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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 September 30, 2007

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

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

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. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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

As of November 5, 2007, the registrant had 1,087,641,879 shares of common stock, $0.0001 par value, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

The information in this report for the three and nine months ended September 30, 2007 and 2006 is unaudited but includes all adjustments (consisting only of normal recurring accruals, 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.

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, 2006.

Interim results are not necessarily indicative of results for the full fiscal year.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenues:				
Product sales	$ 3,524	$ 3,503	$10,693	$10,121
Other revenues	87	109	333	312
Total revenues	3,611	3,612	11,026	10,433
Operating expenses:				
Cost of sales (excludes amortization of acquired intangible assets presented below)	792	489	1,942	1,534
Research and development	776	872	2,444	2,315
Selling, general and administrative	730	807	2,360	2,336
Amortization of acquired intangible assets	76	122	224	296
Write-off of acquired in-process research and development	590	—	590	1,101
Other items	254	—	543	—
Total operating expenses	3,218	2,290	8,103	7,582
Operating income	393	1,322	2,923	2,851
Interest and other income and (expense), net	(21)	39	(20)	140
Income before income taxes	372	1,361	2,903	2,991
Provision for income taxes	171	259	572	874
Net income	$ 201	$ 1,102	$ 2,331	$ 2,117
Earnings per share:				
Basic	$ 0.19	$ 0.94	$ 2.07	$ 1.79
Diluted	$ 0.18	$ 0.94	$ 2.06	$ 1.77
Shares used in calculation of earnings per share:				
Basic	1,086	1,167	1,127	1,181
Diluted	1,090	1,178	1,133	1,194

See accompanying notes.

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

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,389	$ 1,283
Marketable securities	4,561	4,994
Trade receivables, net	2,154	2,124
Inventories	2,076	1,903
Other current assets	1,526	1,408
Total current assets	11,706	11,712
Property, plant and equipment, net	5,922	5,921
Intangible assets, net	3,445	3,747
Goodwill	11,314	11,302
Other assets	1,065	1,106
	$ 33,452	$ 33,788
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 438	$ 555
Accrued liabilities	3,654	4,589
Convertible notes	—	1,698
Other debt	136	100
Total current liabilities	4,228	6,942
Deferred tax liabilities	294	367
Convertible notes	5,080	5,080
Other long-term debt	6,097	2,134
Other non-current liabilities	848	301
Contingencies		
Stockholders' equity:		
Preferred stock; $0.0001 par value; 5 shares authorized; none issued or outstanding	—	—
Common stock and additional paid-in capital; $0.0001 par value; 2,750 shares authorized; outstanding - 1,087 shares in 2007 and 1,166 shares in 2006	24,806	24,155
Accumulated deficit	(7,894)	(5,203)
Accumulated other comprehensive (loss) income	(7)	12
Total stockholders' equity	16,905	18,964
	$ 33,452	$ 33,788

See accompanying notes.

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

	Nine Months Ended September 30,	
	2007	2006
Cash flows from operating activities:		
Net income	$ 2,331	$ 2,117
Write-off of acquired in-process research and development	590	1,101
Depreciation and amortization	900	763
Asset impairment	392	—
Other items, net	379	205
Changes in operating assets and liabilities:		
Trade receivables, net	(15)	(355)
Inventories	(114)	(378)
Other assets	(68)	(26)
Accounts payable	(119)	(11)
Accrued income taxes	(934)	326
Other accrued liabilities	529	405
Net cash provided by operating activities	3,871	4,147
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,033)	(834)
Cash paid for acquisitions, net of cash acquired	(698)	(1,888)
Purchases of marketable securities	(4,236)	(3,981)
Proceeds from sales of marketable securities	4,431	2,052
Proceeds from maturities of marketable securities	278	858
Other	(37)	(136)
Net cash used in investing activities	(1,295)	(3,929)
Cash flows from financing activities:		
Repurchases of common stock	(5,000)	(1,755)
Repayment of convertible notes	(1,702)	—
Repayment of debt assumed in Abgenix, Inc. acquisition	—	(653)
Proceeds from issuance of notes, net	3,982	—
Proceeds from issuance of convertible notes and related transactions, net	—	440
Proceeds from issuance of warrants	—	774
Proceeds from issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan, net	244	367
Other	6	60
Net cash used in financing activities	(2,470)	(767)
Increase (decrease) in cash and cash equivalents	106	(549)
Cash and cash equivalents at beginning of period	1,283	1,840
Cash and cash equivalents at end of period	$ 1,389	$ 1,291

See accompanying notes.

AMGEN INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2007
(Unaudited)

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2007 and 2006 is unaudited but includes all adjustments (consisting of only normal recurring adjustments, unless otherwise indicated), which we consider 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.

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. During the three months ended September 30, 2007, we wrote-off $90 million of excess inventory principally due to changing regulatory and reimbursement environments. Inventories consisted of the following (in millions):

	September 30, 2007	December 31, 2006
Raw materials	$ 184	$ 205
Work in process	1,228	1,090
Finished goods	664	608
	$ 2,076	$ 1,903

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

Intangible assets and goodwill

Intangible assets are recorded at cost, less accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives ranging from 5 to 15 years on a straight-line basis (weighted-average remaining amortization period of 9 years at September 30, 2007). Intangible assets primarily consist of acquired product technology rights of $2.9 billion, net of accumulated amortization of $1.5 billion, which relate to the identifiable intangible assets acquired in connection with the Immunex Corporation ("Immunex") acquisition in July 2002. Amortization of acquired product technology rights is included in "Amortization of acquired intangible assets" in the Condensed Consolidated Statements of Operations. Intangible assets also include acquired technology used in research and development ("R&D") with alternative future uses ("acquired R&D technology rights"), primarily the XenoMouse® technology acquired in the Abgenix, Inc. ("Abgenix") acquisition. Amortization of the acquired R&D technology rights is included in "Research and development" in the Condensed Consolidated Statements of Operations. Amortization of other intangible assets is principally included in "Cost of sales (excludes amortization of acquired intangible assets)" and "Selling, general and administrative" expense in the Condensed Consolidated Statements of Operations. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

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

Product sales

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

Sales of our products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates, wholesaler chargebacks, discounts and other incentives (collectively "sales incentives") and returns. Taxes assessed by government authorities on the 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 ("Johnson & Johnson"), 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 Johnson & Johnson and do recognize the product sales made by Johnson & Johnson into our exclusive market. Sales in our exclusive market are derived from our sales to our customers, as adjusted for spillover. We are employing an arbitrated audit methodology to measure each party's spillover based on estimates of and subsequent adjustments thereto of third-party data on shipments to end users and their usage.

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

Research and development costs

R&D costs, which are expensed as incurred, are primarily comprised of costs and expenses for salaries and benefits associated with R&D personnel; overhead and occupancy; clinical trial and related clinical manufacturing, including contract services and other outside costs, process development and quality assurance; information systems and amortization of technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners.

Acquired in-process research and development

The fair value of acquired in-process research and development ("IPR&D") projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred. In the three months ended September 30, 2007, we wrote-off $270 million and $320 million of acquired IPR&D related to the Alantos Pharmaceuticals Holding, Inc. ("Alantos") and Ilypsa, Inc. ("Ilypsa") acquisitions, respectively. In the three months ended June 30, 2006, we wrote-off $1.1 billion of acquired IPR&D related to the Abgenix acquisition. Acquired IPR&D is considered part of total R&D expense. See Note 8, "Acquisitions" for further discussion.

Earnings per share

Basic earnings per share ("EPS") is based upon the weighted-average number of common shares outstanding. Diluted EPS is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options, restricted stock (including restricted stock units) and other equity awards under our employee compensation plans and potential issuance of stock upon the assumed conversion of our 2011 Convertible Notes, 2013 Convertible Notes, 2032 Modified Convertible Notes 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Income (Numerator):				
Net income for basic and diluted EPS	$ 201	$ 1,102	$ 2,331	$ 2,117
Shares (Denominator):				
Weighted-average shares for basic EPS	1,086	1,167	1,127	1,181
Effect of Dilutive Securities	4	11	6	13
Weighted-average shares for diluted EPS	1,090	1,178	1,133	1,194
Basic earnings per share	$ 0.19	$ 0.94	$ 2.07	$ 1.79
Diluted earnings per share	$ 0.18	$ 0.94	$ 2.06	$ 1.77

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

Recent accounting pronouncements

In June 2007, the Financial Accounting Standards Board ("FASB") ratified Emerging Issues Task Force Issue ("EITF") No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*" ("EITF No. 07-3"). EITF No. 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. We will adopt EITF No. 07-3 as of January 1, 2008, and it is not expected to have a material impact on our results of operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. ("FIN") 48, "*Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109*" ("FIN 48"), which became effective for us as of January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement and classification in our financial statements of tax positions taken or expected to be taken in a tax return.

For tax benefits to be recognized under FIN 48, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of January 1, 2007, the gross amount of our liabilities for unrecognized tax benefits ("UTBs") was approximately $945 million and accrued interest related to these UTBs totaled approximately $106 million. Included in the balance is approximately $776 million of UTBs (net of the federal benefit on state taxes) that, if recognized, would affect our effective tax rate. The cumulative effect of applying the recognition and measurement provisions upon adoption of FIN 48 was not material.

FIN 48 also provides guidance on the balance sheet classification of liabilities for UTBs as either current or non-current depending on the expected timing of payments. Upon adoption of FIN 48, we reclassified approximately $240 million of UTBs and related accrued interest from current income taxes payable to non-current liabilities.

As of the adoption of FIN 48, we believed that it was reasonably possible that our liabilities for UTBs may decrease by $350 million to $600 million within the succeeding twelve months due to potential settlement of transfer pricing tax positions on our U.S. income tax returns.

Interest and penalties related to UTBs are classified as a component of our provision for income taxes.

See Note 4, "Income taxes" for further discussion.

2. Restructuring

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. This restructuring plan is 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)

As part of the restructuring plan, we are reducing staff by approximately 12% to 14% or approximately 2,200 to 2,600 positions, resulting in restructuring charges of approximately $200 million to $230 million. In addition, we are re-scoping and making other changes to certain capital projects and closing certain production operations. These actions are primarily focused on rationalizing 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. These and related actions are expected to result in restructuring charges of approximately $470 million to $490 million, consisting primarily of asset impairments and, to a lesser degree, accelerated depreciation. Further, we expect to incur approximately $105 million to $130 million in other restructuring charges principally related to the accrual of losses for leases for certain R&D facilities that will not be used in our operations. The total charges associated with the restructuring plan are expected to be approximately $775 million to $850 million, as compared to our prior estimate of $600 million to $700 million. The increase in the total estimated restructuring charges was primarily the result of additional rationalization of our manufacturing facilities, including the indefinite postponement of our Ireland manufacturing operations and the closure of a clinical manufacturing facility in Thousand Oaks. These estimates of total charges are net of amounts recoverable from our co-promotion partner, Wyeth.

We have initiated a majority of the above-noted actions included in our restructuring plan and expect that all remaining actions will be substantially completed by 2008. During the three and nine months ended September 30, 2007, we incurred $293 million and $582 million, respectively, of restructuring charges. We estimate that the remaining restructuring costs will be incurred during the three months ended December 31, 2007 and, to a lesser degree, in 2008.

The following table summarizes the charges (credits) recorded through September 30, 2007 related to the restructuring plan by type of activity (in millions):

Three Months Ended September 30, 2007	Separation Costs	Asset Impairments	Accelerated Depreciation	Other	Total
Cost of sales (excluding amortization of intangible assets)	$ (1)	$ 4	$ 110	$—	$113
Research and development	(17)	35	—	—	18
Selling, general and administrative	(9)	—	—	(83)	(92)
Other items	104	71	—	79	254
	$ 77	$ 110	$ 110	$ (4)	$293

Nine Months Ended September 30, 2007	Separation Costs	Asset Impairments	Accelerated Depreciation	Other	Total
Cost of sales (excluding amortization of intangible assets)	$ (1)	$ 4	$ 110	$—	$113
Research and development	(17)	35	—	—	18
Selling, general and administrative	(9)	—	—	(83)	(92)
Other items	107	357	—	79	543
	$ 80	$ 396	$ 110	$ (4)	$582

During the three and nine months ended September 30, 2007, we accrued staff separation costs of $104 million and $107 million, respectively, principally consisting of severance. Partially offsetting these amounts in “Cost of sales (excluding amortization of intangible assets)” (COS), “Research and development” and “Selling, general and administrative” (SG&A) expenses for the three and nine months ended September 30, 2007 are the

reversal of previously accrued expenses for bonuses and stock-based compensation awards, ($27 million), which will be forfeited as a result of the employees' termination.

In connection with the preparation of our financial statements for the three months ended June 30, 2007, we decided to re-scope and make changes to certain capital projects and to close certain production operations. In particular, these decisions included the re-scoping of our planned Ireland manufacturing operations, the construction of which was previously reported to have been delayed, certain revisions to our planned manufacturing expansion in Puerto Rico and, to a lesser degree, moderated expansion of our research facilities. As a result of these decisions, we recorded asset impairment charges of $286 million during the three months ended June 30, 2007. Subsequently, in connection with the preparation of our financial statements for the three months ended September 30, 2007, we made additional decisions related to the rationalization of our manufacturing facilities, including the indefinite postponement of our Ireland manufacturing operations and the closure of a clinical manufacturing facility in Thousand Oaks. Primarily as a result of these decisions, we recorded additional asset impairment charges of $110 million during the three months ended September 30, 2007.

In connection with the rationalization of our worldwide network of manufacturing facilities discussed above, during the three months ended September 30, 2007 we also decided to accelerate the closure of one of our ENBREL commercial bulk manufacturing operations. The decision to accelerate the closure of this manufacturing operation was principally based on a thorough review of the supply plans for bulk ENBREL inventory across its worldwide manufacturing network, including consideration of expected increases in manufacturing yields, and the determination that the related assets no longer had any alternative future uses in our operations. Because the related estimated future cash flows for this manufacturing operation are sufficient to recover the respective book values, we are required to accelerate depreciation of the related assets rather than immediately impairing their carrying values. The amount included in COS in the table above, $110 million, represents the excess of the accelerated depreciation expense recognized during the three and nine months ended September 30, 2007 over the depreciation that would otherwise have been recorded, $4 million, if there were no plans to accelerate the closure of this manufacturing operation. See further discussion below regarding the recovery of a portion of the cost of such excess accelerated depreciation from Wyeth.

Other restructuring amounts included in SG&A for the three and nine months ended September 30, 2007 represent cost recoveries, ($83 million), for certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Wyeth. Other restructuring expenses, $79 million, included in Other items for the three and nine months ended September 30, 2007 primarily relate to the loss accruals for leases for certain R&D facilities that will not be used in our business.

The majority of the restructuring charges accrued, principally severance and lease payments, remain unpaid as of September 30, 2007.

The Company records restructuring activities in accordance with FASB Statement No. 144, *Accounting for the Impairment and Disposal of Long-Lived Assets* and FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*.

3. Related party transactions

We own a 50% interest in Kirin-Amgen, Inc. ("KA"), a corporation formed in 1984 with Kirin Brewery 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 Operations. During the three and nine months ended September 30, 2007, our share of KA's profits was $18 million and $40 million, respectively. During the three and nine months ended September 30, 2006, our share of KA's profits was $15 million and $43 million, respectively. At September 30, 2007 and December 31, 2006, the carrying value of

our equity method investment in KA was $281 million and $241 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, Johnson & Johnson and F. Hoffmann-La Roche Ltd. ("Roche") under separate product license agreements for certain geographic areas outside of the United States. During the three and nine months ended September 30, 2007, KA earned royalties from us of $83 million and $253 million, respectively. During the three and nine months ended September 30, 2006, KA earned royalties from us of $82 million and $238 million, respectively. These amounts are included in "Cost of sales (excludes amortization of acquired intangible assets)" in the Condensed Consolidated Statements of Operations.

KA's expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and nine months ended September 30, 2007, we earned revenues from KA of $39 million and $144 million, respectively, for certain R&D activities performed on KA's behalf. During the three and nine months ended September 30, 2006, we earned revenues from KA of $35 million and $98 million, respectively. These amounts are included in "Other revenues" in the Condensed Consolidated Statements of Operations.

4. Income taxes

The effective tax rate for the three months ended September 30, 2007 is higher than the statutory rate primarily as a result of the write-off of non-deductible, acquired IPR&D in connection with the acquisitions of Alantos and Ilypsa partially offset by indefinitely invested earnings of our foreign operations. The effective tax rate for the nine months ended September 30, 2007 is different from the statutory rate primarily as a result of these same factors as well as the favorable resolution of our federal tax examination for certain prior tax years, which was recorded in the second quarter of 2007. 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. As of January 1, 2007, we were no longer subject to U.S. federal income tax examinations for years ending on or before December 31, 2001 or to California state income tax examinations for years ending on or before December 31, 2003.

During the nine months ended September 30, 2007, we effectively settled our examination with the Internal Revenue Service ("IRS") for the years ended December 31, 2002, 2003 and 2004. We agreed to certain adjustments proposed by the IRS arising out of this examination primarily related to transfer pricing tax positions. Our closing agreement with the IRS also covers certain transfer pricing issues for the years ended December 31, 2005 and 2006; however, these years have not been effectively settled.

During the nine months ended September 30, 2007, the gross amount of our UTBs increased approximately $380 million as a result of tax positions taken during the current year, and decreased approximately $480 million related to tax positions taken in prior years, primarily as a result of our tax settlement discussed above. The majority of these changes impacted the January 1, 2007 balance of our UTBs that, if recognized, would affect our effective tax rate.

As of September 30, 2007, we believed that it was reasonably possible that our liabilities for UTBs may decrease by $100 million to $300 million within the succeeding twelve months due to potential tax settlements as well as resolution of other issues identified during the examination process.

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 September 30, 2007 and December 31, 2006 (in millions):

	September 30, 2007	December 31, 2006
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	—
5.85% notes due 2017 (2017 Notes)	1,098	—
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	—
Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes)	80	1,778
Other	237	235
Total borrowings	11,313	9,012
Less current portion	136	1,798
Total non-current debt	$ 11,177	$ 7,214

2008 Floating Rate Notes, 2017 Notes and 2037 Notes

In May 2007, we issued $2.0 billion aggregate principal amount of floating rate notes due in 2008 (the “2008 Floating Rate Notes”), $1.1 billion aggregate principal amount of notes due in 2017 (the “2017 Notes”) and $900 million aggregate principal amount of notes due in 2037 (the “2037 Notes”) in a private placement. The 2008 Floating Rate Notes bear interest at a rate per annum, equal to LIBOR plus 0.08%, which will be reset quarterly. We may redeem the 2008 Floating Rate Notes, in whole or in part, at any time on or after November 28, 2007 at a redemption price equal to 100% of the principal amount being redeemed plus accrued interest. The 2017 Notes and 2037 Notes pay interest at fixed rates of 5.85% and 6.375%, respectively. We may redeem the 2017 Notes and 2037 Notes, in whole at any time or from time to time in part, at 100% of the principal amount of the notes being redeemed plus accrued interest, if any, and a “make-whole” amount, as defined. In the event of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2008 Floating Rate Notes, the 2017 Notes and the 2037 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $16 million and are being amortized over the life of the notes.

A total of $3.2 billion of the net proceeds raised from the issuance of these notes were used to repurchase shares of our common stock under a block trade entered into in May 2007.

2032 Modified Convertible Notes

On March 2, 2007, as a result of certain holders of the 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we repurchased $2.3 billion aggregate principal amount of these convertible notes for their then-accreted value of $1.7 billion in cash, representing approximately 96% of the outstanding balance of these notes. Upon the repurchase of these notes, a pro rata portion, $51 million, of deferred financing and related costs were immediately charged to interest expense during the three months ended March 31, 2007.

