial operations for which a Party has responsibility (other than any matter that could reasonably be expected to adversely affect the other Party's commercialization in its territory), shall be made by such Party and notice thereof shall be submitted to the Commercialization Committee solely for informational purposes. With respect to any commercial matter that could reasonably be expected to adversely affect the other Party's commercialization of Licensed Product in such Party's respective territory, if the Commercialization Committee fails to reach consensus, such matter shall be [*]. Notwithstanding the above, with respect to unresolved matters that could reasonably be expected to adversely affect the other Party's commercialization of Licensed Product and that have been [*], in the event that exigent circumstances require a Party to take action in the best interests of the Licensed Product with respect to its territory, such Party shall be allowed to do so by providing written notice of such decision or action to the Commercialization Committee.

3 GRANT OF LICENSE

- 3.1 Licensed Amgen Patents. Amgen hereby grants Licensee [*] right and license under the Licensed Amgen Patents during the Term, subject to the terms and conditions hereof, solely to research, develop, commercialize, use, import and sell Licensed Product only in the Indications in the Licensee Territory, except that Amgen retains non-exclusive rights in the Licensee Territory to develop, use, commercialize and sell (in accordance with Section 5.3 (Commercialization in Europe) or as otherwise agreed by the Commercialization Committee), and manufacture Licensed Product. Such license to Licensee shall include the right to sublicense only as set forth in Section 3.4 (Licensee Sublicensing). Amgen also hereby grants Licensee [*] right and license under the Licensed Amgen Patents during the Term, subject to the terms and conditions hereof, solely to develop Licensed Product only in the Indications in the Amgen Territory.
- 3.2 Licensed Amgen Know-How. Amgen hereby grants Licensee [*] right and license during the Term, subject to the terms and conditions hereof, to utilize the Licensed Amgen

Know-How solely for the purpose of supporting its research, development, commercialization, use, importation and sale of Licensed Product only in the Indications in the Licensee Territory, except that Amgen retains non-exclusive rights in the Licensee Territory to research, develop, use, import, commercialize and sell (in accordance with Section 5.3 (Commercialization in Europe) or as otherwise agreed by the Commercialization Committee), and manufacture Licensed Product. Such license shall include the right to sublicense only as set forth in Section 3.4 (Licensee Sublicensing). Amgen also hereby grants Licensee [*] right and license during the Term, subject to the terms and conditions hereof, to utilize the Licensed Amgen Know-How solely for the purpose of supporting its development of Licensed Product only in the Indications in the Amgen Territory.

3.3 Licensed Licensee Know-How and Patents. Licensee hereby grants Amgen [*] right and license, subject to the terms and conditions hereof, under the Licensed Licensee Know-How and Licensed Licensee Patents (i) solely for the purpose of the development, commercialization, manufacture, use, importation and sale of Licensed Product in the Amgen Territory for all uses, (ii) solely for the purpose of the development, manufacture, use and importation of Licensed Product in the Licensee Territory (excluding Japan during the Term) and for the purpose of commercialization and sale of Licensed Product in the Licensee Territory (x) during the Term in accordance with Section 5.3 (Commercialization in Europe) or as otherwise agreed by the Commercialization Committee and (y) after the Term for all uses, and (iii) for performing its obligations hereunder, including any supply obligations with respect to Licensed Product. Such license shall include the right to grant sublicenses to those persons and entities to which Amgen (or its Affiliate or licensee) is also granting licenses to any Amgen patent or know-how relating to Licensed Product or the use thereof; provided, however, that: (a) any sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Licensee; (b) Amgen shall be responsible for any disclosure of the Confidential Information of Licensee by such sublicensee in violation of the provisions of Article 10 (Confidentiality and Publications); (c) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; and (d) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions.

3.4 Licensee Sublicensing. Licensee shall have the right to sublicense the rights granted it hereunder only with Amgen's prior written consent, which consent may not be unreasonably withheld or delayed, except with respect to any of the parties [*] for which Amgen may withhold or condition its consent in its sole discretion. Any permitted sublicensee shall be required to enter into a written agreement obligating it to maintain the confidentiality of the Confidential Information of Amgen and Licensee shall be responsible for any disclosure of the Confidential Information of Amgen by such sublicensee in violation of the provisions of Article 10 (Confidentiality and Publications). In addition, such written agreement shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed, and Licensee shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. No sublicense shall operate to excuse Licensee's compliance with its

obligations hereunder. Licensee shall have the right to distribute a Licensed Product in the Licensee Territory through reputable distributors with prior written notice to Amgen.

3.5 Provision of Know-How. Following [*], the Parties shall cooperate to establish procedures for the provision of Licensed Amgen Know-How to Licensee and Licensed Licensee Know-How to Amgen. During the Term, Amgen shall use reasonable efforts to provide all material Licensed Amgen Know-How to Licensee, and Licensee shall use reasonable efforts to provide all material Licensed Licensee Know-How to Amgen. In any event, each of the Parties shall provide to the other any Licensed Amgen Know-How or Licensed Licensee Know-How (respectively) as the other Party shall reasonably request. Notwithstanding the foregoing, Amgen shall have no obligation to provide manufacturing information to Licensee (except as may be expressly agreed to by the Parties pursuant to Section 7.3 (Commercial Supply)) unless provision of such information is necessary to develop and commercialize Licensed Products in accordance with this Agreement and neither Party shall have an obligation to provide information relating to any product other than the Licensed Product.

3.6 Trademarks.

3.6.1. *Grant to Licensee.* Amgen hereby grants to Licensee [*] right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use, import and sell Licensed Product in the Licensee Territory in the Indications under the same Licensed Amgen Trademarks as used by Amgen for Licensed Product in such Indications in the Amgen Territory. Such license shall include the right to sublicense only as set forth in Section 3.4 (Licensee Sublicensing). The Parties acknowledge that the use of the Licensed Amgen Trademarks in the Licensee Territory may have commercial value to Licensee, and that Licensee shall have the right to commercialize Licensed Product in the Indications in the Licensee Territory under the same Licensed Amgen Trademarks as utilized for Licensed Product in such Indications by Amgen in the Amgen Territory. Should the Parties desire that a different trademark be used for Indications in the Licensee Territory, or if additional trademarks to those used in the Amgen Territory are otherwise required, the Parties shall consult and agree upon an additional or replacement trademark (or trademarks) (which additional or replacement trademark(s) shall, as between the Parties, be owned by Amgen). In addition, if the manufacture of Licensed Product for Licensee for use in the Licensee Territory materially varies from the manufacture of Licensed Product for Amgen or its Affiliates for use in the Amgen Territory, then upon the request of Amgen, the Parties shall consult and agree upon a replacement trademark (or trademarks) (which replacement trademark(s) shall, as between the Parties, be owned by Amgen). Upon Amgen's request, Licensee shall include an Amgen trademark designated by Amgen to Licensee in writing (e.g., "Amgen") on all packaging, labeling, promotional and marketing materials for the applicable Licensed Product in equal prominence to those of Licensee in a form and manner approved by Amgen. Amgen hereby grants Licensee a non-exclusive right and license, with the right to sublicense only as set forth in Section 3.4 (Licensee Sublicensing), during the Term, subject to the terms and conditions hereof, to use

such Amgen marks solely for such purpose. Such Amgen marks shall be subject to the quality control provisions set forth in Section 3.7 (Trademark Quality Standards). All uses by Licensee of the Licensed Amgen Trademarks and other Amgen marks permitted hereunder, and all goodwill associated therewith, shall inure solely to the benefit of Amgen.

3.6.2. *Grant to Amgen.* Licensee hereby grants to Amgen [*] right and license during the Term to use Licensed Licensee Trademarks in connection with Amgen's activities pursuant to Section 5.3 (Commercialization in Europe) and Section 5.5 (Co-Promotion Rights). All uses by Amgen of the Licensed Licensee Trademarks, and all goodwill associated therewith, shall inure solely to the benefit of Licensee. Upon any termination or expiration of this Agreement, such license shall become paid-up and perpetual, and shall include the right to use the relevant Licensed Licensee Trademarks in connection with Licensed Product in all indications and throughout the Territory unless, at Licensee's option, Licensee decides to assign the relevant Licensed Licensee Trademarks (and the associated goodwill) to Amgen at no charge.

3.7 Trademark Quality Standards. Each Party shall (i) maintain such reasonable quality standards for the Licensed Amgen Trademarks (with respect to Licensee) or the Licensed Licensee Trademarks (with respect to Amgen) at least as high as the standards it maintains for its own trademarks of a similar nature and shall comply with the other Party's reasonable specifications and usage standards supplied to it in writing (and as may be updated by written notice from time to time); (ii) not use any Licensed Amgen Trademark (with respect to Licensee) or Licensed Licensee Trademark (with respect to Amgen) in a manner that suggests any connection with any product other than a Licensed Product or any service; and (iii) not use or display the Licensed Amgen Trademarks (with respect to Licensee) or the Licensed Licensee Trademarks (with respect to Amgen) in any manner that might dilute, tarnish, disparage or reflect adversely on the other Party or such marks. Prior to using any Licensed Amgen Trademark (with respect to Licensee) or Licensed Licensee Trademark (with respect to Amgen), the Parties shall agree upon a guideline for use of such trademarks, including the review procedure and timing. From time to time, upon request by a Party, the other Party shall provide representative specimens of the usage of the Licensed Amgen Trademarks (with respect to Licensee) or Licensed Licensee Trademarks (with respect to Amgen) used in the marketing or promotion of a Licensed Product in order to review such usage. Amgen shall not seek to register or obtain ownership rights in any Licensed Licensee Trademark (or confusingly similar trademark) and Licensee shall not seek to register or obtain ownership rights in any Licensed Amgen Trademark or any trademark used by Amgen in connection with Licensed Product in the Amgen Territory in any indication (or confusingly similar trademark to any of the foregoing).

3.8 Retained Rights and Limitations. Except as expressly granted in this Article 3, no rights are granted to Licensee hereunder to Licensed Amgen Patents, Licensed Amgen Know-How or Licensed Amgen Trademarks outside the Indications, or outside the Licensee Territory. Except to the extent expressly set forth in Sections 7.2 (Clinical Supply) or 7.3 (Commercial Supply), no rights are granted to Licensee hereunder to make or have made

a Licensed Product or any other product. No rights are granted to Licensee hereunder to import or export a Licensed Product manufactured by Amgen or its licensee, except as specifically contemplated herein. No rights are granted herein to Licensee to control the research, development or commercialization of a Licensed Product in the Amgen Territory except, with respect to development, as otherwise agreed by the Parties through the Development Committee and, with respect to commercialization, as allowed under Section 5.5 (Co-Promotion Rights). No rights to either Party's patents, trademarks or other intellectual property or proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved.

4 DEVELOPMENT AND REGULATORY ACTIVITIES

- 4.1 Collaboration for Development. The Parties shall use Reasonably Diligent Efforts to develop the Licensed Product in the NSCLC Indication, and in such Additional Indications as may be mutually agreed upon by the Parties for the Licensed Product through the Development Committee, and such development shall be conducted in accordance with the Development Plan. The Parties shall also use Reasonably Diligent Efforts to develop Licensed Product in such other Indications, as may be mutually agreed upon by the Parties through the Development Committee, and development, if any, of Licensed Product in any such mutually agreed Indication(s) shall be conducted in accordance with the then-current Development Plan approved by the Development Committee for Licensed Product in such Indication(s).
- 4.2 Preclinical Development in Indications. Licensee shall not conduct any preclinical research with respect to Licensed Product without the prior written approval of the Development Committee. Any such research shall be conducted in accordance with a research plan to be agreed in writing by the Parties through the Development Committee. If such research is approved by the Development Committee, Licensee shall promptly and diligently conduct such research (itself or through a subcontractor) and shall keep Amgen updated with respect to such pre-clinical research activities through the Development Committee, and as may be requested by Amgen from time to time.
- 4.3 Clinical Trials.
- 4.3.1. *Conduct of Clinical Trials Outside Japan.* Amgen shall have the sole right and obligation to manage and conduct all aspects of all clinical trials for the Licensed Product in the NSCLC Indication that have been Initiated as of [*] in the Territory (excluding Japan) and all Ongoing Studies. To the extent any of the Ongoing Studies currently contemplate use of Japanese sites, Licensee shall be obligated to conduct the Japanese aspects of the Ongoing Studies pursuant to Amgen's overall management of such studies. Amgen shall have the first right, but not the obligation, to manage and conduct all aspects of all clinical trials for the Licensed Product in the NSCLC Indication that are Initiated from and after [*] in the Territory (excluding Japan). Licensee shall have the first right, but not the obligation, to manage and conduct all aspects of all clinical trials for the Licensed Product in the first Additional Indication in the Territory (and shall have the

obligation to do so in Japan). For all other Indications, responsibilities between the Parties shall be decided by the Development Committee.

4.3.2. *Licensee's Conduct of Clinical Trials in Japan.* Except with respect to Ongoing Studies, Licensee shall have the sole right and obligation to manage and conduct all aspects of all clinical trials for the Licensed Product in all Indications in Japan, including (i) designing study protocols; (ii) establishing/contracting with clinical trial sites, investigators and clinical research organizations; (iii) enrolling clinical trial subjects; (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings; (v) analyzing and summarizing clinical trial results; (vi) forecasting clinical manufacturing production requirements; and (vii) reporting on study design, study outcome, other communications and regulatory filings to the MHLW. Licensee shall keep the Development Committee updated with respect to all of its clinical trials in Japan for the Licensed Product in all Indications.

4.4 Regulatory Activities.

4.4.1. *Licensee Responsibility.* Licensee shall own and be solely responsible for filing, obtaining and maintaining all Regulatory Approvals for the Licensed Product in the Indications in the Licensee Territory and any approval for any product labeling or promotional materials in the Licensee Territory with respect thereto; and unless otherwise agreed or required by applicable Law, all such approvals shall be held in the name of Licensee. Licensee shall also be responsible for any post-approval activities required to be conducted by any Governmental Authority in the Licensee Territory for Licensed Product; provided that any post-marketing studies not required by the MHLW or any other Governmental Authority in the Licensee Territory, shall be submitted to and approved by the Development Committee prior to commencing any such post-marketing studies (as set forth in Section 4.5 (Voluntary Post-Marketing Studies)), and in any event, Licensee shall submit a proposal detailing such post-marketing studies required by any Governmental Authority in the Licensee Territory to the Development Committee for review (not approval) and shall keep the Development Committee apprised of the progress and results thereof.

4.4.2. *Amgen Responsibility.* Amgen shall own and be solely responsible for filing, obtaining and maintaining all Regulatory Approvals for the Licensed Product in the Indications in the Amgen Territory and any approval for any product labeling or promotional materials in the Amgen Territory with respect thereto; and unless otherwise agreed or required by applicable Law, all such approvals shall be held in the name of Amgen (or its designee). Amgen shall also be responsible for any post-approval activities required to be conducted by any Governmental Authority in the Amgen Territory for any Licensed Product; provided that any post-marketing studies not required by the FDA or any other Governmental Authority in the Amgen Territory, shall be submitted to and approved by the Development Committee prior to commencing any such post-marketing studies (as set forth in Section 4.5 (Voluntary Post-Marketing Studies)), and in any event, Amgen shall

submit a proposal detailing such post-marketing studies required by any Governmental Authority in the Amgen Territory to the Development Committee for review (not approval) and shall keep the Development Committee apprised of the progress and results thereof.

- 4.5 Voluntary Post-Marketing Studies. Should either Party desire to conduct any post-marketing studies (other than post-marketing studies required by any Governmental Authority in such Party's respective territory under the Collaboration), such Party shall submit a proposal detailing such post-marketing studies to the Development Committee for review and approval. The Development Committee shall give due consideration to any concern expressed by a Party that the conduct of any such post-marketing study could reasonably be expected to adversely affect such Party's development or commercialization of a Licensed Product in any Indication. Should the Development Committee approve any such post-marketing study, the then-current applicable development plan shall be amended accordingly and the Party proposing to conduct such post-approval study shall conduct such study in accordance with the amended development plan and shall keep the Development Committee apprised of the progress and results thereof.
- 4.6 Development in Combination. Licensee shall not, without Amgen's prior express written consent, conduct any development of Licensed Product in combination with any other pharmaceutical product. Amgen reserves the right to develop Licensed Product in combination with other Amgen products or product candidates but does not intend to develop a single pharmaceutical agent containing both Licensed Product and another pharmaceutical product. If Amgen proposes to conduct development of Licensed Product in combination with another Amgen product or product candidate, the Parties shall discuss conducting such development within the Collaboration. If and only if the Parties do not agree on conducting such development within the Collaboration, then Amgen shall have the right to conduct such development outside the Collaboration at its sole expense. For the avoidance of doubt, nothing in this Section 4.6 (Development in Combination) is intended to limit or take away from the exclusive right of Licensee to sell Licensed Product in the Licensee Territory in accordance with Sections 3.1 (Licensed Amgen Patents) and 3.2 (Licensed Amgen Know-How).
- 4.7 Sharing of Regulatory Filings. Each Party shall disclose to the other Party a draft copy of any Regulatory Filing for a Licensed Product in an Indication no less than [*] days prior to filing it with a Governmental Authority. Each Party shall consider in good faith any comments made by the other Party with respect to such filings. Where documents are not in English, each Party shall also provide an English translation. Amgen shall maintain a centralized database which contains all clinical trial data accumulated from all clinical trials of a Licensed Product conducted by, on behalf of, or with the support of each Party under the Collaboration (in a computer readable format as reasonably specified by Amgen), and each Party shall have full access to the database. Upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings or Regulatory Approvals for a Licensed Product in such Party's respective territory under the Collaboration, in each case as reasonably necessary for the requesting Party's development or commercialization of such Licensed Product as permitted

hereunder (and/or, with respect to Amgen, as reasonably necessary for the manufacture of such Licensed Product). Notwithstanding the foregoing, (i) Amgen shall not be required to provide to Licensee nor to allow Licensee to access (but shall provide a right of reference as set forth in Section 4.13 (Amgen Cooperation – Manufacturing Information) to the extent necessary) to Amgen’s manufacturing information with respect to a Licensed Product or any sections of any Regulatory Filing related thereto, and (ii) neither Party shall have an obligation to provide information relating to any product other than a Licensed Product.

- 4.8 Quality Agreement. Promptly following [*], the quality assurance departments of Amgen and Licensee shall develop and agree upon a quality agreement governing the quality and specifications of clinical Licensed Product to be supplied hereunder (with commercial product handled separately through the supply agreement to be entered into pursuant to Section 7.3 (Commercial Supply) or one or more additional quality agreements) including with respect to product quality and product complaints (to the extent not covered in a separate safety agreement entered into pursuant to Section 4.10 (Safety Agreement)) with respect to the Licensed Product. The quality agreement will be documented in writing, and routinely updated by mutual written agreement of the Parties.
- 4.9 Transfer of Regulatory Filing. Promptly after [*], Amgen shall transfer to Licensee all Regulatory Filings in Japan with respect to the Licensed Product. Licensee shall not transfer title in, fail to maintain or otherwise attempt in any manner to dispose of any Regulatory Filings or Regulatory Approvals or other governmental licenses, approvals or certificates for Licensed Product in Japan without the express prior written approval of Amgen. Notwithstanding the foregoing, Amgen shall have no obligation to transfer any Regulatory Filing if effectuating such transfer may give rise to any material delay in, or make less likely, the receipt of any Regulatory Approval or might otherwise adversely affect any such Regulatory Filing. Should any such transfer be so delayed: (i) Amgen shall take steps reasonably necessary to provide Licensee the necessary access to such Regulatory Filing; and (ii) Amgen shall thereafter transfer such Regulatory Filing at such time as such delay or adverse effect is no longer likely to occur.
- 4.10 Safety Agreement. Promptly following [*] the safety departments of Amgen and Licensee shall develop and agree upon safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning adverse events with respect to the Licensed Product sufficient to permit each Party, its Affiliates, permitted licensees (including permitted sublicensees) to comply with Law, including, to the extent applicable, those obligations contained in applicable Governmental Authority regulations (including those of the FDA, EMEA and MHLW). The safety data exchange procedures shall be documented in writing, and promptly updated if required by changes in Law or by agreement of the Parties.
- 4.11 Adverse Event Reporting. Each Party shall be responsible for reporting to the relevant Governmental Authorities in its respective territory all adverse events with respect to the Licensed Product anywhere in the Territory, to the extent required by and in accordance with Law. Each Party shall ensure that its Affiliates, and permitted licensees (including permitted sublicensees), as applicable, comply with all such reporting obligations. Each

Party will designate a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events with respect to Licensed Product.

4.12 Regulatory Communications.

4.12.1. *Licensee Responsibility.* Licensee shall have primary responsibility for all correspondence and for any official communication (except as Amgen may be required by Law or a Governmental Authority to communicate) regarding the Licensed Product in Indications with applicable Governmental Authorities in the Licensee Territory (other than (i) as set forth in Section 4.12.2 (Amgen Responsibility), with respect to the NSCLC Indication for the Licensed Product; and (ii) with respect to manufacturing in the Territory (except with respect to any aspects of manufacturing for which Licensee has assumed responsibility as expressly provided in Section 7.4 (Responsibility for Regulatory Filings with Respect to Manufacturing)), and Licensee shall do so in a timely manner and in accordance with Law. Without prejudice to the time periods relevant to Regulatory Filings pursuant to Section 4.7 (Sharing of Regulatory Filings), Licensee shall supply to Amgen a copy of: (a) all material correspondence and communications to any such Governmental Authority at least [*] days 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 (b) all material correspondence and communications from any such Governmental Authority within [*] days after receipt of any such correspondence. Materials provided pursuant to Section 4.7 (Sharing of Regulatory Filings) need not be re-provided pursuant to this Section 4.12.1 (Licensee Responsibility) unless changed. Where correspondence or communications are not in English, Licensee shall also provide an English summary and translation. Licensee shall consider in good faith any comments or suggestions made by Amgen with respect to any such communication. Amgen shall, upon Licensee's request, reasonably cooperate with Licensee in responding to any inquiry made by a Governmental Authority in the Licensee Territory regarding Licensed Product in any Indications, and, with respect to Japan, Licensee shall reimburse all reasonable, documented, out-of-pocket expenses incurred by Amgen in connection therewith. Amgen shall be entitled to observe and participate in any discussions between Licensee and any Governmental Authority relating to Licensed Product, and Licensee shall give Amgen at least [*] days prior written notice thereof (or prompt written notice, if [*] days notice is impractical). Should Licensee be unable to solicit Amgen's participation in any such discussion (as, for example, with respect to a call or visit to Licensee by such Governmental Authority without notice), then Licensee shall provide Amgen prompt written notice of such communication with a summary of the discussion.

4.12.2. *Amgen Responsibility.* Amgen shall have exclusive responsibility for all correspondence and for any official communication (except as Licensee may be required by Law or a Governmental Authority to communicate or as expressly provided in Section 4.12.1 (Licensee Responsibility)) regarding (i) the Licensed Product in Indications with applicable Governmental Authorities in the Amgen

Territory, (ii) the Licensed Product in the NSCLC Indication with applicable Governmental Authorities in the Territory (other than Japan), provided that, in the Licensee Territory, such responsibility shall transition to Licensee as of the time that a Regulatory Filing seeking Regulatory Approval has been submitted by Licensee, and further provided that Amgen shall reasonably cooperate with Licensee in such transition in accordance with Section 4.12.1 (Licensee Responsibility) and (iii) regarding the manufacture of the Licensed Product in the Territory. Without prejudice to the time periods relevant to Regulatory Filings pursuant to Section 4.7 (Sharing of Regulatory Filings), Amgen shall supply to Licensee a copy of: (a) all material correspondence and communications to any such Governmental Authority at least [*] days 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 (b) all material correspondence and communications from any such Governmental Authority within [*] days after receipt of any such correspondence. Amgen shall consider in good faith any comments or suggestions made by Licensee with respect to any such communication. Licensee shall reasonably cooperate with Amgen in responding to any inquiry made by a Governmental Authority in the Amgen Territory regarding Licensed Product in any Indications. Licensee shall be entitled to observe and participate in any discussions between Amgen and any Governmental Authority relating to Licensed Product, and Amgen shall give Licensee at least [*] days prior written notice thereof (or prompt written notice, if [*] days notice is impractical). Should Amgen be unable to solicit Licensee's participation in any such discussion (as, for example, with respect to a call or visit to Amgen by such Governmental Authority without notice), then Amgen shall provide Licensee prompt written notice of such communication with a summary of the discussion. Notwithstanding the above, Amgen shall not be required to disclose manufacturing information (except as set forth in Section 4.13 (Amgen Cooperation – Manufacturing Information)).

- 4.13 Amgen Cooperation – Manufacturing Information. Upon Licensee's request, Amgen will reasonably cooperate with Licensee to make and provide copies of any direct communications by Amgen either to or from the Governmental Authorities having jurisdiction in the Licensee Territory regarding the manufacture of any Licensed Product by Amgen for supply to Licensee; provided, however, that Amgen's obligation to provide Licensee with manufacturing and process information is limited to the circumstance where the information is reasonably required for Licensee to carry out its development and commercialization responsibilities, or access to such information is required by Law or a Governmental Authority having jurisdiction in the Licensee Territory; but Licensee shall only be entitled to use such information to the extent required by such Law or Governmental Authority or to the extent reasonably required to carry out its development and commercialization responsibilities hereunder. Amgen shall 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 (in order to better protect the confidentiality of such information).

- 4.14 Recalls. The Parties shall exchange their internal standard operating procedures as to product recalls (“SOPs”) reasonably promptly after [*] and thereafter, reasonably promptly after such SOPs are approved or modified. If either Party becomes aware of information about quantities of a Licensed Product supplied by Amgen to Licensee which may not conform to the specifications for a Licensed Product then in effect, or for which there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, or for which a Licensed Product itself is or is likely to be the subject of a Recall in the Territory, it shall promptly so notify the other Party and the Party having the right to control such a Recall pursuant to Section 4.14.1 (Licensee Right) or 4.14.2 (Amgen Right) shall have the right to take immediate action with notice to the other Party when the regulatory timeframes or public safety considerations so require. The Parties will meet (in person, by telephone or otherwise) to discuss the circumstances of any potential Recall and to consider appropriate courses of action, which courses of action with respect to a Recall shall be consistent with the internal SOP of the Party having the right to control such Recall pursuant to Section 4.14.1 (Licensee Right) or 4.14.2 (Amgen Right), and the other Party shall make available to the Party having the right to control such Recall all pertinent records which the Party having the right to control such Recall may reasonably request to assist in effecting any Recall (provided, however, Amgen shall be obligated to provide manufacturing information to Licensee only to the extent necessary for Licensee to conduct such Recall, and Amgen shall 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) as appropriate (in order to better protect the confidentiality of such information). In the event of an order of a Governmental Authority having jurisdiction in the Territory mandating a Recall, the Party having the right to control such a Recall pursuant to subsection 4.14.1 (Licensee Right) or 4.14.2 (Amgen Right) shall promptly comply with such order with written notice to the other Party.
- 4.14.1. *Licensee Right*. Licensee shall have the sole right to control a Recall of a Licensed Product in the Licensee Territory in all Indications. Licensee shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.14 (Recalls) for such periods as may be required by Law, but in any event for no less than [*] years.
- 4.14.2. *Amgen Right*. Amgen shall have the sole right to control a Recall of a Licensed Product in the Amgen Territory in all Indications. Amgen shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.14 (Recalls) for such periods as may be required by Law, but in any event for no less than [*] years.

4.15 Cooperation.

- 4.15.1. *Cooperation Generally.* Subject to the oversight of the Development Committee as set forth in Article 2 (Collaboration Scope and Governance), and without limiting any of the Parties' obligations hereunder, the Parties shall provide each other with any cooperation reasonably requested by the other with respect to Licensee's development of Licensed Product in the Licensee Territory, and Amgen's development of Licensed Product in the Amgen Territory.
- 4.15.2. *Licensee Development in Japan.* Licensee shall keep the Development Committee fully and promptly informed of the progress and results of Licensee's development activities with respect to Licensed Product in Japan and shall take into consideration, and act on as appropriate, any reasonable requests by the Development Committee with respect thereto.