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

6. Stockholders' equity

Stock repurchase programs

The following table reflects a summary of activity under our stock repurchase programs for the nine months ended September 30, 2007 and 2006 (in millions):

	2007		2006	
	Shares	Dollars	Shares	Dollars
First quarter	8.8	$ 537	46.6	$3,374
Second quarter	73.9(1)	4,463	13.0	876
Third quarter	2.5(1)	—	7.3	505
Total	85.2	$5,000	66.9	$4,755

(1) The total number of shares repurchased during the three months ended June 30, 2007 excludes 2,527,937 of shares received in July 2007 in connection with the final settlement of a block trade entered into in May 2007, which is discussed in Note 5, "Financing Arrangements" above (also see "Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities" in Part II herein).

As of September 30, 2007, $1.5 billion was available for stock repurchases under our stock repurchase program authorized by the Board of Directors in December 2006. In July 2007, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock. 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 and blackout periods in which we are restricted from repurchasing shares, and may include private block purchases as well as market transactions.

Comprehensive income

Our comprehensive income includes net income, unrealized gains and losses on our available-for-sale securities and foreign currency forward and option contracts, which qualify and are designated as cash flow hedges, and foreign currency translation adjustments. During the three and nine months ended September 30, 2007, total comprehensive income was $208 million and $2.3 billion, respectively. During the three and nine months ended September 30, 2006, total comprehensive income was $1.1 billion and $2.1 billion, respectively.

7. Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those that are tax-related. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

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

8. Acquisitions

Alantos Pharmaceuticals Holding, Inc.

On July 16, 2007, we completed the acquisition of Alantos, which was accounted for as a business combination. Alantos was a privately held company that specialized in the development of drugs for the treatment of diabetes and inflammatory diseases. Pursuant to the merger agreement, we paid cash of approximately $300 million to acquire all of the outstanding shares of Alantos. Alantos' operations are included in our condensed consolidated financial statements commencing July 16, 2007. Pro forma results of operations for the three and nine months ended September 30, 2007 as though the acquisition of Alantos had taken place at the beginning of 2007 would not differ significantly from the actual reported results for those periods.

The purchase price paid, including transaction costs, were preliminarily allocated to IPR&D of approximately $270 million and other net assets acquired of approximately $11 million. The excess of the purchase price over the fair values of assets and liabilities acquired of approximately $22 million was assigned to goodwill. The IPR&D write-off, which was recognized in our Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2007, relates to an orally administered treatment for type II diabetes that is in phase 2a clinical development. We have development and commercialization rights for this product candidate in the United States. Under a collaboration agreement, a corporate partner has the rights to develop and commercialize this product candidate outside the United States.

Ilypsa, Inc.

On July 18, 2007, we completed the acquisition of Ilypsa, which was accounted for as a business combination. Ilypsa was a privately held company that specialized in the development of non-absorbed drugs for renal disorders. Pursuant to the merger agreement, we paid cash of approximately $400 million to acquire all of the outstanding shares of Ilypsa. Ilypsa's operations are included in our condensed consolidated financial statements commencing July 18, 2007. Pro forma results of operations for the three and nine months ended September 30, 2007 as though the acquisition of Ilypsa had taken place at the beginning of 2007 would not differ significantly from the actual reported results for those periods.

The purchase price paid, including transaction costs, were preliminarily allocated to IPR&D of approximately $320 million and other net assets acquired of approximately $54 million. The excess of the purchase price over the fair values of assets and liabilities acquired of approximately $29 million was assigned to goodwill. The IPR&D write-off, which was recognized in our Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2007, relates to a phosphate binder that at the date of acquisition was in phase 2 clinical trials for the treatment of hyperphosphatemia in chronic kidney disease ("CKD") patients on hemodialysis.

9. Subsequent event

On November 2, 2007, we established a $2.5 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support, which matures in November 2012 and replaces our prior $1.0 billion unsecured revolving credit facility.

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 Securities and Exchange Commission ("SEC") contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business 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, 2006.

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.

Our principal products include Aranesp®, EPOGEN®, Neulasta®/NEUPOGEN® and ENBREL, all of which are sold in the United States. ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. Our international product sales consist principally of European sales of Aranesp® and Neulasta®/NEUPOGEN®. International product sales represented approximately 20% of total product sales for each of the three and nine months ended September 30, 2007. Most patients receiving our principal products for approved indications are covered by either government or private payer health care programs. Therefore, sales of our principal products and sales growth 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. For additional information about our principal products, their 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, 2006.

We primarily earn revenues and income and generate cash from sales of human therapeutic products in the areas of supportive cancer care, nephrology, inflammation and, beginning in the third quarter 2006, oncology when we received U.S. Food and Drug Administration ("FDA") approval and launched Vectibix™

(panitumumab), our first cancer therapeutic. Total product sales for the three and nine months ended September 30, 2007 grew 1% and 6%, respectively, principally driven by ENBREL and Neulasta® sales, which were substantially offset by a decrease in Aranesp® sales. In particular for the three and nine months ended September 30, 2007, U.S. Aranesp® sales declined 36% and 17%, respectively, primarily reflecting a decrease in demand resulting from recent regulatory and reimbursement developments as discussed in more detail below.

For the three and nine months ended September 30, 2007, net income and diluted earnings per share were $201 million and $2.3 billion and $0.18 per share and $2.06 per share, respectively. As discussed in more detail below, our results of operations for the three and nine months ended September 30, 2007 reflect charges for the write-off of $590 million of acquired IPR&D related to the acquisitions of Alantos and Ilypsa and restructuring activities of $293 million and $582 million, respectively, primarily related to asset impairments, accelerated depreciation, staff separation costs and loss accruals for leases for certain R&D facilities in connection with our previously announced restructuring plan.

As of September 30, 2007, cash, cash equivalents and marketable securities were $6.0 billion, of which approximately $5.3 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. The total debt outstanding was $11.3 billion as of September 30, 2007.

As discussed in more detail below, certain of our products, principally Aranesp® and EPOGEN®, face various challenges arising from regulatory and reimbursement developments that began in 2007 and will continue to face future challenges, including the potential for further revisions to product labels and loss of or restrictions on reimbursement coverage. In addition, increased competition, including additional approved indications for existing competitive products, has and will continue to present challenges to certain of our products, as discussed in more detail below.

Our anemia products, Aranesp® and EPOGEN®, belong to a class of drugs referred to as erythropoiesis-stimulating agents, or ESAs. Aranesp® is used primarily in the United States and in Europe for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN® is used in the United States to treat anemia associated with CKD. Reaction to regulatory and reimbursement developments affecting ESAs has resulted in decreased demand for our anemia products and in particular for Aranesp®. These developments reflect in large part adverse safety results observed in clinical studies involving ESAs in off-label uses performed by us, including our Anemia of Cancer phase 3 study (the “AoC 103 Study”), and by third-parties.

Worldwide Aranesp® sales and, in particular, sales in the U.S. supportive cancer care setting have been and will continue to be materially adversely affected by some or all of the following developments, the full extent of which cannot be determined at this time.

- In February 2007, the United States Pharmacopoeia Dispensing Information (“USP DI”) Drug Reference Guides removed Aranesp® for use in the treatment of Anemia of Cancer (“AoC”). Thereafter, virtually all Medicare contractors have stopped reimbursing for Aranesp® use in AoC patients. In addition, to a lesser degree, there has been a decline in Aranesp® use in AoC for patients covered by private insurance plans.
- On March 9, 2007, the FDA approved updated safety information, including a boxed warning, in the prescribing information for the class of ESAs, including Aranesp® and EPOGEN®.
- On May 10, 2007, the Oncologic Drugs Advisory Committee (“ODAC”) met to discuss the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. 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 or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels. 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. On November 8, 2007, we announced updates to ESA product package inserts and related matters which recognize input from the ODAC meeting. See further discussion of these matters below.

- On July 30, 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 establishes the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia ("CIA"), and who all together accounted for approximately 50% of the U.S. cancer patients receiving Aranesp® prior to its issuance. We believe that the majority of CIA patients who received treatment with ESAs, including Aranesp®, were initiated at hemoglobin ("Hb") levels above 10 grams per deciliter ("g/dL") and were maintained with Hb levels above 10 g/dL with continued therapy prior to the issuance of the Decision Memorandum. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10 g/dL, we believe that such restriction has and will continue to change 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 will continue to have a material adverse effect on the use, reimbursement and sales of Aranesp®. However, as CMS has not yet provided final guidance to Medicare contractors with respect to the implementation of the Decision Memorandum, we will continue to evaluate what its eventual impact will be 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 and only one private payer has implemented certain restrictions based upon it, we believe that some private payers may implement and follow some or all of the restrictions included in the Decision Memorandum. Further, due to difficulties in administering a two-tier medical practice, we believe some healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage, resulting in those covered by private insurance plans receiving the same care as Medicare patients.

  On November 8, 2007, we announced our intention to submit new evidence to the CMS to support a reconsideration of their Decision Memorandum on ESAs.

- The FDA held a joint meeting of the Cardiovascular-Renal Drug Advisory Committee ("CRDAC") and the Drug Safety and Risk Management Advisory Committee ("DSaRMAC") (referred to collectively as "CRDAC/DSaRMAC") on September 11, 2007, which evaluated the safety data on ESA use in renal disease. CRDAC and DSaRMAC are committees of external experts who advise the FDA about the safety and efficacy of drug products for use in treating patients in the renal setting. These committees are advisory only and FDA officials are not bound or limited by their recommendations. However, the FDA commonly follows the recommendations of its advisory panels. The CRDAC/DSaRMAC recommended against revising the ESA product labels to state that the target Hb level should not exceed 11 g/dL, recommended that the ESA dosages used to achieve the Hb levels in the lower target groups in the Normal Hematocrit Cardiac Trial and the Correction of Hemoglobin and Outcomes In Renal Insufficiency ("CHOIR") studies were sufficient to form the basis for ESA dosage recommendations and discussed potential clinical studies involving ESAs. On November 8, 2007, we announced updates to the ESA product package inserts and related matters which recognize input from the CRDAC/DSaRMAC meeting. See further discussion of these matters below.
- On October 29, 2007, the European Agency for the Evaluation of Medicinal Products ("EMEA") issued a press release about upcoming changes to product information for ESAs stipulating a uniform

target Hb range for all ESAs of 10 g/dL to 12 g/dL with a warning not to exceed a concentration of 12 g/dL.

- On November 8, 2007, we announced updates to the Aranesp® and EPOGEN®/PROCRIT® package inserts in collaboration with the FDA and Johnson and Johnson Pharmaceutical Research & Development ("J&JPRD"), which recognize input from the ODAC and CRDAC/DSaRMAC meetings. The changes to the labeling include modifications to the boxed warnings, additional language in the indications and usage section, addition of an oncology study to the warnings section, and clarification of the Hb range for chronic renal failure ("CRF") patients in the dosage and administration section. We also announced that we have developed a comprehensive clinical study pharmacovigilance program, including six new proposed clinical trials designed to assess the safety of ESAs when used to treat CIA in specific tumor types and outstanding questions about ESA safety in both investigational and labeled settings. Upon agreement by the FDA, these studies will be added to our ongoing pharmacovigilance program, which was previously agreed to with the FDA. In addition, we continue to be in discussions with the FDA and intend to submit further modifications to ESA product labeling to address other issues raised at the ODAC meeting, which we expect will result in additional revisions to class labeling for ESAs.

EPOGEN® sales have also been adversely affected, although to a lesser degree, by the reaction to regulatory and reimbursement developments that began in 2007 and will continue to face future challenges. In addition to the March 9, 2007 updated safety information, including a boxed warning, and the recommendations from the CRDAC/DSaRMAC meeting that impact both EPOGEN® and Aranesp®, discussed above, we believe that EPOGEN® sales will continue to be adversely affected by some or all of the following developments, the full extent of which cannot be determined at this time.

- On July 20, 2007, CMS published revisions to its Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease ("EMP"), effective January 1, 2008, which require a 50% reduction in Medicare reimbursement if a patient's Hb is above 13 g/dL for three or more consecutive months and a reduction of the monthly dosing limits to 400,000 international units ("IUs") of EPOGEN® from 500,000 IUs. Although not effective until January 1, 2008, physicians have continued to evaluate the revisions to the EMP in making treatment and dosing decisions.
- On August 30, 2007, the National Kidney Foundation ("NKF") distributed to the nephrology community the final updated Kidney Disease Outcomes Quality Initiative ("KDOQI") clinical practice guidelines and recommendations for anemia in CKD. The NKF's Anemia Work Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, the NKF-KDOQI™ 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. Physicians have continued to evaluate the KDOQI guidelines in making treatment and dosing decisions.
- As discussed further above in connection with Aranesp® sales, on November 8, 2007, we announced updates to the Aranesp® and EPOGEN®/PROCRIT® package inserts in collaboration with the FDA and J&JPRD and related developments, which recognize input from the CRDAC/DSaRMAC meeting.

Certain of our products are also facing a number of competitive challenges as well. For example:

- Roche's pegylated-erythropoietin ("peg-EPO") product, MIRCERA®, which will compete with Aranesp®, received approval by the European Commission on July 26, 2007 to treat anemia associated with CKD and was launched in certain European Union ("EU") countries in the third quarter of 2007 with additional countries expected to launch in the fourth quarter of 2007. 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, Roche has been found to infringe a total of ten claims from four of Amgen's EPO patents. Roche filed a biologic license application ("BLA") with the FDA for their peg-EPO product and announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia associated with CRF including patients on dialysis and patients not on dialysis. Amgen will now seek a permanent injunction to prevent Roche from commercializing its peg-EPO product in the United States in violation of our affirmed patent rights. The injunction hearing is scheduled to begin on November 15, 2007 and proceed for three days in December on dates yet to be determined by the Court. (See "Item 1. Legal Proceedings – *Roche Matters*" in Part II herein.)
- Shire Pharmaceuticals Group ("Shire") launched Dynepo™ (Epoetin delta), an erythropoietin product which will compete with Aranesp®, in Germany in the first quarter of 2007 and in the UK in the second quarter of 2007. Dynepo™ is expected to be launched in certain other EU countries throughout the remainder of 2007.
- The first biosimilar erythropoietin product by Sandoz, with co-marketers Hexal and Medice, was approved in the EU in the third quarter of 2007 and will impact sales within the ESA class, including Aranesp®. This product, under the brand names Binocrit® (Epoetin alfa), Epoetin alfa Hexal® (Epoetin alfa) and Abseamed® (Epoetin alfa), was launched in Germany and the UK in the third quarter 2007 with additional EU countries expected to launch in the first quarter of 2008. A second biosimilar product in the ESA class, Retacrit™ (epoetin zeta), by Hospira/STADA received a positive opinion from the EMEA in the third quarter of 2007 and is expected to be approved in the fourth quarter of 2007 and launched in certain EU countries in the first quarter of 2008. The first biosimilar G-CSF products, which will impact sales within the G-CSF class, including NEUPOGEN® and Neulasta®, may be approved in the EU in the first quarter of 2008, and could be available soon thereafter.
- ENBREL operates in an extremely competitive environment as evidenced by the number of competitive products, including HUMIRA®, Remicade®, Orencia®, Rituxan®, Raptiva® and Amevive®, and product candidates, which may include new indications for existing products. Although these competing products have helped to grow both the rheumatology and dermatology segments, they have also resulted in ENBREL experiencing share loss in both of these segments.

Further, as a result of safety concerns related to patient survival, we previously announced that we had discontinued Vectibix™ treatment in our Panitumumab Advanced Colorectal Cancer Evaluation ("PACCE") trial, a non-registration-enabling trial evaluating the addition of Vectibix™ to standard chemotherapy and Avastin® (bevacizumab) for the treatment of first-line metastatic colorectal cancer ("mCRC"). We recently announced that we and the FDA have adopted changes to the U.S. prescribing information for Vectibix™ based on the results of the PACCE trial. The update is intended to highlight to clinicians the greater risk seen when Vectibix™ is combined with Avastin® and the specific chemotherapy used in the PACCE trial to treat patients with first-line mCRC. Vectibix™ is not indicated for the first-line treatment of mCRC and the new safety information applies to an unapproved use of Vectibix™.

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (the "FDAAA"), which created significant additions to the FDA's authority. The FDAAA expanded the FDA's authority, among other things, 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 Risk Evaluation and Mitigation Strategy ("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, could result in significant civil monetary penalties.

For further discussion on the above matters and related items, refer to “Reimbursement” below and to “Item 1A. Risk Factors” in Part II herein.

As a result of the above developments and, in particular the regulatory and reimbursement changes that began in 2007 involving ESA products, and their resulting impact on our operations, 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 part of the restructuring plan, we are reducing staff by approximately 12% to 14% or approximately 2,200 to 2,600 positions, resulting in restructuring charges of approximately $200 million to $230 million. In addition, we are re-scoping and making other changes to certain capital projects and closing certain production operations. These actions are primarily focused on rationalizing 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. In particular, these actions include the indefinite postponement of our planned Ireland manufacturing operations, the construction of which was previously reported to have been re-scoped and delayed, certain revisions to our planned manufacturing expansion in Puerto Rico, the accelerated closure of one of our ENBREL commercial bulk manufacturing operations, the closure of a clinical manufacturing facility in Thousand Oaks and, to a lesser degree, moderated expansion of our research facilities. These and related actions are expected to result in restructuring charges of approximately $470 million to $490 million, consisting primarily of asset impairments and, to a lesser degree, accelerated depreciation. Further, we expect to incur approximately $105 million to $130 million in other restructuring charges principally related to the accrual of losses for leases of certain R&D facilities that will not be used in our operations. The total charges associated with the restructuring plan are expected to be approximately $775 million to $850 million, as compared to our prior estimate of $600 million to $700 million. The increase in the total estimated restructuring charges was primarily the result of additional rationalization of our manufacturing facilities, including the above-noted actions with respect to our Ireland manufacturing operations and the closure of a clinical manufacturing facility. These estimates of total charges are net of amounts recoverable from our co-promotion partner, Wyeth. Approximately 50% of the total estimated restructuring charges will result in cash outlays, primarily associated with staff separation costs throughout 2008 and, to a lesser degree, lease payments over the lease terms, ending in 2023.

As discussed in more detail in Note 2, “Restructuring,” to the Condensed Consolidated Financial Statements, we have initiated a majority of the above-noted actions included in our restructuring plan and expect that all remaining actions will be substantially completed by 2008. During the three and nine months ended September 30, 2007, we incurred $293 million and $582 million, respectively, of restructuring charges. We estimate that the remaining restructuring costs will be incurred during the three months ended December 31, 2007 and, to a lesser degree, in 2008.

In connection with our efforts to improve our cost structure, we are refocusing our spending on critical R&D and operational priorities. In addition, we are seeking 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 ESA pharmacovigilance studies; ii) regulatory affairs, safety and compliance functions as these remain critical in the current regulatory environment; iii) clinical studies to advance our late-stage pipeline, including previously initiated mega-trials; iv) the advancement of earlier stage compounds and v) research efforts in inflammation, oncology and metabolic diseases. Further, we are also seeking partners to assist in the development of certain technologies, including our recent agreement with Daiichi Sankyo to develop and commercialize denosumab in Japan. We may also divest of or seek partners to assist in the funding of operations in certain geographic markets, such as Japan, and may divest of certain less significant marketed products.

For the three and nine months ended September 30, 2007 and 2006, operating income was as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Operating Income	$ 393	$ 1,322	(70)%	$ 2,923	$ 2,851	3%

Operating income as a percentage of product sales was 11% and 38% for the three months ended September 30, 2007 and 2006, respectively. For the nine months ended September 30, 2007 and 2006, operating income as a percentage of product sales was 27% and 28%, respectively. Operating income for the three and nine months ended September 30, 2007 was negatively impacted by the write-off of $590 million of acquired IPR&D incurred in connection with the Alantos and Ilypsa acquisitions and the above-described restructuring charges totaling $293 million and $582 million, respectively. Operating income for the nine months ended September 30, 2006 was negatively impacted by the $1.1 billion write-off of acquired IPR&D incurred in connection with the Abgenix acquisition.

We focus our R&D on novel human therapeutics for the treatment of grievous illness. In the past, we had substantially expanded our R&D capabilities to manage and execute increasingly larger and more complex clinical trials and to build the capacity to advance more compounds into and through the clinic. However, as a result of recent regulatory and reimbursement developments discussed above, we have and will continue to assess the optimal level of our R&D investment. These efforts will assist in allowing us to provide continued support of key activities as discussed above. To the extent future sales are negatively affected as a result of these or other challenges, we may be required to further adjust our R&D investment plans.

On July 16, 2007, we completed our acquisition of Alantos, which was accounted for as a business combination. Alantos was a privately held company that specialized in the development of drugs for the treatment of diabetes and inflammatory diseases. Pursuant to the merger agreement, we paid cash of approximately $300 million to acquire all of the outstanding shares of Alantos. The transaction provides Amgen with Alantos' lead drug candidate, a DPP-IV inhibitor in clinical development (phase 2a) for the treatment of type II diabetes.

On July 18, 2007, we completed our acquisition of Ilypsa, which was accounted for as a business combination. Ilypsa was a privately held company that specialized in the development of non-absorbed drugs for renal disorders. Pursuant to the merger agreement, we paid cash of approximately $400 million to acquire all of the outstanding shares of Ilypsa. The transaction provides Amgen with Ilypsa's lead drug candidate, a phosphate binder in clinical development (phase 2) for the treatment of hyperphosphatemia in CKD patients on hemodialysis.

On September 21, 2007, the Committee for Medicinal Products for Human Use ("CHMP") issued a positive opinion recommending Vectibix™ for conditional approval in the EU for patients with refractory mCRC with non-mutated (wild-type) KRAS genes. The CHMP had previously adopted a negative opinion with respect to the approval of Vectibix™ in the EU to treat patients with mCRC whose disease has progressed on or following all standard chemotherapy regimens, in response to which we had requested a re-examination in accordance with European regulations.

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, 2006 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 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 May 14, 2007, CMS issued its Proposed national coverage decision ("NCD") and on July 30, 2007, issued its Decision Memorandum. As CMS has not yet provided final guidance to Medicare contractors with respect to the implementation of the Decision Memorandum, we continue to evaluate what impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp®, and our business and results of operations. A complete 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 take other potentially limiting or costly actions if we or others identify side effects 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 both government and private payer healthcare programs. Medicare and Medicaid government healthcare programs' payment policies for drugs and biologicals are subject to various laws and regulations. Since January 1, 2005, in the physician clinic setting and since January 1, 2006, in the hospital outpatient setting, 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%"). 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 first quarter of 2008 will be based in part on certain historical sales and sales incentive data for Aranesp® from October 1, 2006 through September 30, 2007. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician office and the 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. Prior to January 1, 2006, Medicare's hospital outpatient prospective payment system ("OPPS"), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized the average wholesale price ("AWP") as the basis of Medicare Part B payment for covered outpatient drugs and biologics administered in the hospital outpatient setting. From 2003 to 2005, CMS applied an "equitable adjustment" such that the Aranesp® reimbursement rate was based on the AWP of PROCRIT®, Johnson & Johnson's recombinant human erythropoietin product marketed in the United States, using a dose conversion ratio. In 2006 and 2007, CMS did not apply an "equitable adjustment" to tie the reimbursement rate for Aranesp® to PROCRIT®. On November 1, 2007, CMS released its 2008 OPPS final rule that does not apply an "equitable adjustment" to the reimbursement rate for Aranesp® to PROCRIT®, however, in the past CMS has maintained that it reserves the right to apply an "equitable adjustment" in the hospital outpatient setting to the payment rate for Aranesp® in future years.

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 rate 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®). 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.

Since April 1, 2006, the ESRD Program reimbursement has been subject to a revised Hematocrit Measurement Audit Program Memorandum ("HMA-PM"), a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. This policy, EMP, was revised, effective October 1, 2006, to provide that if a patient's Hb is greater than 13 g/dL, providers are instructed to reduce the patient's EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN® and Aranesp® dose and the provider does not submit medical documentation to support maintaining a patient's Hb above 13 g/dL, reimbursement will be reduced to the level it would have been had the provider reduced dosage by 25%. On July 20, 2007, CMS published further revisions to the EMP, 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 and a reduction of the monthly dosing limits to 400,000 IUs of EPOGEN®, from 500,000 IUs, and to 1,200 micrograms ("mcgs") of Aranesp®, from 1,500 mcgs.

Changes resulting from the Medicare Prescription Drug Improvement and Modernization Act (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 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA. While we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For example, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN®. The demonstration project was scheduled to start in January 2006, but 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, on December 29, 2006, the Medicare Payment Advisory Commission ("MedPAC") released its second Congressionally-mandated report 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, the Company allocates its 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 MedPAC's 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 is 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 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.

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 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 NCD. Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. During the initial comment period which ended on April 13, 2007, we submitted comments to CMS which included a detailed and thorough review of the available clinical data, noted a series of important considerations and made a number of specific recommendations for the agency to consider in developing a NCD. 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. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;
- Anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent CIA;
- Prophylactic use to reduce tumor hypoxia;
- Patients with erythropoietin-type resistance due to neutralizing antibodies; and
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

Additionally, in the Decision Memorandum, CMS provides coverage for ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia under the following conditions:

- The Hb level immediately prior to initiation or maintenance of ESA treatment is < 10 g/dL (or the hematocrit is < 30%);
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 unit ("U")/kilogram ("kg")/three times weekly for Epoetin and 2.25 mcg/kg/weekly for darbepoetin alfa. Equivalent doses may be given over other approved time periods;

- Maintenance of ESA therapy is the starting dose if the Hb level remains below 10 g/dL (or hematocrit is < 30%) 4 weeks after initiation of therapy and the rise in Hb is > 1 g/dL (hematocrit > 3%). However, if after the first 4 weeks the Hb is > 10 g/dL, ESA treatment is not covered;
- For patients whose Hb rises < 1 g/dL (hematocrit rise < 3%) compared to pretreatment baseline over 4 weeks of treatment and whose Hb level remains < 10 g/dL after the 4 weeks of treatment (or the hematocrit is < 30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the Hb rises < 1 g/dL (hematocrit rise < 3 %) compared to pretreatment baseline by 8 weeks of treatment;
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in Hb > 1 g/dL (hematocrit > 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to < 10 g/dL (or the hematocrit is < 30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose; and
- ESA treatment duration for each course of chemotherapy under the above conditions includes the eight weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Under the provisions of the Decision Memorandum, Medicare contractors may continue to issue local coverage determinations based on the existing Medicare policy of “reasonable and necessary determinations” on all uses of ESAs that are not determined by the Decision Memorandum.

The Decision Memorandum establishes the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA and who all together accounted for approximately 50% of the U.S. cancer patients receiving Aranesp® prior to its issuance. We believe that the majority of CIA patients who received treatment with ESAs, including Aranesp®, were initiated at Hb levels above 10 g/dL and were maintained with Hb levels above 10 g/dL with continued therapy prior to the issuance of the Decision Memorandum. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10 g/dL, we believe that such restriction has and will continue to change 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 will 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 and only one private payer has implemented certain restrictions based upon it, we believe that some private payers may implement and follow some or all of the restrictions included in the Decision Memorandum. Further, due to difficulties in administering a two-tier medical practice, we believe some healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage, resulting in those covered by private insurance plans receiving the same care as Medicare patients.

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.

Further, the Deficit Reduction Act of 2005 (“DRA”) included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these

provisions that became effective on January 1, 2006, will increase the level of Medicaid rebates paid by us. Although we continue to evaluate the impact of the DRA, we believe it will not have a material adverse impact on our business. 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 Manufacturer 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 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 rule will have on our business.

Results of Operations

Product sales

For the three and nine months ended September 30, 2007 and 2006, worldwide product sales and total product sales by geographic region were as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Aranesp®	$ 818	$ 1,067	(23)%	$ 2,787	$ 3,015	(8)%
EPOGEN®	602	633	(5)%	1,851	1,850	0%
Neulasta®/NEUPOGEN®	1,100	998	10%	3,159	2,899	9%
ENBREL	821	705	16%	2,374	2,087	14%
Sensipar®	122	83	47%	335	223	50%
Vectibix™	41	—	n/a	137	—	n/a
Other	20	17	18%	50	47	6%
Total product sales	$ 3,524	$ 3,503	1%	$10,693	$10,121	6%
Total U.S.	$ 2,809	$ 2,864	(2)%	$ 8,572	$ 8,296	3%
Total International	715	639	12%	2,121	1,825	16%
Total product sales	$ 3,524	$ 3,503	1%	$10,693	$10,121	6%

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 and nine months ended September 30, 2007 grew 1% and 6%, respectively, principally driven by ENBREL and Neulasta® sales, which were substantially offset by a decline in Aranesp® sales. In particular for the three and nine months ended September 30, 2007, U.S. Aranesp® sales declined 36% and 17%, respectively, primarily reflecting a decrease in demand resulting from recent regulatory and reimbursement developments as discussed in more detail below. International product sales for the three and nine months ended September 30, 2007 were favorably impacted by $46 million and $129 million, respectively, from foreign currency exchange rate changes. Excluding the favorable impact of foreign currency exchange rate changes, international product sales increased 5% and 9% over the three and nine months ended September 30, 2006, respectively.

Aranesp®

For the three and nine months ended September 30, 2007 and 2006, total Aranesp® sales by geographic region were as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Aranesp® - U.S.	$ 460	$ 720	(36)%	$ 1,692	$ 2,029	(17)%
Aranesp® - International	358	347	3%	1,095	986	11%
Total Aranesp®	$ 818	$ 1,067	(23)%	$ 2,787	$ 3,015	(8)%

The decrease in U.S. Aranesp® sales for the three and nine months ended September 30, 2007 was principally driven by a decline in demand. The decline primarily reflects reaction to regulatory and reimbursement developments that began in 2007, primarily in the supportive cancer care setting and, to a lesser extent, a decline in our segment share. In particular, these regulatory and reimbursement developments, which are discussed in more detail in the "Overview" section above, include the Decision Memorandum issued by CMS on July 30, 2007, which significantly restricts Medicare reimbursement for use of Aranesp® in CIA and which we believe has also, to a lesser degree, negatively impacted Aranesp® use in CIA for patients covered by private insurance plans. In addition, these developments include the loss of virtually all Medicare reimbursement for use of Aranesp® in AoC and, to a lesser degree, the decline in Aranesp® use in AoC for patients covered by private insurance plans. Finally, these developments include the ESA safety-related label change, which occurred on March 9, 2007.

The increase in international Aranesp® sales for the three months ended September 30, 2007 was due to changes in foreign exchange which positively impacted sales by approximately $24 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales for the three month period decreased 4%. International sales for this period were negatively impacted in Europe by dosing conservatism in oncology and price pressures across all ESAs. International sales for the nine months ended September 30, 2007 was favorably impacted by foreign currency exchange rate changes of $69 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales for the nine month period increased 4%. Sales growth for the nine month period reflects the continued dosing conservatism in the European oncology segment and the pricing pressure noted in the three months ended September 30, 2007 partially offsetting certain segment growth and share gains, largely occurring during the first quarter of 2007.

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:

- reimbursement developments including:
  - CMS Decision Memorandum issued on July 30, 2007 which significantly restricts Medicare reimbursement for the use of Aranesp® in CIA including the final implementation guidance to Medicare contractors that CMS has yet to provide and any related impact on private payers' reimbursement or healthcare providers' prescribing behavior.
  - reimbursement changes resulting from current or future product label changes;
  - reimbursement and cost containment pressures by third-party payers, including governments and private insurance plans;

- regulatory developments, including:
  - product safety-related label changes occurring on March 9, 2007 in the United States for the class of ESAs, including Aranesp® and EPOGEN®;
  - recommendations made at the ODAC meeting on May 10, 2007 to include more restrictions on ESA labels and to require companies with currently approved ESAs to conduct additional clinical trials. As discussed further below, on November 8, 2007, we announced updates to the ESA package inserts and related matters which recognize input from the ODAC meeting;
  - results from the CRDAC/DSaRMAC meeting on September 11, 2007 including i) recommendations against revising the ESA product labels to state that the target Hb level should not exceed 11 g/dL, ii) recommendations that the ESA dosages used to achieve the Hb levels in the lower target groups in the Normal Hematocrit Cardiac Trial and CHOIR studies were sufficient to form the basis for ESA dosage recommendations and iii) discussions of potential clinical studies involving ESAs. As discussed further below, on November 8, 2007, we announced updates to the ESA package inserts and related matters which recognize input from the CRDAC/DSaRMAC meeting;
  - upcoming changes to product information from the EMEA for the class of ESAs, including Aranesp®, in Europe;
  - product label changes occurring on November 8, 2007 in the United States for the class of ESAs, including Aranesp® and EPOGEN®, and continuing discussions with the FDA regarding additional pharmacovigilance clinical trials and further modifications to the ESA product labels. These developments are in part due to the recommendations made at the ODAC meeting on May 10, 2007 and the CRDAC/DSaRMAC meeting on September 11, 2007;
- adverse events or results from clinical trials or studies performed by us or by others, such as those referred to in the “Overview” section above, 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, including:
  - Roche’s peg-EPO product, MIRCERA®, approved by the European Commission on July 26, 2007 to treat anemia associated with CKD which was launched in certain EU countries in the third quarter of 2007 and is expected to be launched in additional European countries in the fourth quarter of 2007;
  - Shire’s erythropoietin product Dynepo™ (Epoetin delta), launched in Germany in the first quarter of 2007 and in the UK in the second quarter of 2007 and is expected to be launched in certain other EU countries throughout the remainder of 2007;
  - biosimilar products launched in the third quarter of 2007 or expected to be launched in 2008 in certain European countries;
- our ability to differentiate Aranesp® from current and potential future competition; and
- pricing strategies;

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 product sales.

EPOGEN®

For the three and nine months ended September 30, 2007 and 2006, total EPOGEN® sales were as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
EPOGEN® - U.S.	$ 602	$ 633	(5)%	$ 1,851	$ 1,850	0%

EPOGEN® sales for the three months ended September 30, 2007 decreased primarily due to a decline in dose/utilization and increased discounts partially offset by patient population growth of 3%. The decline in dose/utilization reflects reaction to regulatory and reimbursement developments, which began in 2007, as discussed in more detail in the "Overview" section above. These developments include the issuance of the KDOQI guidelines, the revisions to the EMP and the March 9, 2007 ESA safety-related label change. We believe physicians have continued to evaluate these developments in making treatment and dosing decisions. For the nine months ended September 30, 2007, EPOGEN® sales reflect the increase in patient population growth and positive revised estimates of dialysis demand (spillover) for prior quarters (see Note 1, "Summary of significant accounting policies – *Product sales*" to the Condensed Consolidated Financial Statements for further discussion) offset by the decline in dose/utilization.

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:
  - reimbursement changes resulting from CMS' July 20, 2007 published revisions to its EMP, effective January 1, 2008, which require a 50% reduction in Medicare reimbursement if a patient's Hb is above 13 g/dL for three or more consecutive months and a reduction of the monthly dosing limits to 400,000 IUs of EPOGEN® from 500,000 IUs;
  - reimbursement changes resulting from current or future product label changes;
  - changes in reimbursement rates or a change in the basis for reimbursement by the federal government;
- regulatory developments, including:
  - product safety-related label changes occurring on March 9, 2007 in the United States for the class of ESAs, including Aranesp® and EPOGEN®;
  - results from the CRDAC/DSaRMAC meeting on September 11, 2007 including i) recommendations against revising the ESA product labels to state that the target Hb level should not exceed 11 g/dL, ii) recommendations that the ESA dosages used to achieve the Hb levels in the lower target groups in the Normal Hematocrit Cardiac Trial and CHOIR studies were sufficient to form the basis for ESA dosage recommendations and iii) discussions of potential clinical studies involving ESAs. As discussed further below, on November 8, 2007, we announced updates to the ESA package inserts and related matters which recognizes input from the CRDAC/DSaRMAC meeting;

- product label changes occurring on November 8, 2007 in the United States for the class of ESAs, including Aranesp® and EPOGEN® and any related developments with respect to ESAs. These developments are in part due to the recommendations made at the ODAC meeting on May 10, 2007 and the CRDAC/DSaRMAC meeting on September 11, 2007;

- governmental or private organization regulations or guidelines relating to the use of our products, including:
  - changes in medical guidelines resulting from the NKF issuance of the final updated KDOQI guidelines, that recommend that physicians target Hb in the range of 11 g/ dL to 12 g/dL and also stipulate that the target not be above 13 g/dL;
  - legislative actions;
- adverse events or results from clinical trials or studies performed by us or by others, such as those referred to in the "Overview" section above, 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; and
- pricing strategies;

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 product sales.

Neulasta®/NEUPOGEN®

For the three and nine months ended September 30, 2007 and 2006, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Neulasta® - U.S.	$ 598	$ 560	7%	$ 1,744	$ 1,636	7%
NEUPOGEN® - U.S.	232	212	9%	636	609	4%
U.S. Neulasta®/NEUPOGEN® - Total	830	772	8%	2,380	2,245	6%
Neulasta® - International	165	130	27%	472	363	30%
NEUPOGEN® - International	105	96	9%	307	291	5%
International Neulasta®/NEUPOGEN® - Total	270	226	19%	779	654	19%
Total Worldwide Neulasta®/NEUPOGEN®	$ 1,100	$ 998	10%	$ 3,159	$ 2,899	9%

The increase in U.S. sales of Neulasta®/NEUPOGEN® for the three months ended September 30, 2007 was primarily driven by favorable wholesaler inventory changes. The increase in international Neulasta®/NEUPOGEN® sales for the three months ended September 30, 2007 reflects both increased conversion to Neulasta® from NEUPOGEN® and changes in foreign exchange, which positively impacted third quarter combined international sales by $18 million. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 12%.

The increase in U.S. Neulasta®/NEUPOGEN® sales for the nine months ended September 30, 2007 was driven by demand for Neulasta® due to segment growth and favorable changes to wholesaler inventory levels. The increase in international Neulasta®/NEUPOGEN® sales for the nine months ended September 30, 2007 was driven by the continued conversion to Neulasta® from NEUPOGEN® and changes in foreign exchange, which positively impacted the nine months ended September 30, 2007 combined sales by $50 million. Excluding the impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 11%.

For the remainder of 2007, we believe sales growth for Neulasta®/NEUPOGEN® will depend on patient growth and further segment penetration of Neulasta® in the moderate-risk population that would benefit from its use in first and subsequent chemotherapy cycles. NEUPOGEN® competes with Neulasta® in the United States and Europe. Worldwide NEUPOGEN® sales have been adversely impacted by conversion to Neulasta®. However, we believe that most of the conversion in the United States and Europe has occurred.

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:

- competitive products or therapies, including biosimilar products that may be approved in the EU sometime in 2008 and be available shortly thereafter;
- 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, which may 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;
- patient growth;
- penetration of existing segments; 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 product sales.

ENBREL

For the three and nine months ended September 30, 2007 and 2006, total ENBREL sales by geographic region were as follows (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
ENBREL - U.S.	$ 777	$ 669	16%	$ 2,247	$ 1,983	13%
ENBREL - International	44	36	22%	127	104	22%
Total ENBREL	$ 821	$ 705	16%	$ 2,374	$ 2,087	14%

ENBREL sales growth for the three and nine months ended September 30, 2007 was driven by demand due to increases in both patients and net sales price. While ENBREL continued to maintain a leading position in both rheumatology and dermatology, the sales growth during the three and nine months ended September 30, 2007 was affected by slight share declines in the United States in both segments versus the corresponding prior year periods 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 such as psoriasis for HUMIRA®, and new competitive products coming to market, such as Johnson & Johnson's CNTO 1275 (ustekinumab) and CNTO 148 (golimumab) and, in part, our ability to differentiate ENBREL based on its safety profile and efficacy;
- growth in the rheumatology and dermatology segments;
- 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, which may 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 new indications.