5 COMMERCIALIZATION

- 5.1 Operational Control in Licensee Territory. Licensee shall have control and responsibility for commercialization of the Licensed Product in the Licensee Territory in all Indications, subject to Section 5.3 (Commercialization in Europe), Amgen's right to co-promote in accordance with Section 5.5 (Co-Promotion Rights) or as otherwise agreed by the Commercialization Committee. Licensee shall promote and commercialize the Licensed Product using only professional and well-trained employees of Licensee, and may utilize a contract sales organization hired only on a fee-for-service basis in connection with a Licensed Product upon prior written notice to Amgen except with respect to Europe for which region the Parties shall engage in good faith discussions as how best to utilize the capabilities of Amgen with respect to commercialization activities in Europe. In no event shall Licensee use the sales personnel of a Third Party pharmaceutical or biotech company or affiliate thereof without Amgen's prior written approval. Licensee shall reasonably consider any interest that Amgen may have in providing its sales personnel to supplement the sales personnel of Licensee.
- 5.2 Operational Control in the Amgen Territory. Amgen shall have control and responsibility for commercialization of the Licensed Product in the Amgen Territory in all Indications, subject to Licensee's right to co-promote in accordance with Section 5.5 (Co-Promotion Rights).
- 5.3 [*] With respect to [*].
- 5.4 Responsibilities. Each Party shall conduct such commercialization in accordance with the then-current commercialization plan approved by the Commercialization Committee. Subject to the foregoing, with respect to Licensee and Licensed Product in Indications in the Licensee Territory, and Amgen and Licensed Product in Indications in the Amgen Territory, each Party's responsibilities shall include: (i) execution of the global commercial plan approved by the Commercialization Committee within each Party's respective territory (e.g., strategies for branding, product positioning, pre-launch activities (e.g., market research), launch and post-launch marketing and promotion, and field sales

force optimization); (ii) pricing and reimbursement; (iii) determination of packaging and labeling (provided, however, that each Party shall have the right to participate in any discussions with Governmental Authorities in the other Party's territory with respect to labeling in accordance with Section 4.12 (Regulatory Communications)); (iv) creation of promotional materials regarding the Licensed Product which are intended for distribution to Third Parties (including medical professionals) and to such Party's sales force (subject to Section 3.7 (Trademark Quality Standards)); (v) conducting post-marketing studies required by a Governmental Agency; (vi) determining and conducting promotion activities; and (vii) conducting sales, distribution and medical affairs activities, including booking sales (i.e., recognizing all revenues), taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables and collecting prescription tracking, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions.

5.5 Co-Promotion Rights. Amgen shall have the right, on an Indication-by-Indication basis, upon [*] months prior written notice to Licensee, to co-promote each Licensed Product in one or more Indications in one or more countries of the Licensee Territory, and Licensee shall have the right, on an Indication-by-Indication basis, upon [*] months prior written notice to Amgen, to co-promote Licensed Product in one or more Indications in one or more countries in the Amgen Territory, from and after the First Commercial Sale of such Licensed Product in the applicable country. Each Party shall provide the other Party with any information reasonably requested by the other Party to allow the other Party to consider whether to exercise such right. Neither party shall have the right to elect to co-promote in any country of the other Party's territory after the First Commercial Sale of such Licensed Product has taken place in that country. Should a Party elect to co-promote a Licensed Product in one or more Indications in the other Party's territory, such Party may elect to provide up to [*] of the details for such Indication, and such Party's notice of exercise of its option shall specify the percentage of total details (up to such [*] maximum) that such Party desires to perform for such Indication. The Parties shall discuss the means by which each sales force has the appropriate incentives to promote the Licensed Product. The Parties shall cooperate to allocate details between them on an equitable basis in good faith, taking into account geography, settings, provider category and detailing position, as well as each Party's sales force composition and strategic focus in the applicable country or territory, as applicable, so as not to unreasonably interfere with the other Party's commercialization activities hereunder but each Party shall have the right to make the final decision with respect to commercialization of Licensed Product in its territory. Each Party shall have the right to terminate its co-promotion activities with respect to any or all Indications for a Licensed Product and/or in one or more countries of the other Party's territory upon [*] days notice to the other Party, and the Parties shall cooperate to transition such activities to the other Party with a minimum of disruption. At the request of either Party, the Parties shall enter into a written agreement detailing the terms and conditions of such co-promotion effort, consistent with the terms and conditions set forth in this Agreement.

5.6 Compliance with Laws, Regulations and Guidelines. Each Party shall comply with Law with respect to the development and commercialization of the Licensed Product in the

Indications in connection with the Collaboration. Neither Party shall be required to undertake any activity relating to the commercialization of a Licensed Product in, with respect to Licensee, the Licensee Territory, or with respect to Amgen, the Amgen Territory, that it believes, in good faith, may violate any Law.

5.7 Cooperation.

- 5.7.1. *Cooperation Generally.* Subject to the oversight of the Commercialization Committee as set forth in Article 2 (Collaboration Scope and Governance), and without limiting any of the Parties' obligations hereunder, the Parties shall provide each other with any cooperation reasonably requested by the other with respect to Licensee's commercialization of Licensed Product in the Licensee Territory, and Amgen's commercialization of Licensed Product in the Amgen Territory.
- 5.7.2. *Licensee Commercialization in Japan.* Without limiting any of its obligations hereunder, Licensee shall keep the Commercialization Committee fully and promptly informed of the progress and results of Licensee's commercialization activities with respect to Licensed Product in Japan and shall take into consideration, and act on as appropriate, any reasonable requests by the Commercialization Committee with respect thereto.

6 DILIGENT EFFORTS; DISTRACTING PROGRAMS AND TRANSACTIONS

- 6.1 Reasonably Diligent Efforts. Each Party shall use Reasonably Diligent Efforts to develop, and obtain Regulatory Approval for and commercialize in its respective territory, in all cases in accordance with the then-current Development Plan or commercialization plan, as applicable, the Licensed Product in the NSCLC Indication, and in such Additional Indications as may be mutually agreed upon by the Parties through the Development Committee.
- 6.2 Activities Outside the Collaboration. Except as set forth in Sections 6.3 (Addition of Distracting Products) and 6.4 (Distracting Transactions), prior to the Distracting Product Expiration Date, neither Party shall, itself or through its Affiliates, directly or indirectly, [*]. For the avoidance of doubt, either Party may, itself or through its Affiliates, directly or indirectly, [*] and [*] any Distracting Product prior to [*] for such Distracting Product.
- 6.3 Addition of Distracting Products. Each of the Parties may pursue [*] the clinical development of a Distracting Product (and manufacture Distracting Product for such purpose) at its sole expense until such time as the Party is ready to [*] of such Distracting Product with the first Governmental Authority. The Party developing the Distracting Product (the "*Developing Party*") shall provide prompt written notice to the other Party (the "*Non-Developing Party*") upon the [*] for such Distracting Product, and thereafter update the Development Committee at least annually, regarding the progress and results of the [*] of such Distracting Product. As of the time the Developing Party has [*] for such Distracting Product, the Non-Developing Party shall have the right to [*] of Licensed Product throughout the Territory, including having a [*] by any of the committees provided for under this Agreement, and shall [*] in the best interests of

Licensed Product. The Developing Party shall provide prompt written notice of the [*] for a Distracting Product to the Non-Developing Party, but in no event later than [*] after the occurrence of such [*]. At least [*] prior to the expected date of [*] of such Distracting Product, the Developing Party shall provide the Commercialization Committee a commercialization plan for such Distracting Product (and any other Information related to such Distracting Product reasonably requested by any member of the other Party of the Commercialization Committee, including the [*] for such Distracting Product) for the Non-Developing Party's review and determination of whether to include such Distracting Product in the Collaboration. The Non-Developing Party will have the right to approve inclusion of the Distracting Product into the Collaboration within [*] days following the date the Developing Party provides the commercialization plan for the Distracting Product to the Commercialization Committee (and the Developing Party shall seek to promptly provide to the Non-Developing Party any other Information reasonably requested during such period). If the Non-Developing Party approves the inclusion of such Distracting Product into the Collaboration, such Distracting Product shall be deemed a Licensed Product and the Parties shall [*] with respect to such Licensed Product [*] of this Agreement, in each case except as set forth in Section 6.5 (Collaboration Terms with respect to a Distracting Product). If the Non-Developing Party does not approve the inclusion of such Distracting Product into the Collaboration, the Developing Party shall [*]; provided however, (i) the Developing Party shall [*] of such Distracting Product in the Territory during the Term; and (ii) as of the time the Developing Party has s[*] of such Distracting Product, the Non-Developing Party shall (x) have the right to [*] of Licensed Product throughout the Territory, including having a [*] any of the committees provided for under this Agreement, and shall [*] in the best interests of Licensed Product, and (y) have the right to [*], with respect to Licensed Product throughout the Territory (collectively the items in clauses (i) and (ii), the "*Distracting Product Commercial Conditions*"). The Developing Party shall provide prompt written notice of the [*] of such Distracting Product to the Non-Developing Party, but in no event later than [*] days after the occurrence of such [*]. Unless and until a Distracting Product has been approved for inclusion in the Collaboration pursuant to this Section 6.3 (Addition of Distracting Products), the Developing Party shall ensure that information and materials relating to the Collaboration are not shared with or used for the benefit of, and are sequestered from, personnel working on the Distracting Program (and vice versa) and that no personnel working on the Distracting Program works on the Collaboration (and vice versa). The obligations of the Developing Party and the rights of the Non-Developing Party under this Section 6.3 (Addition of Distracting Products) shall expire [*] (the applicable date, the "*Distracting Product Expiration Date*"); provided, however, that any right (other than a right to receive annual progress reports) of the Non-Developing Party under this Section 6.3 (Addition of Distracting Products) that is triggered (e.g., the applicable event occurs to permit exercise of such right) prior to the Distracting Product Expiration Date shall survive, and with respect to any Distracting Product for which the first [*] of such Distracting Product had been filed prior to the Distracting Product Expiration Date, (1) if such Distracting Product is included into the Collaboration, such inclusion (and the corresponding rights and obligations under this Agreement) shall survive such expiration, and (2) if such Distracting Product is not included into the Collaboration, the Distracting

Product Commercial Conditions, and the obligation to maintain the Distracting Program separate from the Licensed Product program, shall survive such expiration with respect to such Distracting Product.

- 6.4 Distracting Transactions. In the event that either Party or any of its Affiliates (a “*Distracting Transaction Party*”), directly or indirectly, enter into, or agree with a Third Party to enter into, a Distracting Transaction, then it shall provide prompt written notice to the other Party, but in no event later than [*] days after the closing of the Distracting Transaction, specifying the identity of the actual or potential Distracting Transaction Affiliate(s) and describing in reasonable detail, to the extent permitted by Law and without disclosing any proprietary information of or about the Distracting Program, the Distracting Program and its focus. Unless and until the Distracting Products have been approved for inclusion in the Collaboration pursuant to Section 6.3 (Addition of Distracting Products), the Distracting Transaction Party shall ensure that information and materials relating to the Collaboration are not shared with or used for the benefit of, and are sequestered from, such Distracting Transaction Affiliate(s) and personnel working on the Distracting Program (and vice versa) and that no personnel working on the Distracting Program works on the Collaboration (and vice versa). The notice provided by the Distracting Transaction Party shall include a notification as to whether the Distracting Transaction Party intends to: (i) Divest the Distracting Program, in which case it shall hold separate such Distracting Program and use its commercially reasonable, good-faith efforts to Divest such Distracting Program; (ii) terminate such Distracting Program, in which case the Distracting Transaction Party shall terminate all activities of such program within [*] days after the closing of the Distracting Transaction, during which period the Distracting Transaction Party shall hold separate such Distracting Program; or (iii) continue the development of such Distracting Program at its sole expense subject to Section 6.3 (Addition of Distracting Products). In the event the Distracting Transaction Party selects option (i) and fails to complete such divestiture within [*] of the closing of the Distracting Transaction, then the Distracting Transaction Party shall be deemed to have selected option (iii) (effective as of the date of the notice provided pursuant to this Section 6.4 (Distracting Transactions). In the event a Distracting Product is already being commercialized at the time of the closing of the Distracting Transaction, such Distracting Product shall trigger the Distracting Product Commercial Conditions, including the obligation to [*] the other Party, unless and until (a) the Distracting Transaction Party has completed the divestiture of such Distracting Program under option (i) or fully terminated such Distracting Program under option (ii); or (b) the Parties negotiate and consummate terms and conditions under which such Distracting Product shall be included in the Collaboration.
- 6.5 Collaboration Terms with respect to a Distracting Product. Upon inclusion of a Distracting Product into the Collaboration as a Licensed Product pursuant to Section 6.3 (Addition of Distracting Products), the following exceptions with respect to Article 8 shall apply: (i) [*] will be applicable with respect to such Licensed Product; (ii) from and after inclusion of the Licensed Product in the Collaboration, the Parties will [*], such that the Non-Developing Party will [*] and the Developing Party will [*]; (iii) the non-Developing Party will [*] for such Licensed Product; and (iv) if Licensee is the Developing Party or the Distracting Transaction Party with respect to such new Licensed

Product, the [*] with respect to such new Licensed Product shall be [*] of such new Licensed Product in Japan. Further, each Party shall have primary responsibility for Patent Matters of the patents and patent applications Controlled by it relating to such Licensed Product not already being handled hereunder with respect to another Licensed Product in the Collaboration, and each Party shall have the first right to enforce such patents (and the corresponding know-how) in its respective commercial territory. The Parties will discuss in good faith how best to provide clinical and commercial supply of such Licensed Product and the handling of regulatory responsibilities with respect to the manufacture of such Licensed Product.

- 6.6 Additional Indications. The Parties shall develop and commercialize the Licensed Product in the NSCLC Indication and will discuss the merits of pursuing additional indications. Should either Party wish to develop or commercialize the Licensed Product in an indication other than the NSCLC Indication, such Party shall submit to the Development Committee for review and approval a written proposal for the expansion of the definition of Indications to include such indication. The Party wanting to develop any such additional Indication shall provide the Development Committee any and all information reasonably requested by the Development Committee in order to allow the Development Committee to understand the circumstances and relevant factors with respect to such request. The Development Committee shall have the right to approve or reject the expansion of the definition of Indications in accordance with Section 2.9.4 (Decision Making). Should the Development Committee approve expansion of the definition of Indication to include the newly proposed indication, then such indication shall, from such point forward, be an Indication for all purposes under this Agreement. Should the Development Committee not approve the addition of the newly proposed indication, then the Parties shall not develop or commercialize such Licensed Product in the indication so proposed under the Collaboration nor outside the Collaboration.

7 **MANUFACTURE AND SUPPLY**

- 7.1 Manufacturing Rights. No rights are granted to Licensee hereunder to manufacture Licensed Product or to obtain Licensed Product from any entity other than Amgen or its designee. Licensee shall not manufacture Licensed Product or obtain Licensed Product from any entity other than Amgen or its designee, except as expressly provided in this Agreement, the Clinical Supply Schedule or a supply agreement separately entered into between the Parties.
- 7.2 Clinical Supply. Licensee shall obtain its requirements of Licensed Product for use in clinical development solely from Amgen or its designee, and Amgen shall supply or shall cause its designee to supply Licensee with Licensee's requirements of Licensed Product for use in clinical development, except to the extent expressly set forth on the Clinical Supply Schedule attached hereto. The terms for providing such clinical supply are set forth on the Clinical Supply Schedule. The Parties may determine to include in a commercial supply agreement to be entered into in accordance with Section 7.3 (Commercial Supply) with respect to Licensed Product provisions for clinical supply of such Licensed Product.

7.3 **Commercial Supply.** Licensee shall obtain its requirements of Licensed Product for commercial use in the Licensee Territory solely from Amgen or, at Amgen's option, Amgen's designee, and Amgen shall supply or, at Amgen's option, shall cause its designee to supply Licensee with Licensee's requirements of Licensed Product for commercial use. Upon the request of either Party, the Parties shall negotiate in good faith a commercial supply agreement for the commercial supply of Licensed Product to Licensee for use in the Licensee Territory. The terms of such commercial supply agreement shall be materially consistent with the Supply Agreement Term Sheet Schedule attached hereto. At Amgen's election, in lieu of entering into a commercial supply agreement with respect to Licensed Product, Licensee will contract directly with the Third Party manufacturer(s) used by Amgen for supply of Licensed Product in order to obtain Licensee's requirements of Licensed Product.

7.4 **Responsibility for Regulatory Filings with Respect to Manufacturing.** Amgen shall be solely responsible for the preparation and submission of all regulatory filings required to be filed with any Governmental Authority in the Territory with respect to the manufacture of Licensed Product supplied to Licensee by Amgen (including with respect to the use of any contract manufacturer to produce such Licensed Product on Amgen's behalf) (the foregoing "Manufacturing Filing Responsibilities"), except to the extent that either: (i) Licensee has assumed responsibility for aspects of manufacturing pursuant to the Clinical Supply Schedule, a commercial supply agreement between the Parties or other agreement between the Parties; or (ii) Amgen has maintained manufacturing responsibility but notifies Licensee that it wishes to transition Manufacturing Filing Responsibilities with respect to Licensed Product to Licensee. In any of the foregoing cases, the Parties shall cooperate to transition such responsibility. In any such case, Licensee thereafter shall be solely responsible for the Manufacturing Filing Responsibilities and shall provide Amgen the same rights with respect to correspondence, communication and regulatory filings related to such manufacturing as provided for other correspondence, communication and Regulatory Filings in Sections 4.7 (Sharing of Regulatory Filings) and 4.12.1 (Licensee Responsibility) (including as if regulatory filings for manufacturing of Licensed Product were Regulatory Filings). Each Party shall provide the Party responsible for such regulatory filings any cooperation reasonably requested by such responsible Party in connection with any such filings.

8 PAYMENT

8.1 **License Payments by Licensee.** In consideration of the rights granted by Amgen to Licensee hereunder, Licensee shall make the following payments to Amgen:

- 8.1.1. *License Fee.* Licensee shall pay Amgen a non-refundable, non-creditable license fee in the amount of One Hundred Million U.S. Dollars (US\$100,000,000) within [*] days after [*].
- 8.1.2. *Development Milestone Payments.* Licensee shall pay Amgen the following non-refundable, non-creditable development and commercial milestone payments as set forth below, in each case within [*] days after the occurrence of the

corresponding event with respect to the first Licensed Product to achieve such event. If a milestone payment becomes due for occurrence of a milestone event with respect to Licensed Product in a particular country or region of the Territory (i.e., the United States, Europe or Japan) for a particular Indication and Licensee has not paid a milestone payment listed prior in order in the below table to the milestone payment then due for such Licensed Product with respect to such country or region for such Indication, then Licensee shall pay all such previously listed and unpaid milestone payment concurrently with payment of the milestone payment then due (regardless of whether or not the milestone event corresponding to the previously unpaid milestone payment has occurred with respect to such Licensed Product in such country or region for such Indication). For the avoidance of doubt, in the event the first sale of a Licensed Product takes place for a use recognized by insurance payers, established drug compendia or other process enabling payment or reimbursement prior to Regulatory Approval, Licensee shall pay Amgen both the Regulatory Approval and First Commercial Sale milestone payments with respect to such first sale event.

<u>Milestone Event</u>	<u>Payment Amount (in US Dollars)</u>	
	[*]	[*]
[*]		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

8.2 Cost Sharing and Profit Sharing Arrangement.

8.2.1. *Cost Sharing and Profit Sharing.*

(i) The Parties shall share Development Costs for the Licensed Product on a worldwide basis (excluding Japan), such that Licensee shall bear a sixty percent (60%) share and Amgen shall bear a forty percent (40%) share.

(ii) The Parties shall share Operating Expenses for the Licensed Product on a worldwide basis (excluding Japan), such that Licensee shall bear a fifty percent (50%) share and Amgen shall bear a fifty percent (50%) share.

(iii) The Parties shall share all Gross Profit generated under the Collaboration for the Licensed Product in all Indications in the Territory (excluding Japan) (when recognized, in accordance with GAAP) equally, with each Party having a fifty percent (50%) share.

(iv) Neither the license fee nor any of the development milestone payments paid by Licensee pursuant to Section 8.1 (License Payments by Licensee), nor any amounts paid by License with respect to Japan or supply therefor, to Amgen shall be included in the cost sharing and profit sharing arrangement between the Parties.

8.2.2. *Reports.* Within [*] days after the end of each [*] Quarter, each Party shall provide to the other Party a written report specifying in reasonable detail (and any other supporting information reasonably requested by the Parties) the Gross Profit, Operating Expenses and Development Costs for such Party incurred during such [*] Quarter (excluding Japan), and, if reasonably requested by the other Party, supporting documentation. Such written report of each Party shall state for such [*] Quarter and for each country covered by such Party's territory under the Collaboration (excluding Japan): (i) such Party's Development Costs; (ii) such Party's Operating Expenses and the calculation thereof; and (iii) such Party's Gross Profit and the calculation thereof (including specifying gross sales, the Net Sales by or on behalf of such Party, its Affiliates or licensees during the applicable [*] Quarter (detailed with gross invoiced amounts and deductions, including Cost of Goods Sold), Cost of Sales and Recoveries, if any). Any reports that contain currency conversions shall provide the details and background information used to calculate such conversions. In no event will any individual cost be counted more than once (e.g., the same individual cost will not be included within Development Costs and Other Collaboration Costs). The Parties will report all amounts required under this Section 8.2.2 (Reports) in U.S. Dollars.

8.2.3. *Reconciliation and Payment.* Within [*] days after each Party's receipt of such report (and any requested supporting documentation), Amgen shall calculate each Party's share of the total Development Costs, Operating Expenses and the Gross Profit for the applicable [*] Quarter, in each case in accordance with Section 8.2.1 (Cost Sharing and Profit Sharing) and perform one reconciliation of the Development Costs, and a second reconciliation of Operating Expenses and Gross Profit to derive each Party's Net Operating Profit, and provide to Licensee a written report of each such reconciliation calculation. With respect to each reconciliation calculation, if one Party owes a payment to the other Party, then such owing Party shall make such payment to the other Party within [*] days after delivery of such report to Licensee.

8.3 Royalty Payments with respect to Sales in Japan. In consideration of the rights granted by Amgen to Licensee hereunder, Licensee shall pay Amgen a royalty of [*] on Net Sales of Licensed Product (across all Indications) in Japan during the Term.

8.4 Calculation of Net Sales. In calculating Net Sales:

8.4.1. *Free Products.* Any disposal of a Licensed Product at no charge for, or use of a Licensed Product without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales.

- 8.4.2. *Bundled Products.* Where a Licensed Product is sold in a Bundle, then for the purposes of calculating the Net Sales under this Agreement, such Licensed Product shall be deemed to be sold for an amount equal to $(X \div Y) \times Z$, where: X is the average sales price during the applicable reporting period generally achieved for such Licensed Product (or, should more than one Licensed Product be included in a Bundle with a product other than a Licensed Product, the sum of such average sales prices for the included Licensed Product) in the applicable country or territory; Y is the sum of the average sales price during the applicable reporting period generally achieved in the applicable country or territory, when sold alone, by each pharmaceutical product included in the Bundle; and Z equals the price at which the Bundle was actually sold. In the event that a Licensed Product or one or more of the other pharmaceutical products in the Bundle are not sold separately, the Parties shall confer in good faith to determine an equitable fair market price to apply to such bundled Licensed Product.
- 8.4.3. *Non-Monetary Consideration.* Upon any sale or other disposal of Licensed Product that should be included within Net Sales for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, then for purposes of calculating the Net Sales under this Agreement, such Licensed Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Licensed Product in the country in which such sale or other disposal occurred when such Licensed Product is sold alone and not with other products.
- 8.5. Reports for Net Sales in Japan. Beginning with the [*] Quarter after the First Commercial Sale of a Licensed Product in Japan and thereafter for each [*] Quarter until the expiration of Licensee's obligation to pay royalties hereunder with respect to Japan pursuant to Section 8.3 (Royalty Payments with respect to Sales in Japan), royalty payments and reports of the sale of each Licensed Product in Japan for each [*] Quarter will be calculated and delivered by Licensee to Amgen under this Agreement within [*] days after the end of each such [*] Quarter. Each payment of royalties will be accompanied by a report of Net Sales of each Licensed Product in Japan stating: (i) Net Sales of each Licensed Product in Japan (on a Licensed Product-by-Licensed Product basis) by or on behalf of Licensee, its Affiliates or licensees during the applicable [*] Quarter (detailed with gross invoiced amounts, deductions and Net Sales); and (ii) a calculation of the royalty payment due from Licensee hereunder for such [*] Quarter. Any reports that contain currency conversions shall provide the details and background information used to calculate such conversions. Licensee shall include in such reports such additional information as reasonably requested by Amgen, whether to enable Amgen to comply with its obligations to its licensors or otherwise.
- 8.6. No Wrongful Reductions. Licensee shall not attempt to reduce compensation rightly due to Amgen hereunder by shifting compensation otherwise payable to Licensee from a Third Party with respect to a Licensed Product to another product or service for which no royalties are payable by it hereunder.

- 8.7 **Payment Method.** All payments made hereunder between the Parties shall be made in U.S. Dollars except as set forth in Section 8.9 (Blocked Currency). Licensee shall pay all sums due hereunder by check, wire transfer, or electronic funds transfer (EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.11 (Withholding) and Section 8.12 (VAT)).
- 8.8 **Audits.** Each Party shall keep complete and accurate records relating to expenses and costs pertaining to the development and sale of the Licensed Product in its respective territory in sufficient detail to permit the other Party to confirm the accuracy of all payments due hereunder, and such records shall be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 8.8 (Audits)) to inspection for [*] following the end of the period to which they pertain. Each Party shall have the right, at its own expense, to have an independent, certified public accountant, selected by it review the records of the other Party upon reasonable notice and during regular business hours. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. Each Party's audit rights with respect to any [*] Year shall expire [*] after the end of such year and the books and records for any particular [*] Year shall only be subject to [*]. Should the inspection lead to the discovery of a discrepancy to the detriment of the auditing Party, then the other Party shall pay to the auditing Party the amount of the discrepancy plus interest accrued at the Contract Interest Rate, compounded daily from the day the relevant payment(s) were due. Should the inspection lead to the discovery of a discrepancy to the detriment of the Party being audited, then the auditing party shall pay to the other Party the amount of the discrepancy without interest. The auditing Party shall pay the full cost of the inspection unless the discrepancy is to the detriment of the auditing Party and is greater than [*] of the amount actually paid for the audited period, in which case the Party being audited shall pay the cost of such inspection.
- 8.9 **Blocked Currency.** If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, each Party shall have the right and option to make such payments by depositing the amount thereof in local currency to the other Party's account in a bank or depository designated by such other Party in the applicable country or territory.
- 8.10 **Taxes.** All Taxes levied on account of a payment made by Licensee to Amgen pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 8.11 (Withholding).
- 8.11 **Withholding.** In the event that Law requires a Party to pay or withhold Taxes with respect to any payment to be made by such Party pursuant to this Agreement, such Party shall notify the other Party in writing of such payment or withholding requirements prior to making the first payment to the other Party in which any such payment or withholding of Taxes will be deducted and provide such assistance to the other Party, including the

provision of such documentation as may be required by a tax authority, as may be reasonably necessary in the other Party's efforts to claim an exemption from or reduction of such Taxes. If the Party required to make the payment pursuant to this Agreement, in accordance with Law, withholds Taxes from the amount due, it shall remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes within [*] days following payment thereof. If Taxes are paid to a tax authority, the Party that made the withholding shall provide such assistance to the other Party as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

- 8.12 VAT. All payments due Amgen from Licensee pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by Licensee upon receipt of a valid VAT invoice).
- 8.13 Late Payment. Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate, compounded daily, calculated on the number of days such payment is delinquent. This Section 8.13 (Late Payment) shall in no way limit any other remedies available to either Party.
- 8.14 Third Party Royalties. Except as expressly set forth in Sections 8.11 (Withholding) and 8.12 (VAT), Licensee shall not have the right to make any deduction from amounts payable to Amgen pursuant to Sections 8.1 (License Payments by Licensee) and 8.3 (Royalty Payments with respect to Sales in Japan) of this Agreement on account of any royalty or other amount payable to any Third Party.