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

Selected operating expenses

The following table summarizes selected operating expenses for the three and nine months ended September 30, 2007 and 2006 (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Product sales	$ 3,524	$ 3,503	1%	$10,693	$10,121	6%
Operating expenses:						
Cost of sales (excludes amortization of acquired intangible assets)	$ 792	$ 489	62%	$ 1,942	$ 1,534	27%
% of product sales	22%	14%		18%	15%	
Research and development	$ 776	$ 872	(11)%	$ 2,444	$ 2,315	6%
% of product sales	22%	25%		23%	23%	
Selling, general and administrative	$ 730	$ 807	(10)%	$ 2,360	$ 2,336	1%
% of product sales	21%	23%		22%	23%	
Amortization of acquired intangible assets	$ 76	$ 122	(38)%	$ 224	$ 296	(24)%
Write-off of acquired in-process research and development	$ 590	$ —	100%	$ 590	$ 1,101	(46)%
Other items	$ 254	$ —	100%	$ 543	$ —	100%

Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see “Condensed Consolidated Statements of Operations”), increased 62% and 27%, respectively, for the three and nine months ended September 30, 2007. The increase for the three and nine months ended September 30, 2007 was primarily driven by product mix, due to higher sales of ENBREL, which is more costly to manufacture; excess capacity charges at our manufacturing facility in Puerto Rico and the write-off of excess inventory related to changing regulatory and reimbursement environments and certain new product presentations. The Company expects excess capacity charges to continue to occur through 2008 due principally to declining product sales and related demand for Aranesp® resulting from regulatory and reimbursement developments. Cost of sales margin throughout this period is expected to be similar to the three months ended September 30, 2007 due to excess capacity charges and product sales mix.

The increase for the three and nine months ended September 30, 2007 was also the result of restructuring charges of $113 million, of which $110 million related to accelerated depreciation resulting from the decision to accelerate the closure of one of our ENBREL commercial bulk manufacturing operations in connection with the rationalization of our worldwide network of manufacturing facilities. See Note 2, “Restructuring,” to the Condensed Consolidated Financial Statements for further discussion.

Research and development

R&D expenses, which are expensed as incurred, are primarily comprised of costs and expenses for salaries and benefits associated with R&D personnel; overhead and occupancy; clinical trial and related clinical manufacturing, including contract services and other outside costs, process development and quality assurance; information systems and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners.

R&D expenses decreased 11% for the three months ended September 30, 2007, which was primarily attributable to decreases of $48 million in clinical trial and manufacturing costs primarily due to the

optimization of ongoing trials, $35 million in in-licensing expenses due to the initiation of fewer in-licensing agreements, $34 million from collaborations primarily from the benefit derived from licensing denosumab in Japan to Daiichi Sankyo and $30 million in staff-related costs, partially offset by an increase in acquisition-related costs of $23 million.

R&D expenses for the three and nine months ended September 30, 2007 include $18 million of restructuring costs, comprised of $35 million in charges related to asset impairments offset by a $17 million benefit associated with the reversal of previously accrued expenses for bonuses and stock-based compensation awards, which will be forfeited as a result of the employees' termination. See Note 2, "Restructuring," to the Condensed Consolidated Financial Statements for further discussion.

R&D expense increased 6% for the nine months ended September 30, 2007 primarily due to increases of $62 million in clinical trial and manufacturing costs, $51 million in staff-related costs, $60 million in outside expenses, $23 million in acquisition-related costs and $18 million for the above-noted restructuring costs, partially offset by a decrease of $42 million in in-licensing expenses and $34 million from collaborations primarily from the benefit derived from licensing denosumab in Japan to Daiichi Sankyo.

Selling, general and administrative

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 occupancy costs and other general and administrative costs.

For the three months ended September 30, 2007, the 10% decrease in SG&A is primarily attributable to $83 million in cost recoveries for certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Wyeth. See Note 2, "Restructuring," to the Condensed Consolidated Financial Statements for further discussion. In addition, outside marketing expenses in support of our principal products, including Wyeth profit share related to ENBREL decreased approximately $10 million due to lower promotion and advertising spending offsetting higher ENBREL profit share. These decreases were partially offset by an increase in legal costs associated with ongoing litigation of approximately $33 million.

For the nine months ended September 30, 2007, the 1% increase in SG&A is primarily due to increases in outside marketing expenses in support of our principal products, including Wyeth profit share related to ENBREL of approximately $82 million. Furthermore, legal costs associated with ongoing litigation increased approximately $44 million. These increases were partially offset by the above-mentioned restructuring benefit.

Amortization of acquired intangible assets

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

Write-off of acquired in-process research and development

The fair value of acquired IPR&D projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are immediately expensed. In the three months ended September 30, 2007, we wrote-off a total of $590 million of acquired IPR&D. This amount is comprised of $270 million in connection with the Alantos acquisition related to an orally administered treatment for type II diabetes that at the date of acquisition was in phase 2a clinical trials and $320 million in connection with the Ilypsa acquisition related to a phosphate binder that at the date of acquisition was in phase 2 clinical trials for the treatment of hyperphosphatemia in CKD patients on hemodialysis. In the nine months ended September 30, 2006, we wrote-off $1.1 billion of acquired IPR&D related to the Abgenix acquisition. This amount is comprised of approximately $770 million related the rights which we did not own pursuant to our agreement with Abgenix to jointly develop and commercialize panitumumab and approximately $330 million related to a royalty that we

would have owed to Abgenix in respect of future sales of denosumab as a result of using certain of Abgenix's patented technology in the development of this product candidate. Panitumumab was Abgenix's fully human monoclonal antibody which, at acquisition, was in phase 2/3 clinical trials for the treatment of certain types of cancer. Denosumab is a fully human monoclonal antibody that is a key mediator of the resorptive phase of bone remodeling and was in phase 2/3 clinical trials for various types of bone diseases at the time of the Abgenix acquisition.

We used the "income method" to determine the estimated fair values of the acquired IPR&D, which uses a discounted cash flow model and applies a probability weighting based on estimates of successful product development and commercialization to estimated future net cash flows resulting from projected revenues and related costs. The estimated after-tax cash flows were probability weighted at success rates of 38% for the Alantos product candidate, 77% for the Ilypsa product candidate, and 43% to 85% for the Abgenix technologies. These success rates take into account the stages of completion and the risks surrounding successful development and commercialization of the underlying technologies. These cash flows were then discounted to present value using a discount rate of 10%. The incremental R&D expenses assumed to be incurred to obtain necessary regulatory approval for the Alantos and Ilypsa product candidates are immaterial. The incremental R&D expenses assumed to be incurred to obtain necessary regulatory approvals for the various indications of panitumumab were estimated at the time of acquisition at approximately $300 million and would be incurred during the fiscal years 2006 through 2011. The elimination of the royalty on potential future sales of denosumab did not result in us incurring any incremental R&D expenses.

The major risks and uncertainties associated with the timely and successful completion of development and commercialization of these product candidates are our ability to confirm their safety and efficacy based on the data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not able to market a human therapeutic without obtaining regulatory approvals, and such approvals require completing clinical trials that demonstrate a product candidate is safe and effective.

The above assumptions were prepared solely for the purposes of estimating fair values of these product candidates as of the date of their acquisition. However, we cannot provide assurance that the underlying assumptions used to forecast the cash flows or the timely and successful completion of development and commercialization will materialize, as estimated. Consequently, the eventual realized value of the acquired IPR&D may vary from its estimated value at the date of acquisition.

Other items

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 in "Other items."

During the three and nine months ended September 30, 2007, the Company incurred staff separation costs of $104 million and $107 million, respectively.

In addition, the Company recorded asset impairment charges of $71 million and $357 million during the three and nine months ended September 30, 2007, respectively. Included in the charges for the nine months ended September 30, 2007 are $286 million of asset impairment charges incurred during the three months ended June 30, 2007.

Also, in connection with the restructuring plan, we recorded $79 million in charges during the three and nine months ended September 30, 2007 primarily related to the loss accruals for leases for certain R&D facilities that will not be used in our business.

Interest and other income and (expense), net

Interest and other income and (expense), net for the three months ended September 30, 2007 was $21 million of expense compared to $39 million of income for the three months ended September 30, 2006. The decrease is primarily the result of increased interest expense related to the issuance of $4.0 billion of debt in May 2007. Interest and other income and (expense), net for the nine months ended September 30, 2007 was $20 million of expense compared to $140 million of income for the nine months ended September 30, 2006. The decrease was principally attributable to the increased interest expense related to the debt issued in May 2007 and the write-off of $51 million of deferred financing and related costs in March 2007 resulting from the repayment of the convertible debt.

Income taxes

Our effective tax rates for the three and nine months ended September 30, 2007 were 46.0% and 19.7%, respectively, compared with 19.0% and 29.2% for the three and nine months ended September 30, 2006, respectively. The increase in our effective tax rate for the three months ended September 30, 2007 was primarily due to the non-deductible, acquired IPR&D incurred in connection with the acquisitions of Alantos and Ilypsa in 2007 and the favorable resolution of prior years' federal and state examinations in 2006, partially offset by the research and experimentation tax credit ("R&E Credit") which was re-enacted in the fourth quarter of 2006 and enhanced in 2007, and an increase in the amount of earnings that are intended to be invested indefinitely outside the United States. Our effective tax rate for the nine months ended September 30, 2007 has decreased primarily due to the lower amount of non-deductible, acquired IPR&D written-off in connection with the acquisitions of Alantos and Ilypsa in 2007 compared with the amount written-off in connection with the acquisition of Abgenix in 2006, the greater tax benefit from the favorable resolution of our prior years' federal examination in 2007 compared with the favorable resolutions in 2006, the re-enacted and enhanced R&E Credit, and an increase in the amount of earnings that are intended to be invested indefinitely outside the United States.

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

Recent and proposed accounting pronouncements

In June 2007, the FASB ratified EITF No. 07-3, which requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. We will adopt EITF No. 07-3 as of January 1, 2008, and it is not expected to have a material impact on our results of operations or financial position.

In July 2006, the FASB issued FIN 48, which became effective for us as of January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement and classification in our financial statements of tax positions taken or expected to be taken in a tax return.

For tax benefits to be recognized under FIN 48, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. As of January 1, 2007, the gross amount of our liabilities for UTBs was approximately $945 million and accrued interest related to these UTBs totaled approximately $106 million. Included in the balance is approximately $776 million of UTBs (net of the federal benefit on state taxes) that, if recognized, would affect our effective tax rate. The cumulative effect of applying the recognition and measurement provisions upon adoption of FIN 48 was not material.

FIN 48 also provides guidance on the balance sheet classification of liabilities for UTBs as either current or non-current depending on the expected timing of payments. Upon adoption of FIN 48, we reclassified approximately $240 million of UTBs and related accrued interest from current income taxes payable to non-current liabilities.

As of the adoption of FIN 48, we believed that it was reasonably possible that our liabilities for UTBs might decrease by $350 million to $600 million within the succeeding twelve months due to potential settlement of transfer pricing tax positions on our U.S. income tax returns.

Interest and penalties related to UTBs are classified as a component of our provision for income taxes.

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

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 requires or permits 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. The FSP, if issued as proposed, would become effective for calendar year end companies like us in the first 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 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 proposed method of accounting for cash settled convertible debt securities is adopted by the FASB as described above, it would have an adverse impact on our past and future reported financial results. As the final guidance has not been issued, we cannot predict its ultimate outcome.

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

For additional discussion on this issue, see “Item 1A. Risk Factors” – “*The accounting method for our convertible debt securities may be subject to change.*” in Part II herein.

Financial Condition, Liquidity and Capital Resources

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

	September 30, 2007	December 31, 2006
Cash, cash equivalents and marketable securities	$ 5,950	$ 6,277
Total assets	33,452	33,788
Current debt	136	1,798
Non-current debt	11,177	7,214
Stockholders’ equity	16,905	18,964

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.

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at September 30, 2007, approximately $5.3 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. If these funds are repatriated for use in our U.S. operations, substantial additional taxes will be required to be paid.

Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of September 30, 2007 and December 31, 2006 (in millions):

	September 30, 2007	December 31, 2006
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	—
5.85% notes due 2017 (2017 Notes)	1,098	—
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	—
Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes)	80	1,778
Other	237	235
Total borrowings	11,313	9,012
Less current portion	136	1,798
Total non-current debt	$ 11,177	$ 7,214

Certain of our financing arrangements contain non-financial covenants and as of September 30, 2007 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 and A2 with a negative outlook by Moody's Investors Service, Inc. See Note 5, "Financing arrangements" and Note 9, "Subsequent events" to our Condensed Consolidated Financial Statements for further discussion of the financing arrangement transactions that occurred in 2007 and Note 5, "Financing arrangements" in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2006 for additional discussion of our financing arrangements. Also see "Overview — *Recent and proposed accounting pronouncements*" discussion for potential future impacts to financing arrangements.

Cash flows

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

	Nine months ended September 30,	
	2007	2006
Net cash provided by operating activities	$ 3,871	$ 4,147
Net cash used in investing activities	(1,295)	(3,929)
Net cash used in financing activities	(2,470)	(767)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2007 decreased from the prior year nine months ended due to increased disbursements from the timing of payments

in the ordinary course of business partially offset by higher receipts from customers. (See Condensed Consolidated Statements of Cash Flows.)

Investing

Capital expenditures totaled $1.0 billion during the nine months ended September 30, 2007, compared with $834 million during the same period last year. The capital expenditures during the nine months ended September 30, 2007 were primarily associated with ongoing manufacturing capacity and site expansions in Puerto Rico and other locations and investment in our global enterprise resource planning ("ERP") system. We currently estimate 2007 spending on capital projects and equipment to be approximately $1.4 billion.

Capital expenditures for the nine months ended September 30, 2006 were primarily associated with ongoing manufacturing capacity and site expansion in Ireland, Puerto Rico and other locations and costs associated with implementing our ERP system.

As discussed above in the "Overview" section, we incurred asset impairment charges of approximately $106 million and $392 million in the three and nine months ended September 30, 2007, respectively, in connection with the rationalization of our worldwide manufacturing operations and, to a lesser degree, the moderation of the expansion of our research facilities.

On July 16, 2007, we completed our acquisition of Alantos and pursuant to the merger agreement, we paid $300 million in cash, net of cash acquired and transaction costs. On July 18, 2007, we completed our acquisition of Ilypsa and pursuant to the merger agreement, we paid $398 million of cash, net of cash acquired and transaction costs of $2 million.

Financing

In May 2007, we issued $2.0 billion aggregate principal amount of 2008 Floating Rate Notes, $1.1 billion aggregate principal amount of 5.85% notes due in 2017 and $900 million aggregate principal amount of 6.375% notes due in 2037. The 2008 Floating Rate Notes will bear interest at a rate per annum, equal to LIBOR plus 0.08%, which will be reset quarterly. A total of $3.2 billion of the net proceeds raised from the issuance of these notes were used to repurchase shares of our common stock under a block trade entered into in May 2007.

On March 2, 2007, as a result of certain holders of the 2032 Modified Convertible Notes exercising their March 1, 2007 put option, we repurchased $2.3 billion aggregate principal amount of Convertible Notes at their then-accreted value for $1.7 billion in cash, or approximately 96%, of the outstanding balance of these notes.

During the nine months ended September 30, 2007 and 2006, we repurchased 85.2 million and 66.9 million shares of our common stock, respectively, at a total cost of $5.0 billion and $4.8 billion, respectively. As of September 30, 2007, we had $1.5 billion available for stock repurchases under our stock repurchase program authorized by the Board of Directors in December 2006. In July 2007, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of common stock. 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 and blackout periods in which we are restricted from repurchasing shares, 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 pursuant to the employee stock purchase plan. Employee stock option exercises and proceeds from the sale of stock by us pursuant to the employee stock purchase plan provided $244 million and $367 million of cash during the nine months ended September 30, 2007 and 2006, 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.

Contractual Obligations

We adopted FIN 48 on January 1, 2007 (see Note 1, "Summary of significant accounting policies—*Recent accounting pronouncements*" to the Condensed Consolidated Financial Statements for further discussion). On the date of adoption, the current liabilities for UTBs (net of federal benefit on state taxes) and related accrued interest totaled approximately $705 million. As of September 30, 2007, this amount has decreased to approximately $300 million. Noncurrent liabilities for UTBs (net of federal tax benefits on state taxes) and related accrued interest totaling approximately $240 million on January 1, 2007 (approximately $500 million at September 30, 2007) are not included in the contractual obligations table because, due to their nature, there is a high degree of uncertainty regarding the timing of future cash outflows and other events that extinguish these liabilities.

For a discussion of material changes to our long-term debt obligations, see "Financial Condition, Liquidity and Capital Resources – *Cash flows – Financing*" above.

Item 4. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance Amgen's management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2007.

Management determined that, as of September 30, 2007, 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

Certain of our legal proceedings are reported in our Annual Report on Form 10-K for the year ended December 31, 2006 with material developments since that report described in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2007 and June 30, 2007, and below. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

Transkaryotic Therapies ("TKT") and Aventis Litigation

The U.S. Supreme Court previously denied Amgen's petition for a writ of certiorari and the case was remanded to the United States District Court of Massachusetts (the "Massachusetts District Court") for further proceedings on the validity of U.S. Patent No. 5,955,422 and whether to grant injunctive relief. The Massachusetts District Court set a schedule for briefs on whether the record should be opened for further evidence. On July 17, 2007, the Court entered a ruling refusing to reopen the record to allow additional evidence concerning the issue of validity of the `422 patent. Briefs have been submitted by the parties concerning the validity of the `422 patent. The Court has set a hearing on December 10, 2007, for issues on remand.

Average Wholesale Price Litigation

State of Montana v. Abbott Laboratories, Inc., et al. & Corp., et al.

On September 24, 2007, the case was remanded to the Montana District Court.

State of Nevada v. American Home Products Corp., et al.

On September 24, 2007, the case was remanded to the Nevada District Court.

Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc., et al.

On September 1, 2007, the case was remanded to the Commonwealth Court for Pennsylvania.

People of State of Illinois v. Abbott Laboratories, Inc., et al.

On September 1, 2007, the case was remanded to the Circuit Court for Cook County, Illinois.

County of Erie v. Abbott Laboratories, Inc., et al.

On September 1, 2007, the case was remanded to the Supreme Court of New York, Erie County.

State of Mississippi v. Abbott Laboratories, Inc., et al.

On September 1, 2007, the case was remanded to the Chancery Court of Hinds County, Mississippi, First Judicial District.

County of Schenectady v. Abbott Laboratories, Inc., et al.

On September 1, 2007, the case was remanded to the Supreme Court of New York, Schenectady County.

County of Oswego v. Abbott Laboratories, Inc., et al.

On September 1, 2007, the case was remanded to the Supreme Court of New York, Oswego County.

Johnson & Johnson Matters

Ortho Biotech Products, L.P. ("Ortho Biotech") Antitrust Litigation

On October 18, 2007, the United States District Court for the District of New Jersey entered an Order extending the date of discovery deadlines and summary judgment deadlines.

Ortho Biotech Arbitration

On October 25, 2007, Ortho Biotech filed an arbitration demand with American Arbitration Association, pursuant to a prior arbitral order and the parties' product license agreement, in an attempt to reform the established methodology which accounts for U.S. Epoetin alfa sales into the other party's contractual market segment, or spillover sales. Ortho alleges that introduction of Aranesp® affected a "fundamental change" in the U.S. ESA market and correspondingly rendered the previously-established spillover methodology inaccurate and unreliable. Under its demand, Ortho seeks a new order reforming the spillover methodology and, assuming that a new methodology is approved, retroactive application of the methodology back to the introduction of Aranesp®.