9 INTELLECTUAL PROPERTY

- 9.1 Ownership. Except to the extent expressly specified to the contrary in this Agreement: (i) each Party shall retain and own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created solely by such Party; (ii) the Parties shall jointly own all right, title, and interest in and to all patent rights, trade secrets, proprietary rights and other intellectual property rights conceived or created jointly by the Parties pursuant to the Collaboration and, subject to the provisions of this Agreement (including those licenses granted pursuant to Article 3 (Grant of License)), neither Party shall have any duty to account or obtain the consent of the other Party (such consent deemed given hereunder) in order to exploit, license or assign such intellectual property rights; and (iii) inventorship and authorship of any invention or work of authorship conceived or created by either Party, or jointly by the Parties, shall follow the rules of the U.S. Patent and Trademark Office and the Laws of the United States (without reference to any conflict of law principles).
- 9.2 Prosecution and Maintenance.
- 9.2.1. *In Licensee Territory*.
- (i) [*] shall have the right, but not the obligation, to control, itself or through outside counsel reasonably acceptable to [*] and directed by [*], the

preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) (the foregoing collectively "*Patent Matters*") with respect to [*] as well as preparation and filing for any [*] shall reasonably [*].

- (ii) [*] it shall give [*] reasonable notice thereof [*] and continue the prosecution or maintenance of such patent, trademark or application and [*] with respect to [*] control Patent Matters with respect to such patent, trademark or application [*] in accordance with this Section 9.2.1(ii) ([*] shall control, itself or through outside counsel reasonably acceptable to [*] and directed by [*] with respect to [*] as well as preparation and filing for any patent term extensions or similar protections [*].

9.2.2. [*] *Territory*. [*] shall control and be [*] responsible for all Patent Matters with respect to its patent rights, trademark rights and other intellectual property [*]. [*] shall control and be [*] responsible for Patent Matters with respect to Joint Patents [*]. [*]

9.3 Defense and Settlement of Third Party Claims. [*] that a [*] by the [*], [*] shall have the [*] right [*] that a [*] by the [*] shall have the [*] right to [*] with respect to [*] Subject to such [*] may [*] this Section 9.3 (Defense and Settlement of Third Party Claims), [*] with respect to [*]. The [*] shall seek and reasonably [*] for such matter. [*] shall keep [*], and shall [*]

[*].

9.4 Enforcement.

9.4.1. *In Licensee Territory*. Each Party shall promptly notify the other Party in writing if it reasonably believes that any Licensee Territory Patents and Trademarks or Licensed Amgen Know-How in the Licensee Territory (collectively, "*Licensee Territory IP*") are infringed or misappropriated by a Third Party in the Licensee Territory.

(i) [*]. Without limiting the foregoing, [*].

(ii) [*] Without limiting the foregoing, [*].

9.4.2. *Amgen Territory*. Licensee shall promptly notify Amgen in writing if it reasonably believes that any patent, trademark, know-how or other intellectual property Controlled by Amgen that relates to the Licensed Product are infringed or misappropriated by a Third Party in the Amgen Territory. [*].

- 9.5 Allocation of Recoveries. All Recoveries [*] shall be [*]. With respect to [*], all Recoveries shall [*]. Any Recoveries that are [*] shall be [*]. For the avoidance of doubt, after any termination or expiration of this Agreement, [*] shall have [*].
- 9.6 Patent Term Extensions. Each Party shall provide reasonable assistance to the other Party in connection with obtaining SPCs for Licensed Amgen Patents consistent with the rights of the other Party to control such matters as specified in Section 9.2 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such SPC in a particular country, each Party shall make available to the other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the SPC in such country.
- 9.7 Employee Agreements. Prior to [*] relating to [*], [*] shall have [*] pursuant to which [*] and appropriate, and substantially including: [*] It is understood and agreed by the Parties that [*] and that the [*] shall be sufficient to [*] Each Party shall [*].
- 9.8 Patent Marking. Licensed Product marketed and sold by or on the behalf of Licensee hereunder shall be marked with appropriate patent numbers or indicia of Licensed Amgen Patents, to the extent permitted by Law in the Licensee Territory.
- 9.9 Cooperation. Each Party shall provide the other Party, at the other Party's reasonable request, such assistance and cooperation as may be requested with respect to any Patent Matters, litigation or other activities related to patent rights and other intellectual property.

10 CONFIDENTIALITY AND PUBLICATIONS

- 10.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by, or otherwise obtained from, the other Party pursuant to this Agreement, in whatever form or medium (collectively, "*Confidential Information*") (including information known by the employees of Amgen KK, a wholly-owned subsidiary of Amgen, and/or materials in the possession of Amgen KK prior to the consummation of the transactions contemplated in that certain Sale and Purchase Agreement executed concurrently herewith, which shall be considered the Confidential Information of Amgen). Licensee acknowledges the value of Confidential Information (including data provided by Amgen hereunder) and shall have no right to and shall not utilize any Confidential Information of Amgen for activities in the Territory (including, with respect to the research, development or commercialization of any Distracting Product or other programs or products of Licensee in the Territory or for any other purpose) except as expressly provided for in this Agreement. For the avoidance of doubt, Confidential Information of a Party shall include all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can

reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as such to be considered Confidential Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

- (i) was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;
- (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- (iv) was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- (v) was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

10.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, and (b) to the extent such disclosure is reasonably necessary or useful in conducting development under this Agreement; (ii) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for a Licensed Product, or otherwise required by Law; provided, however, that if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it shall, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing, shall use its reasonable efforts to

secure confidential treatment of such Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; or (iv) to the extent mutually agreed to by the Parties.

10.3 Terms and Conditions Confidential. Neither Party shall disclose the terms and conditions of this Agreement except as may be required by Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [*] days' notice to the other Party and reasonably considering comments provided by such other Party within [*] days after such notice). Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Notwithstanding the foregoing, the Parties shall agree upon and release a mutual press release to announce the execution of this Agreement for use in responding to inquiries about the Agreement; thereafter, Licensee and Amgen may each disclose to Third Parties the information contained in such press release without the need for further approval by the other. Each Party shall additionally have the right to issue additional press releases in regards to this Agreement and/or the Licensed Product with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [*] days' notice to the other Party and reasonably considering comments provided by such other Party within [*] days after such notice).

10.4 Prior Agreement. This Agreement supersedes the Confidential Disclosure Agreement between the Parties dated [*], as amended and supplemented, including any written requests thereunder, (the "*Prior Agreement*") with respect to information disclosed thereunder relating to the Licensed Product and the research and development related thereto. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Agreement.

10.5 Publications.

10.5.1. *Publication Plan.* The Parties shall regularly consult (no less than [*]) and confer with respect to a global publication plan for Licensed Product with the understanding that neither Party can publish without the consent of the other Party. Should the Parties agree in writing that the publication with respect to Licensed Product by Amgen or Licensee is appropriate, then Amgen or Licensee, respectively, shall have the right to make such publication subject to Section 10.5.2 (Oversight and Review).

10.5.2. *Oversight and Review.* Except as required by Law or court order, with respect to any publication or presentation concerning the activities conducted in the

Territory hereunder with respect to Licensed Product, including studies or clinical trials carried out by a Party under this Agreement, the Party desiring to publish or present any such publication or presentation (the “Publishing Party”): (i) shall transmit to the other Party (the “Reviewing Party”) for review and comment a copy of the proposed publication or presentation, at least [*] days prior to the submission of the proposed publication or presentation to a Third Party; (ii) shall postpone the publication or presentation for up to an additional [*] days upon request by the Reviewing Party in order to allow the consideration of appropriate patent applications or other protection to be filed on information contained in the publication or presentation; (iii) upon request of the Reviewing Party, shall remove all Confidential Information of the Reviewing Party from the information intended to be published or presented; and (iv) shall consider all reasonable comments made by the Reviewing Party to the proposed publication or presentation.

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

11 REPRESENTATIONS, WARRANTIES AND COVENANTS

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

- 11.1.1. As of [*], it is duly organized and validly existing under the Laws of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
- 11.1.2. As of [*], this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of [*] violate any Law; and the person or persons executing this Agreement on such Party’s behalf have been duly authorized to do so by all requisite corporate action;

- 11.1.3. To its knowledge, as of [*] no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or shall be necessary for, or in connection with, the entering into of this Agreement or the transaction contemplated by this Agreement, or (except for regulatory approvals, licenses, clearances and the like necessary for the 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;
 - 11.1.4. [*];
 - 11.1.5. As of [*], it has not been debarred or the subject of debarment proceedings by any Governmental Authority; and
 - 11.1.6. It has not granted as of [*] any right to any Third Party relating to any patent, trademark or other proprietary right that conflicts with the rights granted to the other Party hereunder.
- 11.2 Amgen Representations and Warranties. Amgen hereby represents and warrants that, as of [*]:
- 11.2.1. Amgen has provided Licensee with [*] with respect to Licensed Product, and has [*] information relating to [*] that are [*] Licensed Product [*] provided to Licensee;
 - 11.2.2. Amgen has disclosed to Licensee [*] as set forth on the [*] Schedule, and has [*] Licensee with [*] that are [*] Licensed Product [*];
 - 11.2.3. To the best of Amgen’s knowledge, there are [*] with respect to [*] outside the [*], and there is no [*] of the [*] outside the [*]; and
 - 11.2.4. Except as referenced on the [*] Schedule, to the best of Amgen’s knowledge Amgen has [*] which [*] that the [*] of an [*].
- 11.3 Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 11 (Representations, Warranties and Covenants), LICENSEE AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, THE LICENSED AMGEN PATENTS, LICENSED AMGEN TRADEMARKS, LICENSED AMGEN KNOW-HOW, LICENSED LICENSEE PATENTS, LICENSED LICENSEE TRADEMARKS, LICENSED LICENSEE KNOW-HOW, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.
- 11.4 Covenants. Each of the Parties hereby covenants to the other Party as follows:

- 11.4.1. It shall 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 Governmental Authority;
- 11.4.2. It shall carry out its activities hereunder in compliance with Law (including relevant Laws relating to economic sanctions and bribery);
- 11.4.3. It shall not misappropriate any trade secret(s) of a Third Party in connection with the performance of its activities hereunder; and
- 11.4.4. It shall not grant any right to any Third Party relating to any patent, trademark or other proprietary right that conflicts with the rights granted to the other Party hereunder.

12 LIMITATIONS OF LIABILITY; INSURANCE

- 12.1 Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 12.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 12 (Indemnification), (ii) breach of Section 10.1 (Confidentiality; Exceptions), 10.2 (Authorized Disclosure), or (iii) gross negligence or intentional misconduct of a Party.
- 12.2 Insurance. During the Term and for [*] thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry in the Territory (or reasonable self-insurance sufficient to provide materially the same level and type of protection).

13 INDEMNIFICATION

- 13.1 Indemnity. Subject to the remainder of this Article 13 (Indemnification), Licensee shall defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees and agents (collectively, "*Amgen Indemnitees*"), at Licensee's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees incurred by any Amgen Indemnitees until such time as Licensee has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) paid to a Third Party

(collectively, “Losses”) arising out of any claim, action, lawsuit, or other proceeding (other than a shareholder derivative suit or like action) (collectively, “Claims”) brought against any Amgen Indemnitee by a Third Party to the extent such Losses result from (i) the gross negligence or willful misconduct of Licensee, or its Affiliates or agents in exercising its rights or performing its obligations under this Agreement, or (ii) a material breach by Licensee of this Agreement, including any failure of Licensee’s representations or warranties in Section 11.1 (Mutual Representations and Warranties) to be true in any material respect when made, but excluding such Losses to the extent they arise from (y) or (z) below. Subject to the remainder of this Article 13 (Indemnification), Amgen shall defend, indemnify, and hold harmless Licensee, its Affiliates, and their respective directors, officers, employees and agents (collectively, “Licensee Indemnitees”), at Amgen’s cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys’ fees incurred by any Licensee Indemnitees until such time as Amgen has acknowledged and assumed its indemnification obligation hereunder with respect to the applicable claim) arising out of any Claim brought against any Licensee Indemnitee by a Third Party to the extent such Losses result from (y) the gross negligence or willful misconduct of Amgen, or its Affiliates or agents in exercising its rights or performing its obligations under this Agreement, or (z) a material breach by Amgen of this Agreement, including any failure of Amgen’s representations or warranties in Section 11.1 (Mutual Representations and Warranties) to be true in any material respect when made, but excluding such Losses to the extent they arise from (i) or (ii) above. The indemnification obligations of this Article 13 (Indemnification) shall not apply to commercial supply obligations; any indemnification obligations related to commercial supply shall be handled under the supply agreement to be entered into pursuant to Section 7.3 (Commercial Supply).

13.2 Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Licensee Indemnitee or an Amgen Indemnitee (the “*Indemnified Party*”) may seek indemnification under this Article 13 (Indemnification), the Indemnified Party shall promptly notify the other Party (the “*Indemnifying Party*”) of the Claim or Loss and, when known, the facts constituting the basis for the Claim; provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 13.2 (Claim for Indemnification) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall promptly assume defense thereof at its own expense. The Indemnified Party shall not settle or compromise any Claim by a Third Party for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party’s expense

and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Article 10 (Confidentiality and Publications).

- 13.3 Joint Losses. Any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees ("*Joint Loss(es)*") arising from Third Party claims, suits, actions or demands (other than those subject to indemnification pursuant to Section 13.1 (Indemnity) or addressed under Section 9.3 (Defense and Settlement of Third Party Claims)) resulting directly or indirectly out of [*] shall be treated as [*]. In the event a Party becomes aware of a claim which, if resulting in a Joint Loss, it intends to treat as [*], such Party shall inform the other Party of such claim as soon as reasonably practicable after it receives notice thereof. With respect to any such Third Party claims, the Party conducting or operationally controlling the activity giving rise to the claim shall have the right to assume direction and control of the defense of such claim. The Party not in control of such defense shall co-operate as reasonably requested in the defense of the claim. The Party in control of any such claim shall keep the other Party regularly and fully informed about the claim and defense, and shall cooperate with the other Party in facilitating its involvement as reasonably requested. The Party not in control of such defense may participate, subject to such control, in such defense or settlement with its own counsel. The Party in control shall not settle any such claim without the other Party's prior written consent, such consent not to be unreasonably withheld or delayed.

14 TERM AND TERMINATION

- 14.1 Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect until terminated in accordance with this Article 14 (Term and Termination).

- 14.2 Termination. This Agreement may be terminated as follows:

- 14.2.1. *Termination for Breach*. If either Party believes that the other Party or its Affiliate is in material breach of this Agreement, then such Party may deliver notice of such material breach to the other Party. If the breaching Party (or its Affiliate) fails to cure such material breach within [*] days after the receipt of such notice (or [*] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [*] days after the end of such cure period and effective upon delivery.
- 14.2.2. *Termination for Challenge*. Amgen shall have the right to terminate this Agreement by written notice to Licensee should Licensee, its Affiliate or its or their sublicensee bring or join any challenge to the validity or enforceability of any Licensed Amgen Patent or Licensed Amgen Trademark.
- 14.2.3. *Change of Control Termination*. Amgen shall have the right to terminate this Agreement in accordance with Section 15.3 (Change of Control).
- 14.2.4. *Failure of Licensee to Use Reasonably Diligent Efforts*. In the event Licensee fails to use Reasonably Diligent Efforts with respect to the development and

commercialization of Licensed Product in a Major Market Country, and fails to cure such breach within [*] days after the receipt of such notice, without limiting other available remedies, Amgen shall have the right to terminate this Agreement for the entire region of Europe, if such Major Market Country is within Europe, or for the entire region of Asia, if such Major Market Country is within Asia. In the event Licensee fails to use Reasonably Diligent Efforts with respect to the development and commercialization of Licensed Product in a country other than a Major Market Country, and fails to cure such breach within [*] days after receipt of such notice, without limiting other available remedies, Amgen shall have the right to terminate this Agreement in such particular country. For the purpose of this provision, “*Major Market Country*” means [*].

- 14.3 Effect of Termination. Expiration or termination of this Agreement shall have the following effects: In the event of any termination or expiration of this Agreement: [*] Any termination or expiration of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled. Upon termination or expiration of this Agreement, [*]
- 14.4 Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 14.3 (Effect of Termination), in the event of any expiration or termination of this Agreement the following provisions shall survive: Articles 10 (Confidentiality and Publications) (except with respect to Section 10.5 (Publications)); 12 (Limitations of Liability; Insurance); 13 (Indemnification); 14 (Term and Termination) and 15 (Miscellaneous); and Sections 3.3 (Licensed Licensee Know-How and Patents); 3.6.2 (Grant to Amgen); 6.3 (Addition of Distracting Products) and 6.4 (Distracting Transactions) (with respect only to sequestration of personnel and information and any accrued payment obligations and the ancillary provisions with respect thereto); 8.1.1 (License Fee); 8.1.2 (Development Milestone Payments) (with respect to milestones reached prior to such expiration or termination); 8.2 (Cost Sharing and Profit Sharing Arrangement) (with respect to Development Costs and Operating Expenses incurred, and Gross Profit generated, prior to such expiration or termination); 8.3 (Royalty Payments with respect to Sales in Japan) through 8.6 (No Wrongful Reductions) (inclusive) (with respect to sales made prior to such expiration or termination); 8.7 (Payment Method) through 8.14 (Third Party Royalties) (inclusive); 9.1 (Ownership); 9.5 (Allocation of Recoveries) (with respect to periods prior to such expiration or termination); and 11.3 (Disclaimer of Warranties).
- 14.5 Transition Period. During the [*] period following [*] (the “*Transition Period*”), the Parties shall cooperate to transition the development (including any ongoing trials, to the extent permitted by Law) and commercialization of, regulatory responsibility for, and, if applicable, manufacture of the Licensed Product in the Territory in Indications from Licensee to Amgen. Licensee shall take all actions reasonably requested by Amgen to facilitate such transition, and the Parties shall conduct such transition expeditiously and as reasonably necessary to minimize disruption in the development and commercialization of a Licensed Product in the Territory. The Parties shall each be responsible for [*] in accordance with this Section 14.5 (Transition Period), provided that, in the event of

termination by Licensee under Section 14.2.1 (Termination for Breach), [*] in accordance with this Section 14.5 (Transition Period).

- 14.6 **Bankruptcy.** All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code Sections 101 et seq. (“*Bankruptcy Code*”), licenses of rights to “intellectual property” as defined under the Bankruptcy Code. The Parties agree that the non-bankrupt Party shall retain and may fully exercise all of its rights and elections under Law. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a bankrupt Party the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property which at that date is known to be necessary or useful to Licensed Product (then the subject of research, development or commercialization) for the non-bankrupt Party’s territory and all embodiments of such intellectual property; and same, if not already in the other Party’s possession, shall be promptly delivered to the other Party (a) upon any such commencement of a bankruptcy proceeding, upon the other Party’s written request therefor (which request must identify the specific intellectual property), unless the bankrupt Party (or a trustee on behalf of the bankrupt Party) elects within [*] days to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the bankrupt Party, upon written request therefor by the other Party.

15 MISCELLANEOUS

- 15.1 **Affiliates.** Each Party shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates (including by licensing rights hereunder where such rights are held in the name of any such Affiliate), provided that each Party shall be responsible for its Affiliates’ performance hereunder.
- 15.2 **Assignment.** Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by Licensee without the prior written consent of Amgen. Amgen may assign this Agreement, and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Amgen shall have the right to assign its rights and delegate its obligations under this Agreement with respect to Licensed Product to a Party or Parties to which Amgen licenses or transfers rights with respect to such product in the Amgen Territory. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 15.3 **Change of Control.** Licensee shall give Amgen written notice within [*] days after the public announcement or disclosure of any proposed Change of Control of Licensee. In the event of the occurrence of any Change of Control of Licensee, then upon written

notice by Amgen to Licensee: [*]. In addition, should such Change of Control involve [*], Amgen shall have the right to [*].

15.4 Choice of Law. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of California without regard to its conflicts of law provisions.

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- 15.5 Construction. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person shall be construed to include the person’s permitted successors and assigns, (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.
- 15.6 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 15.7 Currency. With respect to amounts received or expenses incurred in a currency other than U.S. Dollars, such amounts received or expenses incurred shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by whichever of Licensee or Amgen (or an Affiliate of one of them) recorded such receipt or expenditure, for the respective reporting period, related to recording such amounts received or expenses incurred in its books and records that are maintained in accordance with GAAP. If a Party is not required to perform such currency conversion for its GAAP reporting with respect to the applicable period, then for such period such Party shall convert its amounts received and expenses incurred into U.S. Dollars using a rate of exchange which corresponds to the [*] rate as published in the Wall Street Journal, Eastern U.S. Edition on [*] day of the [*] Quarter (or such other publication as agreed-upon by the Parties). Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.
- 15.8 Entire Agreement. This Agreement, including the attached Appendices, Schedules and Exhibits constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same. The foregoing is without prejudice to the Parties’ rights and obligations pursuant to the Sale and Purchase Agreement, License

Agreement relating to Japan rights to multiple products, and the Vectibix Supply Agreement, each between the Parties and executed concurrently herewith.

- 15.9 Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest (“*Force Majeure*”); provided, however, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect) and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.
- 15.10 Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 15.11 Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.
- 15.12 Jurisdiction and Venue. Each Party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of California (“*State Court*”) and the courts of the United States of America located in the State of California (“*Federal Court*”), for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party’s respective address set forth in Section 15.14 (Notices) (as such address may be changed by notice delivered pursuant to such section) shall be effective service of process for any action, suit or proceeding in the applicable Federal Court or State Court with respect to any matters to which it has submitted to jurisdiction in this Section 15.12 (Jurisdiction and Venue). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Federal Court or State Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of any transaction contemplated hereby shall be conducted in English. Notwithstanding the foregoing, either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction.
- 15.13 No Set-Off. No Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

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

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

If to Licensee: Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-Chome
Chuo-ku, Osaka 540-8645
Japan
Attention: General Manager, Global Licensing and Business Development
Telephone: [*]
Facsimile: [*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 15.14 (Notices).

15.15 Reimportation. Licensee shall undertake all steps necessary to prevent any Licensed Product provided to or made for or on behalf of Licensee for use or sale inside the Licensee Territory from being distributed or sold in the Amgen Territory, except where Amgen and Licensee agree that the exporting person or entity is in possession of all regulatory authorizations and intellectual property licenses necessary for such export, import and sale. Licensee shall notify Amgen if it becomes aware of the exportation of a Licensed Product from the Licensee Territory and discuss with Amgen the same.

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

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

- 15.18 Third Party Beneficiaries. Except as expressly provided with respect to Amgen Indemnitees or Licensee Indemnities in Article 13 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.
- 15.19 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.

(Signature page follows)

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

**TAKEDA PHARMACEUTICAL
COMPANY LIMITED**

AMGEN INC.

By: /s/ Yasuchika Hasegawa

Name: Yasuchika Hasegawa

Title: President

By: /s/ Kevin W. Sharer

Name: Kevin W. Sharer

Title: Chairman of the Board,
CEO and President

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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.

Supply Agreement
by and between
Amgen Inc.
and
Takeda Pharmaceutical Company Limited
dated
February 1, 2008

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Supply Agreement

This Supply Agreement (this “*Agreement*”) is entered into as of the 1st day of February, 2008 (the “*Effective Date*”) by and between Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, U.S.A. (“*Amgen*”), and Takeda Pharmaceutical Company Limited, a Japanese corporation having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan (“*Purchaser*”). Amgen and Purchaser are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*”.

Recitals

WHEREAS, Amgen and Purchaser have entered into the License Agreement of even date herewith (the “*License Agreement*”) regarding, among other things, Amgen’s proprietary product Vectibix (as defined below).

WHEREAS, pursuant to the License Agreement, Purchaser has the right to develop and commercialize Vectibix in Licensee Indications in the Territory (each as defined below).

WHEREAS, Purchaser has requested and Amgen has agreed to supply Purchaser, on the terms set forth herein, with Drug Product (as defined below) for clinical and commercial use in Licensee Indications in the Territory.

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

1. DEFINITIONS

- 1.1 “*Affiliate*” shall mean any corporation or other entity which directly or indirectly controls, is controlled by or is under common control with a Party, for so long as such control exists. For the purposes of this Section 1.1 (“*Affiliate*”), “control” and its cognates shall mean: (i) in the case of any corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for the election of directors thereof; or (ii) in the case of any non-corporate entity, direct or indirect ownership of more than fifty percent (50%).
- 1.2 “*Allocable Overhead*” shall mean [*]. Allocable Overhead may be allocated based upon [*].
- 1.3 “*Available SKU*” shall mean an SKU (stock keeping unit) of Drug Product set forth on the Vectibix Available SKU Schedule or added to such schedule pursuant to Section 2.2.6 (Available SKUs).
- 1.4 “*Bulk Drug Substance*” shall mean Vectibix in purified bulk form.
- 1.5 “[*] *Quarter*” shall mean a three-month period beginning on [*].
- 1.6 “[*] *Year*” shall mean a one-year period beginning on [*] and ending on [*].
- 1.7 “*Change Notice*” shall have the meaning set forth in Section 2.9 (Changes to Manufacturing).
- 1.8 “*Confidential Information*” shall have the meaning set forth in Section 4.1

(Confidentiality; Exceptions).

- 1.9 “*Contract Interest Rate*” shall mean the rate equal to [*] plus [*] rate effective for the date [*], as published by The Wall Street Journal, Eastern U.S. Edition, on the [*] (or, if unavailable on such date, the [*] on which such rate is available), or, if lower, the maximum rate permitted by Law.
- 1.10 “*Direct Costs*” shall mean [*].
- 1.11 “*Drug Product*” shall mean Bulk Drug Substance in finished, labeled form in accordance with the Specifications.
- 1.12 “*Employment Costs*” shall mean [*].
- 1.13 “*Federal Court*” shall have the meaning set forth in Section 8.11 (Jurisdiction and Venue).
- 1.14 “*Force Majeure*” shall have the meaning set forth in Section 8.8 (Force Majeure).
- 1.15 “*FTE*” shall mean the equivalent of the work of one employee full time for one 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, shall not be counted with any multiplier (e.g. time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
- 1.16 “*FTE Rate*” shall mean [*] (as of the [*]), increasing by [*] of the then-current FTE Rate on [*].
- 1.17 “*GAAP*” shall mean U.S. generally accepted accounting principals, consistently applied.
- 1.18 “*Governmental Authority*” shall mean any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.
- 1.19 “*Indirect Costs*” shall mean Employment Costs and Allocable Overhead [*].
- 1.20 “*Law*” shall mean, individually and collectively, any and all laws, ordinances, rules, directives administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.
- 1.21 “*License Agreement*” shall have the meaning set forth in the recitals of this Agreement.
- 1.22 “*Licensee Indication*” shall mean an indication designated as a “Licensee Indication” pursuant to the License Agreement.
- 1.23 “*Long-Range Projections*” or “*LRP*” shall have the meaning set forth in Section 2.2.1.2 (Long-Range Forecast).
- 1.24 “*Necessary Approval*” shall mean all approvals, permits, licenses, registrations, authorizations, or similar permissions required by Law for the purchase, transit, export or import of Drug Product hereunder.
- 1.25 “*Net Sales*” shall have the meaning set forth in the License Agreement for such term.
- 1.26 “*Rolling Forecast*” shall have the meaning set forth in Section 2.2.1.1 (Provision of Forecasts).
- 1.27 “*Specifications*” shall mean the specifications for Drug Product as set forth in the

Specifications Schedule.

- 1.28 “Standard Costs” shall mean, with respect to an Available SKU, [*].
- 1.29 “State Court” shall have the meaning set forth in Section 8.11 (Jurisdiction and Venue).
- 1.30 “Support Costs” shall mean [*]. For the avoidance of doubt, any costs and expenses included in Standard Costs shall not also be included in Support Costs.
- 1.31 “Taxes” shall mean any tax, excise or duty, other than taxes upon income.
- 1.32 “Territory” shall mean Japan.
- 1.33 “Third Party” shall mean any entity other than a Party or an Affiliate of a Party.
- 1.34 “VAT” shall mean any value added tax.
- 1.35 “Vectibix” shall mean Amgen’s proprietary fully human anti-EGFr monoclonal antibody known in the U.S. as Vectibix™.

2. SUPPLY OF DRUG PRODUCT

- 2.1 Supply of Drug Product; Requirements. Subject to the terms and conditions of this Agreement: (i) except as expressly provided in Section 2.14 (Alternate Supply), Purchaser agrees to purchase from Amgen hereunder all of Purchaser’s (and its permitted licensees’) requirements of Vectibix and Drug Product for any use from Amgen; and (ii) Amgen agrees to sell to Purchaser all of Purchaser’s (and its permitted licensees’) requirements of Vectibix and Drug Product for uses permitted under the License Agreement. Certain rights and licenses with respect to the use and sale of Vectibix are granted to Purchaser pursuant to the License Agreement, and no rights with respect to Vectibix (including with respect to any intellectual property related to Vectibix) are granted or shall be implied hereunder.
- 2.2 Forecasts and Orders.
- 2.2.1 *Provision of Forecasts.* Purchaser shall provide to Amgen forecasts of its requirements of Drug Product as follows:
- 2.2.1.1 **ROLLING FORECAST.** On a [*] basis during the term of this Agreement, Purchaser shall provide to Amgen a rolling [*] forecast setting forth, [*], Purchaser’s requirements for Drug Product by Available SKU for the Territory (a “*Rolling Forecast*”). Purchaser shall provide to Amgen by the [*] (i.e., [*]) a Rolling Forecast for the period beginning as of the [*] in which the Rolling Forecast is due (e.g., by [*] Purchaser shall submit a Rolling Forecast for the [*] period from [*] through [*]). The initial [*] of the Rolling Forecast shall be denoted therein as [*], and the remainder of the [*] shall be denoted as [*] (in chronological order). Promptly following the [*], the Parties shall mutually agree upon the initial Rolling Forecast which shall include, at a minimum, the supply requirements necessary.
- 2.2.1.2 **LONG-RANGE FORECAST.** [*] per [*] Year, at a particular [*] to be agreed to by the Parties, Purchaser shall provide to Amgen along with a Rolling Forecast its projected requirements for Drug Product by Available SKU for the Territory for the [*] in which the projection is due plus the [*] period that follows (a “*Long-Range Projection*” or “*LRP*”). The first [*] and subsequent

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[*] of the LRP shall be the same as the Rolling Forecast which the LRP accompanies. The LRP shall specify, by [*] for the period covered by the Rolling Forecast and by [*] for [*] of the LRP, Purchaser’s requirements for Drug Product by Available SKU for the Territory. The initial [*] of the LRP shall be denoted therein as [*], and the remainder of the [*] through [*] shall be denoted as [*] (in chronological order). The forecast for [*] of the LRP shall be non-binding, but Purchaser shall use its reasonable good-faith efforts to provide the best estimate of its requirements for such [*].

2.2.2 *Purchase Orders.* The forecast for [*] of a Rolling Forecast (the “*Purchase Order Period*”) shall be binding purchase orders with respect to the forecasted quantities of each Available SKU for such [*] and may not be varied. Amgen may deliver each [*] ordered quantity of Available SKUs at anytime during the applicable delivery [*].

2.2.3 *Forecast Variance.* With respect to each Rolling Forecast, the forecasted quantities for each Available SKU set forth in such Rolling Forecast for [*] thereof shall be binding. The forecasted quantities of each Available SKU for the Purchase Order Period shall be binding (as set forth in Section 2.2.2 (Purchase Orders)) and Purchaser may not vary such ordered quantities. The forecasted quantities of each Available SKU for [*] of a Rolling Forecast (the “*Binding Forecast Period*”) shall be binding, but Purchaser shall be permitted to vary such forecasted quantities only as set forth in this Section 2.2.3 (Forecast Variance). For each [*] within the Binding Forecast Period of a Rolling Forecast, Purchaser shall be permitted to vary the forecasted quantity of an Available SKU for such [*] (e.g., [*]) by a specified percentage of such forecasted quantity in Purchaser’s forecasted quantity of such Available SKU for such same [*] (e.g., [*]) in the next subsequent Rolling Forecast. The specified percentages for permitted variance by [*] during the Binding Forecast Period are set forth below.

[*]	[*]	[*]	[*]	[*]	[*]	[*]
Percentage	[*]	[*]	[*]	[*]	[*]	[*]

For purposes of example, if in a Rolling Forecast covering [[*]] through [*] the quantity of a particular Available SKU forecasted for [*] is [*] units, then in the next subsequent Rolling Forecast (covering [*] through [*]) the aggregate quantity of such Available SKU forecasted for [*] shall be no less than [*] units and no more than [*] units.

2.2.4 *Non-Compliant Forecasts.* In the event Purchaser provides a Rolling Forecast that contains a forecast for any [*] therein that is not in compliance with Section 2.2.3 (Forecast Variance), Purchaser shall provide notice of such non-compliance to Amgen in writing. Amgen shall have the right to adjust such non-compliant forecasted quantity for such [*] to increase or reduce the amount forecasted for such [*] by up to the minimum amount necessary to bring such forecasted quantity into compliance with such provision. By way of example, if the Rolling Forecast covering the period from [*] through [*] forecasted a quantity of [*] units of a particular Available SKU for [*], and the next subsequent Rolling Forecast

(covering the period from [*] through [*] forecasted a quantity of [*] units for such Available SKU for [*], which exceeds the permitted [*] percent variance for such period (as set forth in Section 2.2.3 (Forecast Variance)), then Amgen shall have the right (but not the obligation) to reduce the quantity of such Available SKU forecasted for [*] in such Rolling Forecast to any number between [*] and [*] units (inclusive). In such event, Amgen shall provide to Purchaser the Rolling Forecast revised to be in compliance with the terms of this Clinical Supply Schedule, and such Rolling Forecast shall be deemed the Rolling Forecast for the applicable period.

- 2.2.5 *Orders not in Compliance with Forecasts.* Amgen shall have no obligation to fill any purchase order placed by Purchaser that exceeds the maximum amount permitted hereunder as set forth in Section 2.2 (Forecasts and Orders), and shall have the right to reduce any excessive purchase order by up to the minimum amount necessary to bring such purchase order into conformance with this Agreement. If Purchaser does not want to receive the full amount of any purchase order, Amgen shall have the right to invoice Purchaser for the full amount ordered hereunder and Purchaser shall be obligated to pay such full invoice amount; and Amgen shall have the right, in its sole discretion, to either deliver to Purchaser the full amount of Drug Product ordered hereunder for such [*] (in which case Purchaser shall receive and accept such Drug Product), use the unwanted portion of the ordered Drug Product for other purposes or otherwise dispose of the unwanted portion of the ordered Drug Product.
- 2.2.6 *Available SKUs.* The Vectibix Available SKU Schedule attached hereto sets forth the Available SKUs as of [*]. Amgen shall add any new SKUs used by Amgen outside the Territory to the Vectibix Available SKU Schedule by written notice to Purchaser, and such SKUs shall be Available SKUs and Purchaser shall have the right to order such added Available SKUs. The Parties shall mutually agree upon the first period for which such new Available SKU can be ordered by Purchaser, and upon any permitted adjustments to Purchaser's then applicable Rolling Forecast and LRP to enable Purchaser to add units of the newly Available SKU in substitution for units of previously forecasted Available SKUs; provided that, the Parties shall seek to minimize any disruption to Amgen's introduction of the new Available SKU outside the Territory and Amgen's manufacturing plans based on the previously established Rolling Forecast. All purchase orders of Purchaser hereunder shall be for Available SKUs set forth on (or added to) the Vectibix Available SKU Schedule, and Purchaser shall not have the right to order Bulk Drug Substance hereunder (except as incorporated in such Drug Product) unless formulation, fill and finish manufacturing activities are assumed by Purchaser pursuant to Section 2.14 (Alternate Supply).
- 2.2.7 *Quantities Forecast and Ordered.* Purchaser shall forecast and order quantities of an Available SKU according to full standard lot sizes of manufactured Drug Product. Amgen shall communicate to Purchaser full standard lot sizes. The Parties shall coordinate and cooperate, through the Manufacturing Committee or otherwise, to modify Rolling Forecasts, LRPs and purchase orders as needed to reflect for each [*] a quantity of an Available SKU that is divisible by full standard

lot sizes for such Available SKU. Amgen shall have no obligation to manufacture or use partial lots of Drug Product to meet Purchaser's purchase orders or forecasts.

2.2.8 *Commercial and Non-Commercial.* For forecast and order purposes under this Agreement, Purchaser shall separately specify the quantity of each Available SKU to be used for commercial purposes (which shall include Drug Product used for post-marketing commitments and samples distributed for free or less than full sale price) and the quantity of each Available SKU to be used for non-commercial purposes (including clinical development), as if they were distinct and separate Available SKUs.

2.3 Provision of Drug Product. Amgen shall use its reasonably diligent efforts to fill purchase orders for Available SKUs placed by Purchaser in accordance with Section 2.2 (Forecasts and Orders), so long as Purchaser is in compliance with its obligations hereunder and under the License Agreement. Drug Product shall be provided [*] or, if Amgen supplies Bulk Drug Substance following assumption of formulation, fill and finish manufacturing activities by Purchaser pursuant to Section 2.14 (Alternate Supply), [*]. Purchaser shall: (i) receive each shipment, (ii) promptly notify Amgen when the shipment has been received; and (iii) forward to Amgen any applicable chain of custody forms, in-transport temperature recorder(s) and receipt verification documentation and such other documentation reasonably requested by Amgen.

2.4 Labeling and Packaging. Amgen shall perform primary labeling (i.e., labeling of vials) of Drug Product supplied hereunder. Purchaser shall be responsible for and bear all costs associated with the design, development, quality release and any required approvals of any Governmental Authority of all primary labels of Drug Product supplied hereunder. Purchaser shall perform its design, development, quality release and approval obligations hereunder in a timely manner sufficient for Amgen to satisfy its supply obligations hereunder for Drug Product. Purchaser shall select and contract with a party in the Territory mutually acceptable to the Parties for producing primary labels for Drug Product for Purchaser. Purchaser shall consult with Amgen with respect to any proposed primary labels (or changes thereto), including design, size, material and other properties. Prior to final approval of any primary label for use with Drug Product, Purchaser shall provide to Amgen samples thereof for its review and approval. Amgen shall have no obligation to use, or provide Drug Product labeled with, primary labels that have not been approved by Amgen. Amgen shall be responsible for procuring all primary labels directly from Purchaser's label provider and Purchaser shall cooperate to enable such direct procurement by Amgen. Purchaser shall perform, be solely responsible for and bear all costs associated with final packaging and secondary labeling of Drug Product supplied hereunder. If at any time Amgen elects to transition the performance of primary labeling to a Third Party mutually agreeable to the Parties (or to Purchaser if mutually agreed), then the Parties shall promptly meet to discuss and implement such a transition of such responsibilities.

2.5 Necessary Approvals. Purchaser shall be responsible, at its own cost, for obtaining, maintaining and submitting all Necessary Approvals, except that Amgen will be responsible for obtaining and maintaining all Necessary Approvals related to the export of Drug Product ordered by Purchaser hereunder, any drug master file submitted by or on behalf of Amgen and the accreditation of any foreign manufacturers used by Amgen in the

Territory with respect to Drug Product ordered by Purchaser. Each Party shall reasonably cooperate with the other with respect to obtaining, maintaining and submitting all Necessary Approvals. Each Party shall also promptly provide to the other Party copies of Necessary Approvals as reasonably requested. At least [*] days prior to the first scheduled export of Drug Product or Bulk Drug Substance hereunder, Purchaser shall provide to Amgen copies of all documentation of the Necessary Approvals obtained by Purchaser. Purchaser thereafter shall promptly provide Amgen with supplemental documentation promptly in the event of any changes to Necessary Approvals or other regulatory compliance documents, as well as upon request by Amgen. Amgen shall not have any obligation to export Drug Product, or to provide Drug Product to Purchaser, unless and until Purchaser demonstrates to Amgen that Purchaser has received all Necessary Approvals for which it has responsibility.

- 2.6 Product Specifications. A Amgen certificate of analysis shall accompany each shipment of Drug Product to Purchaser. Purchaser shall be responsible for any failure of Drug Product to meet the Specifications to the extent caused by shipping or handling conditions after delivery to Purchaser hereunder.
- 2.7 Product Testing; Noncompliance. Purchaser shall have [*] days from the date of delivery of Drug Product to Purchaser's premises in which to test, at Purchaser's cost, a shipment for compliance with the Specifications and notify Amgen of any non-compliance. Purchaser shall use its reasonably diligent efforts to obtain and test the Drug Product as soon as reasonably practicable. Amgen and Purchaser shall agree on the testing procedures to be employed and the Third Parties to be contracted to conduct testing hereunder. Purchaser shall be responsible for storage and maintenance of the Drug Product until it is tested and released. In the event Purchaser determines that a shipment of Drug Product (or portion thereof) did not, upon delivery, meet the Specifications, Purchaser shall notify Amgen in writing (within the [*] day period set forth above) and provide Amgen with complete copies of all testing data and a reasonably detailed explanation of the reasons for such suspected non-compliance. If Amgen disagrees with such initial determination of non-compliance and the Parties can not come to agreement, Amgen and Purchaser shall elect an independent Third Party to review the data and/or repeat the testing and make a final determination, which shall be binding upon both Purchaser and Amgen. If the shipment is determined by the independent Third Party to have been, upon delivery, in compliance with the Specifications, Purchaser shall pay the costs of such testing; if the shipment is found not to have been in compliance with the Specifications upon delivery, Amgen shall pay the costs of such testing. In the event any shipment (or portion thereof) shall be agreed or determined pursuant to this Section 2.7 (Product Testing; Noncompliance) to have failed to comply with the Specifications upon delivery, Purchaser shall, at Amgen's election and expense, either destroy the shipment or return the shipment to Amgen. Amgen shall replace the Available SKUs found to have been not in compliance with the Specifications upon delivery, as Purchaser's sole remedy (other than indemnity under Section 6.2.2 (Amgen Obligation)) with respect to such non-complying Drug Product. Purchaser shall be responsible for, and Amgen shall have no obligation to provide replacement Drug Product for, any Available SKUs supplied hereunder other than the Available SKUs agreed or determined to be not in compliance with the Specifications upon delivery. Purchaser shall be solely responsible for taking all steps necessary to determine that Drug Product is suitable for commercial release before making such Drug Product available for human use.
- 2.8 Notice of Reports. Purchaser shall provide Amgen within [*] written notice of any and all material problems (including adverse events) with any Drug Product hereunder that have been reported to Purchaser by any of its customers or Third Parties (including any events reportable to Governmental Authorities in the United States under 21 CFR §314.80) or of which Purchaser becomes aware and shall cooperate with Amgen in any efforts to investigate and cure such problems.

2.9 Changes to Manufacturing.

2.9.1 *Changes by Amgen.* If Amgen determines to make a material change to the manufacturing of Drug Product to be supplied to Purchaser hereunder (e.g., material change to Specifications or manufacturing process), it shall provide Purchaser prompt written notice of such determination (a “*Change Notice*”). Such notice shall provide the relevant details of such change (“*Manufacturing Change*”) (but Amgen shall have no obligation to include any confidential Amgen manufacturing information) and the proposed date for such change. The Parties shall meet and determine if such change would require notice to or approval by a Governmental Authority in the Territory.

2.9.1.1 CHANGES NOT REQUIRING APPROVAL. If a proposed change does not require notice to or approval of any such Governmental Authority, then Amgen shall have the right to provide Drug Product to Purchaser hereunder in accordance with the Manufacturing Change [*] days from the date of the Change Notice. If such change requires notice to (but not the approval of) a Governmental Authority in the Territory, then the Parties shall cooperate to promptly submit such notice and Amgen shall continue to provide Purchaser Drug Product as prior to the Manufacturing Change to allow for such notice to such Governmental Authority and after [*] days from the date of the Change Notice (or such earlier time as such notice to the relevant Governmental Authority has been made (and any required waiting periods have expired)) Amgen shall have the right to provide Drug Product to Purchaser hereunder in accordance with the Manufacturing Change.

2.9.1.2 CHANGES REQUIRING APPROVAL. If a proposed Manufacturing Change requires the approval of a Governmental Authority in the Territory, then Purchaser shall use its reasonably diligent efforts to obtain such approval, and Amgen shall continue to provide Drug Product as prior to the Manufacturing Change as necessary to allow Purchaser to obtain the required approval; provided, however, that Amgen shall have the right to transition Purchaser to an alternate source of supply in accordance with Section 2.14 (Alternate Supply) at any time upon written notice given by Amgen to Purchaser. If Purchaser does not obtain approval of a proposed Manufacturing Change from the Governmental Authority in the Territory within the relevant time period, or becomes aware of a potential failure to timely receive such approval, Purchaser shall promptly notify Amgen thereof. In such event, Amgen shall have the right to transition Purchaser to an alternate source of supply in accordance with Section 2.14 (Alternate Supply) at any time upon written notice given by Amgen to Purchaser.

Notwithstanding anything to the contrary in this Section 2.9 (Changes to Manufacturing), Amgen shall have the right to immediately make any change required to protect patient safety or as required by Law, and shall give Purchaser prompt written notice thereof.

- 2.9.2 *Changes for Regulatory Necessity.* If the applicable Governmental Authorities in the Territory require a Manufacturing Change in order to permit Purchaser to use or sell Drug Product in Licensee Indications in the Territory, Purchaser shall immediately inform Amgen of the same in writing and provide Amgen any related information as reasonably requested by Amgen. Amgen shall use reasonable diligence efforts to implement the Manufacturing Change for Drug Product to be supplied hereunder, and the Parties shall discuss and cooperate in good faith to minimize the time for and disruption of such transition to Drug Product conforming to such Manufacturing Change; provided, however, that Amgen shall have the right to transition Purchaser to an alternate source of supply in accordance with Section 2.14 (Alternate Supply) at any time upon written notice given by Amgen to Purchaser. If Amgen elects to transition Purchaser to an alternate source of supply, the Parties shall cooperate to facilitate such transition so as to minimize disruption to the Parties and shall discuss in good faith the feasibility of Amgen providing transitional supply conforming to the Manufacturing Change until the transition obligations under Section 2.14 have been completed. In any case, Purchaser shall be responsible for all incremental costs incurred by Amgen (including Amgen FTEs at the FTE Rate) in developing and providing Drug Product in accordance with the Manufacturing Change.
- 2.9.3 *Regulatory Communication.* In the event of any Manufacturing Change pursuant to this Section 2.9 (Changes to Manufacturing), Amgen shall cooperate with Purchaser to provide to the applicable Governmental Authority in the Territory documentation required by Law to be provided with respect to such change (through Purchaser or directly to the relevant Governmental Agency). In no event will Amgen be obligated under this Agreement to (i) conduct any studies (pre-clinical, clinical or other) to support Purchaser's regulatory filings or (ii) transfer to Purchaser any technology, know-how, cell lines or other materials in connection with any Manufacturing Change implemented by Amgen. Should Purchaser request that Amgen agree to conduct additional work for the purpose of supplementing Purchaser's regulatory filing in the Territory, the Parties shall discuss in good faith the terms and conditions (including economic terms) upon which Amgen in its discretion may agree to conduct such work and any agreement of the Parties with respect thereto shall be reflected in writing and signed by each of the Parties. Purchaser shall provide to Amgen copies of all regulatory filings and correspondence submitted or received by Purchaser or its agents in connection with any Manufacturing Changes, and any other documentation reasonably requested by Amgen related thereto.

- 2.10 Shortage; Allocation. In the event of a shortage of Drug Product such that Amgen reasonably believes that it will not be able to supply Purchaser's requirements (as set forth in a Rolling Forecast) and its own requirements (including those of any other Amgen licensees' and distributors), Amgen shall provide written notice to Purchaser thereof. If Amgen actually cannot supply Purchaser's purchase orders in accordance with this Agreement and Amgen's requirements (including those of any other Amgen licensees' and distributors), then Amgen shall reasonably allocate Drug Product (on an Available SKU by Available SKU basis) such that [*]. Allocation of Drug Product in accordance with this Section 2.10 (Shortage; Allocation) will be Purchaser's exclusive remedy with respect to any shortage of Drug Product.
- 2.11 Manufacturing Regulatory Responsibility. The responsibilities of the Parties with respect to communication and regulatory filings with Governmental Authorities related to Vectibix and Drug Product shall be as set forth in the License Agreement, including Sections 4.12.2 (Amgen Responsibility) and 7.4 (Responsibility for Regulatory Filings with Respect to Manufacturing) of the License Agreement.
- 2.12 Inspections and Review of Records. If Purchaser is notified in writing by a Governmental Authority within the Territory that an inspection of Amgen's manufacturing facilities or a review of Amgen's batch records for Bulk Drug Substance or Drug Product by that authority is required by Law, Amgen agrees to reasonably cooperate and allow such Governmental Authority to inspect such manufacturing facilities or review such records to the extent reasonably required. Purchaser shall give Amgen reasonable advance written notice of any such notification by a Governmental Authority. Purchaser shall reimburse Amgen for any costs incurred by Amgen in connection with any such inspections, as well as the cost of any Amgen personnel time at the FTE Rate.
- 2.13 Purchaser Inspections. Subject to the terms and conditions of this Agreement, Purchaser may visit and inspect, at its own expense, (i) Amgen's manufacturing facilities for Bulk Drug Substance or Drug Product (but not Amgen's Third Party manufacturer's facilities without Amgen's prior written approval), (ii) Amgen's quality control and analytical laboratories for the testing of Bulk Drug Substance or Drug Product, and (iii) Amgen's documents and records relating to (i) and (ii) above, in each case to the extent such facilities or records relate solely to the Drug Product or constituent Bulk Drug Substance supplied to Purchaser pursuant to this Agreement. Purchaser's inspections will be limited in scope to what is reasonably necessary to confirm that Amgen has complied with current Good Manufacturing Practices (as defined in the United States Code of Federal Regulations) in manufacturing the Bulk Drug Substance and/or Drug Product. Purchaser may conduct inspections no more frequently than once in any [*] period. It is anticipated that any inspections conducted in accordance with this Section 2.13 (Purchaser Inspections) shall be for a duration of no more than [*]. Purchaser will coordinate all inspections with Amgen and provide Amgen with no less than [*] prior written notice of any inspection. Inspections shall be conducted in accordance with Amgen procedures during normal hours of operation, in the presence of Amgen representatives. Any information obtained by Purchaser in the course of such inspections shall be treated as Amgen Confidential Information, and the Purchaser personnel conducting such inspections shall not share any such information with other employees of Purchaser, other than (on a need-to-know basis) whether or not such inspection showed any Amgen failure to comply

with current Good Manufacturing Practices and the details of any such non-compliance. Amgen shall have no obligation under this Agreement to provide Purchaser with any information regarding Amgen's manufacturing facility, any information pertaining to the manufacture of products other than Bulk Drug Substance or Drug Product, or proprietary manufacturing information (including cell lines, host cells and vectors). Purchaser shall reimburse Amgen for any costs incurred by Amgen in connection with any such inspections, as well as the cost of any Amgen personnel time at the FTE Rate.

2.14 Alternate Supply.

2.14.1 *Process of Transition.* In the event Amgen provides a notice to Purchaser of the intent to transition the manufacturing (either in the entirety, only the formulation, fill and finish manufacturing activities, or only the manufacture of Bulk Drug Substance (if Amgen has previously transitioned the formulation, fill and finish manufacturing activities)) of Drug Product (such manufacturing activities to be transitioned, the "Transitioned Manufacturing"), to an alternate source pursuant to Sections 2.9 (Changes to Manufacturing), 2.14.3 (Bulk Drug Substance), 7.4 (Termination by Amgen for Discontinuation) or 7.4 (Change of Control), then Amgen and Purchaser shall cooperate to transition the Transitioned Manufacturing to a mutually acceptable Third-Party manufacturer. Purchaser shall contract directly with the Third-Party manufacturer and shall be responsible for the Transitioned Manufacturing of Drug Product for Purchaser, its Affiliates and sublicensees for Licensee Indications in the Territory. Amgen shall cooperate to provide to such Third-Party manufacturer, under obligations of confidentiality, [*] such Transitioned Manufacturing of Drug Product for Purchaser in the Licensee Indications in the Territory. Amgen shall also, in connection therewith, grant to such Third-Party manufacturer a non-exclusive license to use such manufacturing technology solely for the purposes of performing the Transitioned Manufacturing of Drug Product for Purchaser for the Licensee Indications in the Territory. Purchaser shall be solely responsible for all costs associated with the transition to such Third-Party manufacturer (including payment at the FTE Rate for hours of [*] provided by Amgen) and all costs associated with the purchase of Drug Product from such Third-Party manufacturer. Amgen shall have no responsibility to Purchaser for Purchaser's supply of Drug Product to be provided by a Third-Party manufacturer pursuant to this Section 2.14 (Alternate Supply).

2.14.2 *Completion of Transition.* The Parties shall use their commercially reasonable efforts to complete the transition of the Transitioned Manufacturing as soon as practicable. Upon request of Purchaser, Amgen shall provide [*] for the transition of the manufacturing of Bulk Drug Substance, as the case may be, in each case as reasonably necessary to facilitate the transition of the Transitioned Manufacturing, but in no event shall Amgen have any obligation to provide [*] with respect to the transition of the Transitioned Manufacturing. Amgen shall continue to provide to Purchaser supply of Drug Product in accordance with Purchaser's purchase orders for Drug Product in the Licensee Indications in the Territory in accordance with Section 2.2 (Forecasts and Orders) until the Third-Party manufacturer is approved by the applicable Regulatory Authorities to perform the Transitioned Manufacturing of the Drug Product in the Licensee Indications in the Territory (the

“*Transition Period*”) or, if sooner, [*] following delivery of Amgen’s notice to transition the Transitioned Manufacturing. Amgen shall have the right to meet such obligation by manufacturing and providing to Purchaser a quantity of Drug Product that the Parties agree would be reasonably sufficient to prevent the disruption of the sales of Drug Product in the Licensee Indications in the Territory during the Transition Period. Notwithstanding the foregoing, in no event shall Amgen have any obligation to perform Transitioned Manufacturing or provide [*] beyond such [*] period.

2.14.3 *Transition Plan.* The transfer of Transitioned Manufacturing and continued supply of Drug Product pursuant to this Section 2.14 (Alternate Supply) shall be conducted in accordance with a transition plan which shall be mutually approved by the Parties and which sets forth responsibilities and schedules for transferring the Transitioned Manufacturing as expeditiously as practicable. Amgen will have no obligation to perform any additional process development with respect to the Transitioned Manufacturing of Drug Product following a determination to transition the Transitioned Manufacturing of Drug Product. If during the transition Purchaser seeks to change the process for the Transitioned Manufacturing or fails to timely pay any amount due hereunder, Amgen shall have no further obligation to provide [*] for such transition. If mutually agreed by the Parties, any Transitioned Manufacturing of Drug Product may be transitioned to Purchaser instead of a contract manufacturer.

2.14.4 *Bulk Drug Substance.* Amgen shall have the right at anytime, upon written notice to Purchaser, to transition the formulation, fill and finish manufacturing activities of Drug Product to an alternate source pursuant to this Section 2.14 (Alternate Supply). In the event Amgen transitions only the formulation, fill and finish manufacturing activities of Drug Product to an alternate source pursuant to this Section 2.14 (Alternate Supply), then thereafter Amgen’s obligations under this Agreement with respect to Drug Product shall instead apply only with respect to Bulk Drug Substance, as applicable and appropriate, and the provisions hereunder applicable to Drug Product shall instead apply to Bulk Drug Substance, as applicable and appropriate. In such event, the Parties shall promptly meet to establish a forecasting and order procedure applicable to Bulk Drug Substance, and the forecasting and order procedure set forth in Section 2.2 (Forecasts and Orders) shall no longer apply.

2.14.5 *Manufacturing Improvements.* Subject to Section 2.14.1 (Process of Transition), the Parties shall consider whether to share manufacturing improvements with respect to Drug Product in circumstances where Amgen transitions manufacturing activities to Purchaser or a Third-Party manufacturer on behalf of Purchaser. Unless the Parties otherwise mutually agree in writing, neither Party shall have any obligation to share manufacturing improvements with respect to Transitioned Manufacturing with the other Party or its Third-Party manufacturer following the transition of such Transitioned Manufacturing.