Roche Matters

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

On August 27, 2007, the United States District Court for the Massachusetts District Court granted Amgen's motions for summary judgment that the '349, '422 and '933 patents are not invalid for obviousness-type double patenting over the `008 patent and that certain of the asserted patent claims are not invalid for indefiniteness, lack of written description or lack of enablement. On August 28, 2007, the Massachusetts District Court granted Amgen's motion for summary judgment of infringement of claim 1 of the '422 patent and denied all of the parties' remaining pending summary judgment motions, except Amgen's motion for summary judgment relating to Roche's antitrust allegations, which the Massachusetts District Court has taken under advisement. During the period starting September 4, 2007 and ending October 18, 2007, Amgen's patent infringement claims were tried before a jury along with certain of Roche's defenses and counterclaims of non-infringement and patent invalidity. Roche's defenses and counterclaims of invalidity based on obviousness-type double patenting and unenforceability based on alleged inequitable conduct were tried to the Massachusetts District Court in separate proceedings. On September 25, 2007, the Massachusetts District Court granted judgment as a matter of law that Roche had not satisfied its burden of proving that '422 claim 1 is anticipated. On October 16, 2007, the Massachusetts District Court granted judgment as a matter of law that Amgen had not satisfied its burden to prove that Roche's peg-EPO product infringes claim 7 of the '349 patent. On October 17, 2007, the Massachusetts District Court granted judgment as a matter of law that Amgen had not satisfied its burden to prove that Roche's peg-EPO product infringes claim 9 of the '933 patent. On October 23, 2007, the jury rendered a verdict that ten claims of the '933, '868 and '698 patents will be infringed by Roche and that all asserted claims of the '422, '933, '868, '698 and '349 patents are valid. On the same day, the Massachusetts District Court ruled that Roche did not meet its burden to prove inequitable conduct by Amgen during patent prosecution. On October 30, 2007, the Massachusetts District Court granted Roche's post-trial motion that Amgen had failed to prove that Roche will infringe claim 12 of the `933 patent under the Doctrine of Equivalents, overturning the jury's verdict of patent infringement. The Massachusetts District Court has yet to rule on certain of Roche's invalidity defenses of obviousness-type double patenting, on whether Roche infringes claim 14 of the '933 patent or on Amgen's summary judgment motion relating to Roche's antitrust allegations. An evidentiary hearing has been set for November 15, 2007 and continuing for three days in December on dates yet to be set by the Massachusetts District Court, during which the Massachusetts District Court will hear evidence concerning Amgen's request for a permanent injunction to prevent Roche from commercializing its peg-EPO product in the United States until expiration of the infringed patents, the latest of which expires in 2013.

Amgen Inc., et al. v. Ariad Pharmaceuticals, Inc. ("Ariad")

The United States District Court for the District of Delaware granted Ariad's motion for leave on September 13, 2007 and Ariad filed its amended counterclaims. On October 9, 2007 Amgen filed its reply to Ariad's amended counterclaims. The Court scheduled a separate trial in March 2009 on the two additional patents, U.S. Patent Nos. 6,150,090 and 5,804,374.

Securities Class Actions

Connecticut Retirement Plans & Trust Funds v. Amgen Inc. et al.

The three previously disclosed securities class actions, Mendall v. Amgen Inc., et al., Jaffe v. Amgen Inc., et al., Eldon v. Amgen Inc., et al., Rosenfield v. Amgen Inc. et al. and Public Employees' Retirement Association of Colorado v. Amgen Inc., et al., were consolidated into one action captioned, Connecticut Retirement Plans & Trust Funds v. Amgen Inc. et al. before the United States District Court for the Central District of California (the "California Central District Court"). The amended complaint was filed on October 2, 2007.

Derivative class actions

State

The two previously disclosed state derivate lawsuits, Larson v. Sharer, et al. and Anderson v. Sharer, et al., were consolidated into one action captioned Larson v. Sharer et al. before the Ventura County Superior Court. A third state derivate lawsuit, Weil v. Sharer et al., was filed on August 13, 2007 in Ventura County Superior Court and was also consolidated with the Larson action.

On September 20, 2007, the state derivative lawsuit of Schreiman v. Sharer, et al. filed in Ventura County Superior Court on May 10, 2007, was dismissed without prejudice.

Federal

On September 21, 2007, the derivative lawsuit of Rosenblum v. Sharer, et al. was filed with the Central District of California. The federal derivative lawsuit alleges the same claims and requests the same relief as the consolidated state derivative action. The complaint alleges that the defendants breached their fiduciary duties, wasted corporate assets and were unjustly enriched. Plaintiffs allege that the defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions as well as the Amgen market strategy caused damage to the Company resulting in several inquiries, investigations and lawsuits that are costly to defend. The complaint also alleges insider trading by the defendants. Plaintiffs seek treble damages based on various causes of action, reformed corporate governance, equitable and/or injunctive relief, restitution, disgorgement of profits, benefits and other compensation, and legal costs.

Third- party payors class actions

On August 8, 2007, Ironworkers v. Amgen Inc., on August 15, 2007 Watters (State of Michigan) v. Amgen Inc. and August 28, 2007, Sheet Metal v. Amgen Inc., third-party payor class action lawsuits were filed against Amgen in the Central District of California. Similar to previously filed third-party payor class actions, in each action the plaintiff alleges that Amgen marketed its anemia medicines, EPOGEN® and Aranesp®, for "off-label" uses, or uses that are not approved by the FDA, and claims that, as a result, the plaintiff paid for unwarranted prescriptions. Specifically, the complaints allege that Amgen promoted EPOGEN® and Aranesp® for: treating cancer patients who are not on chemotherapy; treating quality of life symptoms associated with anemia, such as fatigue; and reaching Hb targets above the FDA-approved level. Each plaintiff asserts claims under California's consumer protection statutes and for breach of implied warranty and unjust enrichment and plaintiffs seek to represent a nationwide class of individuals and entities. Further, in Sheet Metal v. Amgen,

plaintiff also name privately owned dialysis centers DaVita and Fresenius as co-defendants and includes a RICO claim.

On October 29, 2007, in the United Food & Commercial Workers Central Pennsylvania and Regional Health & Welfare Fund v. Amgen Inc., the Vista Healthplan Inc. v. Amgen Inc., and the Painters District Council No. 30 Health & Welfare Fund v. Amgen. Inc. third-party payor class actions, a motion to dismiss and a motion to transfer each of the three cases were heard before California Central District Court. The California Central District Court also heard a motion to consolidate the three aforementioned lawsuits which Amgen opposed.

ERISA Class Action

On August 20, 2007, Harris v. Amgen Inc., et al., an ERISA class action lawsuit was filed against Amgen and certain of its Board of Directors in the California Central District Court. Plaintiffs claim that Amgen and various Board members breached their fiduciary duties by failing to inform current and former employees who participated in the Amgen Retirement and Savings Manufacturing Plan and the Amgen Savings Plan of the alleged off-label promotion of both Aranesp® and EPOGEN® while a number of studies allegedly demonstrated safety concerns in patients using ESAs.

Other

On August 23, 2007, Amgen received a letter from the United States Senate Subcommittee on Permanent Investigations of the Senate Committee on Homeland Security and Governmental Affairs (the “Subcommittee”) regarding corporate tax benefits involving foreign entities or jurisdictions. The Subcommittee letter requested information regarding the Company’s effective tax rate for the second quarter, the amount of tax reserves and portion of reserves for issues related to foreign affiliates, and tax benefits associated with foreign affiliates for which the Company may have paid significant fees to tax advisors. The Company submitted its response to the letter on September 20, 2007.

On October 25, 2007, Amgen received a subpoena from the United States Attorney’s Office, Eastern District of New York, for production of documents relating to its products. The Company intends to cooperate fully in responding to the subpoena.

On November 1, 2007, Amgen received a subpoena from the United States Attorney’s Office, Western District of Washington, for production of documents relating to its products. The Company intends to cooperate fully in responding to the subpoena.

On November 2, 2007, the Sheet Metal Workers National Health Fund filed suit in the United States District Court for the District of New Jersey against Amgen Inc. and Amgen USA Inc. The lawsuit alleges both federal and state antitrust violations as well as violations of California’s Unfair Competition Law. The complaint alleges that Amgen engaged in an “anti-competitive tying arrangement and pricing scheme” involving the sale of three of our marketed products, NEUPOGEN®, Neulasta® and Aranesp®. Plaintiff seeks injunctive and compensatory relief for this alleged anticompetitive behavior. Amgen has not yet been served in this action.

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 take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.

We and certain of our licensors and partners conduct research, preclinical testing and clinical trials for our product candidates. In addition, we manufacture and contract manufacture and certain of our licensors and partners manufacture our product candidates. We also manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the EMEA in European countries, Canada, Australia and Japan. 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 of our products. Further, on September 27, 2007, President Bush signed into law the FDAAA, which created significant additions to the FDA's authority. The FDAAA expanded the FDA's authority, among other things, 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, could result in significant civil monetary penalties.

In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, remains costly to maintain. With the occurrence of a number of high profile safety events with certain pharmaceutical products such as Vioxx® and Bextra®, regulatory authorities, 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. As a result, safety signals from clinical trials or other sources are receiving greater scrutiny which may lead to fewer treatments being approved by the FDA or other regulatory bodies, termination of clinical trials before completion or longer or additional clinical trials for new or existing indications for our products and product candidates that may result in substantial additional expense. 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 ESA 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 as a result of Congressional concerns, such changes could have a material or adverse effect on the use of our ESA products. (See "— *Before we commercialize*

and sell any of our product candidates, 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.")

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 healthcare provider prescribing behavior, use of our products, regulatory or private health organization medical guidelines and reimbursement for our products. (See "— *Guidelines and recommendations published by various organizations can reduce the use of our products." 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*.") For example on March 9, 2007, based upon data from our AoC 103 Study, Johnson & Johnson's 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 prescribing information for the class of ESAs, including Aranesp® and EPOGEN®. Additionally, on November 8, 2007, we announced updates to the Aranesp® and EPOGEN®/PROCRIT® package inserts which reflect ongoing interactions with the FDA regarding the safety and benefit/risk profile of ESAs. (See "— *The labeling changes to our ESAs and requirement of additional clinical trials as a result of the May 10, 2007 ODAC and September 11, 2007 CRDAC/DSaRMAC panel meetings may adversely impact the use, sales and reimbursement of our ESAs*.") Further, on October 29, 2007, the EMEA issued a press release about upcoming changes to product information for ESAs stipulating a uniform target Hb range for all ESAs of 10 g/dL to 12 g/dL with a warning not to exceed a concentration of 12 g/dL. Lastly, we recently became aware that the interim data recently presented by the independent German Hodgkins Study Group ("GHSG") show no statistically significant difference between Epoetin alfa and placebo on overall survival and serious adverse events. While this study is run by GHSG, and we do not have control over the data conduct or analysis, we are working with the study investigators to ensure that these study results are shared with regulatory agencies.

In addition, we announced in March 2007 that we had discontinued Vectibix™ treatment in our PACCE trial, a non-registration-enabling trial evaluating the addition of Vectibix™ to standard chemotherapy and Avastin® (bevacizumab) for the treatment of first-line mCRC. The decision to discontinue Vectibix™ treatment in the trial was based on a preliminary review of data from a pre-planned interim efficacy analysis which revealed a statistically significant difference in progression-free survival in favor of the control arm. An unplanned analysis of overall survival also demonstrated a difference favoring the control arm. We recently announced that we and the FDA have adopted changes to the U.S. prescribing information for Vectibix™ based on the results of the PACCE trial highlighting to clinicians the greater risk seen when Vectibix™ is combined with Avastin® and the specific chemotherapy used in the PACCE trial to treat patients with first-line mCRC. Vectibix™ is not indicated for the first-line treatment of mCRC and the new safety information applies to an unapproved use of Vectibix™.

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 restrictions on the sale or use of such products, including potential withdrawal of the product 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 the withdrawal of, such product 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 in 2006, 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 needle-less 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 with the needle-less 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 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 or other risk management activities may be imposed by regulators. 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.

If we or others identify side effects or other safety concerns before or after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, reformulation of our products may be required or other risk management activities may be imposed by regulators, additional clinical trials may be required, changes in labeling of our products, changes in guidelines and reimbursement and changes to or re-approvals of our manufacturing facilities may be required, any of which could have a material adverse effect on sales 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*.") Regulatory agencies such as the FDA could require us to engage in risk management activities, possibly 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. Certain specific labeling or label changes may be necessary 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 changes in clinical practice and options. Before any of our products are approved for commercial use, regulatory bodies could decide that the product label include certain warning language as part of an evolving label change to a particular class of products. In addition, after any of our products are approved for commercial use, we or regulatory bodies could decide, and have in the past decided, that changes to our product labeling are required. For example, the FDA has instituted a class label change for the three ESAs marketed in the United States to add information about pure red cell aplasia ("PRCA") to the adverse event profile section and for the boxed warning in the prescribing information of the label described above. We are in discussions with the FDA with respect to the class of TNF inhibitor agents around several safety issues. Such discussions may result in additional patient safety information in the form of a boxed warning that will apply to the ENBREL label as has been the case with other TNF inhibitor agents.

Any significant concerns raised about the safety or efficacy of our products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to our manufacturing processes or to seek re-approval of our manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. The labeling of a new product, 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. If the labeling of a new product, a revision of product labeling or the regulatory actions described above 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. In addition, if regulatory authorities determine that we or our licensor or partner conducting R&D activities on our behalf have not complied with regulations in the R&D of a product candidate, new indication or information to support a current indication, then they may not approve the product candidate 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.

Before we commercialize and sell any of our product candidates, 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. The results of these clinical trials are used as the basis to obtain regulatory approval from government 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. 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 and therefore, we may spend as much as several years 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 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 and associated delays in product candidates reaching the market. 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. 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 clinical trials that may delay the clinical program, prohibit regulatory approval of our product candidates or additional indications for our currently approved products, or may render the product candidate commercially infeasible. 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 “mega-site” trial (involving 200 or more sites) in first line non-small cell lung cancer, 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 on this basis.

We focus our R&D on novel human therapeutics for the treatment of grievous illness. In the past, we had substantially expanded our R&D capabilities to manage and execute increasingly larger and more complex clinical trials and to build the capacity to advance more compounds into and through the clinic. However, as a result of recent regulatory and reimbursement developments, we have and will continue to assess the optimal level of our R&D investment. These efforts will assist in allowing us to provide continued support of key activities including i) current and future ESA pharmacovigilance studies; ii) regulatory affairs, safety and compliance functions as these remain critical in the current regulatory environment; iii) clinical studies to advance our late-stage pipeline, including previously initiated mega-trials; iv) the advancement of earlier stage compounds and v) research efforts in inflammation, oncology and metabolic diseases. To the extent future sales are negatively affected as a result of these or other challenges, we may be required to further adjust our R&D investment plans. Such actions could delay obtaining approval or reduce the number of indications and market potential of our product candidates.

The labeling changes to our ESAs and requirement of additional clinical trials as a result of the May 10, 2007 ODAC and September 11, 2007 CRDAC/DSaRMAC panel meetings may adversely impact the use, sales and reimbursement of our ESAs.

On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. 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 or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

Responding to questions posed by the FDA, the seventeen ODAC members voted on these questions and the results of these votes, as follows, could limit the use of our ESAs:

- Fifteen of the panel members voted to recommend additional restrictions on ESA labels;
- The panel voted unanimously to recommend additional clinical trials be conducted to more clearly define the benefits and risks associated with the use of ESAs;
- Twelve of the panel members voted to recommend additions to ESA labels to state that ESAs are not indicated for use in specific tumor types;
- Fifteen of the panel members voted to recommend a defined Hb level in asymptomatic patients for initiation of treatment with ESAs; and
- Sixteen panel members voted to recommend changes to ESA labels recommending discontinuation of ESA therapy following the completion of a chemotherapy regimen and reevaluation of the degree of anemia with subsequent chemotherapy regimen.

However, eleven of the seventeen panel members voted against recommending lowering the upper limit of the Hb range in the current ESA labels. While 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, no specific restrictions or studies were recommended at the ODAC meeting. Although not required, the FDA has and will likely continue to take into consideration the recommendations by the ODAC in our ongoing discussions with the FDA regarding our ESA.

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. Responding to questions posed by the FDA, the nineteen committee members voted on these questions as follows:

- The committees voted 5 Yes and 14 No as to whether ESA product labels should be changed to state that the target Hb should not exceed ~11 g/dL for patients on hemodialysis;
- The committees voted 5 Yes and 14 No as to whether ESA product labels should be changed to state that the target Hb should not exceed ~11 g/dL for patients who are not on dialysis;
- The committees discussed but did not vote on whether randomized clinical studies should examine an array of Hb targets; and
- The committees voted 14 Yes, 3 No and 2 abstained as to whether the ESA dosages used to achieve the Hb levels in the lower target groups in the Normal Hematocrit Cardiac Trial and CHOIR studies are sufficient to form the basis for ESA dosage recommendations.

The committees also discussed potential study designs to evaluate ESA hypo-responders and dosing algorithms that could be tested in clinical studies.

On November 8, 2007, we announced updates to the Aranesp® and EPOGEN®/PROCRIT® package inserts which reflect ongoing interactions with the FDA regarding the safety and benefit/risk profile of ESAs. These changes recognize input from the ODAC meeting held on May 10, 2007, and the joint CRDAC/DSaRMAC meeting held on September 11, 2007.

The revised boxed warning provides disease specific guidance for CRF, cancer, and perisurgery indications, including the following modifications:

- The boxed warning has additional language specific to renal failure that states: “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.”
- The boxed warning for the cancer indication has been updated to describe studies in patients with advanced breast, head and neck, lymphoid and non-small cell lung malignancies. These studies administered ESAs to target a hemoglobin level greater than or equal to 12 g/dL and were associated with shortened overall survival and/or time to tumor progression. The warning specifically states: “The risks of shortened survival and tumor promotion have not been excluded when ESAs are dosed to target a hemoglobin of less than 12 g/dL. To minimize these risks as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusions.” Physicians are further advised to use ESAs only if patients are receiving concomitant myelosuppressive chemotherapy and to discontinue ESA treatment following the completion of a chemotherapy course.
- The boxed warning for the perisurgery indication has additional language specific to perisurgery patients stating: “EPOGEN® increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.”

The WARNINGS, Increased Mortality, Serious Cardiovascular and Thromboembolic Events were modified to include “Patients with chronic renal failure and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular events and mortality than other patients.” The WARNINGS, Increased Mortality and/or Tumor Progression section was modified to include a table summarizing studies added to the label, including the Phase 3 study in lymphoid malignancies (161 study).

The DOSAGE AND ADMINISTRATION instructions for CRF patients were modified to individualize dosing to achieve and maintain hemoglobin levels between the range of 10 to 12 g/dL. For patients who do not attain a hemoglobin level within this range, despite the use of appropriate ESA dose titrations over a 12-week period, the instructions were modified to not administer higher ESA doses and to use the lowest dose that will maintain a hemoglobin level sufficient to avoid the need for recurrent red blood cell transfusions. Additional instructions include that monitoring of the hemoglobin level should be continued and discontinuation of ESAs if responsiveness does not improve and the patient needs recurrent red blood cell transfusions.

DOSAGE AND ADMINISTRATION instructions for cancer patients were modified to reinforce that ESA therapy should be discontinued following the completion of a chemotherapy course. The labeling continues to recommend that the dose should be adjusted for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for red blood cell transfusion and not to exceed the upper safety limit of 12 g/dL.

The patient populations covered in the indications have not changed. However, the revised labeling reiterates that ESAs are not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy. For the Aranesp® product labeling the oncology indication now states that in controlled clinical trials, ESA use has not been demonstrated to improve symptoms of anemia, quality of life, fatigue, or patient well-being. The updated EPOGEN® product labeling no longer contains patient-reported outcomes from older clinical studies that did not meet recent criteria for inclusion in the label based on FDA draft guidance, but does state EPOGEN® use improved exercise tolerance and patient-reported physical function in dialysis patients.