2.15 Use of Contract Manufacturer. The Parties acknowledge that Amgen shall have the right at any time to utilize Third-Party manufacturers in the manufacture of Bulk Drug Substance and/or formulation, fill and finish manufacturing activities of Drug Product. If

Amgen utilizes a Third-Party manufacturer in the manufacture of Drug Product, the Parties shall discuss and cooperate to implement any adjustments to the forecasting or other terms under this Agreement as reasonably necessary to be consistent and permit compliance with the terms of the Third-Party manufacturer agreements. If Amgen utilizes a Third-Party manufacturer in the manufacture of Drug Product, Amgen shall have the right at any time by written notice to Purchaser to cause Purchaser to [*]. In such event, Purchaser shall [*]. Upon Purchaser [*], Amgen shall have no further obligation to perform such manufacturing for Purchaser and Purchaser shall assume responsibility therefor.

- 2.16 Cessation of Manufacturing. In the event Amgen determines that it will no longer manufacture (either in the entirety or only the formulation, fill and finish manufacturing activities) commercial Drug Product for its own use outside the Territory, then Amgen shall have the right to notify Purchaser thereof and to transition Purchaser to an alternate source for such manufacturing in accordance with Section 2.14 (Alternate Supply).
- 2.17 Change of Control. In the event Purchaser undergoes a Change of Control (as defined in the License Agreement), Purchaser shall notify Amgen thereof within five days and Amgen shall have the right, by notice given to Purchaser at any time, to transition Purchaser to an alternate source for some or all manufacturing activities in accordance with Section 2.14 (Alternate Supply).
- 2.18 Manufacturing Committee. At the request of Amgen, the Parties shall establish a Manufacturing Committee to regularly coordinate and discuss matters related to manufacturing and supply of Drug Product hereunder. The Manufacturing Committee shall be a forum for the Parties to discuss supply matters, but shall not have binding authority or authority to amend, modify or waive compliance with this Agreement. The Manufacturing Committee shall be formed promptly following request by Amgen. Unless otherwise agreed by the Parties, the Manufacturing Committee shall be comprised of three members appointed by Amgen and three members appointed by Purchaser. The Manufacturing Committee shall be led by two co-chairs, one appointed by each of the Parties. The Manufacturing Committee shall have the right to delegate any of its responsibilities to one or more subcommittees as it determines appropriate. Each Party shall have the right to replace its committee members or co-chairs by written notice to the other Party. The Manufacturing Committee shall meet quarterly in person, via teleconference or videoconference or otherwise, or as otherwise agreed by the Parties. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Manufacturing Committee 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 as reasonably required to resolve particular matters requested by such Party by at least five business days written notice to the co-chair appointed by the other Party. All committee meetings must have at least one member appointed by each Party in attendance. Amgen shall have the right to terminate its participation in the Manufacturing Committee by [*] days prior written notice to Purchaser. Unless and until a Manufacturing Committee is established hereunder, or in the event the Manufacturing Committee is terminated hereunder, matters subject to the Manufacturing Committee shall be dealt with directly between Amgen and Purchaser.
- 2.19 Quality Agreement. Promptly following the [*], the quality assurance departments of

Amgen and Purchaser will develop and agree upon a quality agreement governing the quality and Specifications of Drug Product to be supplied hereunder, including with respect to product quality and product complaints (to the extent not covered in a separate safety agreement with respect to Vectibix entered into accordance with the License Agreement. The quality agreement will be documented in writing, and routinely updated by mutual written agreement of the Parties.

3. PAYMENT

- 3.1 Pricing. Purchaser shall pay for the supply of Drug Product in accordance with the pricing terms set forth on the Pricing Schedule attached hereto.
- 3.2 Third Party Payments. In addition to payments under Section 3.1 (Pricing), Purchaser shall pay all royalties and other amounts payable by Amgen to Third Parties due to the manufacture, use and/or supply Drug Product, or any component thereof, and/or sale of Drug Product to, by or on behalf of Purchaser, its Affiliates and licensees; provided that, if Purchaser pays any such payment under Section 8.10 (Sublicense Payments) of the License Agreement, it shall not be obligated to make a duplicative payment under this Section 3.2 (Third Party Payments). In the event Amgen determines there will be any such applicable Third Party royalties or other payments under this Section 3.2 (Third Party Payments), Amgen shall notify Purchaser of such obligations and the relevant terms associated therewith and Purchaser shall comply with such obligations and, upon request of Amgen, shall perform such obligations directly to the Third Party. Prior to [*] for [*] which would result in [*] under [*], Amgen shall use reasonable efforts to consult with Purchaser and will duly consider any comments provided by Purchaser.
- 3.3 Support Costs. On a quarterly basis, Purchaser shall pay to Amgen all Support Costs incurred with respect to such quarter. Amgen shall invoice Purchaser for any amounts payable by Purchaser under this Section 3.3 (Support Costs).
- 3.4 Taxes. All Taxes levied on account of a payment made by Purchaser to Amgen pursuant to this Agreement will be subject to the withholding and remittance provisions of Section 3.5 (Withholding).
- 3.5 Withholding. In the event that Law requires Purchaser to pay or withhold Taxes with respect to any payment to be made by Purchaser pursuant to this Agreement, Purchaser shall notify Amgen in writing of such payment or withholding requirements prior to making the payment to Amgen and provide such assistance to Amgen, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in Amgen's efforts to claim an exemption from or reduction of such Taxes. Purchaser will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish Amgen with proof of payment of such Taxes within [*] days following payment thereof. If Taxes are paid to a tax authority, Purchaser shall provide such assistance to Amgen as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.
- 3.6 VAT. All payments due Amgen from Purchaser pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by Purchaser upon receipt of a valid VAT invoice).
- 3.7 Terms of Payment. Amounts payable by Purchaser hereunder shall be payable within [*]

4. CONFIDENTIALITY

- 4.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the term of this Agreement and for [*] years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, “*Confidential Information*”). Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:
- 4.1.1 was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;
 - 4.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
 - 4.1.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
 - 4.1.4 was independently developed by the receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or
 - 4.1.5 was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.
- 4.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) to the extent such disclosure is to a Governmental Authority as reasonably necessary in filing regulatory filings, obtaining regulatory approval or fulfilling post-approval regulatory obligations for Vectibix, or otherwise required by Law, provided, however, that if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party’s Confidential Information it shall, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (ii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; or (iii) to the extent mutually agreed to by the Parties.

- 4.3 Terms and Conditions Confidential. Neither Party shall disclose the terms and conditions of this Agreement except to permitted assignees or as may be required by Law. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Governmental Authority in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement (with price terms requested to be redacted in any event), and in any event each Party shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Each Party shall additionally have the right to issue press releases with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [*] days' notice to the other Party and reasonably considering comments provided by such other Party within three business days after such notice).
- 4.4 Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 5.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as of [*] as follows:
- 5.1.1 As of [*], it is duly organized and validly existing under the Laws of its jurisdiction of incorporation and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;
- 5.1.2 As of [*], this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of [*] violate any Law; the person or persons executing this Agreement on such Party's behalf has been duly authorized to do so by all requisite corporate action;
- 5.1.3 To its knowledge, as of [*] no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under any applicable Laws currently in effect, is or shall be necessary for, or in connection with, the transaction contemplated by this Agreement (except

for any Japanese Ministry of Health, Labour and Welfare or other regulatory approvals, licenses, clearances and the like necessary for the manufacture, import, export or transport 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; and

5.1.4 Each Party represents and warrants that it has not been debarred or the subject of debarment proceedings by any Governmental Authority.

5.2 Party Representations and Warranties; Disclaimer.

5.2.1 *Specification.* [*].

5.2.2 *Use.* Purchaser represents and warrants that it is acquiring Drug Product only for clinical development and for commercial sale in the Licensee Indications in the Territory, in each case in accordance with the License Agreement,

5.2.3 *Disclaimer.* EXCEPT AS SPECIFICALLY PROVIDED FOR IN SECTION 5.2.1 (Specification), THE BULK DRUG SUBSTANCE AND DRUG PRODUCT IS PROVIDED WITH NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT THE BULK DRUG SUBSTANCE OR DRUG PRODUCT IS FREE FROM THE RIGHTFUL CLAIM OF ANY THIRD PARTY BY WAY OF INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OR THE LIKE. FURTHER, EXCEPT TO THE EXTENT SPECIFICALLY PROVIDED FOR IN SECTION 5.2.1 (Specification) AMGEN DOES NOT WARRANT OR MAKE ANY REPRESENTATION REGARDING THE USE, RESULTS OF THE USE OR APPROPRIATENESS OF THE USE OF BULK DRUG SUBSTANCE OR DRUG PRODUCT OR ANY PRODUCT MADE USING BULK DRUG SUBSTANCE OR DRUG PRODUCT. PURCHASER SHALL CONDUCT ITS OWN ANALYSIS OF THE BULK DRUG SUBSTANCE OR DRUG PRODUCT AND ASSUME ALL RESPONSIBILITY FOR THE QUALITY AND USE OF THE BULK DRUG SUBSTANCE OR DRUG PRODUCT AND PRODUCTS MADE USING BULK DRUG SUBSTANCE OR DRUG PRODUCT (INCLUDING BUT NOT LIMITED TO ALL PRODUCT LIABILITY) EXCEPT TO THE EXTENT SPECIFICALLY PROVIDED IN SECTION 6.2.2 (Amgen Obligation) AND, EXCEPT TO THE EXTENT SPECIFICALLY PROVIDED IN SECTION 4.3.2 (Amgen Obligation), PURCHASER'S SOLE REMEDY FOR FAILURE OF THE BULK DRUG SUBSTANCE OR DRUG PRODUCT TO CONFORM TO THE SPECIFICATIONS WILL BE REPLACEMENT OF THE BULK DRUG SUBSTANCE OR DRUG PRODUCT IN ACCORDANCE WITH SECTION 2.7 (Product Testing; Noncompliance) ABOVE.

5.3 Covenants.

5.3.1 *For Use within Territory.* Purchaser covenants that it shall order Drug Product hereunder only as it reasonably anticipates it will need for such purposes.

5.3.2 *Forecasts.* Purchaser covenants to use its reasonably diligent efforts and all available information in its forecasting for Drug Product pursuant to Section 2.2

(Forecasts and Orders) above, and agrees to use its reasonably diligent efforts to comply with all such forecasts given to Amgen.

- 5.3.3 *Debarment.* Neither Party shall knowingly use in connection with the activities to take place pursuant to this Agreement any employee or consultant that has been debarred or the subject of debarment proceedings by any regulatory agency.
- 5.3.4 *Product Integrity.* Purchaser covenants to use all commercially reasonable efforts to ensure that Drug Product is not damaged, altered, or spoiled in any way, including during storage and transportation, after delivery of Drug Product to Purchaser hereunder.
- 5.3.5 *Compliance with United States Regulations.* Purchaser covenants that it shall comply with all U.S. Laws prohibiting the re-export, directly or indirectly, of certain controlled U.S.-origin items without a license to parties located in certain countries or appearing on certain U.S. Government lists of restricted parties; U.S. Laws prohibiting participation in non-U.S. boycotts that the United States does not support; and U.S. Laws prohibiting the sale of products to parties from any country subject to U.S. economic sanctions or who are identified on related U.S. Government lists of restricted parties.

5.4 **Disclaimer of Warranties.** EXCEPT AS SET FORTH IN THIS ARTICLE 5 (Representations, Warranties and Covenants), PURCHASER AND AMGEN EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

6. LIMITATION OF LIABILITY, INSURANCE AND INDEMNIFICATION

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

6.2 **Indemnity.**

- 6.2.1 *Licensee Obligation.* Subject to Section 6.3 (Limitations of Liability) and Section 6.1 (Insurance), Purchaser shall indemnify and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees, and agents (including subcontractors) (collectively, “*Amgen Indemnitees*”), at Purchaser’s cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys’ fees incurred by any Amgen Indemnitees until such time as Purchaser has assumed the defense of such claim) paid to a Third Party (collectively, “*Losses*”) arising out of any claim, action, lawsuit, or other proceeding (collectively, “*Claims*”) brought against any Amgen Indemnitee by a Third Party to the extent such Losses result from (i) a

material breach of any representation or warranty of Purchaser under Section 5.1 (Mutual Representations and Warranties) or Section 5.2.2 (Use), (ii) a material breach of any material obligation in this Agreement or (iii) Purchaser's, its Affiliate's, agent's or licensee's development or commercialization of Vectibix but excluding such Losses to the extent they arise from (i), (ii) or (iii) in Section 6.2.2 (Amgen Obligation) below.

6.2.2 *Amgen Obligation.* Subject to Section 6.3 (Limitations of Liability) and Section 6.1 (Insurance), Amgen shall indemnify and hold harmless Purchaser, its Affiliates, and their respective directors, officers, employees and agents (collectively, "*Purchaser Indemnitees*"), at Amgen's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any Purchaser Indemnitee until such time as Amgen has assumed the defense of such claim) arising out of any Claim brought against any Purchaser Indemnitee by a Third Party to the extent such Losses result from (i) a material breach of any representation or warranty of Purchaser under Section 5.1 (Mutual Representations and Warranties) or Section 5.2.1 (Specification), (ii) a material breach of any material obligation in this Agreement, or (iii) a [*]. Any obligation of Amgen under this Section 6.2.2 (Amgen Obligation) with respect to any [*]. Notwithstanding anything herein to the contrary, Amgen, its Affiliates and agents shall not have any liability for any Losses arising out of or resulting from [*]. Without prejudice to the foregoing, if Amgen notifies Purchaser of the [*] hereunder, Purchaser shall comply with Amgen's instructions with respect to such [*]; provided that, if Purchaser elects not to comply with Amgen's instructions with respect to such [*]. The indemnification obligations under this Section 6.2.2 (Amgen Obligation) exclude Losses to the extent they arise from (i), (ii) or (iii) of Section 6.2.1 (Purchaser Obligation) above.

6.2.3 *Claim for Indemnification.* Whenever any Claim or Loss shall arise for which a Purchaser Indemnitee or an Amgen Indemnitee (the "*Indemnified Party*") may seek indemnification under this Section 6.2 (Indemnification), the Indemnified Party shall promptly notify the other Party (the "*Indemnifying Party*") of the Claim or Loss and, when known, the facts constituting the basis for the Claim; provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under Section 6.2.1 (Purchaser Obligation) or 6.2.2 (Amgen Obligation), as the case may be, shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnifying Party shall have the right to assume the defense of the Claim on behalf of the Indemnified Party. Upon assumption of the defense of the Claim by the Indemnifying Party, the Indemnifying Party shall have exclusive control of the defense and settlement of the Claim. The Indemnified Party shall not settle or compromise any Claim by a Third Party for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, which will not be unreasonably withheld. The Indemnifying Party shall not be liable for any settlement or compromising of a Claim by the Indemnified Party without the Indemnifying Party's prior written consent, which will not be unreasonably withheld. In no event shall the Indemnifying Party settle any Claim without the

prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and shall make available to the Indemnifying Party reasonably requested information under the control of the Indemnified Party, which information shall be subject to Section 4.1 (Confidentiality; Exceptions) of this Agreement. The provisions of this Section 6.2 (Indemnification) shall govern indemnification with respect to the manufacture and supply of Drug Product and the indemnification provisions of the License Agreement shall not apply with respect to such activities.

- 6.3 **Limitations of Liability.** IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 6.3 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 6 (Limitation of Liability; Insurance and Indemnification), (ii) breach of Article 4 (Confidentiality) or (iii) gross negligence or willful misconduct of a Party.

7. TERM AND TERMINATION

- 7.1 **Term.** This Agreement shall commence on the Effective Date and shall terminate upon the earliest to occur of any of the following: (i) the Parties mutually agree in writing to terminate this Agreement; (ii) either Party terminates this Agreement, pursuant to Section 7.2 (Termination by Either Party); and (iii) this Agreement terminates automatically pursuant to Section 7.3 (Termination of License Agreement) or Section 7.4 (Termination by Amgen for Discontinuation).
- 7.2 **Termination by Either Party.**
- 7.2.1 **Breach.** If a Party is in material breach of this Agreement, then the other Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the breaching Party. In such written notice, the noticing Party shall identify the actions or conduct that such Party would consider to be an acceptable cure of such material breach (if curable). If the breaching Party fails to cure such material breach within [*] days after the receipt of such notice (or [*] days with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [*] days after the end of such cure period and effective upon delivery.
- 7.2.2 **Bankruptcy.** Either Party may terminate this Agreement, effective immediately upon the giving of written notice to the other Party, if the other Party (i) becomes

bankrupt or insolvent, or files a petition in bankruptcy or makes a general assignment for the benefit of creditors or otherwise acknowledges in writing insolvency, or is adjudged bankrupt, and such Party (A) fails to assume this Agreement in any such bankruptcy proceeding within [*] days after filing or (B) assumes and assigns this Agreement to a Third Party; (ii) goes into or is placed in a process of complete liquidation; (iii) a trustee or receiver is appointed for any substantial portion of such Party's business and such trustee or receiver is not discharged within [*] days after appointment; (iv) any case or proceeding shall have been commenced or other action taken against such Party in bankruptcy or seeking liquidation, reorganization, dissolution, a winding-up arrangement, composition or readjustment of its debts or any other relief under any applicable bankruptcy, insolvency, reorganization or similar Law now or hereafter in effect and is not dismissed or converted into a voluntary proceeding governed by clause (i) above within [*] days after filing; or (v) there shall have been issued a warrant of attachment, execution, distraint or similar process against any substantial part of the property of such Party and such event shall have continued for a period of [*] days and none of the following has occurred: (A) it is dismissed, (B) it is bonded in a manner reasonably satisfactory to the other Party, or (C) it is discharged.

7.3 Termination of License Agreement. This Agreement shall terminate automatically in the event that the License Agreement, or the license with respect to Vectibix under the License Agreement, expires or is terminated for any reason.

7.4 Termination by Amgen for Discontinuation. This Agreement shall terminate automatically in the event Amgen transitions the entirety of manufacturing of Drug Product pursuant to Section 2.14 of this Agreement.

7.5 Effect of Termination. In the event of expiration or termination of this Agreement:

7.5.1 The Parties shall cooperate to perform hereunder as necessary to effectuate the purposes of the Transition Period provided for in Section 14.5 (Transition Period) of the License Agreement (if applicable);

7.5.2 Purchaser shall promptly pay Amgen for all purchase orders for which Amgen has not been paid and Amgen will be obligated to deliver to Purchaser the supply represented by such purchase orders paid (if not previously provided), and Amgen shall invoice Purchaser, and Purchaser shall pay Amgen within [*] days of the date of such invoice, for any goods in-process or other costs incurred on behalf of Purchaser which goods or costs (or portion thereof) cannot be practically used for other purposes.

7.5.3 Purchaser shall promptly pay Amgen all other accrued but unpaid payments due Amgen under the Agreement; and

7.5.4 The following terms and conditions of this Agreement shall survive:

7.5.4.1 Sections 2.5 (Provision of Drug Product); 2.5 (Necessary Approvals); 2.7 (Product Testing; Noncompliance); 5.2.3 (Disclaimer); 5.3.1 (For Use within Territory); 5.3.4 (Product Integrity); 5.3.5 (Compliance with United States Regulations) and Article 3 (Payment) (all of the foregoing solely with respect to Drug Product provided prior to such termination). In

addition, Sections 5.3.1 (For Use within Territory); and 5.3.4 (Product Integrity) shall survive with respect to Drug Product provided by an alternate supplier pursuant to Section 2.14 (Alternate Supply)); and

- 7.5.4.2 Sections 2.8 (Notice of Reports); 3.5 (Withholding); 3.7 (Annual Determination) (solely with respect to a final reconciliation following termination); 2.5.2 (Disclaimer); 5.4 (Disclaimer of Warranties) and this Section 7.5 (Effect of Termination); and Articles 4 (Confidentiality); 6 (Limitation of Liability, Insurance and Indemnification) and 8 (Miscellaneous).

8. MISCELLANEOUS

- 8.1 Affiliates. Amgen shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates, provided Amgen shall be responsible for such Affiliates' performance hereunder. Where this Agreement makes reference to costs incurred by Amgen, such reference shall be deemed to include costs incurred by Amgen's Affiliates or its Third-Party agents (provided, however, that such costs shall not be double-counted as costs of Amgen and such Affiliates or such Third-Party agents).
- 8.2 Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by Purchaser without the prior written consent of Amgen. Amgen may assign this Agreement, and its rights and obligations hereunder without prior written consent to any Affiliate or, with prior notice, in connection with the transfer or sale of all or substantially all of the business of Amgen to which this Agreement relates. Amgen shall have the right to assign any or all of its rights and delegate any or all of its obligations under this Agreement to a Party or Parties to whom Amgen licenses or transfers rights with respect to Vectibix outside the Territory; and upon request of Amgen, Purchaser will execute a novation with respect to any such assignment. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.
- 8.3 Choice of Law. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of California without regard to its conflicts of law provisions.

- 8.4 **Construction.** The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The word “will” shall be construed to have the same meaning and effect as the word “shall”. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (iii) any reference herein to any person shall be construed to include the person’s permitted successors and assigns, (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (v) all references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control.
- 8.5 **Counterparts.** This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.
- 8.6 **Currency.** All amounts due hereunder are expressed in U.S. Dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, such Net Sales invoiced or expenses incurred shall be converted into the U.S. Dollar equivalent using a rate of exchange which corresponds to the rate used by whichever of Purchaser or Amgen (or an Affiliate of one of them) recorded such receipt or expenditure, for the respective reporting period, related to recording such Net Sales or expenses in its books and records that are maintained in accordance with GAAP. Any royalty amount shall be calculated based upon the U.S. Dollar equivalent calculated in accordance with the foregoing.
- 8.7 **Entire Agreement.** This Agreement, including any Schedules and Exhibits, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same. This Agreement does not supersede the License Agreement. In the event of any conflict between the terms of the License Agreement and those contained herein, the relevant provisions of the License Agreement shall control.

- 8.8 **Force Majeure.** Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest (“*Force Majeure*”); provided, however, that the affected Party promptly notifies the other Party in writing (and continues to provide status updates to the other Party for the duration of the effect) and further provided that the affected Party shall use its reasonably diligent efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed. For the purposes of this Section 8.8 (Force Majeure), a Force Majeure affecting Amgen’s Affiliate or a Third-Party contract manufacturer of Amgen shall operate to excuse any delay or failure in performance as and to the same extent of a Force Majeure affecting a Party as specified above.
- 8.9 **Further Assurances.** Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.
- 8.10 **Headings.** Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.
- 8.11 **Jurisdiction and Venue.** Each Party hereby irrevocably submits to the exclusive jurisdiction of the courts of the State of California (“*State Court*”) and the courts of the United States of America located in the State of California (“*Federal Court*”), for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of any transaction contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party’s respective address set forth in Section 8.13 (Notices) (as such address may be changed by notice delivered pursuant to such section) shall be effective service of process for any action, suit or proceeding in the applicable Federal Court or State Court with respect to any matters to which it has submitted to jurisdiction in this Section 8.11 (Jurisdiction and Venue). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Federal Court or State Court, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of any transaction contemplated hereby shall be conducted in English. Notwithstanding the foregoing, either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction.

8.12 **No Set-Off.** No Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

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

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

If to Purchaser: Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome, Chuo-ku
Osaka 540-8645, Japan
Attention: General Manager, Global Licensing & Business Development
Telephone: [*]
Facsimile: [*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 8.13 (Notices).

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

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

8.16 **Third Party Beneficiaries.** Except as expressly provided with respect to Indemnitees in Article 6 (Indemnification), there are no Third Party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.

- 8.17 United Nations Convention. Notwithstanding anything to the contrary contained in this Agreement, the United Nations Convention on Contracts for the International Sale of Goods shall have no application to, and shall be of no force and effect with respect to, this Agreement or the matters herein set forth or contemplated.
- 8.18 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.

(Signature page immediately follows)

CONFIDENTIAL

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

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Yasuhiko Yamanaka
Name: Yasuhiko Yamanaka
Title: Director
General Manager, Pharmaceutical Marketing Division

AMGEN INC.

By: /s/ Kevin W. Sharer
Name: Kevin W. Sharer
Title: Chairman of the Board, CEO
and President

CONFIDENTIAL

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Schedule

Pricing

A. Price for Commercial Product. The price ("Supply Price") for commercial Drug Product shall be [*].

B. Price for Non-Commercial Product. The price for non-commercial Drug Product shall be [*].

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.

SALE AND PURCHASE AGREEMENT

by and between

AMGEN INC.

and

TAKEDA PHARMACEUTICAL COMPANY LIMITED

Dated as of February 1, 2008

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EXHIBITS

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This Sale and Purchase Agreement (including its Exhibits and Schedules, this “*Agreement*”) is entered into as of February 1, 2008 by and between Amgen Inc., a Delaware corporation (“*Seller*”), and Takeda Pharmaceutical Company Limited, a Japanese corporation (“*Buyer*”). Seller and Buyer are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*”.

RECITALS:

WHEREAS, Seller owns all of the issued and outstanding shares of capital stock of Amgen Kabushiki Kaisha, a Japanese corporation (the “*Company*”);

WHEREAS, Seller, through the Company, is engaged in Japan in the business of developing and conducting clinical trials and other studies with respect to certain of Seller’s products in support of their approval for commercial sale in Japan (the “*Business*”);

WHEREAS, Seller desires to sell and transfer to Buyer and Buyer desires to purchase and assume from Seller the Transferred Shares, as more particularly set forth herein;

WHEREAS, in connection with the foregoing, Seller and Buyer are entering into the License Agreements and the Supply Agreement concurrently with this Agreement; and

WHEREAS, the respective boards of directors (or similar bodies) of each of Seller and Buyer have approved the execution and delivery of, and performance under, this Agreement and each of the Ancillary Agreements by such Party, in each case upon the terms and subject to the conditions set forth in this Agreement or the relevant Ancillary Agreement.

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

ARTICLE I

DEFINITIONS AND TERMS

Section 1.1 Certain Definitions. As used in this Agreement, the following terms have the meanings set forth below:

“*Affiliate*” means, with respect to Seller or Buyer, any Person which directly or indirectly controls, is controlled by or is under common control with Seller or Buyer, as the case may be, for so long as such control exists. For the purposes of this definition, “*control*” means (a) in the case of any corporate entity, direct or indirect ownership of more than 50% of the stock having the right to vote for the election of directors thereof, or (b) in the case of any non-corporate entity, direct or indirect ownership of more than 50% of the equity or income interest therein.

“*Aggregate Loss Limit*” means [*]% of the Purchase Price.

“*Agreement*” has the meaning set forth in the Preamble.

“*Ancillary Agreements*” means collectively the License Agreements and the Supply Agreement.

“*Base Net Asset Value*” means [*], which represents (a) the total assets shown on the Pro Forma Balance Sheet, minus (b) the total liabilities shown on the Pro Forma Balance Sheet.

“*Benefit Plan*” has the meaning set forth in Section 3.10(a).

“*Books and Records*” means all books, ledgers, files, reports, plans, records, manuals, laboratory notebooks, presentations, computer files, emails and other materials (in physical or electronic form or any other form or medium) of, or maintained by, the Company, but excluding any such items to the extent (a) any applicable Law prohibits their transfer, (b) any transfer thereof otherwise would subject Seller or the Company to any material liability, or (c) they are required for, related to, or used in connection with, any of the Excluded Assets or Excluded Liabilities.

“*Business*” has the meaning set forth in the Recitals.

“*Business Day*” means any day other than a Saturday, a Sunday or a day on which banks in Tokyo, Japan or New York, New York are authorized or obligated by applicable Law or executive order to close.

“*Buyer*” has the meaning set forth in the Preamble.

“*Buyer Indemnified Parties*” has the meaning set forth in Section 7.2(a).

“*Chosen Courts*” has the meaning set forth in Section 9.9.

“*Claim Notice*” has the meaning set forth in Section 7.4(a).

“*Closing*” means the closing of the sale and purchase of the Transferred Shares that is the subject of this Agreement.

“*Closing Date*” has the meaning set forth in Section 2.4.

“*Closing Date Balance Sheet*” means the unaudited balance sheet of the Company, which shall set forth the Closing Date Total Assets and Closing Date Total Liabilities of the Company as of the Closing, prepared, or caused to be prepared, by Buyer in accordance with Section 2.7 hereof and, in the event of a Seller’s Objection, as adjusted by either the agreement of Buyer and Seller, or by the CPA Firm, acting pursuant to Section 2.7.

“*Closing Date Exchange Rate*” means the average of the rates of exchange for the conversion of Japanese Yen into U.S. Dollars (or vice versa), quoted under Foreign Exchange in the Wall Street Journal Eastern Edition, for [*] ending on and including [*] immediately prior to [*].

“*Closing Date Net Asset Value*” means an amount in Japanese Yen, which represents (a) the Closing Date Total Assets shown on the Closing Date Balance Sheet, minus (b) the Closing Date Total Liabilities shown on the Closing Date Balance Sheet.

“*Closing Date Total Assets*” means the total assets of the Company on the Closing Date, as determined by applying consistent principles, practices, methodologies and policies as those set forth in the Pro Forma Balance Sheet.

“*Closing Date Total Liabilities*” means the total liabilities of the Company on the Closing Date, as determined by applying consistent principles, practices, methodologies and policies as those set forth in the Pro Forma Balance Sheet.

“*Code*” means the Internal Revenue Code of 1986, as amended.

“*Common Stock*” has the meaning set forth in Section 3.6(b).

“*Company*” has the meaning set forth in the Recitals.

“*Competition Laws*” means the Japanese Act concerning Prohibition of Private Monopoly and Maintenance of Fair Trade, the U.S. Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended, and all other applicable Laws that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade.

“*Confidentiality Agreement*” means the confidentiality agreement between Seller and Buyer, effective as of [*], as amended.

“*Contracts*” means all material agreements, contracts, leases and subleases, purchase orders, arrangements, commitments and licenses (other than this Agreement, the Ancillary Agreements and the Intercompany Contracts) to which the Company is a party, whether written or oral, except to the extent included in Excluded Assets.

“*CPA Firm*” means [*] or an alternative accounting firm as to which Seller and Buyer shall mutually agree.

“*Critical Employees*” has the meaning set forth in Section 5.8(d)(i).

“*Designated Facilities*” has the meaning set forth in Section 5.8(d)(ii).

“*Direct Claim*” has the meaning set forth in Section 7.5.

“*Documents of Title*” means collectively (a) the share certificates (*kabu-ken*) representing the Transferred Shares, (b) a copy of the board resolution of the Company approving the transfer of the Transferred Shares to Buyer as contemplated hereby, and (c) the written resignations of the directors of the Company effective as of [*].

“*Employees*” means all current employees of the Company as of [*] or as of [*], as the case may be.

“*Encumbrance*” means any lien, pledge, charge, claim, encumbrance, security interest, option, mortgage, easement or similar restriction, including, in the case of the Transferred Shares, any right of first refusal or restriction on voting.

“*Excluded Assets*” means collectively the Intellectual Property and other assets listed on Schedule 1.1(a) of the Seller Disclosure Schedule.

“*Excluded Liabilities*” means all the liabilities of Seller or any of its Affiliates relating to, arising out of or resulting from the Excluded Assets, whether incurred before, on or after [*]

“*Facility Resources*” has the meaning set forth in Section 5.8(d)(ii).

“*Final Determination*” means when (a) the parties to the dispute have reached an agreement in writing, (b) a court of competent jurisdiction shall have entered a final and non-appealable order or judgment, or (c) an arbitration or like panel shall have rendered a final and non-appealable determination with respect to disputes the parties have agreed to submit thereto.

“*Governmental Authorizations*” means all licenses, permits, certificates and other authorizations and approvals primarily required for, related to, or used in connection with, the Business and issued by or obtained from a Government Entity.

“*Government Entity*” means any Japanese, U.S. or other federal, national, state or local governmental, quasi-governmental, administrative, judicial, regulatory or self-regulatory authority, body, agency, court, tribunal, commission or similar entity with competent jurisdiction.

“*Hazardous Substance*” means any substance that is listed, defined, designated or classified as hazardous or toxic under, or otherwise regulated pursuant to, applicable Laws.

“*Historical Financial Statements*” has the meaning set forth in Section 3.7.

“*Indemnified Parties*” has the meaning set forth in Section 7.2(a).

“*Indemnifying Party*” has the meaning set forth in Section 7.4(a).

“*Independent Accounting Firm*” has the meaning set forth in Section 5.5(a)(ii).

“*Individual Loss Limit*” means [*].

“*Intellectual Property*” means (a) trademarks, service marks, brand names, certification marks, collective marks, d/b/a’s, domain names, logos, symbols, trade dress, assumed names, fictitious names, trade names and other indicia of origin, all applications and registrations for the foregoing, and all goodwill associated therewith and symbolized thereby, including all renewals of same (collectively, “*Trademarks*”), (b) inventions and discoveries, whether patentable or not, and all patents, registrations, invention disclosures and applications therefor, including divisions, continuations, continuations-in-part and renewal applications, and including renewals, extensions and reissues (collectively, “*Patents*”), (c) trade secrets,

confidential information and know-how, including processes, schematics, business methods, formulae, drawings, prototypes, models, designs, customer lists and supplier lists (collectively, “*Trade Secrets*”), (d) published and unpublished works of authorship, whether copyrightable or not (including databases and other compilations of information), including mask rights and computer software, copyrights therein and thereto, registrations and applications therefor, and all renewals, extensions, restorations and reversions thereof (collectively, “*Copyrights*”), and (e) any other intellectual property or proprietary rights.

“*Intercompany Contract*” has the meaning set forth in Section 5.7.

“*Japanese GAAP*” means generally accepted accounting principles as applied in Japan.

“*JFTC*” has the meaning set forth in Section 5.4.

“*Knowledge*” or any similar phrase means the collective actual knowledge of [*] and [*], in the case of Seller, or of [*] and [*], in the case of Buyer.

“*Laboratory Access*” has the meaning set forth in Section 5.8(d)(ii).

“*Law*” means any common law principle, law, statute, ordinance, rule, regulation, code, order, writ, judgment, injunction or decree enacted, issued, promulgated, enforced or entered by a Government Entity.

“*Leased Real Property*” means all real property that is the subject of those leases and subleases governing real property leased by the Company, owned by persons other than the Company, and listed on Schedule 1.1(b) of the Seller Disclosure Schedule.

“*LIBOR*” means the [*] London Interbank Offered Rate with respect to deposits in U.S. Dollars which appears on the Reuters Screen LIBOR01 Page as of [*.], London time, on the day that is [*] days in London preceding [*.].

“*License Agreements*” means the License Agreements entered into by and between Seller and Buyer concurrently with this Agreement, including one with respect to multiple products, including Vectibix™ (panitumumab), and another with respect to AMG706.

“*Losses*” has the meaning set forth in Section 7.2(a).

“*Material Adverse Effect*” means an effect on the assets or properties of the Company that is materially adverse, on a long-term basis, to the Transferred Business, taken as a whole; provided, however, that none of the following (or the results thereof) shall be a Material Adverse Effect: (a) any change in Law or accounting standards or interpretations thereof applicable to the Transferred Business, (b) any change in economic, political or business conditions or industry-wide or financial market conditions generally, (c) any loss of employees of, or other adverse effect on, the Transferred Business as a result of the execution, delivery and performance of this Agreement or the Ancillary Agreements or the announcement of the transactions contemplated hereby or thereby, or (d) any effect on the Excluded Assets or Excluded Liabilities.

“*Material Contracts*” has the meaning set forth in Section 3.13(a).

“*NAV Threshold Amount*” means the Japanese Yen equivalent of [*], calculated using the Closing Date Exchange Rate.

“*Notice Period*” has the meaning set forth in Section 7.4(a).

“*Ordinary Course*” means the conduct of the Business in accordance with the Company’s normal day-to-day customs, practices and procedures.

“*Party*” and “*Parties*” have the meanings set forth in the Preamble.

“*Permitted Encumbrances*” means (a) Encumbrances reflected or reserved against or otherwise disclosed in the Historical Financial Statements, (b) mechanics’, materialmen’s, warehousemen’s, carriers’, workers’ or repairmen’s liens or other similar common law or statutory Encumbrances arising or incurred in the Ordinary Course, (c) liens for Taxes, assessments and other governmental charges not yet due and payable or due but not delinquent or being contested in good faith by appropriate proceedings, (d) with respect to real property, (i) easements, quasi-easements, licenses, covenants, rights-of-way, rights of re-entry or other similar restrictions, including any other agreements, conditions or restrictions that would be shown by a current title registration or other similar registration, report or listing, (ii) any conditions that may be shown by a current survey or physical inspection, and (iii) zoning, building, subdivision or other similar requirements or restrictions, (e) Encumbrances incurred in the Ordinary Course since the date of the Historical Financial Statements, (f) Encumbrances created by or resulting from the actions of or ownership by Buyer, and (g) Encumbrances that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect.

“*Person*” means an individual, a corporation, a *kabushiki kaisha*, a partnership, an association, a limited liability company, a Government Entity, a trust or any other entity or organization.

“*Post-Closing Notification*” has the meaning set forth in Section 5.4.

“*Pro Forma Balance Sheet*” means the pro forma balance sheet of the Company as of [*], in the form mutually agreed upon by Buyer and Seller, a copy of which Pro-Forma Balance Sheet is attached to this Agreement as Exhibit 1.1.

“*Purchase Price*” has the meaning set forth in Section 2.3.

“*Purchase Price Adjustment Amount*” has the meaning set forth in Section 2.7(e).

“*Representatives*” means, with respect to any Person, such Person’s Affiliates and such Person’s and its Affiliates’ respective directors, officers, employees, consultants, advisors and legal counsels.

“[*] *Employees*” has the meaning set forth in Section 5.8(d)(i).

“[*] *Period*” has the meaning set forth in Section 5.8(d)(i).

“*Section 338 Forms*” has the meaning set forth in Section 5.5(a)(i).

“*Section 338(g) Election*” has the meaning set forth in Section 5.5(a)(i).

“*Seller*” has the meaning set forth in the Preamble.

“*Seller Confidential Information*” has the meaning set forth in Section 5.9(a).

“*Seller Disclosure Schedule*” has the meaning set forth in Article III.

“*Seller Indemnified Parties*” has the meaning set forth in Section 7.3.

“*Seller Required Approvals*” means all consents, approvals, waivers, authorizations, notices, submissions and filings that are required to be listed and are listed on Schedules 3.3(a) and 3.3(b) of the Seller Disclosure Schedule.

“*Seller’s Objection*” has the meaning set forth in Section 2.7(b).

“*Seller’s Plans*” means the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, the Amgen Inc. Amended and Restated 1993 Equity Incentive Plan, the Amgen Inc. Amended and Restated 1997 Special Non-Offer Equity Incentive Plan, the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan, the Amgen Inc. Global Management Incentive Plan and the Amgen Inc. Japan Performance Incentive Plan, and related forms of stock option grant agreements and restricted stock unit agreements under each plan, as applicable, and any other equity or other incentive plan of Seller applicable to any current or former employee of the Company.

“*Service Providers*” has the meaning set forth in Section 5.8(d)(i).

“*Supply Agreement*” means the Supply Agreement entered into by and between Seller and Buyer concurrently with this Agreement.

“*Support Services*” has the meaning set forth in Section 5.8(d)(ii).

“*Tax Proceedings*” has the meaning set forth in Section 5.5(d)(i).

“*Tax Returns*” means all reports and returns required to be filed with respect to Taxes.

“*Taxes*” means all Japanese, U.S. or other federal, national, state or local and all foreign taxes, including income, real and personal property, stamp, transfer, value-added, sales, use, excise, franchise, workers’ compensation, unemployment insurance, social security, withholding or similar taxes, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties.

“*Third-Party Claim*” has the meaning set forth in Section 7.4(a).

“*Transferred Business*” means the Business (excluding the Excluded Assets and the Excluded Liabilities), taken collectively with all rights to be transferred by Seller to Buyer under the License Agreements.

“*Transfer Taxes*” has the meaning set forth in Section 5.5(f).

“*Transferred Shares*” has the meaning set forth in Section 3.6(b).

Section 1.2 Other Terms. Where any term is defined in a particular clause of this Agreement, that term shall have the meaning ascribed to it in that clause throughout this Agreement.

ARTICLE II

SALE AND PURCHASE OF THE COMPANY

Section 2.1 Sale and Purchase. On the terms and subject to the conditions set forth herein, at [*], Seller shall sell, convey, transfer, assign and deliver to Buyer, and Buyer shall purchase and assume from Seller, the Transferred Shares.

Section 2.2 Excluded Assets. Prior to [*], Seller shall cause the Company to assign, transfer, convey and deliver (including by way of corporate split) to Seller or its designee all right, title and interest in and to all of the Excluded Assets; it being understood that all the rights of the Company in and to the Intellectual Property of Seller shall terminate as of [*], except to the extent expressly provided in the License Agreements. Seller or its designee shall assume and be responsible for all Excluded Liabilities.

Section 2.3 Purchase Price. On the terms and subject to the conditions set forth herein, in consideration of the sale of the Transferred Shares, at [*], Buyer shall pay to Seller an amount in cash equal to the U.S. Dollar equivalent to the Base Net Asset Value, calculated using the Closing Date Exchange Rate (the “*Purchase Price*”), subject to adjustment in accordance with Section 2.7.

Section 2.4 Closing. The Closing shall take place at the offices of [*] at [*] on the later to occur of (a) [*]following[*] (b) March 31, 2008, or otherwise at such other time and place as the Parties may mutually agree. The date on which the Closing occurs is called the “*Closing Date*”.

Section 2.5 Deliveries by Buyer. At [*] Buyer shall deliver to Seller the following:

- (a) the Purchase Price, in immediately available funds by wire transfer to an account or accounts, which have been designated by Seller by notice at least [*] prior to [*];
- (b) the certificate to be delivered pursuant to Section 6.3(d); and
- (c) such other customary instruments of transfer, assumptions, filings or documents, in form and substance reasonably satisfactory to Seller, as may be required to give effect to this Agreement.

Section 2.6 Deliveries by Seller. At [*], Seller shall deliver, or cause to be delivered, to Buyer the following:

- (a) the Documents of Title;
- (b) the certificate to be delivered pursuant to Section 6.2(d); and
- (c) such other customary instruments of transfer, assumptions, filings or documents, in form and substance reasonably satisfactory to Buyer, as may be required to give effect to this Agreement.

Section 2.7 NAV Adjustment. (a) As soon as practicable but in no event more than [*] days following [*], Buyer shall prepare, or cause to be prepared, and deliver to Seller the Closing Date Balance Sheet, which shall set forth the Closing Date Total Assets and the Closing Date Total Liabilities of the Company as of the Closing, and which shall be prepared in the same manner, with consistent classification and estimation methodology, as the Pro Forma Balance Sheet was prepared. Upon completion of the Closing Date Balance Sheet, (i) Buyer shall (A) derive the Closing Date Net Asset Value from the Closing Date Balance Sheet, and (B) calculate in accordance with Section 2.7(e) the Purchase Price Adjustment Amount (if any) to be paid by Buyer to Seller or by Seller to Buyer, as the case may be, and (ii) deliver to Seller the Closing Date Balance Sheet and calculations in reasonable explanatory detail with respect to items (A) and (B) referred to in clause (i).

(b) Seller and Seller's accountants shall complete their review of the Closing Date Balance Sheet, and Buyer's calculation of the Closing Date Net Asset Value and the Purchase Price Adjustment Amount (if any), within [*] days after Seller's receipt thereof. In the event that Seller determines that the Closing Date Balance Sheet or any related calculation has not been prepared on the basis set forth in Section 2.7(a), Seller shall, on or before the last day of such [*]-day period, so inform Buyer in writing ("*Seller's Objection*"), setting forth a specific description of the basis of Seller's determination and the adjustments to the Closing Date Balance Sheet and the corresponding adjustments to the Closing Date Net Asset Value that Seller believes should be made; provided, however, that no item of dispute shall be the subject of Seller's Objection unless the aggregate amount of Seller's adjustments would cause the Closing Date Net Asset Value (if accepted in accordance with the succeeding clause) to differ from the Closing Date Net Asset Value reflected on the Closing Date Balance Sheet delivered by Buyer by more than the NAV Threshold Amount. If no Seller's Objection is received by Buyer on or before the last day of such [*]-day period, then the Closing Date Net Asset Value set forth on the Closing Date Balance Sheet delivered by Buyer shall be final. Buyer shall have [*] days from its receipt of Seller's Objection to review and respond to Seller's Objection.

(c) If Seller and Buyer are unable to resolve all of their disagreements with respect to the proposed adjustments set forth in Seller's Objection within [*] days following the completion of Buyer's review of Seller's Objection, they shall refer any remaining disagreements to the CPA Firm which, acting as experts and not as arbitrators, shall determine, on the basis set forth in and in accordance with Section 2.7(a), and only with respect to the remaining differences so submitted, whether and to what extent, if any, the

Closing Date Balance Sheet and the Closing Date Net Asset Value require adjustment. Buyer and Seller shall instruct the CPA Firm to deliver its written determination to Buyer and Seller no later than [*] days after the remaining differences underlying Seller's Objection are referred to the CPA Firm. The CPA Firm's determination shall be conclusive and binding upon Buyer and Seller and their respective Affiliates. Buyer and Seller shall make readily available, or procure to be made readily available, to the CPA Firm all relevant books and records and any work papers (including the work papers of the parties' respective accountants, to the extent permitted by such accountants, but excluding any books, records or other materials that constitute Excluded Assets) relating to the Closing Date Balance Sheet and Seller's Objection and all other items reasonably requested by the CPA Firm in connection therewith. The fees and disbursements of the CPA Firm shall be borne equally by Seller and Buyer.

(d) Buyer shall timely provide to Seller and its accountants full access to the books and records of the Company and to any other information, including work papers of its accountants (to the extent permitted by such accountants), and to any employees during regular business hours and on reasonable advance notice, to the extent necessary for Seller to review the Closing Date Balance Sheet and to prepare, or cause to be prepared, Seller's Objection and materials for presentation to the CPA Firm in connection with Section 2.7(c). Buyer and its accountants shall have full access to all information used by Seller in preparing Seller's Objection, including work papers of its accountants (to the extent permitted by such accountants), but excluding any books, records or other materials that constitute Excluded Assets.

(e) The Purchase Price shall be adjusted (the "*Purchase Price Adjustment Amount*") by (i) the Base Net Asset Value, minus (ii) the Closing Date Net Asset Value, expressed as a positive, if positive, or as a negative, if negative; provided, however, that, if the amount that would otherwise constitute a Purchase Price Adjustment Amount is equal to or less than the NAV Threshold Amount, no adjustment to the Purchase Price shall be made and no Purchase Price Adjustment Amount shall be payable; provided, further, that Buyer or Seller, as the case may be, shall pay the full amount (including the NAV Threshold Amount) of any Purchase Price Adjustment Amount that is more than the NAV Threshold Amount. If the Purchase Price Adjustment Amount is more than the NAV Threshold Amount and a negative number, then the Purchase Price shall be increased by the Purchase Price Adjustment Amount and Buyer shall promptly (and in any event within [*]) after the final determination thereof pay to Seller the U.S. Dollar equivalent of the Purchase Price Adjustment Amount, calculated using the Closing Date Exchange Rate, plus interest on such U.S. Dollar amount from [*] to, but not including, [*] at LIBOR calculated on a 365-day basis, by wire transfer of immediately available funds to an account designated by Seller. If the Purchase Price Adjustment Amount is more than the NAV Threshold Amount and a positive number, then the Purchase Price shall be decreased by the Purchase Price Adjustment Amount and Seller shall promptly (and in any event within [*]) after the final determination thereof pay to Buyer the U.S. Dollar equivalent of the Purchase Price Adjustment Amount, calculated using the Closing Date Exchange Rate, plus interest on such U.S. Dollar amount from [*] to, but not including, [*] at LIBOR calculated on a 365-day basis, by wire transfer of immediately available funds to an account designated by Buyer.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the disclosure schedule delivered by Seller to Buyer on [*] (the “*Seller Disclosure Schedule*”), as of [*], Seller represents and warrants to Buyer as follows:

Section 3.1 Organization. Seller is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and assets and to conduct its business as it is currently being conducted.

Section 3.2 Corporate Authorization. Seller has full corporate power and authority to execute and deliver this Agreement, and to perform its obligations hereunder. The execution, delivery and performance by Seller of this Agreement has been duly and validly authorized and no additional corporate or shareholder authorization or consent is required in connection with the execution, delivery and performance by Seller of this Agreement.

Section 3.3 Consents and Approvals. Except as set forth on Schedule 3.3(a) of the Seller Disclosure Schedule, no consent, approval, waiver, authorization, notice, submission or filing is required to be obtained by Seller from, or to be given by Seller to, or made by Seller with, any Government Entity, in connection with the execution, delivery and performance by Seller of this Agreement, except where the failure to do so would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect or materially impair or delay Seller’s ability to perform its obligations hereunder. Except as set forth on Schedule 3.3(b) of the Seller Disclosure Schedule, no consent, approval, waiver, authorization, notice, submission or filing is required to be obtained by Seller from, or to be given by Seller to, or made by Seller with, any Person which is not a Government Entity in connection with the execution, delivery and performance by Seller of this Agreement, except where the failure to do so would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect or materially impair or delay Seller’s ability to perform its obligations hereunder.

Section 3.4 Non-Contravention. The execution, delivery and performance by Seller of this Agreement do not and will not (a) violate any provision of the certificate of incorporation, bylaws or articles of incorporation (or similar organizational documents) of Seller or the Company, (b) assuming the receipt of all Seller Required Approvals set forth on Schedule 3.3(b) of the Seller Disclosure Schedule, to the Knowledge of Seller, result in the breach of, or constitute a default under, or result in the termination, cancellation or acceleration (whether after the filing of notice or the lapse of time or both) of, any material right or obligation of the Company under, or result in a loss of any material benefit to which the Company is entitled under, any Contract, or result in the creation of any Encumbrance upon the Transferred Shares, or (c) assuming the receipt of all Seller Required Approvals set forth on Schedule 3.3(a) of the Seller Disclosure Schedule or required to be made or obtained by Buyer, to the Knowledge of Seller, violate or result in a breach of, or constitute a default under, any Law to which the Company is subject or any Governmental Authorization, other than, in the cases of clauses (b) and (c), violations, breaches, defaults, terminations, cancellations, accelerations or Encumbrances that would not, individually or in the aggregate, be reasonably likely to have a

Material Adverse Effect or materially impair or delay Seller's ability to perform its obligations hereunder.

Section 3.5 Binding Effect. This Agreement, when duly executed and delivered by Buyer, constitutes a valid and legally binding obligation of Seller, enforceable against Seller in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar Laws affecting creditors' rights and remedies generally and to general principles of equity, including principles of commercial reasonableness, good faith and fair dealing (regardless of whether enforcement is sought in a proceeding at law or in equity).

Section 3.6 Company. (a) The Company is a corporation duly organized and validly existing under the Laws of Japan, the Company is not insolvent or subject to any insolvency or similar proceedings, and no order has been made or petition presented or resolution passed for the winding up of the Company. The Company has all requisite corporate power and authority to own, lease and operate its properties and assets and to conduct its business as it is currently being conducted. Seller has made available to Buyer complete and correct copies of the articles of incorporation of the Company as currently in effect.

(b) As of [*], the authorized capital stock of the Company consists of 10,000 shares of common stock (the "*Common Stock*"), of which 9,500 shares of Common Stock are issued and outstanding (the "*Transferred Shares*"). The Transferred Shares have been duly authorized and validly issued in compliance with applicable Japanese Laws, and are fully paid and non-assessable. There are no outstanding (i) securities of the Company convertible into or exchangeable for any shares of capital stock of the Company, (ii) options, warrants or other rights to purchase or subscribe for shares of capital stock of the Company from the Company or that otherwise require the issuance of shares of capital stock by the Company, or (iii) contracts, commitments, agreements, understandings or arrangements of any kind relating to the issuance or repurchase of any shares of capital stock of the Company, any such convertible or exchangeable securities or any such options, warrants or rights which, in any of the foregoing cases, is binding upon the Company.

(c) Seller is the registered and beneficial owner of the Transferred Shares. Seller has good and valid title to the Transferred Shares, free and clear of all Encumbrances, and, upon consummation of the transactions contemplated hereby, at [*], subject only to the registration of the Transferred Shares in the shareholder register (*kabunushi meibo*) of the Company, Seller will convey to Buyer good and valid title to the Transferred Shares, free and clear of all Encumbrances.

(d) The Company does not own, directly or indirectly, any shares of capital stock or other equity interests in any Person, and it is not a member of or participant in any joint venture partnership or similar Person.

Section 3.7 Historical Financial Statements. Set forth on Schedule 3.7 of the Seller Disclosure Schedule is a copy of the unaudited balance sheet and income statement of the Company, including the Excluded Assets and the Excluded Liabilities, for each of the fiscal years ended [*] and [*] and for the [*] months ended [*] (the "*Historical Financial Statements*"). The Historical Financial Statements fairly present, in all material respects, the financial condition

and results of operations of the Company as of the dates thereof or for the periods presented therein in substantial conformity with Japanese GAAP, applied on a consistent basis, except as otherwise noted therein and subject, in the case of the interim Historical Financial Statements, to normal year-end adjustments and certain presentation items therein.

Section 3.8 Litigation and Claims. Except as set forth on Schedule 3.8 of the Seller Disclosure Schedule:

(a) there is no civil, criminal or administrative action, suit, demand, claim, hearing or proceeding pending or, to the Knowledge of Seller, threatened against the Company, other than those that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect or materially impair or delay Seller's ability to effect the Closing; and

(b) the Company is not subject to any order, writ, judgment, injunction, decree or award of any Government Entity or any arbitrator or arbitrators, other than those that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect or materially impair or delay Seller's ability to effect the Closing.

Section 3.9 Taxes. Except as set forth on Schedule 3.9 of the Seller Disclosure Schedule or as would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect:

(a) the Company has filed all material Tax Returns required to be filed by it on or before [*] (taking into account all applicable extensions), and the Company has paid all Taxes shown therein as due and owing;

(b) the Tax Returns referred to in Section 3.9(a) above are correct and complete in all material respects;

(c) all deficiencies asserted or assessments made as a result of the examination of such Tax Returns have been paid in full;

(d) no material issues have been raised in writing by the relevant taxing authority in connection with the examination of such Tax Returns or are currently pending; and

(e) no waivers of statute of limitations have been given or requested with respect to any Taxes of the Company.

Section 3.10 Benefit Plans. (a) Seller has listed on Schedule 3.10(a) of the Seller Disclosure Schedule each material written employment, compensation, benefit, severance or similar contract, agreement, arrangement, program, policy or plan providing for workers' compensation, disability benefits, severance, supplemental unemployment benefits, vacation benefits, medical benefits or post-retirement insurance, pension or retirement, or for deferred compensation, profit-sharing, bonuses, stock options, stock appreciation rights or other forms of incentive compensation or benefits that are maintained or contributed for the benefit of any current or former employee of the Company (each, a "*Benefit Plan*"). Seller has made available to Buyer copies of each such Benefit Plan; provided, however, that Buyer acknowledges that

(b) Each Benefit Plan is in substantial compliance with its terms and applicable Japanese or (with respect to Seller's Plans only) U.S. Laws, other than failures to comply that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect. Except as mandated by applicable Japanese or (with respect to Seller's Plans only) U.S. Laws or as set forth on Schedule 3.10(b) of the Seller Disclosure Schedule, there has been no amendment to, or material change in employee participation or coverage under, any Benefit Plan that would increase materially the expense of maintaining such Benefit Plan above the level of expense incurred in respect thereof for the most recent fiscal year ended prior to [*].

(c) Except as set forth on Schedule 3.10(c) of the Seller Disclosure Schedule, none of the execution, delivery or performance of this Agreement will by itself require a payment, or cause acceleration of vesting of a right to payment, under any Benefit Plan.

Section 3.11 Compliance with Laws. Except as set forth on Schedule 3.11 of the Seller Disclosure Schedule, (a) the Company is in compliance with all applicable Laws, other than failures to comply that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect, and (b) the Company has all Governmental Authorizations necessary for the conduct of the Business as currently conducted, other than those the absence of which would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect; it being understood that nothing in this representation is intended to address any compliance issue that is specifically addressed by any other representation or warranty set forth herein.