We submitted these changes to the FDA under the regulatory mechanism known as a “changes being effected” (“CBE”) submission and these changes are effective immediately. However, discussions with the FDA are ongoing, and we intend to submit further modifications to ESA product labeling to address other issues raised

at the ODAC meeting. We expect these discussions will result in additional revisions to class product labeling.

Although we cannot predict what further action the FDA may take, or the extent or impact of any such action, the updates to the labels for Aranesp® and EPOGEN® described above may further impact reimbursement of our ESAs, in particular the Decision Memorandum and its implementation and the EMP, and negatively impact healthcare provider prescribing behavior, use of our ESA products, regulatory or private health organization medical guidelines and sales for our ESA products, which could 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*.")

Further, we have discussed six additional study concepts with the FDA to address potential safety concerns in patients with non-small cell lung cancer (two studies) and lymphoproliferative malignancy (four studies). Based on the safety signals observed with higher hemoglobin levels, a study to evaluate the effect of hemoglobin target on the risk/benefit profile of ESAs is also planned. The original pharmacovigilance program included both investigator-sponsored and company-sponsored studies, and became part of a formal post-marketing commitment with the FDA in 2006. Overall, we believe that the ongoing and planned pharmacovigilance studies will result in a robust body of well-controlled data to address concerns regarding survival and tumor progression in these patient populations, including a total of three studies in breast cancer, three studies in lung cancer (one in small cell lung cancer and two in non-small cell lung cancer), five studies in lymphoproliferative malignancy, one study in head and neck cancer, and one study to evaluate the effect of target hemoglobin levels.

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 or additional label restrictions and may have a material adverse effect on our business and results of operations, and any negative results from such trials could materially affect the use, reimbursement and sales of our ESA products. (See "*– Before we commercialize and sell any of our product candidates, 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 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 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 May 14, 2007, CMS issued its Proposed NCD and on July 30, 2007, issued its Decision Memorandum. As CMS has not yet provided final guidance to Medicare contractors with respect to the implementation of the Decision Memorandum, we continue to evaluate what impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp®, and our business and results of operations. A complete 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 take other potentially limiting or costly actions if we or others identify side effects 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 both government and private payer healthcare programs. Medicare and Medicaid government healthcare

programs' payment policies for drugs and biologicals are subject to various laws and regulations. Since January 1, 2005, in the physician clinic setting and since January 1, 2006, in the hospital outpatient setting, 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%"). 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 first quarter of 2008 will be based in part on certain historical sales and sales incentive data for Aranesp® from October 1, 2006 through September 30, 2007. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician office and the 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. Prior to January 1, 2006, Medicare's hospital OPPS, which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized the AWP as the basis of Medicare Part B payment for covered outpatient drugs and biologics administered in the hospital outpatient setting. From 2003 to 2005, CMS applied an "equitable adjustment" such that the Aranesp® reimbursement rate was based on the AWP of PROCRIT®, Johnson & Johnson's recombinant human erythropoietin product marketed in the United States, using a dose conversion ratio. In 2006 and 2007, CMS did not apply an "equitable adjustment" to tie the reimbursement rate for Aranesp® to PROCRIT®. On November 1, 2007, CMS released its 2008 OPPS final rule that does not apply an "equitable adjustment" to the reimbursement rate for Aranesp® to PROCRIT®, however, in the past CMS has maintained that it reserves the right to apply an "equitable adjustment" in the hospital outpatient setting to the payment rate for Aranesp® in future years.

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 rate 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®). 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.

Since April 1, 2006, the ESRD Program reimbursement has been subject to a revised HMA-PM, a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. This policy, EMP, was revised, effective October 1, 2006, to provide that if a patient's Hb is greater than 13 g/dL, providers are instructed to reduce the patient's EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN® and Aranesp® dose and the provider does not submit medical documentation to support maintaining a patient's Hb above 13 g/dL, reimbursement will be reduced to the level it would have been had the provider reduced dosage by 25%. On July 20, 2007, CMS published further revisions to the EMP, 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 and a reduction of 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.

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 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA.

While we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For example, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN®. The demonstration project was scheduled to start in January 2006, but 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, on December 29, 2006, the MedPAC released its second Congressionally-mandated report 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, the Company allocates its 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 MedPAC's 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 is 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 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.

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 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. During the initial comment period which ended on April 13, 2007, we submitted comments to CMS which included a detailed and thorough review of the available clinical data, noted a series of important considerations and made a number of specific recommendations for the agency to consider in developing a NCD. 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. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;

- Anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent CIA;
- Prophylactic use to reduce tumor hypoxia;
- Patients with erythropoietin-type resistance due to neutralizing antibodies; and
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

Additionally, in the Decision Memorandum, CMS provides coverage for ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia under the following conditions:

- The Hb level immediately prior to initiation or maintenance of ESA treatment is < 10 g/dL (or the hematocrit is < 30%);
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/three times weekly for Epoetin and 2.25 mcg/kg/weekly for darbepoetin alfa. Equivalent doses may be given over other approved time periods;
- Maintenance of ESA therapy is the starting dose if the Hb level remains below 10 g/dL (or hematocrit is < 30%) 4 weeks after initiation of therapy and the rise in Hb is > 1 g/dL (hematocrit > 3%). However, if after the first 4 weeks the Hb is > 10 g/dL, ESA treatment is not covered;
- For patients whose Hb rises < 1 g/dL (hematocrit rise < 3%) compared to pretreatment baseline over 4 weeks of treatment and whose Hb level remains < 10 g/dL after the 4 weeks of treatment (or the hematocrit is < 30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the Hb rises < 1 g/dL (hematocrit rise < 3 %) compared to pretreatment baseline by 8 weeks of treatment;
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in Hb > 1 g/dL (hematocrit > 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to < 10 g/dL (or the hematocrit is < 30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose; and
- ESA treatment duration for each course of chemotherapy under the above conditions includes the eight weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Under the provisions of the Decision Memorandum, Medicare contractors may continue to issue local coverage determinations based on the existing Medicare policy of “reasonable and necessary determinations” on all uses of ESAs that are not determined by the Decision Memorandum, including myelodysplastic syndrome (“MDS”).

The Decision Memorandum establishes the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA and who all together accounted for approximately 50% of the U.S. cancer patients receiving Aranesp® prior to its issuance. We believe that the majority of CIA patients who received treatment with ESAs, including Aranesp®, were initiated at Hb levels above 10 g/dL and were maintained with Hb levels above 10 g/dL with continued therapy prior to the issuance of the Decision Memorandum. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than

10 g/dL, we believe that such restriction has and will continue to change 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 will 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 and only one private payer has implemented certain restrictions based upon it, we believe that some private payers may implement and follow some or all of the restrictions included in the Decision Memorandum. Further, due to difficulties in administering a two-tier medical practice, we believe some healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage, resulting in those covered by private insurance plans receiving the same care as Medicare patients. Also, although the Decision Memorandum did not directly affect reimbursement for treatment of MDS, we also believe that certain physicians have reduced ESA utilization in this setting.

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.

Further, the DRA of 2005 included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that became effective on January 1, 2006, will increase the level of Medicaid rebates paid by us. Although we continue to evaluate the impact of the DRA, we believe it will not have a material adverse impact on our business. 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 rule will have on our business.

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, nearly all Medicare contractors dropped reimbursement for Aranesp® for AoC. (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 economic 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 patents 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, Roche has been found to infringe a total of ten claims from four of Amgen's EPO patents. Roche filed a BLA with the FDA for their peg-EPO product and announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia associated with CRF including patients on dialysis and patients not on dialysis. We will now seek a permanent injunction to prevent Roche from commercializing its peg-EPO product in the United States in violation of our affirmed patent rights. The injunction hearing is scheduled to begin on November 15, 2007, and proceed for three days in December on dates yet to be determined by the Court. This lawsuit is described in "Item 1. Legal Proceedings— *Roche Matters.*" (See "— *Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do*.") 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. In addition, we have had our principal erythropoietin patent and our principal G-CSF patent expire in the EU.

Product		General Subject Matter	Expiration
Epoetin alfa	U.S.	— Process of making erythropoietin	8/15/2012
		— Product claims to erythropoietin	8/20/2013
		— Pharmaceutical compositions of erythropoietin	8/20/2013
		— Cells that make certain levels of erythropoietin	5/26/2015
darbepoetin alfa	U.S.	— Glycosylation analogs of erythropoietin proteins	5/15/2024
	Europe[1]	— Glycosylation analogs of erythropoietin proteins	10/12/2010
		— Glycosylation analogs of erythropoietin proteins	8/16/2014
Filgrastim	U.S.	— G-CSF polypeptides	12/3/2013
		— Methods of treatment using G-CSF polypeptides	12/10/2013
pegfilgrastim	U.S.	— Pegylated G-CSF	10/20/2015
	Europe[1]	— Pegylated G-CSF	2/8/2015
etanercept	U.S.	— Methods of treating TNF — dependent inflammatory response	9/5/2009
		— TNFR proteins and pharmaceutical compositions	9/5/2009
		— TNFR DNA vectors, cells and processes for making proteins	10/23/2012
panitumumab	U.S.	— Human monoclonal antibodies to EGFr	5/5/2017
cinacalcet HCl	U.S.[2]	— Calcium receptor-active molecules	12/14/2016
		— Calcium receptor-active molecules	12/14/2016
		— Calcium receptor-active molecules	12/14/2016
		— Calcium receptor-active molecules	10/23/2015
	Europe[1]	— Calcium receptor-active molecules	10/23/2015

(1) In some cases these European patents may also be entitled to supplemental protection in one or more countries in Europe and the length of any such extension will vary country by country.

(2) An application for patent term extension has been submitted and is currently pending 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 follow-on biologics or biosimilar products (as they are generally known in the EU) 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 anticipated cost savings from our recently announced restructuring plans.

As a result of recent developments and, in particular the regulatory and reimbursement changes to our ESA products, 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 part of the restructuring plan, we are reducing staff by approximately 12% to 14% or approximately 2,200 to 2,600 positions, re-scoping and making other changes to certain capital projects and closing certain production operations. As a result of our restructuring plan, we expect to reduce costs beginning in 2008. Our ability to achieve anticipated savings is dependent upon various future developments, some of which are beyond our control. We may also not realize, 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 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 unanticipated and unforeseen changes to our business, we may face further restructuring and/or reorganization activities in the future.

In addition, our reduction of staff will be 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 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 NKF distributed to the nephrology community final updated KDOQI clinical practice guidelines and clinical practice recommendations for anemia in CKD. The NKF's Anemia Work Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, the NKF-KDOQI™ 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. 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, nearly all Medicare contractors stopped reimbursing for Aranesp® use in AoC patients.

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 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 licensors or partners 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. Further, 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 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 take other potentially limiting or costly actions if we or others identify side effects after our products are on the market*." and "*– Before we commercialize and sell any of our product candidates, 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 "Item 1. Legal Proceedings" 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 (in the case of monetary damages, in the period in which such damages are incurred).

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 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 "Item 1. Legal Proceedings – *Average Wholesale Price Litigation*" and are updated as required in subsequent 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 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 the three and nine months ended September 30, 2007 have been 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. We currently expect to incur approximately $775 million to $850 million in restructuring charges in connection with this restructuring plan. For the three and nine months ended September 30, 2007, we have incurred related restructuring charges of $293 million and $582 million, respectively. 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 anticipated cost savings from our recently announced restructuring plans*.") 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, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to September 30, 2007, the trading price of our common stock has ranged from a high of $76.50 per share to a low of $49.01 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 other companies and organizations
- business development or licensing activities
- product development or other business announcements by us or our competitors
- regulatory matters or actions
- 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
- 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 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 derived from biological sources, including mammalian tissues, bovine serum and HSA. We are

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 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 regulatory approval for the alternative materials and manufacturing processes could increase our associated costs or result in the recognition of an impairment in the carrying value of certain related assets, which could have a material and adverse affect on our results of operations.

Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales.

We currently manufacture and market all our principal products, and we plan to manufacture and market many of our potential products. 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 take other potentially limiting or costly actions if we or others identify side effects 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, or otherwise
- 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 patient prescriptions, primarily due to variation in the expected production yield from Boehringer Ingelheim Pharma KG ("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 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 a new contract manufacturer. In order to maintain supply, mitigate risks associated with all of the bulk manufacturing for Aranesp®, Neulasta® and NEUPOGEN® and the vast majority of our formulation, fill and finish operations located in Puerto Rico, 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, expand our use of third-party contract manufacturers and maintain a state of regulatory compliance. Key manufacturing projects include: 1) expansion of existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate denosumab; 2) construction, qualification and licensure of new formulation and filling facilities at our Puerto Rico site and 3) expansion of our Fremont, CA 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. For example, we are dependent upon a single FDA approved third-party contract manufacturer for the formulation, fill and finish of Vectibix™. 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 formulation, fill and finish 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, or otherwise
- inability of third-party suppliers to provide raw materials and components
- natural or other disasters, including hurricanes
- failures to comply with regulatory requirements, including those of the FDA

For example, this facility in Puerto Rico has experienced manufacturing component shortages and has had evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output. 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.

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 due to 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 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.

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 expectations, 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.

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 Johnson & Johnson, Abbott, Biogen, Genentech, Bristol-Myers Squibb, Novartis and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. While ENBREL continues to maintain a leading position in both rheumatology and dermatology, it has experienced and continues to experience share loss to competitors. (See "*— 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*.") Additionally, Aranesp® competes or will potentially compete in the EU with:

Product	Company	Countries	Timing for Launch
EPREX®	Johnson & Johnson	EU	Launched
Neorecormon®	Roche	EU	Launched
		Germany,UK	Launched
Dynepo™	Shire	Italy, Spain, France	Q4 2007
Biosimilar Erythropoietin	Sandoz with co-marketers Hexal and Medice	Germany, UK	Launched
		Others	2008
Biosimilar Erythropoietin	Hospira/Stada	Germany, UK	2008
		Others	2008
peg-EPO/MIRCERA®	Roche	Germany, UK, Netherlands, Austria Sweden, Switzerland	August-November 2007 (approved by European Commission on July 26, 2007)

In addition, Astellas/FibroGen are co-developing an erythropoietic small molecule and Affymax is developing an erythropoietin mimetic for the treatment of anemia. Vectibix™, our oncology therapeutic in the United States to treat patients with mCRC, competes with Imclone's Erbitux®. 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 take other potentially limiting or costly actions if we or others identify side effects 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. We believe that as these patents have expired, some companies have and other companies may receive approval for and market biosimilar 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, we expect that the first biosimilar G-CSF product may be approved in the EU some time in 2008 and could be available shortly thereafter, and that it would compete with Neulasta® and NEUPOGEN®. We cannot predict whether or to what extent the entry of biosimilar products or other competing products would 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.

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 follow-on biologics. 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 and guidance by the FDA. During this current Congressional session, several members of Congress expressed interest in the issue, a number of bills have been introduced, and the House and Senate have held hearings. A Senate follow-on biologics bill has been approved by a Senate Committee but has not been presented to the full Senate for a vote. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for issuance of regulations and guidance any final legislation would contain. Until such legislation is created, we cannot predict when follow-on biologics 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 recent developments and, in particular the regulatory and reimbursement changes to our ESA products, 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. Our plan has 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
- we are implementing an enterprise resource planning 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 clinics, dialysis centers, hospitals and pharmacies. One of these products, EPOGEN®, is primarily sold to free-standing dialysis clinics, which have recently experienced significant consolidation. Two organizations, DaVita Inc. and Fresenius Medical Care North America, Inc. ("Fresenius") own or manage a large number of the outpatient dialysis facilities located in the United States and account for a significant majority of all EPOGEN® sales in the free-standing dialysis clinic setting. In October 2006, we entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius, on its behalf and on behalf of certain of its affiliates, to purchase, and we have agreed to supply, all of Fresenius' commercial requirements for erythropoietic stimulating proteins 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.

This concentration and consolidation has increased these entities' purchasing leverage and 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 will be 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 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, is 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 take other potentially limiting or costly actions if we or others identify side effects 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 based on what we believe to be current best practices, we cannot assure you that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. If we 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, including 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 the issuer's 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 recently considered whether the accounting for convertible debt securities that requires or permits 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. The FSP, if issued as proposed, would become effective for calendar year end companies like us in the first 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 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 proposed method of accounting for cash settled convertible debt securities is adopted by the FASB as described above, it would have an adverse impact on our past and future reported financial results. As the final guidance has not been issued, we cannot predict its ultimate outcome.

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

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

In connection with our ongoing process improvement activities associated with products we manufacture, we continually invest in our various manufacturing practices and related processes with the objective of increasing production yields and success rates to gain increased cost efficiencies and capacity utilization. We are investigating alternative manufacturing processes that do not require the use of certain biologically-sourced raw materials. The development or implementation of such processes could result in changes to or redundancies with our existing manufacturing operations. Depending on the timing and outcomes of these efforts and our other estimates and assumptions regarding future product sales, the carrying value of certain manufacturing facilities or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations.

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

During the three months ended September 30, 2007, 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 and blackout periods in which we are restricted from repurchasing shares 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 September 30, 2007 is as follows:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum $ Value that May Yet Be Purchased Under the Programs (1)
July 1 - July 31	2,528,472**(2)**	$ 0.01	2,527,937**(2)**	$ 6,539,425,047
August 1 - August 31	10,256	48.51	—	6,539,425,047
September 1 - September 30	759	55.80	—	6,539,425,047
	2,539,487**(3)**	0.22	2,527,937**(3)**	

(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 total number of shares repurchased in July 2007 includes 2,527,937 of shares received in connection with the final settlement of a block trade entered into in May 2007 (see Note 6, “Stockholders’ equity” to the Condensed Consolidated Financial Statements for further discussion).

(3) 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

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 discussed in more detail in the “Overview” section of the MD&A in Part I herein, this restructuring plan is primarily the result of regulatory and reimbursement developments that began in 2007 involving ESA products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. The restructuring plan, as announced on August 15, 2007, included certain charges for asset impairments resulting from decisions primarily focused on rationalizing 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. Subsequently, in connection with the preparation of our financial statements for the three months ended September 30, 2007, we made additional decisions related to the rationalization of our manufacturing facilities, including the indefinite postponement of our Ireland manufacturing operations and the closure of a clinical manufacturing facility in Thousand Oaks. Primarily as a result of these decisions, we recorded additional asset impairment charges of $110 million during the three months ended September 30, 2007.

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: November 9, 2007

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

AMGEN INC.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	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, between Amgen Inc. and Citibank N.A. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	6.50% Notes Due December 1, 2007. (Filed as an exhibit to Form 8-K filed on December 5, 1997 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997, between Amgen Inc. and Citibank, N.A. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	Officer’s Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between Amgen Inc. and Citibank, N.A., establishing a series of securities entitled “6.50% Notes Due December 1, 2007” (Filed as an exhibit to Form 8-K filed on December 5, 1997 and incorporated herein by reference.)
4.6	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Officer’s Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between Amgen Inc. and Citibank, N.A., establishing a series of securities entitled “8 1/8% Debentures due April 1, 2097.” (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.8	Form of Liquid Yield Option™ Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	Indenture, dated as of March 1, 2002, between Amgen Inc. and LaSalle Bank National Association. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.10	First Supplemental Indenture, dated March 2, 2005, between Amgen Inc. and LaSalle Bank National Association. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.11	Indenture, dated as of August 4, 2003, between Amgen Inc. and JPMorgan Chase Bank. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

4.12	Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.13	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.14	Officers' Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.15	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.)
4.16	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.17	Indenture, dated as of May 6, 2005, between Amgen Inc. and LaSalle Bank National Association. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.18	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006, between Amgen Inc. and JPMorgan Chase Bank, N.A, as trustee (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).
4.19	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 between Amgen Inc. and JPMorgan Chase Bank, N.A., as trustee (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).
4.20	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.)
4.21	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.)
4.22	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.
4.23	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).
4.24	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+	Amended and Restated 1991 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.)
10.2+	Amgen Inc. Director Equity Incentive Program (As Amended and Restated March 7, 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.)
10.3+	Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements for Amgen Inc. Director Equity Incentive Program. (Filed as exhibits to Form 8-K on December 8, 2005 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 incorporated herein by reference.)
10.9+	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.)
10.10+	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.)
10.11+	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.)
10.12+	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.)
10.13+*	Fourth Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005).
10.14+	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.)
10.15+	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.)
10.16+	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.)
10.17+	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.)
10.18+	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.)
10.19+	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.)
10.20+	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.)
10.21+	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).
10.22+	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).
10.23+	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.)