Section 3.12 Labor. Except as set forth on Schedule 3.12 of the Seller Disclosure Schedule:

(a) the Company is not a party to or bound by any material labor agreement, union contract or collective bargaining agreement with respect to the Employees.

(b) the Company is in compliance in all material respects with all labor Laws applicable to the Business and the Employees, is not engaged in any unfair labor practices contrary to Laws applicable to the Employees and no unfair labor practice charge or complaint against the Company is pending or, to Seller's Knowledge, threatened before any Government Entity.

(c) there is no pending or, to the Knowledge of Seller, threatened strike, walkout or other work stoppage or any union organizing effort by any of the Employees.

Section 3.13 Contracts. (a) Schedule 3.13(a) of the Seller Disclosure Schedule sets forth a complete and accurate list of the following Contracts ("*Material Contracts*"):

- (i) service agreements with clinical research organizations relating to the Licensed Products (as defined in the License Agreements);

- (ii) leases and subleases governing the Leased Real Property;
- (iii) joint venture and partnership agreements;
- (iv) mortgages, indentures, loan or credit agreements, security agreements or other agreements and instruments relating to the borrowing of money or extension of credit, in each case in excess of [*];
- (v) other written Contracts that are not cancelable by the Company on notice of [*] days or some lesser period and that require payment by the Company after [*] of more than [*] on an annual basis; and
- (vi) any agreement containing a non-competition provision restricting the Company.

(b) Subject to existing confidentiality obligations, Seller has made available to Buyer copies of all written Material Contracts and accurate written descriptions of all material terms of all oral Material Contracts.

(c) To the Knowledge of Seller, all Material Contracts are in full force and effect and are enforceable against each party thereto in accordance with the terms thereof. Assuming the receipt of all Seller Required Approvals set forth on Schedule 3.3(b) of the Seller Disclosure Schedule, there does not exist under any Material Contract any violation, breach or event of default or event or condition that (whether after the filing of notice or the lapse of time or both) would constitute a violation, breach or event of default thereunder on the part of the Company or, to the Knowledge of Seller, any other party thereto, except as set forth on Schedule 3.13(c) of the Seller Disclosure Schedule and except for such violations, breaches, events or conditions that would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect or materially impair the ability of Seller or Buyer to perform their respective obligations under this Agreement.

Section 3.14 Absence of Changes. Except as set forth on Schedule 3.14 of the Seller Disclosure Schedule and except as expressly provided in this Agreement (including the transfer of Excluded Assets pursuant to Section 2.2 and the termination of Intercompany Contracts pursuant to Section 5.7) or any Ancillary Agreement, since [*], Seller and the Company have conducted the Business only in the Ordinary Course, and the Company has not experienced any event or condition that, individually or in the aggregate, has had or is reasonably likely to have, a Material Adverse Effect, taking into account Seller's announcements of its intention to sell, and the fact that it is selling, the Company.

Section 3.15 Real and Personal Property. The Company does not own any real property. Except as set forth on Schedule 3.15 of the Seller Disclosure Schedule, the Company has a valid and binding leasehold interest in the Leased Real Property, and has good title to the personal property it owns or leases, free and clear of all Encumbrances, other than Permitted Encumbrances.

Section 3.16 Absence of Liabilities. Except as reflected, reserved against or otherwise disclosed in the Historical Financial Statements and except as set forth on Schedule 3.16 of the

Seller Disclosure Schedule, the Company does not have any liabilities, other than liabilities of a nature not required to be reflected, reserved against or otherwise disclosed in the Historical Financial Statements and liabilities that were incurred since the date of the Historical Financial Statements and would not, individually or in the aggregate, be reasonably likely to have a Material Adverse Effect.

Section 3.17 Insurance. Schedule 3.17 of the Seller Disclosure Schedule lists all material insurance policies of the Company covering its properties, assets, employees and operations (including policies providing property, casualty, liability, and workers' compensation coverage). All of such policies or renewals thereof are in full force and effect and, to the Knowledge of Seller, will continue in full force and effect until [*].

Section 3.18 Finders' Fees. Except for [*], all of whose fees will be paid by Seller, there is no investment banker, broker, finder or other intermediary that has been retained by or is authorized to act on behalf of Seller or the Company who might be entitled to any fee or commission from Seller or the Company in connection with the transactions contemplated hereby or by any Ancillary Agreement.

Section 3.19 No Other Representations or Warranties. Except for the representations and warranties contained in this Article, neither Seller nor any other Person makes any other express or implied representation or warranty on behalf of Seller.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF BUYER

As of [*], Buyer represents and warrants to Seller as follows:

Section 4.1 Organization. Buyer is a corporation duly organized, validly existing and in good standing under the Laws of Japan. Buyer has all requisite corporate power and authority to own, lease and operate its properties and assets and to conduct its business as it is currently being conducted.

Section 4.2 Corporate Authorization. Buyer has full corporate power and authority to execute and deliver this Agreement, and to perform its obligations hereunder. The execution, delivery and performance by Buyer of this Agreement has been duly and validly authorized and no additional corporate or shareholder authorization or consent is required in connection with the execution, delivery and performance by Buyer of this Agreement.

Section 4.3 Consents and Approvals. Except for the Post-Closing Notification, no consent, approval, waiver, authorization, notice, submission or filing is required to be obtained by Buyer from, or to be given by Buyer to, or made by Buyer with, any Government Entity or other Person in connection with the execution, delivery and performance by Buyer of this Agreement, other than those the failure of which to obtain, give or make would not, individually or in the aggregate, materially impair or delay the ability of Buyer to effect the Closing or to perform its obligations under this Agreement.

Section 4.4 Non-Contravention. The execution, delivery and performance by Buyer of this Agreement do not and will not (a) violate any provision of the certificate of incorporation, bylaws or articles of incorporation (or similar organizational documents) of Buyer, (b) result in the breach of, or constitute a default under, or result in the termination, cancellation, modification or acceleration (whether after the filing of notice or the lapse of time or both) of, any material right or obligation of Buyer under, or result in a loss of any material benefit to which Buyer is entitled under, any contract, agreement or arrangement to which it is, or its assets are, subject, or result in the creation of any Encumbrance upon any of its assets, or (c) assuming the filing of the Post-Closing Notification and the receipt of the Seller Required Approvals set forth on Schedule 3.3(a) of the Seller Disclosure Schedule, to the Knowledge of Buyer, violate or result in a breach of, or constitute a default under, any Law to which Buyer is subject, other than, in the case of clauses (b) and (c), violations, breaches, defaults, terminations, cancellations, accelerations, losses or Encumbrances that would not, individually or in the aggregate, impair or delay the ability of Buyer to effect the Closing or to perform its obligations under this Agreement.

Section 4.5 Binding Effect. This Agreement, when duly executed and delivered by Seller, constitutes a valid and legally binding obligation of Buyer, enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar Laws affecting creditors' rights and remedies generally and to general principles of equity, including principles of commercial reasonableness, good faith and fair dealing (regardless of whether enforcement is sought in a proceeding at Law or in equity).

Section 4.6 Finders' Fees. Except for [*], all of whose fees will be paid by Buyer, there is no investment banker, broker, finder or other intermediary that has been retained by or is authorized to act on behalf of Buyer or any Affiliate of Buyer who might be entitled to any fee or commission from Buyer in connection with the transactions contemplated hereby or by any Ancillary Agreement.

Section 4.7 Litigation and Claims. There is no civil, criminal or administrative action, suit, demand, claim, hearing or proceeding pending or, to the Knowledge of Buyer, threatened against Buyer that, individually or in the aggregate, would impair or delay the ability of Buyer to effect the Closing. Buyer is not subject to any order, writ, judgment, injunction, decree or award of any Government Entity or any arbitrator or arbitrators that, individually or in the aggregate, would impair or delay the ability of Buyer to effect the Closing.

Section 4.8 Financial Capability. On [*], Buyer will have sufficient funds to effect the Closing and all other transactions contemplated hereby or by any Ancillary Agreement.

Section 4.9 No Other Representations or Warranties. Except for the representations and warranties contained in this Article, neither Buyer nor any other Person makes any other express or implied representation or warranty on behalf of Buyer.

ARTICLE V

COVENANTS

Section 5.1 Access and Information. (a) During the period from [*] until [*], subject to any applicable Laws relating to the exchange of information and existing confidentiality obligations, Seller shall, or shall cause the Company to, provide to Buyer and its Representatives information reasonably requested by Buyer relating to the assets of the Company (other than the Excluded Assets), the Books and Records and the Employees; provided, however, that in no event shall Buyer be entitled to any information that (i) based on advice of Seller's counsel, would create any potential liability under applicable Laws, including Competition Laws, or would destroy any legal privilege, or (ii) in the reasonable judgment of Seller, would result in the disclosure of any Trade Secrets of Seller or any third party; it being understood that Buyer shall reimburse Seller promptly for expenses it incurs in complying with any such request by or on behalf of Buyer. All requests for information made pursuant to this clause (a) shall be directed to such Person or Persons as Seller shall designate. All information received pursuant to this clause (a) shall be governed by the terms of the Confidentiality Agreement.

(b) Buyer agrees to retain all Books and Records in existence on [*] for a reasonable period following [*] and to make personnel of Buyer available to Seller, in each case to the extent that such access is reasonably necessary for Seller to comply with the terms of this Agreement, any Ancillary Agreement or any applicable Law. In no event shall either Party have access to the consolidated Tax Returns of the other Party.

Section 5.2 Conduct of Business. During the period from [*] until [*], except as set forth on Schedule 5.2 of the Seller Disclosure Schedule or otherwise expressly contemplated by this Agreement (including the transfer of Excluded Assets pursuant to Section 2.2 and the termination of Intercompany Contracts pursuant to Section 5.7) or any Ancillary Agreement, or as Buyer shall otherwise consent in writing (which consent shall not be unreasonably withheld or delayed), (a) Seller shall conduct, and shall cause the Company to conduct, the Business in the Ordinary Course, and (b) Seller shall not, and shall cause the Company not to, with respect to the Business:

- (i) change or amend the articles of incorporation of the Company;
- (ii) issue or sell or authorize for issuance and sale any shares of capital stock of the Company, or any securities convertible into or exchangeable for, or options with respect to, or warrants to purchase or rights to subscribe for, any shares of capital stock of the Company;
- (iii) declare, set aside or pay any dividend or other distribution in respect of the shares of Common Stock of the Company;
- (iv) directly or indirectly redeem, purchase or otherwise acquire any shares of Common Stock of the Company;
- (v) merge or consolidate the Company with or into any other Person or engage in any business combination of any kind;

(vi) change any material accounting principles, practices, methodologies or policies, other than as may be required by Japanese GAAP, U.S. generally accepted accounting principles or applicable Laws;

(vii) grant any material increase in the compensation payable by the Company to any of its directors or officers or to the Employees or in the amount of existing benefits under any Benefit Plan, in each case other than increases in the Ordinary Course (including any merit, special or promotional increase, bonus or equity incentive award) or as may be required by applicable Laws, and except for any one-time payment to the Employees that Seller, in its sole discretion, may make or fund;

(viii) other than any capital expenditure or commitment not to exceed [*], enter into any Material Contract or terminate or amend, in any material manner, any Material Contract;

(ix) take any action that would cause insurance coverage for the Business at currently existing levels to cease to be maintained in full force and effect;

(x) write off or write down, or make any sale, assignment or transfer of any material asset of the Company outside of the Ordinary Course, except for the transfer of Excluded Assets pursuant to Section 2.2;

(xi) waive or release any material right or claim of the Company;

(xii) incur any long-term indebtedness for borrowed money, other than in the Ordinary Course; and

(xiii) enter into any agreement obligating Seller or the Company to do any of the foregoing.

Section 5.3 Commercially Reasonable Efforts. Seller and Buyer shall cooperate and use their respective commercially reasonable efforts to fulfill as promptly as practicable the conditions precedent to the other Party's obligations hereunder. To the extent that, as an accommodation to Buyer and with Buyer's written consent, Seller incurs costs that Buyer otherwise would have to incur in order to secure any consent, approval, waiver or authorization, Buyer shall promptly reimburse Seller for any such costs that are invoiced by Seller to Buyer.

Section 5.4 JFTC Post-Closing Notification. Within [*] days following [*], Buyer shall file with the Japan Fair Trade Commission ("*JFTC*") a post-Closing notification in connection with the implementation of this Agreement and the transactions contemplated hereby (the "*Post-Closing Notification*") and shall provide Seller with evidence of such filing reasonably satisfactory to Seller. The costs (including all legal costs) of, and incidental to, such filing and any administrative fees and other fees (including any filing fee) payable to the JFTC shall be borne by Buyer. Subject to applicable Laws relating to the exchange of information and existing confidentiality obligations, (i) Buyer and Seller shall cooperate and consult in good faith in relation to the preparation and filing of the Post-Closing Notification and any other notification, submission or filing with the JFTC; provided, however, that, if the information requested contains information that is confidential or proprietary to the providing Party, such Party shall

not be required to disclose such information to the other Party and may procure the submission thereof directly to the JFTC or to the legal advisors of the Parties appointed to handle the requisite submission with strict instructions that such information is provided solely for submission to the JFTC or such other Government Entity and may not be disclosed to any other party, and (ii) prior to the filing of the Post-Closing Notification or any other notification, submission or filing with the JFTC by Buyer, Seller shall have approved the final content thereof (which approval shall not be unreasonably withheld or delayed). Buyer shall timely inform Seller of any meetings that Buyer may have with the JFTC and Representatives of Seller shall be permitted to attend such meetings. If any Party receives any correspondence or communication from the JFTC, such Party shall, as soon as possible after the receipt thereof, furnish the other Party with a copy of such correspondence or inform the other Party of the content of the communication.

Section 5.5 Tax Matters. (a) *Section 338(g) Election*.

(i) Buyer, at the request of Seller, shall timely make an election under Section 338(g) of the Code (and any comparable provisions of state, local or non-U.S. Tax Law) with respect to its purchase of the Transferred Shares (the "*Section 338(g) Election*"). Seller and Buyer shall jointly prepare the Section 338 Forms and shall timely make any required filings and take any and all other actions necessary to effect the Section 338(g) Election. For purposes of this clause, "*Section 338 Forms*" means all Tax Returns, documents, statements and other forms that are required to be submitted to the U.S. Internal Revenue Service or any state, local or non-U.S. Government Entity in connection with the Section 338(g) Election, including the IRS Forms 8023 and 8883 (including, in each case, any schedules or attachments required to be attached thereto) and any other forms required to be filed by Treasury Regulations promulgated under Section 338 of the Code or instructions to the Tax Returns.

(ii) In connection with the Section 338(g) Election, Seller shall prepare a draft IRS Form 8883 (or successor form) and provide such draft IRS Form 8883 to Buyer no later than [*] days prior to the due date of such IRS Form 8883. If, within [*] days after the receipt of the draft IRS Form 8883, Buyer notifies Seller in writing that Buyer disagrees with the draft IRS Form 8883, then the Parties shall attempt in good faith to resolve their disagreement within the [*] days following Buyer's notification to Seller of such disagreement. If Buyer does not so notify Seller within [*] days after the receipt of the draft IRS Form 8883, or upon resolution of the disputed items by the Parties, the draft IRS Form 8883 shall become the "Final IRS Form 8883". If the Parties are unable to resolve their disagreement within the [*] days following any such notification by Buyer, then the Parties shall submit all such disputed items for resolution to a nationally recognized accounting firm mutually acceptable to the Parties (the "*Independent Accounting Firm*"), whose decision shall be final and binding upon all Persons involved and whose fees and expenses shall be borne equally by the Parties. The IRS Form 8883 delivered by the Independent Accounting Firm shall be the "Final IRS Form 8883". The Parties shall act in good faith to cause the Independent Accounting Firm to deliver the Final IRS Form 8883 within [*] days after such submission. Each Party shall be bound by the allocations described in this clause for all purposes, including determining any Tax, shall (and shall cause its common parent, if any, to) prepare and file all Tax Returns

in a manner consistent with the Section 338(g) Election and such allocations, and shall not take (or permit any Affiliate to take) any position inconsistent with the Section 338(g) Election or such allocations in any Tax Return, any proceeding before a Government Entity or otherwise. The Purchase Price allocation pursuant to the Final IRS Form 8883 shall be appropriately adjusted if and when any Purchase Price adjustments are made pursuant to this Agreement. In the event the allocation is disputed by any Government Entity, the Party receiving the notice of such dispute shall promptly notify and consult with the other Party concerning the resolution of such dispute, and shall keep the other Party apprised of the status of such dispute and the resolution thereof.

(b) *Liability for Taxes.*

(i) Seller shall be liable for all Taxes imposed on the Company for any taxable periods, or portions thereof, ending on or before [*].

(ii) Buyer shall be liable for all Taxes imposed on the Company for any taxable year, or portion thereof, beginning after [*].

(iii) To the extent necessary to determine the liability for Taxes for a portion of a taxable year or period that begins before and ends after [*], the determination of the Taxes for the portion of the year or period ending on, and the portion of the year or period beginning after, [*] shall be determined by assuming that the taxable year or period ended as of the close of business on [*], except that those annual property taxes and similar Taxes and exemptions, allowances or deductions that are calculated on an annual basis shall be prorated on a time basis.

(c) *Tax Returns.* Seller shall file, or cause to be filed, when due all Tax Returns that are required to be filed by or with respect to the Company for taxable years or periods ending on or before [*] and shall pay any Taxes due in respect of such Tax Returns, and Buyer shall file, or cause to be filed, when due all Tax Returns that are required to be filed by or with respect to the Company for taxable years or periods ending after [*]. Seller shall pay Buyer the Taxes for which Seller is liable pursuant to Section 5.5(b) (but which are payable with Tax Returns to be filed by Buyer pursuant to the previous sentence) within [*] days prior to the due date for the filing of such Tax Returns, and Buyer shall timely pay all other Taxes imposed on the Company for the periods, or portions thereof, ending after [*].

(d) *Contest Provisions.*

(i) Buyer shall promptly, but in no event more than [*] days following Buyer's receipt of notice, notify Seller in writing upon receipt by Buyer or any of its Affiliates of notice of any pending or threatened tax audits, assessments, disputes or proceedings ("*Tax Proceedings*") that may affect the Tax liabilities of the Company for which Seller would be liable hereunder; provided, however, that failure to comply with this provision shall not affect Buyer's rights hereunder, except to the extent that Seller is prejudiced by such failure.

(ii) Buyer shall take all reasonable steps necessary to conduct any Tax Proceedings relating to any claim relating to Taxes for which Seller may be liable

hereunder diligently and in good faith, using commercially reasonable efforts to minimize Seller's liability hereunder. Seller shall be entitled to participate in and control at its own expense the conduct or resolution of any Tax Proceedings relating to any claim relating to Taxes for which Seller may be liable hereunder. Neither Buyer nor the Company may agree to settle, compromise or offer to settle or compromise any Tax claim for which Seller may be liable hereunder without the prior written consent of Seller (which consent shall not be unreasonably withheld or delayed).

(e) *Information.* Seller and Buyer agree to furnish, or cause to be furnished, to the other Party, promptly upon reasonable request therefor, information and assistance relating to the Company as Buyer or Seller, as the case may be, reasonably deems necessary in connection with the filing of any Tax Returns, the preparation for any audit by any taxing authority, the response to any inquiry by a taxing authority, the mailing or filing of any notice and the prosecution or defense of any Tax Proceedings or any other filing required to be made with any taxing authority or any other matter related to Taxes.

(f) *Transfer Taxes.* Any transfer, stamp, value-added, sales, use, excise, documentary or other similar Taxes and fees (collectively, "*Transfer Taxes*"), that are payable or that arise as a result of the consummation of the transactions contemplated hereby, and any recording or filing fees with respect thereto, shall be paid by Buyer. Buyer shall prepare and timely file all relevant Tax Returns required to be filed in respect of such Transfer Tax and pay the Transfer Tax shown on such Tax Return.

(g) *Adjustment to Cash Purchase Price.* To the extent allowed under applicable Law, any payment by Buyer or Seller under this Section shall be an adjustment to the Purchase Price.

(h) *Survival of Obligations.* The obligations of the Parties set forth in this Section shall remain in effect until the expiration of the applicable statute of limitations.

Section 5.6 Employee Matters. (a) Seller shall cooperate with Buyer in making any and all appropriate governmental filings, giving employee notices or taking any other actions reasonably necessary to maintain, amend, terminate and administer the Benefit Plans (other than Seller's Plans) as of [*] or after [*], as Buyer deems fit, subject to the other provisions of this Section. Buyer shall pay all costs associated with such actions and shall reimburse Seller for any costs incurred by Seller in complying with its obligations under this Section.

(b) Nothing in this Section, express or implied, is intended to confer upon any Person other than Buyer, Seller, the Indemnified Parties and their respective successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

Section 5.7 Intercompany Contracts and Accounts. Except as otherwise expressly provided in this Agreement or any Ancillary Agreement, Seller shall take all actions necessary, prior to or concurrent with [*], (a) to terminate, wind up or otherwise settle as Seller deems fit all agreements between the Company, on the one hand, and Seller or any of its Affiliates (other than the Company), on the other hand (each, an "*Intercompany Contract*"), and (b) to cause the net amount of intercompany accounts between the Company, on the one hand, and the Seller or any

of its Affiliates (other than the Company), on the other hand, to be satisfied in full by the Seller or by the Company, as the case may be.

Section 5.8 Further Assurances. (a) *General*. From time to time after [*], each Party shall, and shall cause its Affiliates to, promptly do and perform all such further acts and things and shall execute, acknowledge and deliver such other assurances, agreements, certificates, powers of attorney and other 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.

(b) *Nonassignability of Excluded Assets*. Notwithstanding anything to the contrary contained herein, to the extent that the sale, assignment, sublease, transfer, conveyance or delivery or attempted sale, assignment, sublease, transfer, conveyance or delivery by the Company to Seller of any asset that would be an Excluded Asset or any claim or right or any benefit arising thereunder or resulting therefrom is prohibited by any applicable Law or would require any governmental or third party authorizations, approvals, consents or waivers, and such authorizations, approvals, consents or waivers shall not have been obtained prior to [*], [*] shall proceed without the sale, assignment, sublease, transfer, conveyance or delivery of such asset. Following [*], the Parties and their respective Affiliates shall use their commercially reasonable efforts, and cooperate with each other, to, at Seller's option, (i) obtain promptly such authorizations, approvals, consents or waivers and (ii) terminate, wind up or mitigate the costs associated with such asset; provided, however, that none of Seller, Buyer or the Company shall be required to pay any consideration therefor, other than filing, recordation or similar fees, which shall be borne by Seller. If Seller elects to obtain such authorization, approval, consent or waiver pursuant to clause (i), (A) pending such authorization, approval, consent or waiver, the Parties and their respective Affiliates shall cooperate with each other in any mutually agreeable, reasonable and lawful arrangements designed to provide to Seller the benefits of use of such asset (including preserving the confidentiality of any Confidential Information related thereto) and to Buyer the benefits that it would have obtained had such asset been conveyed by the Company to Seller prior to [*]; (B) once authorization, approval, consent or waiver for the sale, assignment, sublease, transfer, conveyance or delivery of any such asset is obtained, Buyer shall, or shall cause the Company to, sell, assign, sublease, transfer, convey or deliver such asset to Seller at no additional cost; and (C) to the extent that any such asset cannot be transferred or the full benefits of use of any such asset cannot be provided to Seller following [*] pursuant to this Section, then Buyer or the Company and Seller shall enter into such arrangements (including subleasing, sublicensing or subcontracting) to provide to the Parties hereto the economic (taking into account Tax costs and benefits) and operational equivalent, to the extent permitted, of obtaining such authorization, approval, consent or waiver and the performance by Buyer or the Company, as the case may be, of the obligations thereunder.

(c) *Additional Assurances in Connection with the Transition of the Excluded Assets*. The Parties acknowledge that it is in their mutual interests to effect the Closing as soon as practicable in accordance with Section 2.4. Buyer acknowledges that Seller intends to work diligently to cause the Company to transfer the Excluded Assets to Seller and/or its designee prior to [*] pursuant to Section 2.2; provided, however, that the Parties expect that all such asset transfers will not have been completed as of [*], and Buyer shall, and shall cause the

Company to, cooperate with Seller from and after [*] to ensure a timely, orderly and complete transition of the Excluded Assets from the Company to Seller and/or its designee in a manner that fully protects the confidential and proprietary nature of such Excluded Assets (including in respect of Buyer). Without limiting the generality of the foregoing, (i) to the extent that any Excluded Asset has not been transferred by the Company to Seller or its designee prior to [*], Buyer shall, or shall cause the Company to, promptly assign and transfer to Seller or its designee all right, title and interest in and to such asset and, to the extent such assignment and transfer would require any governmental or third party authorizations, approvals, consents or waivers, cooperate with Seller in the same manner as that set forth in Section 5.8(b), and (ii) Buyer shall cause the Company and its employees to provide to Seller and/or its designee such services as Seller may reasonably request, at Seller's expense and direction, to complete the timely transition of the Excluded Assets from the Company to Seller and/or its designee, in a manner designed to protect and preserve the Seller Confidential Information (including in respect of Buyer), and to ensure Seller's compliance with applicable Laws and existing third-party obligations in respect of the Excluded Assets, and on such other terms and conditions as the Parties may mutually agree.

(d) [*] and Support Services.

(i) In furtherance of Section 5.8(c), prior to [*] Seller may, and during a period of time after [*] not to exceed [*] (the "[*] Period") at Seller's request, Buyer shall, cause the Company to [*] for the [*] Period those Employees to be identified by Seller and reasonably agreed to by Buyer (the "[*] Employees"); provided, however, that (A) in no event shall the number of such [*] Employees in each area of expertise be less than is reasonably necessary to complete the timely transition of the Excluded Assets from the Company to Seller and/or its designee in compliance with applicable Laws and existing third-party obligations, and (B) such [*] Employees shall include those Employees who have been directly engaged in clinical development operations and clinical safety in respect of the Excluded Assets as of [*], including all [*] and Employees involved in [*]. Without limiting the foregoing, prior to [*] Seller may include in the [*] described herein at least the critical Employees whose names are set forth on Schedule 5.8(d) (the "*Critical Employees*"), and during the [*] Period at Seller's request, Buyer shall cause the Company to use commercially reasonable efforts to ensure that the [*] Employees include at least the Critical Employees. Buyer shall, and shall cause the Company to, use commercially reasonable efforts to facilitate and obtain the relevant [*] in connection with the [*] described herein. Prior to [*] Seller may, and during the [*] Period at Seller's request, Buyer shall, cause the Company to enter into such agreements or arrangements with its consultants and temporary contractors who are directly engaged in [*] in respect of the Excluded Assets as of [*], including at least the critical temporary contractors whose names are set forth on Schedule 5.8(d) (the "*Service Providers*"), to cause them to continue to provide such services [*] after [*] under [*]. Seller and/or its designee shall [*] Employees and the Service Providers, and shall be entitled to [*] Employees and the Service Providers such [*] as Seller and/or its designee may determine in its sole discretion. Notwithstanding anything to the contrary contained herein, Buyer shall cause the Company to provide that any Benefit Plan in which the [*] Employees are eligible to participate will take into account, for purposes of determining eligibility and benefits thereunder, the [*] with the Company, and otherwise to provide

the [*] Employees with such compensation, benefit and other opportunities as to which the [*] Employees would [*] with the Company. During the [*] Period, Buyer shall not, and shall cause the Company not to, provide any [*] Employees or Service Providers, and shall use commercially reasonable efforts to [*] Employees and Services Providers.

(ii) During the [*] Period, at Seller's request, Buyer shall cause the Company to (A) [*] Employees and Service Providers, [*] and information technology resources (collectively, the "Facility Resources") to be agreed by the Parties, comprising (x) in respect of [*] Employees as of [*], and (y) such other additional Facility Resources as the Parties may agree in good faith are reasonably necessary to enable the [*] Employees and Service Providers to complete the timely transition of the Excluded Assets from the Company to Seller and/or its designee, in a manner designed to protect and preserve the Seller Confidential Information (including in respect of Buyer), and to ensure Seller's compliance with applicable Laws and existing third-party obligations in respect of the Excluded Assets (the "Designated Facilities"), (B) permit [*] Employees and Service Providers, (C) provide to Seller and/or its designee such clinical data management services as shall be reasonably requested by Seller in support of the Excluded Assets and are not otherwise being provided by the [*] Employees and Service Providers, including [*] (the "Support Services"), and (D) provide to Seller and/or its designee such [*] as shall be reasonably requested by Seller to ensure drug supply for ongoing clinical studies in connection with the Excluded Assets ("Laboratory Access"). [*]

(e) *Additional Agreements.* To the extent that Seller requests that the rights and obligations of the Parties and/or the Company in connection with the transition of the Excluded Assets (including any [*] of the [*] Employees and arrangements in respect of the [*] Support Services and [*]) be described in further detail in additional written assurances, agreements and other instruments and documents, the Parties shall, and shall cause the Company to, cooperate and work diligently in good faith to negotiate and execute such assurances, agreements and other instruments and documents (including [*] agreements with the [*] Employees, transition services agreements and other similar agreements). Notwithstanding anything to the contrary contained herein, (i) at Seller's request and to the extent practicable, the Parties shall work diligently and in good faith to enter into all or any such agreements prior to [*], and (ii) Seller, in consultation with Buyer, shall be entitled to cause the Company to enter into all or any such agreements prior to [*] and such agreements shall survive [*] and shall not be required to be terminated in accordance with Section 5.7.

(f) *Specific performance.* Buyer acknowledges and agrees that any breach of this Section 5.8 would give rise to irreparable harm for which monetary damages would not be an adequate remedy. Buyer accordingly agrees that, in addition to all other available remedies, Seller shall be entitled to enforce the terms of this Section by decree of specific performance without the necessity of proving the inadequacy of monetary damages as a remedy and to obtain injunctive relief against any breach or threatened breach of this Section.

Section 5.9 Confidentiality. (a) Except as otherwise agreed by Seller in writing (including pursuant to this Agreement or any other Ancillary Agreement), (i) promptly after [*], Buyer shall make a request to the Company to instruct its employees not to disclose to Buyer,

Buyer's Representatives or any other third parties, or use for any purpose whatsoever (except as contemplated by Section 5.8), any information, knowledge or data required for, relating to, or used in connection with, the Excluded Assets or the Excluded Liabilities, including in connection with any services provided by the Company to Seller pursuant to Section 5.8(c)(ii), or which is known to the Company and its employees as a result of their affiliation or cooperation with Seller (the "Seller Confidential Information"); it being understood that, as soon as practicable after [*], Buyer shall use best efforts to enter into an agreement with the Company whereby the Company shall use its reasonable efforts to cause its employees not to disclose to Buyer, Buyer's Representatives or any other third parties, or use for any purpose whatsoever (except as contemplated by Section 5.8), the Seller Confidential Information after the conclusion of such agreement between Buyer and the Company, and Buyer shall enforce such agreement and use reasonable efforts to mitigate any adverse consequences arising from the Company's non-compliance therewith; (ii) Buyer shall not solicit or otherwise encourage the disclosure of Seller Confidential Information by the Company to Buyer or Buyer's Representatives, (iii) if, despite having met its obligations to Seller in clauses (i) and (ii) above, Buyer receives Seller Confidential Information or Seller Confidential Information otherwise becomes known to Buyer, Buyer and Buyer's Representatives shall return or, at Seller's request, destroy such information, and (iv) Buyer and Buyer's Representatives shall not, and Buyer shall obligate the Company pursuant to the agreement between Buyer and the Company referred to in clause (i) above not to, use such information for any purpose whatsoever (other than, with respect to the Company, as contemplated by Section 5.8) or disclose it to any third party. Buyer shall not, and shall cause the Company not to, authorize any use (except as contemplated by Section 5.8) or disclosure to third parties of Seller Confidential Information. If Buyer becomes aware of any violation of the provisions of this Section 5.9, Buyer shall promptly notify Seller and shall take all reasonable steps necessary to cease and cure such violation to Seller's satisfaction. Before [*], Seller shall use best efforts to enter into an agreement with the Company whereby the Company shall cause its employees not to disclose to Buyer, Buyer's Representatives or any other third parties, or use for any purpose whatsoever (except as contemplated by Section 5.8), the Seller Confidential Information prior to, on or after [*] (which agreement shall not be required to be terminated in accordance with Section 5.7). If Seller so requests at any time, Buyer shall request the Company and its employees to promptly return to Seller or, upon notice from Seller, promptly destroy all copies of Seller Confidential Information and all copies, notes, extracts or other derivative works based thereon. Buyer shall request the Company to certify any such destruction of Seller Confidential Information in writing and provide such certification to Seller within 10 days following Seller's request for such destruction.

(b) Buyer and Seller acknowledge that the confidentiality obligations set forth herein shall not extend to information, knowledge and data to the extent that it can be established by Buyer by written documentation that such information (i) was already known to Buyer, other than under an obligation of confidentiality (except to the extent such obligation was to a third party other than Seller or any of its Affiliates and has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure, (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to Buyer, (iii) 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 Buyer in breach of this Agreement, (iv) was independently developed without use of or reference to Confidential Information by Buyer as demonstrated by documented

evidence prepared contemporaneously with such independent development, or (v) was disclosed to Buyer, other than under an obligation of confidentiality (except to the extent such obligation was to a third party other than Seller or any of its Affiliates and has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a third party who had no obligation to Seller or any of its Affiliates not to disclose such information to others.

(c) The confidentiality obligations in this Section shall survive [*] for a period of [*] years. In the event of a breach of the obligations under this Section by Buyer, Seller, in addition to all other available remedies, shall be entitled to injunctive relief to enforce the provisions of this Section in any court of competent jurisdiction.

Section 5.10 Public Disclosure. Neither Party shall disclose the terms and conditions of this Agreement to any other Person, except to such Party's Representatives subject to confidentiality obligations as restrictive as those contained herein and as may be required by applicable Law. Notwithstanding the foregoing, with respect to complying with the disclosure requirements of any Government Entity in connection with any required filing of this Agreement, the Parties shall consult with one another concerning which terms of this Agreement shall be requested to be redacted in any public disclosure of the Agreement, and in any event each Party shall, at the request of the other Party, seek reasonable confidential treatment for any public disclosure by any such Government Entity. Notwithstanding the foregoing, the Parties have agreed upon and shall release a mutual press release to announce the execution of this Agreement in the form attached hereto as Exhibit 5.10 for use in responding to inquiries about this Agreement. Thereafter, Seller and Buyer may each disclose the information contained in such press release without the need for further approval by the other Party. Each Party shall have the right to issue additional press releases with the prior written consent of the other Party or as required to comply with any applicable Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing [*] notice to the other Party and reasonably considering comments provided by such other Party within [*] after such notice).

Section 5.11 Name Change. Within [*] following [*], Buyer shall cause the name of the Company to be changed from Amgen Kabushiki Kaisha to a name selected by Buyer and complete the filing required to reflect such name change in the corporate registration of the Company. With respect to any signs, business cards, stationery or similar materials carrying a Trademark or embodying a Copyright of Seller, Buyer shall, and shall cause the Company to, promptly return to Seller or, upon notice from Seller, destroy all such materials.

Section 5.12 Payment of Certain Liabilities. Notwithstanding anything to the contrary contained herein, Buyer shall cause the Company to timely pay, perform or otherwise satisfy the liabilities reflected on the Closing Date Balance Sheet, including the compensation and other benefits set forth on Schedule 5.2 of the Seller Disclosure Schedule.

ARTICLE VI

CONDITIONS TO CLOSING

Section 6.1 Conditions to the Obligations of Buyer and Seller. The obligations of the Parties to effect the Closing are subject to the satisfaction (or waiver, to the extent permissible under applicable Law) prior to the Closing of the following conditions:

(a) *No Prohibition*. No Law shall be in effect prohibiting the sale and purchase of the Transferred Shares.

Section 6.2 Conditions to the Obligations of Buyer. The obligation of Buyer to effect the Closing is subject to the satisfaction (or waiver by Buyer) prior to [*] of the following conditions:

(a) *Representations and Warranties*. Each of the representations and warranties of Seller contained in this Agreement (considered without regard to any reference to materiality qualifiers such as “material” and “Material Adverse Effect” set forth therein) shall be true and correct as of [*] and as of [*] as if made on and as of [*] (except for such representations and warranties that are made as of a specific date, which shall speak only as of such date), except where the failure of such representations and warranties to be so true and correct has not had and is not reasonably likely to have, individually or in the aggregate with any other failures of such representations and warranties to be true and correct, a Material Adverse Effect.

(b) *Covenants*. Each of the covenants and agreements of Seller to be performed on or prior to [*] shall have been duly performed, except where the failure to perform such covenants and agreements has not had and is not reasonably likely to have, individually or in the aggregate with any other failures to perform such covenants and agreements, a Material Adverse Effect.

(c) *Ancillary Agreements*. Each of the License Agreements and the Supply Agreement shall have become effective in accordance with its terms and shall be in full force and effect.

(d) *Certificate*. Buyer shall have received a certificate, signed by a duly authorized officer of Seller and dated [*], to the effect that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.

Section 6.3 Conditions to the Obligations of Seller. The obligation of Seller to effect the Closing is subject to the satisfaction (or waiver by Seller) prior to the Closing of the following conditions:

(a) *Representations and Warranties*. Each of the representations and warranties of Buyer contained in this Agreement that is qualified by a materiality standard shall be true and correct as of [*] and as of [*] as if made on and as of [*] (except for such representations and warranties that are made as of a specific date, which shall speak only as of such date) and each of the representations and warranties of Buyer contained in this Agreement that is not qualified by a materiality standard shall be true and correct in all material respects as of [*]

and as of [*] as if made on and as of [*] (except for such representations and warranties that are made as of a specific date, which shall speak only as of such date).

(b) *Covenants*. Each of the covenants and agreements of Buyer to be performed on or prior to [*] shall have been duly performed in all material respects.

(c) *Ancillary Agreements*. Each of the License Agreements and the Supply Agreement shall have become effective in accordance with its terms and shall be in full force and effect.

(d) *Certificate*. Seller shall have received a certificate, signed by a duly authorized officer of Buyer and dated [*], to the effect that the conditions set forth in Sections 6.3(a) and 6.3(b) have been satisfied.

ARTICLE VII

SURVIVAL; INDEMNIFICATION; REMEDIES

Section 7.1 Survival. (a) The representations and warranties of Seller and Buyer contained in this Agreement shall survive [*] for the period set forth in this Section. All representations and warranties contained in this Agreement and all claims with respect thereto shall terminate upon the expiration of [*] after [*], except that the representations and warranties contained in Sections 3.1, 3.2, 3.5, 3.6, 4.1, 4.2 and 4.5 shall survive forever; it being understood that, in the event that notice of any claim for indemnification under Section 7.2(a) or 7.3 has been given (within the meaning of Section 9.1) within the applicable survival period, the representations and warranties that are the subject of such indemnification claim shall survive with respect to such claim until the time of Final Determination of such claim.

(b) All covenants and agreements of Seller and Buyer contained in this Agreement shall survive [*] (and shall not be merged into any transfer or closing instruments or documents) for a period of [*] after [*], except that the covenants and agreements contained in Sections 5.1(b), 5.5, 5.8, 5.9 and 5.10 shall survive in accordance with their respective terms; it being understood that, in the event that notice of any claim for indemnification under Section 7.2(a) or 7.3 has been given (within the meaning of Section 9.1) within the applicable survival period, the covenants and agreements that are the subject of such indemnification claim shall survive with respect to such claim until the time of Final Determination of such claim.

Section 7.2 Indemnification by Seller. (a) Seller hereby agrees that, from and after [*], it shall indemnify, defend and hold harmless Buyer and its directors, officers and employees (other than the Employees), each in their capacity as such (the “*Buyer Indemnified Parties*” and, collectively with the Seller Indemnified Parties, the “*Indemnified Parties*”), from, against and in respect of any damages, losses, payments, liabilities, charges, claims, demands, actions, suits, proceedings, judgments, settlements, assessments, deficiencies, taxes, interest, penalties, and costs and expenses (including reasonable accountants’ and attorneys’ fees, and reasonable out-of-pocket disbursements) (collectively, “*Losses*”) imposed on, sustained, incurred or suffered by, any of the Buyer Indemnified Parties, whether in respect of third-party claims, claims between

the Parties, or otherwise, directly or indirectly relating to, arising out of or resulting from (i) subject to Section 7.2(b), any breach of any representation or warranty made by Seller contained in this Agreement for the period such representation or warranty survives, (ii) any breach of any covenant or agreement of Seller contained in this Agreement for the period such covenant or agreement survives, and (iii) any of the Excluded Liabilities.

(b) Seller shall not be liable to the Buyer Indemnified Parties for any individual Loss with respect to the matters contained in Section 7.2(a)(i) unless (i) such individual Loss exceeds the Individual Loss Limit and (ii) the aggregate amount of all such individual Losses in excess of the Individual Loss Limit exceeds the Aggregate Loss Limit, and then only for such Losses in excess of the Aggregate Loss Limit up to an aggregate amount equal to [*]% of the Purchase Price.

Section 7.3 Indemnification by Buyer. Buyer hereby agrees that, from and after [*], it shall indemnify, defend and hold harmless Seller and its directors, officers and employees, each in their capacity as such (the "*Seller Indemnified Parties*"), from, against and in respect of any Losses imposed on, sustained, incurred or suffered by, any of the Seller Indemnified Parties, whether in respect of third-party claims, claims between the Parties, or otherwise, directly or indirectly relating to, arising out of or resulting from (a) any breach of any representation or warranty made by Buyer contained in this Agreement for the period such representation or warranty survives, (b) any breach of a covenant or agreement of Buyer contained in this Agreement for the period such covenant or agreement survives, and (c) the Business, the assets of the Company or the Employees to the extent attributable to the operation or ownership of the Business or the assets of the Company, or the employment of the Employees, following [*] (including liabilities relating to (A) investigation, removal, remediation, containment, cleanup or abatement of the presence, release or threatened release of any Hazardous Substance, whether on-site or off-site, and (B) any claim by any third party, including tort suits for personal or bodily injury, property damage or injunctive relief relating to the presence of, or exposure to, any Hazardous Substance), but excluding the Excluded Liabilities.

Section 7.4 Indemnification Procedures.

(a) In the event that any written claim or demand for which Seller or Buyer, as the case may be, each in its capacity as an indemnifying party (an "*Indemnifying Party*"), may have liability to any Indemnified Party under this Article, other than those relating to Taxes (which are the subject of Section 5.5), is asserted against or sought to be collected from any Indemnified Party by a third party (a "*Third-Party Claim*"), such Indemnified Party shall promptly, but in no event more than [*] days following such Indemnified Party's receipt of a Third-Party Claim, notify the Indemnifying Party of such Third-Party Claim, the amount or the estimated amount of damages sought thereunder to the extent then ascertainable (which estimate shall not be conclusive of the final amount of such Third-Party Claim), any other remedy sought thereunder, any relevant time constraints relating thereto and, to the extent practicable, any other material details pertaining thereto (a "*Claim Notice*"); provided, however, that the failure to timely give a Claim Notice shall affect the rights of an Indemnified Party hereunder only to the extent that such failure has a prejudicial effect on the defenses or other rights available to the Indemnifying Party with respect to such Third-Party Claim. The Indemnifying Party shall have [*] days (or such lesser number of days set forth in the Claim

Notice as may be required by court proceeding in the event of a litigated matter) after receipt of the Claim Notice (the “*Notice Period*”) to notify the Indemnified Party that it desires to defend the Indemnified Party against such Third-Party Claim.

(b) In the event that the Indemnifying Party notifies the Indemnified Party within the Notice Period that it desires to defend the Indemnified Party against a Third-Party Claim, the Indemnifying Party shall have the right to defend the Indemnified Party by appropriate proceedings and shall have the sole power to direct and control such defense at its expense. Once the Indemnifying Party has duly assumed the defense of a Third-Party Claim, the Indemnified Party shall have the right (but not the obligation) to participate in any such defense and to employ separate counsel of its choosing. Any participation by the Indemnified Party in accordance with the preceding sentence shall be at the Indemnified Party’s sole expense unless (i) the Indemnifying Party and the Indemnified Party are both named parties to the proceedings and the Indemnified Party shall have reasonably concluded that representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them, or (ii) the Indemnified Party assumes the defense of a Third-Party Claim after the Indemnifying Party has failed to diligently pursue a Third-Party Claim it has assumed, as expressly provided in the first sentence of Section 7.4(c). The Indemnifying Party shall not settle a Third-Party Claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed).

(c) If the Indemnifying Party (i) elects not to defend the Indemnified Party against a Third-Party Claim, whether by not giving the Indemnified Party timely notice of its desire to so defend or otherwise, or (ii) after assuming the defense of a Third-Party Claim, fails to take reasonable steps necessary to defend diligently such Third-Party Claim within [*] days after receiving notice from the Indemnified Party to the effect that the Indemnifying Party has so failed, the Indemnified Party shall have the right (but not the obligation) to assume its own defense; it being understood that the Indemnified Party’s right to indemnification for a Third-Party Claim shall not be adversely affected by assuming the defense of such Third-Party Claim. The Indemnified Party shall not settle a Third-Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld or delayed).

(d) Except to the extent of any actual or potential differing interests between the Indemnified Party and the Indemnifying Party referred to in Section 7.4(b)(i), the Indemnified Party and the Indemnifying Party shall cooperate in order to ensure the proper and adequate defense of a Third-Party Claim, including by providing reasonable access to each other’s relevant business records and other documents and employees.

(e) The Indemnified Party and the Indemnifying Party shall use reasonable best efforts to avoid production of confidential information (consistent with applicable Law), and to cause all communications among employees, counsel and others representing any party to a Third-Party Claim to be made so as to preserve any applicable attorney-client or work-product privileges.

Section 7.5 Direct Claims. If an Indemnified Party wishes to make a claim for indemnification hereunder for a Loss that does not result from a Third-Party Claim (a “*Direct*

Claim”), other than those relating to Taxes (which are the subject of Section 5.5), the Indemnified Party shall notify the Indemnifying Party of such Direct Claim, the amount or the estimated amount of damages sought thereunder to the extent then ascertainable (which estimate shall not be conclusive of the final amount of such Direct Claim), any other remedy sought thereunder, any relevant time constraints relating thereto and, to the extent practicable, any other material details pertaining thereto. The Indemnifying Party shall have a period of [*] days within which to respond to such Direct Claim. If the Indemnifying Party does not respond within such [*]-day period, the Indemnifying Party shall be deemed to have accepted the Direct Claim. If the Indemnifying Party rejects all or any part of the Direct Claim, the Indemnified Person shall be free to seek enforcement of its rights to indemnification under this Agreement with respect to such Direct Claim.

Section 7.6 Consequential Damages. Notwithstanding anything to the contrary contained herein, no Person shall be liable under this Article for any consequential, punitive, special, incidental or indirect damages, including lost profits.

Section 7.7 Adjustments to Losses. (a) *Insurance*. In calculating the amount of any Loss, the proceeds actually received by the Indemnified Party or any of its Affiliates under any insurance policy or pursuant to any claim, recovery, settlement or payment by or against any other Person, in each case relating to a claim for indemnification hereunder, net of any actual costs, expenses or insurance premiums incurred in connection with securing or obtaining such proceeds, shall be deducted, except to the extent that the adjustment itself would excuse, exclude or limit the coverage of all or part of such Loss. In the event that an Indemnified Party has any rights against a third party with respect to any occurrence, claim or loss that results in a payment by an Indemnifying Party under this Article, such Indemnifying Party shall be subrogated to such rights to the extent of such payment; provided, however, that, until the Indemnified Party recovers full payment of the Loss related to such occurrence, claim or loss, any and all claims of the Indemnifying Party against any such third party on account of said indemnity payment are hereby expressly made subordinate and subject in right of payment to the Indemnified Party’s rights against such third party. Without limiting the generality or effect of any other provision hereof, each Indemnified Party and Indemnifying Party shall duly execute upon request all instruments reasonably necessary to evidence and perfect the subrogation and subordination rights detailed herein, and otherwise cooperate in the prosecution of such claims.

(b) *Taxes*. In calculating the amount of any Loss, there shall be deducted an amount equal to any net Tax benefit actually realized (including the utilization of a Tax loss or Tax credit carried forward) as a result of such Loss by the party claiming such Loss.

(c) *Reimbursement*. If an Indemnified Party recovers an amount from a third party in respect of a Loss that is the subject of indemnification hereunder after all or a portion of such Loss has been paid by an Indemnifying Party pursuant to this Article, the Indemnified Party shall promptly remit to the Indemnifying Party the excess, if any, of (i) the amount paid by the Indemnifying Party in respect of such Loss, plus the amount received from the third party in respect thereof, less (ii) the full amount of such Loss; it being understood that in no event shall the Indemnified Party be required to remit to the Indemnifying Party any amount in excess of the amount paid by the Indemnifying Party hereunder in respect of such Loss.

Section 7.8 Payments. The Indemnifying Party shall pay all amounts payable pursuant to this Article, by wire transfer of immediately available funds, promptly following receipt from an Indemnified Party of a bill, together with all accompanying reasonably detailed back-up documentation, for a Loss that is the subject of indemnification hereunder, unless the Indemnifying Party in good faith disputes the Loss, in which event it shall so notify the Indemnified Party. In any event, the Indemnifying Party shall pay to the Indemnified Party, by wire transfer of immediately available funds, the amount of any Loss for which it is liable hereunder no later than three days following any Final Determination of such Loss and the Indemnifying Party's liability therefor.

Section 7.9 Characterization of Indemnification Payments. All payments made by an Indemnifying Party to an Indemnified Party in respect of any claim pursuant to Section 7.2 or 7.3 shall be treated as adjustments to the Purchase Price for Tax purposes.

Section 7.10 Mitigation. Each Indemnified Party shall use its commercially reasonable efforts to mitigate any indemnifiable Loss. In the event an Indemnified Party fails to so mitigate an indemnifiable Loss, the Indemnifying Party shall have no liability for any portion of such Loss that reasonably could have been avoided had the Indemnified Person made such efforts.

Section 7.11 Exclusive Remedies. The remedies expressly provided in this Agreement shall constitute the sole and exclusive basis for and means of recourse between the Parties or their respective Indemnified Parties with respect to the subject matter hereof, except to the extent any Loss arises out of or results from the intentional misrepresentation or willful misconduct of either Party.

Section 7.12 No Set-Off. Neither Seller nor Buyer shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party by the other Party or its Affiliates.

ARTICLE VIII

TERMINATION

Section 8.1 Termination. This Agreement may be terminated at any time prior to [*]:

- (a) by written agreement of Buyer and Seller; or
- (b) by either Buyer or Seller, by giving notice of such termination to the other Party, if [*] shall not have occurred on or prior to [*], so long as the terminating Party is not in material breach of its obligations under this Agreement.

Section 8.2 Effect of Termination. In the event of the termination of this Agreement in accordance with Section 8.1, this Agreement shall thereafter become void and have no effect, and no Party shall have any liability to the other Party or its Affiliates, or their respective directors, officers or employees, except for the obligations of the Parties contained in this Section and in Sections 5.9, 5.10, 9.1, 9.5, 9.7, 9.8, 9.9, 9.10, 9.11, 9.14 and 9.15 (and any related definitional provisions set forth in Article I), and except that nothing in this Section shall relieve either Party from liability for any breach of this Agreement that arose prior to such termination,

for which liability the provisions of Article VII shall remain in effect in accordance with the provisions and limitations of such Article.

ARTICLE IX

MISCELLANEOUS

Section 9.1 Notices. Any notice required or permitted to be given by this Agreement shall be in writing, in English, and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below, unless changed by notice so given:

If to Seller:

Amgen Inc.
One Amgen Center Drive,
Thousand Oaks, CA 91320
USA
Attention: General Counsel
Telephone: +1-805-447-1000
Facsimile: +[*]

With a copy to:

Sullivan & Cromwell LLP
125 Broad Street
New York, NY 10004
USA
Attention: Francis J. Aquila, Esq.
Telephone: +1 212 558 4048
Facsimile: +[*]

If to Buyer:

Takeda Pharmaceutical Company Limited
1-1, Doshomachi, 4-chome
Chuo-ku, Osaka, 540-8645
Japan
Attention: Hiroshi Shinha
Telephone: [*]
Facsimile: +[*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person or address 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.

Section 9.2 Waivers and Modifications. The failure of either Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by both Parties.

Section 9.3 Assignment. Neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred (whether by operation of Law, general succession or otherwise) by either Party without the prior written consent of the other Party, except as expressly provided in Section 9.6. Any assignment not in accordance with this Agreement shall be void. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

Section 9.4 Third-Party Beneficiaries. Except as expressly provided with respect to the Indemnified Parties in Article VII, there are no third-party beneficiaries intended hereunder and no Person (other than Seller and Buyer) shall have any right or obligation hereunder.

Section 9.5 Entire Agreement. This Agreement, including its Exhibits and Schedules, together with the Ancillary Agreements, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same, except for the Confidentiality Agreement, which shall remain in full force and effect until [*] (it being understood that the obligations therein shall survive the termination of the Confidentiality Agreement in accordance with their respective terms).

Section 9.6 Affiliates. Seller shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates; provided, however, that Seller shall be responsible for such Affiliates' performance hereunder.

Section 9.7 Expenses. Except as otherwise expressly provided in this Agreement or any Ancillary Agreement, whether or not the transactions contemplated hereby or thereby are consummated, all costs and expenses incurred in connection with this Agreement or any Ancillary Agreement and the transactions contemplated hereby or thereby shall be borne by the Party incurring such costs and expenses.

Section 9.8 Choice of Law. This Agreement shall be governed by, and enforced and construed in accordance with, the Laws of the State of New York without regard to its conflicts of law provisions.

Section 9.9 Jurisdiction and Venue. Each Party hereby irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York or any New York State court sitting in New York City (the "*Chosen Courts*") for the purposes of any suit, action or other proceeding arising out of or relating to this Agreement or out of the transactions contemplated hereby. Each Party agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth in Section 9.1 (as such address may be changed by notice delivered pursuant to such Section) shall be effective service of process for any action, suit or proceeding in the applicable Chosen Court with respect to any matters to which it has submitted to jurisdiction in this Section. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in the applicable Chosen Court, and hereby further irrevocably and unconditionally waives and agrees not to plead or

claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Any action brought arising out of or relating to this Agreement or out of the transactions contemplated hereby shall be conducted in English. Notwithstanding the foregoing, either Party shall have the right to seek exigent, injunctive or temporary relief in any court of competent jurisdiction.

Section 9.10 Waiver of Jury Trial. Each Party irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

Section 9.11 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signature pages of this Agreement may be exchanged by facsimile or other electronic means without affecting the validity thereof.

Section 9.12 Construction. (a) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined.

(b) Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms.

(c) The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”.

(d) The word “will” shall be construed to have the same meaning and effect as the word “shall”.

(e) The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted and that no rule of strict construction shall be applied in the interpretation hereof.

(f) Unless the context requires otherwise:

(i) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein),

(ii) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended,

(iii) any reference herein to any Person shall be construed to include such Person’s permitted successors and assigns,

(iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and

(v) all references herein to Articles, Sections, Exhibits or Schedules, unless otherwise expressly provided, shall be construed to refer to Articles, Sections, Exhibits or Schedules of this Agreement.

(g) This Agreement has been executed in English, and the English version of this Agreement shall control.

Section 9.13 Headings. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

Section 9.14 Schedules. The disclosure of any matter in any Schedule to this Agreement shall be deemed to be a disclosure for all purposes of this Agreement to which such matter could reasonably be expected to be pertinent, but shall not be deemed to constitute an admission by Seller or Buyer or to otherwise imply that any such matter is material for the purposes of this Agreement.

Section 9.15 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized. The invalidity or unenforceability of a provision in a particular jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed or caused this Agreement to be executed as of the date first written above.

AMGEN INC.

By: /s/ Kevin W. Sharer
Name: Kevin W. Sharer
Title: Chairman of the Board, CEO and President

TAKEDA PHARMACEUTICAL COMPANY LIMITED

By: /s/ Yasuchika Hasegawa
Name: Yasuchika Hasegawa
Title: President

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: May 12, 2008

/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: May 12, 2008

/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 March 31, 2008 (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: May 12, 2008

/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 March 31, 2008 (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: May 12, 2008

/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.