10.24+	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.)
10.25+	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.)
10.26+*	First Amendment to the Amgen Inc. Executive Nonqualified Retirement Plan.
10.27+	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.)
10.28+	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 herein by reference.)
10.29+	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.)
10.30+	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.)
10.31+*	Fourth Amendment to the Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated January 1, 2005).
10.32+	Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated July 9, 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.)
10.33+	Form of Performance Unit Agreement to the Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated July 9, 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.)
10.34+	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.)
10.35+	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.)
10.36+	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.)
10.37+	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.)
10.38+	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.)
10.39+	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.)
10.40+	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.)
10.41+*	Amendment to Promissory Note, dated August 31, 2007 to Promissory Note, dated June 27, 2001, of Mr. Richard Nanula.
10.42+	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.)
10.43+	Restricted Stock Purchase Agreement, dated December 6, 2004, between Amgen Inc. and Dennis M. Fenton. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.44	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.)

10.45	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.)
10.46	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.)
10.47	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders' Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.48	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.)
10.49	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.)
10.50	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.)
10.51	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.)
10.52	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.)
10.53	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.)
10.54	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.)
10.55	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.)
10.56	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.)

10.57	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.)
10.58	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.)
10.59	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.)
10.60	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.)
10.61	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.)
10.62	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.)
10.63	Asset Purchase Agreement dated May 2, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft (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.)
10.64	Amendment No. 1 dated as of June 25, 2002 and Amendment No. 2 dated as of July 17, 2002 to the Asset Purchase Agreement dated as of September 25, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.65	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., 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.)
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.)
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).
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).
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.)

FOURTH AMENDMENT TO THE
AMGEN INC. SUPPLEMENTAL RETIREMENT PLAN
(As Amended and Restated Effective January 1, 2005)

The following sections of the Amgen Inc. Supplemental Retirement Plan, as amended and restated effective January 1, 2005, (the "Plan") are hereby amended effective as of October 1, 2007, unless provided otherwise herein:

1. Article 5 of the Plan is hereby amended by inserting the underlined provisions within Section 5.1 (Distributions), in which the new paragraph shall read as follows:

"5.1 **Distributions**. Following the termination of your employment with the Company, the Company will pay you the vested balance in your Account. The payment will be made to you (or your Beneficiary) in a lump sum as soon as administratively practicable after the first day of the Plan Year following the Plan Year in which you terminated your employment (or such later date as may be required under applicable law or permitted under an Election Form); subject to any election to the extent it becomes effective pursuant to Section 5.2 below. For purposes of this Plan, the entitlement to a series of annual installment payments, if elected, is treated as the entitlement to a single payment."

2. Article 5 of the Plan is further amended by adding the following new Section 5.2 to the Plan immediately following Section 5.1 thereof:

"5.2 **Special Transition Rule for 2007**. The Committee may, in accordance with Notice 2006-79, provide a limited period in 2007 in which you may make a distribution election with respect to amounts subject to the terms of the Plan, by submitting an Election Form on or before the deadline established by the Committee, which in no event shall be later than December 31, 2007. Any distribution election that you make, which is accepted by the Committee, shall not be treated as a change in either the form or timing of your termination distribution for purposes of Code Section 409A or the Plan. If the distribution election that you submit in accordance with this Section either (a) relates to an amount that would otherwise be paid to you in 2007, or (b) would cause an amount to be paid to you in 2007, such election shall not be effective. You may change your termination distribution election after 2007 only to the extent you make the change at least one year prior to the actual date of your termination of employment, and in accordance with any procedures, forms, and restrictions that the Committee may require. Moreover, although any change must delay the commencement of distribution(s) until at least five years after the year in which the payment would otherwise have been paid, a complete distribution of your Account will be made not later than the end of the 10th year following the year of your termination of employment (and will be paid in that year to the extent otherwise payable in any future year)."

3. Article IX of the Plan is further amended by adding the following new Section 9.7 to the Plan immediately following Section 9.6 thereof:

"9.7 **Taxes and Code Section 409A Compliance**.

(a) Except to the extent specifically provided within this Plan or any separate written agreement between you and the Company, you shall be solely responsible for the satisfaction of any taxes with respect to the severance benefits under this Plan (including, but not limited to your share of employment taxes and penalties on nonqualified deferred compensation). Although the Company intends and expects that the Plan and its payments and benefits will not give rise to the taxes imposed under Section 409A of the Code, neither the Company, nor its employees, directors or agents shall have any obligation to hold any you harmless from any or all of such taxes.

(b) If, at the time of your "separation from service" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(h)), you are a "specified employee" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(i)), the

Company will not pay or provide any "Specified Benefits" (as defined herein) until after the end of the sixth (6th) calendar month beginning after your separation from service (the "409A Suspension Period"). For purposes of this Plan, "Specified Benefits" are any amounts or benefits that would be subject to Section 409A penalties if the Company were to pay them, pursuant to this Plan, on account of your separation from service. Within fourteen (14) calendar days after the end of the 409A Suspension Period, the Participant shall be paid a lump sum payment in cash equal to any Specified Benefits delayed because of the preceding sentence, without interest.

(c) This Plan is intended to comply with Section 409A of the Code, and the Company shall have complete discretion to interpret and construe this Plan and any associated documents in any manner that establishes an exemption from or otherwise conforms them to the requirements of Section 409A. If, for any reason including imprecision in drafting, any Plan provision does not accurately reflect its intended establishment of an exemption from or compliance with Section 409A of the Code, as demonstrated by consistent interpretations or other evidence of intent, the provision shall be considered ambiguous and shall be interpreted by the Company in a fashion consistent herewith, as determined in the sole and absolute discretion of the Company. Notwithstanding Section 7.4 above, the Company reserves the right to unilaterally amend this Plan without your consent in order to accurately reflect its correct interpretation and operation, as well as to maintain an exemption from or compliance with Section 409A of the Code."

To record this Amendment to the Plan as set forth herein, Amgen Inc. has caused its authorized officer to execute this document this 16th day of October 2007.

AMGEN INC.

By: /s/ Brian McNamee

Title: Senior Vice President, Human Resources

FIRST AMENDMENT TO THE
AMGEN INC. EXECUTIVE
NONQUALIFIED RETIREMENT PLAN

The following sections of the Amgen Inc. Executive Nonqualified Retirement Plan (the "Plan") are hereby amended effective as of October 1, 2007, unless provided otherwise herein:

1. Article 5 of the Plan is hereby amended by inserting the underlined provisions within Section 5.1(b) (Distribution upon Termination of Employment after Retirement Date), in which the new paragraph shall read as follows:

"5.1 **Distribution upon Termination of Employment after Retirement Date**. Subject to any election to the extent it becomes effective pursuant to Section 5.2 below, if the Participant's employment with the Company is terminated for any reason on or after the Participant's Retirement Date, the amount credited to the Participant's Nonqualified Retirement Account shall be distributed to the Participant in a lump sum between January 2 and January 31 of the year following the year in which the Participant's employment terminates, unless the Participant elects to be paid in ten or less substantially equal annual installments, beginning between January 2 and January 31 of the year following the year in which the Participant's employment terminates. The Participant must make any election to receive his or her payments in annual installments pursuant to Section 5.2 below. For purposes of this Plan, the entitlement to a series of annual installment payments is treated as the entitlement to a single payment."

2. Article 5 of the Plan is further amended by adding the following new Section 5.2 to the Plan immediately following Section 5.1 thereof:

"5.2 **Special Transition Rule for 2007**. Notwithstanding any other provision of the Plan, the Committee may, in accordance with uniform and nondiscriminatory rules established by the Committee or its delegate and in accordance with Notice 2006-79, provide a limited period in 2007 in which Participants may make distribution elections with respect to amounts subject to the terms of the Plan. Participants shall make any such elections on forms that the Committee provides, and on or before the deadline established by the Committee, which in no event shall be later than December 31, 2007. Any distribution election made by a Participant, and accepted by the Committee, shall not be treated as a change in either the form or timing of a Participant's benefit payment for purposes of Code Section 409A or the Plan. If any distribution election submitted by a Participant in accordance with this Section either (a) relates to an amount that would otherwise be paid to the Participant in 2007, or (b) would cause an amount to be paid to the Participant in 2007, such election shall not be effective. Each Participant may change his or her termination distribution election after 2007 only to the extent the Participant makes the change at least one year prior to the actual date of terminating employment, and in accordance with any procedures, forms, and restrictions that the Committee may require. Moreover, although any change must delay the commencement of the distribution until at least five years after the year in which the payment would otherwise have been paid, a complete distribution of a Participant's Nonqualified Retirement Account will be made not later than the end of the 10th year following the year of the Participant's termination of employment (and will be paid in that year to the extent otherwise payable in any future year)."

3. Article VII of the Plan is further amended by adding the following new Section 7.15 to the Plan immediately following Section 7.14 thereof:

"7.15 **Taxes and Code Section 409A Compliance**.

(a) Except to the extent specifically provided within this Plan or any separate written agreement between a Participant and the Company, a Participant shall be solely responsible for the satisfaction of any taxes with respect to the severance benefits under this Plan (including, but not

limited to the Participant's share of employment taxes and penalties on nonqualified deferred compensation). Although the Company intends and expects that the Plan and its payments and benefits will not give rise to the taxes imposed under Section 409A of the Code, neither the Company, nor its employees, directors or agents shall have any obligation to hold any Participant harmless from any or all of such taxes.

(b) If, at the time of a Participant's "separation from service" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(h)), the Participant is a "specified employee" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(i)), the Company will not pay or provide any "Specified Benefits" (as defined herein) until after the end of the sixth (6th) calendar month beginning after the Participant's separation from service (the "409A Suspension Period"). For purposes of this Plan, "Specified Benefits" are any amounts or benefits that would be subject to Section 409A penalties if the Company were to pay them, pursuant to this Plan, on account of the Participant's separation from service. Within fourteen (14) calendar days after the end of the 409A Suspension Period, the Participant shall be paid a lump sum payment in cash equal to any Specified Benefits delayed because of the preceding sentence, without interest.

(c) This Plan is intended to comply with Section 409A of the Code, and the Company shall have complete discretion to interpret and construe this Plan and any associated documents in any manner that establishes an exemption from or otherwise conforms them to the requirements of Section 409A. If, for any reason including imprecision in drafting, any Plan provision does not accurately reflect its intended establishment of an exemption from or compliance with Section 409A of the Code, as demonstrated by consistent interpretations or other evidence of intent, the provision shall be considered ambiguous and shall be interpreted by the Company in a fashion consistent herewith, as determined in the sole and absolute discretion of the Company. Notwithstanding Section 7.4 above, the Company reserves the right to unilaterally amend this Plan without the consent of any Participant in order to accurately reflect its correct interpretation and operation, as well as to maintain an exemption from or compliance with Section 409A of the Code."

To record this Amendment to the Plan as set forth herein, Amgen Inc. has caused its authorized officer to execute this document this 16th day of October 2007.

AMGEN INC.

By: /s/ Brian McNamee

Title: Senior Vice President, Human Resources

FOURTH AMENDMENT TO THE
AMGEN NONQUALIFIED DEFERRED COMPENSATION PLAN
(As Amended and Restated Effective January 1, 2005)

The following sections of the Amgen Nonqualified Deferred Compensation Plan (the "Plan") are hereby amended effective as of October 1, 2007, unless provided otherwise herein:

1. Article 2 of the Plan is hereby amended by substituting Section 2.5 (Special Transition Rules for 2005) with the following new Section 2.5:

"2.5 **Special Transition Rules for 2007**. Notwithstanding the required deadline for the submission of an initial distribution election under Articles 4, 5, and 6 of the Plan, the Committee may, in accordance with uniform and nondiscriminatory rules established by the Committee or its delegate and in accordance with Notice 2006-79, provide a limited period in 2007 in which Participants may make new distribution elections, or revise existing distribution elections, with respect to amounts subject to the terms of the Plan, by submitting an Election Form on or before the deadline established by the Committee, which in no event shall be later than December 31, 2007. Any distribution election(s) made by a Participant, and accepted by the Committee, shall not be treated as a change in either the form or timing of a Participant's benefit payment for purposes of Code Section 409A or the Plan. If any distribution election submitted by a Participant in accordance with this Section either (a) relates to an amount that would otherwise be paid to the Participant in 2007, or (b) would cause an amount to be paid to the Participant in 2007, such election shall not be effective. Each Participant may change his or her termination distribution election after 2007 only to the extent the Participant makes the change at least one year prior to the actual date of terminating employment, and in accordance with any procedures, forms, and restrictions that the Committee may require. Moreover, although any change must delay the commencement of distribution(s) until at least five years after the year in which the payment would otherwise have been paid, a complete distribution of your vested Account Balance will be made not later than the end of the 10th year following the year of the Participant's termination of employment (and will be paid in that year to the extent otherwise payable in any future year)."

2. Article 5 of the Plan is hereby amended by inserting the underlined provisions within Section 5.1 (Distributions), in which the new paragraph shall read as follows:

"5.1 **Distributions**. Subject to the Deduction Limitation, a Participant shall be entitled to a distribution of the vested interest of his or her Account Balance following Termination of Employment. Such amount will be paid in a lump sum cash payment as soon as administratively practicable after the first day of the Plan Year following the Plan Year in which such Termination of Employment occurs (or such later date as may be required under applicable law or permitted under an Election Form), unless installment payments have been elected under Section 5.2.

A Participant is permitted to make a single distribution election with respect to all amounts deferred under the Plan prior to 2005. For Plan Years beginning after December 31, 2004, a Participant is permitted to make a separate distribution election with respect to each Pan Year's deferrals. Distribution elections for Plan Years beginning after 2007 shall be made on an Election Form within the time and in the manner prescribed by the Committee and may be changed after such date to the extent permitted under the terms of the Plan and Code Section 409A."

3. Article 5 of the Plan is further amended by inserting the underlined provisions within Section 5.2 (Installment Payments), in which the new paragraph shall read as follows:

"5.2 **Installment Payments**. A Participant, in connection with his or her commencement of participation in the Plan (or, if later, during the period specified in Section 2.5 with respect to Participants in the Plan prior to January 1, 2008), may elect on an Election Form to have the vested portion of his or her Account Balance paid under the Annual Installment Method following Termination of Employment, provided that the Participant may make separate elections with respect to the portions of his or her Account Balance that are

attributable to credits made before 2005, as well as for each separate Plan Year starting with 2005. Such Election Form shall specify the number of annual installments to be made, and the portion of the Account Balance to which the election relates. Such installments shall commence as soon as administratively practicable after the end of the Plan Year in which the Participant's Termination of Employment occurs (or such later date as may be required under applicable law). A Participant's entitlement to a series of installment payments is treated as the entitlement to a single payment. Subject to the Deduction Limitation, the Participant's vested Account Balance shall be paid pursuant to the Participant's elected Annual Installment Method in the number of annual installments elected by the Participant; provided, however, the annual installments shall not exceed the lesser of the Participant's Years of Service or ten (10) years; provided, further, that if the value of the Participant's vested Account Balance on his or her Termination of Employment is $50,000 or less, the Participant's election of the Annual Installment Method shall be disregarded and such Account Balance shall be paid in lump sum under Section 5.1."

4. Article 15 of the Plan is hereby amended by adding the following new Section 15.19 to the Plan immediately following Section 15.18 thereof:

"15.19 **Taxes and Code Section 409A Compliance**. Except to the extent specifically provided within this Plan or any separate written agreement between a Participant and the Company, a Participant shall be solely responsible for the satisfaction of any taxes with respect to the severance benefits under this Plan (including, but not limited to the Participant's share of employment taxes and penalties on nonqualified deferred compensation). Although the Company intends and expects that the Plan and its payments and benefits will not give rise to the taxes imposed under Section 409A of the Code, neither the Company, nor its employees, directors or agents shall have any obligation to hold any Participant harmless from any or all of such taxes.

(a) **Section 409A Six-Month Delay Rule**. If, at the time of a Participant's "separation from service" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(h)), the Participant is a "specified employee" (within the meaning of Section 409A of the Code and Treasury Regulations section 1.409A-1(i)), the Company will not pay or provide any "Specified Benefits" (as defined herein) until after the end of the sixth (6th) calendar month beginning after the Participant's separation from service (the "409A Suspension Period"). For purposes of this Plan, "Specified Benefits" are any amounts or benefits that would be subject to Section 409A penalties if the Company were to pay them, pursuant to this Plan, on account of the Participant's separation from service. Within fourteen (14) calendar days after the end of the 409A Suspension Period, the Participant shall be paid a lump sum payment in cash equal to any Specified Benefits delayed because of the preceding sentence without interest.

(b) **Interpretations and Amendments**. This Plan is intended to comply with Section 409A of the Code, and the Company shall have complete discretion to interpret and construe this Plan and any associated documents in any manner that establishes an exemption from or otherwise conforms them to the requirements of Section 409A. If, for any reason including imprecision in drafting, any Plan provision does not accurately reflect its intended establishment of an exemption from or compliance with Section 409A of the Code, as demonstrated by consistent interpretations or other evidence of intent, the provision shall be considered ambiguous and shall be interpreted by the Company in a fashion consistent herewith, as determined in the sole and absolute discretion of the Company. The Company reserves the right to unilaterally amend this Plan without the consent of any Participant in order to accurately reflect its correct interpretation and operation, as well as to maintain an exemption from or compliance with Section 409A of the Code.

To record this Amendment to the Plan as set forth herein, Amgen Inc. has caused its authorized officer to execute this document this 16th day of October 2007.

AMGEN INC.

By: /s/ Brian McNamee

Title: Senior Vice President, Human Resources

AMENDMENT TO PROMISSORY NOTE

The parties hereby agree to amend certain repayment provisions set forth in the Promissory Note between Richard Nanula and Amgen Inc., executed by Richard Nanula on or about June 27, 2001, as follows: Notwithstanding anything to the contrary in Paragraph 1 of the Promissory Note, Staff Member shall pay the total amount of Principal and the remaining interest due (compounded at the rate of 5% per annum on June 27, 2008, June 27, 2009, and on the date of final repayment), in a lump sum on or before June 27, 2010.

Date: September 4, 2007

/s/ Richard D. Nanula
Richard D. Nanula

Date: August 30, 2007

/s/ Charles V. “Chip” Bell
for Amgen Inc.

Exhibit 10.80

Execution Copy

Collaboration Agreement
By and Between
Amgen Inc.
and
Daiichi Sankyo Company, Limited
Dated
July 11, 2007

CONFIDENTIAL

Amgen Contract #200710717

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.

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Collaboration Agreement

This Collaboration Agreement (this *"Agreement"*) is entered into as of the 11th day of July, 2007 (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 Daiichi Sankyo Company, Limited, a Japanese corporation with a principal place of business at 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426 (*"Collaborator"*). Amgen and Collaborator 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 Dmab (as defined below) for the potential treatment of osteoporosis, cancer, rheumatoid arthritis, and other diseases and conditions;

WHEREAS, Amgen wishes to partner with Collaborator for the development and commercialization of Dmab in the Territory (as defined below) in accordance with the terms and conditions hereof;

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

WHEREAS, Collaborator wishes to partner with Amgen with respect to the development and commercialization of Dmab in the Territory in accordance with the terms and conditions hereof;

WHEREAS, the Parties have disputes [*] of various patents relating to [*] owned by each of the Parties [*] (collectively the *"Patent Disputes")*; and

WHEREAS, the Parties wish to [*] settle the Patent Disputes on a world-wide basis.

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. *"Aggregate Maximum"* shall have the meaning set forth in Section 8.8.2 (Maximum Payments).

1.3. *"Agreement"* shall have the meaning set forth in Page 3, Paragraph 1.

1.4. "*Amgen Additional Indication*" shall have the meaning set forth in Section 6.2.1 (Amgen Developed Indications).

1.5. "*Amgen Assumed Item*" shall have the meaning set forth in Section 10.3.1.2 (Amgen [*] Prosecution).

1.6. "*Amgen Development Costs*" shall mean Amgen's (and its Affiliates') fully-burdened, world-wide development costs [*] related to development of Dmab, 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 Dmab, both before and after the Effective Date of this Agreement.

1.8. "*Amgen Indemnitees*" shall have the meaning set forth in Section 14.1 (Indemnity).

1.9. "*Amgen Net Sales*" shall mean Net Sales in the Territory made by or on the behalf of Amgen, its Affiliates or licensees. Amgen Net Sales shall not include sales made to, by or on behalf of Collaborator.

1.10. "*Annual Maximum*" shall have the meaning set forth in Section 8.8.2 (Maximum Payments).

1.11. "*Bundle*" shall mean Dmab sold together with another pharmaceutical compound for a single price.

1.12. "*Calendar Quarter*" shall mean a three-month period beginning on January, April, July or October 1st.

1.13. "*Calendar Year*" shall mean a one-year period beginning on January 1st and ending on December 31st.

1.14. "*Change of Control*" shall mean, with respect to a Party, the occurrence of any of the following events: [*].

1.15. "*Claims*" shall have the meaning set forth in Section 14 (Indemnification).

1.16. "*Collaboration*" shall mean the activities conducted by the Parties hereunder with respect to the development and commercialization of Dmab in the Territory, as described in more detail herein.

1.17. "*Collaborator*" shall have the meaning set forth in Page 3, Paragraph 1.

1.18. "*Collaborator Development Data*" shall mean the preclinical and clinical data generated by or on behalf of Collaborator or its Affiliates in the course of its preclinical (if any) and clinical development of Dmab, on or after the Effective Date of this Agreement.

1.19. "*Collaborator Indemnitees*" shall have the meaning set forth in Section 14.1 (Indemnity).

1.20. "*Collaborator Indications*" shall mean: (i) any and all uses for Oncology indications being developed by Amgen outside the Territory; (ii) any and all uses for the treatment, palliation, prevention or prophylaxis of osteoporosis or rheumatoid arthritis; and (iii)

any other indications that have been added to the definition of Collaborator Indication pursuant to Sections 6.2.1 (Amgen Developed Indications) or 6.2.2 (Collaborator Proposed Indications).

1.21. *"Collaborator Net Sales"* shall mean Net Sales made by or on behalf of Collaborator, its Affiliates or licensees in the Territory.

1.22. *"Commercialization Committee"* shall mean the committee established by the Parties to oversee and coordinate the commercialization of Dmab in the Territory.

1.23. *"Competing Product"* shall mean: (i) any [*], [*],[*]; and (ii) any product that, as a therapeutic mechanism of action,[*]. Competing Product shall not include Dmab.

1.24. "*Competing Program*" shall mean the [*], in the Territory, of any Competing Product. Notwithstanding the foregoing, [*] of a Competing Product in the Territory [*]of such Competing Product [*] shall not be considered a Competing Program.

1.25. "*Competing Transaction*" shall mean any transaction entered into by a Party or its Affiliate after the Effective Date whereby a Third Party that is engaged in a Competing Program becomes an Affiliate of such Party.

1.26. "*Competing Transaction Affiliates*" shall mean those entities that become Affiliates of a Party by virtue of a Competing Transaction.

1.27. "*Competing Transaction Party*" shall mean the Party that enters into a Competing Transaction.

1.28. "*Confidential Information*" shall have the meaning set forth in Section 11.1 (Confidentiality; Exceptions).

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

1.30. *"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 under any agreement with any Third Party.

1.31. *"Defending Party"* shall have the meaning set forth in Section 10.4 (Defense and Settlement of Third Party Claims).

1.32. *"Development Committee"* shall mean the committee established by the Parties to oversee and coordinate the development of Dmab in the Territory.

1.33. *"Divest"* shall mean, with respect to any Competing Program, the sale, exclusive license or other transfer of all of the right, title and interest in and to such Competing Program, including technology, 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 Competing Program by the Competing Transaction Party or its Affiliates.

1.34. *"Dmab"* shall mean Amgen's proprietary product denosumab, a fully human monoclonal antibody that targets the receptor activator of nuclear factor Kappa B Ligand. [*].

1.35. *"Effective Date"* shall have the meaning set forth in Page 3, Paragraph 1.

1.36. *"Federal Court"* shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).

1.37. *"First Commercial Sale"* shall mean the first sale of Dmab following Regulatory Approval by or on the behalf of Amgen or Collaborator, or its or their respective Affiliates or licensees.

1.38. *"Force Majeure"* shall have the meaning set forth in Section 16.8 (Force Majeure).

1.39. *"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.

1.40. *"FTE Rate"* shall mean $[*] per full-time employee per year (as of the Effective Date), increasing by [*] ([*]%) of the then-current FTE Rate on January 1st of 2008 and each subsequent Calendar Year.

1.41. *"GAAP"* shall mean either Japanese or U.S. generally accepted accounting principles, consistently applied, as used by a Party to record the relevant transaction.

1.42. *"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.

1.43. *"Indemnified Party"* shall have the meaning set forth in Section 14.2 (Claim for Indemnification).

1.44. *"Indemnifying Party"* shall have the meaning set forth in Section 14.2 (Claim for Indemnification).

1.45. *"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.

1.46. *"Joint Patents"* shall mean any invention, patent or patent application jointly owned by the Parties pursuant to Section 10.1 (Ownership).

1.47. *"Law"* shall mean, individually and collectively, any and all laws, ordinances, rules, directives and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

1.48. *"Licensed Amgen Know-How"* shall mean Information in Amgen's (or its Affiliate's) possession and Control, as of the Effective Date or thereafter during the Term, that is reasonably necessary for Collaborator to develop or commercialize Dmab in the Territory in the Collaborator Indications. Licensed Amgen Know-How shall include

Amgen Development Data that is reasonably necessary for Collaborator to develop or commercialize Dmab in the Territory in the Collaborator Indications. Licensed Amgen Know-How does not include Amgen manufacturing information.

1.49. *"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.

1.50. *"Licensed Amgen Trademarks"* shall mean any trademark rights Controlled by Amgen in the Territory on or after the Effective Date and corresponding to any trademarks adopted by Amgen for use with Dmab 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).

1.51. *"Licensed Collaborator Know-How"* shall mean Information in Collaborator's (or its Affiliate's) possession and Control, as of the Effective Date or thereafter during the Term, that is reasonably necessary for Amgen to develop or commercialize Dmab within or outside the Territory in any indication. Licensed Collaborator Know-How shall include Collaborator Development Data that is reasonably necessary for Amgen to develop or commercialize Dmab within or outside the Territory in any indication.

1.52. *"Licensed Collaborator Patents"* shall mean those patents and patent applications set forth on the Licensed Collaborator 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.

1.53. *"Licensed Collaborator Trademarks"* shall mean any trademarks adopted by Collaborator for use with Dmab in the Territory in the Collaborator Indications (not including any corporate or house marks).

1.54. *"Losses"* shall have the meaning set forth in Section 14.1 (Indemnity).

1.55. *"MHLW"* shall mean the Japanese Ministry of Health, Labour and Welfare, and any successor agency thereto.

1.56. *"Net Sales"* shall mean with respect to a given period, the gross invoiced sales price for Dmab sold by or for a Party, its Affiliates or licensees hereunder to Third Parties (not including such Party's licensees hereunder, unless and to the extent such licensee is the end-user of such Dmab) during such period, less the total of the following charges or expenses, as determined in accordance with GAAP:

1.56.1.Trade, cash, prompt payment and quantity discounts;

1.56.2.Returns, allowances, rebates, chargebacks and payments to government agencies;

1.56.3. Retroactive price reductions;

1.56.4. 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;

1.56.5. Credits and allowances for product replacement, whether cash or trade; and

1.56.6. 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 Dmab in the Territory and actually given.

1.57. "*Oncology*" shall mean any and all uses for the treatment, palliation, prevention or prophylaxis of cancer or other uncontrolled cell proliferation (including myeloma), and the treatment, palliation, prevention or prophylaxis of the effects of cancer or cancer treatment.

1.58. "*Ongoing Oncology Study*" shall have the meaning set forth in Section 4.7 (Global Development).

1.59. "*Party/Parties*" shall have the meaning set forth in Page 3, Paragraph 1.

1.60. "*Patent Disputes*" shall have the meaning set forth in the recitals.

1.61. "*Payee Party*" shall mean the Party receiving or entitled to receive a payment pursuant to Article 8 (Payment).

1.62. "*Payor Party*" shall mean the Party making or obligated to make a payment pursuant to Article 8 (Payment).

1.63. "*Prior Agreement*" shall have the meaning set forth in Section 11.4 (Prior Agreement).

1.64. "*Publishing Party*" shall have the meaning set forth in Section 11.5 (Publications).

1.65. "*Quarterly Maximum*" shall have the meaning set forth in Section 8.8.2 (Maximum Payments).

1.66. "*Reasonably Diligent Efforts*" shall mean, with respect to a Party, the application of a level of resources, efforts and urgency to develop and commercialize Dmab consistent with such Party's practices in pursuing the development and commercialization of its other high-value pharmaceutical products with similar value and market potential to Dmab 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. For clarity, it is understood that Reasonably Diligent Efforts shall not take into account: (i) any other pharmaceutical product such Party is then discovering, researching, developing, manufacturing or commercializing outside the Collaboration, alone or with one or more collaborators; or (ii) the payments required to be made by such Party to the other Party pursuant to this Agreement.

1.67. "*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 Dmab or any lots thereof.

1.68. *"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 Collaborator Patent, Licensed Collaborator Trademark, Licensed Collaborator Know-How, or Joint Patent, each of the foregoing in the Territory.

1.69. *"Regulatory Approval"* shall mean the product-specific approvals necessary for the distribution, use and sale of Dmab.

1.70. *"Regulatory Filing"* shall mean any filing with any Governmental Authority with respect to the development, marketing, commercialization or reimbursement of Dmab.

1.71. *"[*]"* shall mean clinical development that, as reasonably demonstrated by [*], either: (i) is [*]; or (ii) [*].

1.72. *"Reviewing Party"* shall have the meaning set forth in Section 11.5 (Publications).

1.73. *"Settled Patents"* shall mean all patents and patent applications set forth on the Settled Patents Schedule, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional applications thereof, as well as any patent or patent application [*] as well as any continuations, divisionals, substitutions, continuations-in-part, reissues, reexaminations, provisional and converted provisional applications thereof.

1.74. *"Sites"* shall have the meaning set forth in Section 4.18 (Transition in Oncology Development).

1.75. *"SOPs"* shall have the meaning set forth in Section 4.16 (Recalls).

1.76. *"SPC"* shall mean any patent term extension or related extension of rights, including supplementary protection certificates and similar rights.

1.77. *"State Court"* shall have the meaning set forth in Section 16.11 (Jurisdiction and Venue).

1.78. *"Taxes"* shall mean any tax, excise or duty, other than taxes upon income.

1.79. *"Term"* shall mean the period beginning on the Effective Date and ending on [*], any sooner termination of this Agreement pursuant to Article 15 (Term and Termination) or, in the event of a written extension to this Agreement, such date as specified therein.

1.80. *"Termination Date"* shall have the meaning set forth in Section 15.3.1.

1.81. *"Territory"* shall mean Japan.

1.82. *"Territory IP"* shall have the meaning set forth in Section 10.5.1 (In Territory).

1.83. *"Territory Patents and Trademarks"* shall have the meaning set forth in Section 10.3.1.1 (Collaborator [*] Prosecution).

1.84. *"Third Party"* shall mean any entity other than a Party or an Affiliate of a Party.

1.85. *"Transition Period"* shall have the meaning set forth in Section 15.5 (Transition Period).

1.86. *"VAT"* shall mean any value added tax.

1.87. *Additional Definitions*. Each of the following capitalized terms shall have the meanings set forth in the corresponding Sections of this Agreement indicated in the table below:

Definition	Section
"Amgen"	*Preamble*
"Amgen K.K."	*Section 3.7.1*
"Amgen Royalty Percentage"	*Section 15.3.5*
"Drug Product"	*Schedule: Supply Agreement Term Sheet*
"Oncology Approval"	*Section 8.1.2*
"Partnering Share Percentage"	*Section 15.3.5*
"Prior Agreement"	*Section 11.4*

2. COLLABORATION SCOPE AND GOVERNANCE

2.1. Conduct of the Collaboration. The Parties shall cooperate to develop and commercialize Dmab in the Territory, in accordance with the terms and conditions of this Agreement.

2.2. Ex-Territory Activities. The Parties acknowledge that no rights are granted hereunder to Collaborator with respect to any country outside the Territory, and that Collaborator shall have no authority with respect to the research, development, manufacture or commercialization of Dmab outside the Territory. Amgen shall have the sole right to research, develop, manufacture and commercialize Dmab outside the Territory.

2.3. Activities in Competition with the Collaboration. Except as set forth in Sections 2.4 (Post-Effective Date Affiliates) and 2.5 (Termination or Divestiture), during the Term, [*] shall, itself or through its Affiliates, conduct, participate in, or advise, assist or enable any Third Party to conduct or participate in, any Competing Program.

2.4. Post-Effective Date Affiliates. In the event that either Party enters into a Competing Transaction then the Competing Transaction Party shall provide notice to the other Party, within five (5) business days of the closing of the Competing Transaction, specifying the identity of the Competing Transaction Affiliate(s) and describing in reasonable detail, to the extent permitted by Law and without disclosing any proprietary information, the Competing Program and its focus. During the pendency of any potential Competing Transaction, and until the provisions of Section 2.5 (Termination or Divestiture) are effectuated, the Competing 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 Competing Transaction Affiliate(s).

2.5. Termination or Divestiture. The notice provided pursuant to Section 2.4 (Post-Effective Date Affiliates) shall include a notification as to whether the Competing Transaction Party intends to: (i) Divest the Competing Program, in which case the Competing Transaction Party shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)) and use its commercially reasonable, good-faith efforts to Divest such Competing Program; in the foregoing case, the Competing Transaction Party and its Affiliates (including Competing Transaction Affiliates) shall not assert any intellectual property or proprietary right of the Competing Program to obstruct the Parties' (or their Affiliates' or sublicensees') efforts under the Collaboration or Amgen's (or its Affiliates' or sublicensees') efforts with respect to Dmab outside the Territory during such divestiture period; (ii) terminate such Competing Program, in which case the Competing Transaction Party shall terminate all activities of such program within one hundred and twenty (120) days of the closing of the Competing Transaction, during which period the Competing Transaction Party shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)); in the foregoing case, the Competing Transaction Party and its Affiliates (including Competing Transaction Affiliates) shall not assert any intellectual property or proprietary right of the Competing Program to obstruct the Parties' (or their Affiliates' or sublicensees') efforts under the Collaboration or Amgen's (or its Affiliates' or sublicensees') efforts with respect to Dmab outside the Territory during such termination period or thereafter; or (iii) if Collaborator is the Party providing such notice, [*] pursuant to Section [*] unless the Competing Program constituted the majority of the assets acquired by Collaborator in the Competing Transaction in which case such [*]; during the pendency of such termination and any transition pursuant to Section 15.5 (Transition Period), Collaborator shall hold separate such Competing Program (including ensuring that no personnel working directly on the Collaboration works on a Competing Program (and vice versa), and ensuring that information from the Collaboration is sequestered from personnel working directly on the Competing Program (and vice versa)). In the event the Competing Transaction Party selects option (i) and fails to complete such divestiture within one year of the closing of the Competing Transaction, then such Party shall be deemed to have chosen option (ii), effective as of such one year anniversary, and shall promptly comply with the requirements of such subsection (ii), above.

2.6. Governance. The Collaboration shall be governed by a Development Committee and a Commercialization Committee, which shall coordinate and oversee the development and commercialization, respectively, of Dmab in the Territory. Each such committee shall be formed promptly following the Effective Date.

2.7. Membership. Each of the committees shall be comprised of three (3) members appointed by Amgen, and three (3) members appointed by Collaborator. Each committee shall be led by two (2) co-chairs, one (1) appointed by each of the Parties.

Each of the committees shall have the right to delegate any of its responsibilities to one or more subcommittees as it determines appropriate.

2.8. 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.

2.9. 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.

2.10. 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.

2.11. Development Committee. The Development Committee shall be responsible for: (i) reviewing and approving development plans (and changes thereto) for Dmab in the Territory prior to adoption of such plans or changes by a Party; (ii) providing for communication and discussion between the Parties to optimize the efficacy and safety of the development of Dmab 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 Commercialization Committee regarding the interrelationship between development activities and potential commercialization of Dmab in the Territory; (v) monitoring and reporting on the competitive landscape for Dmab in the Territory (in consultation with the Commercialization Committee); and (vi) communicating with the Parties regarding all of the foregoing.

2.11.1. *Meetings*. The Development Committee shall meet quarterly in person or telephonically (with at least two meetings per Calendar 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 Collaborator'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 five (5) business days written notice to the co-chair appointed by the other Party.

2.11.2. *Reporting*. Each Party shall keep the 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 the Development Committee and as otherwise provided herein, including by promptly providing copies of all clinical data and results for Dmab as reasonably requested by the other Party. Each Party shall fully inform the Development Committee with respect to all relevant facts and activities regarding any Dmab

development matter reasonably requested by any member thereof. At least five (5) business days prior to the first Development Committee meeting of each Calendar Quarter, each Party shall deliver to the 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.

2.11.3. *Development Plans*. At least five (5) business days prior to the first Development Committee meeting of each Calendar Year, Collaborator (and, during the transition period referenced in Section 15.5 (Transition Period) and any other period during which Amgen is developing any Amgen Additional Indication in the Territory, Amgen) shall provide the Development Committee a copy of its proposed development plan for Dmab in the Territory for the next four Calendar Quarters for the Development Committee's review, comment and approval (with Collaborator and Amgen (should Amgen be developing any Amgen Additional Indication in the Territory) each having its own development plan (either by indication or for all indications for which it is responsible in the Territory)). In addition, should a Party seek to make material changes to an approved development plan, then at least five (5) business 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 approval.

2.11.4. *Decision Making*. The Development Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event the committee fails to reach consensus, the committee [*] determination unless the decision relates primarily to [*], in which case the committee [*] determination (in all cases subject to [*]).

2.12. Commercialization Committee. The Commercialization Committee shall be responsible for: (i) reviewing and approving commercialization plans (and changes thereto) for Dmab in the Territory prior to adoption of such plans or changes by a Party; (ii) communicating with the Development Committee regarding the interrelationship between development activities and potential commercialization of Dmab in the Territory; (iii) reviewing and monitoring the activities and progress against the commercialization plans; (iv) monitoring and reporting on the competitive landscape for Dmab in the Territory; (v) establishing appropriate processes for coordinating review of promotional materials for the Territory to ensure compliance with Law and industry best practices; (vi) overseeing the trademark and publication strategies for the Territory; and (vii) communicating with the Parties regarding all of the foregoing.

2.12.1. *Meetings*. The Commercialization Committee shall meet quarterly in person or telephonically (with at least two meetings per Calendar 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 Collaborator'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 five (5) business days written notice to the co-chair appointed by the other Party.

2.12.2. *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 regarding any Dmab commercialization matter reasonably requested by any member thereof. At least five (5) business days prior to the first Commercialization Committee meeting of each Calendar 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.

2.12.3. *Commercialization Plans*. At least five (5) business days prior to the first Commercialization Committee meeting of each Calendar Year, Collaborator (and should Amgen be commercializing any Amgen Additional Indication in the Territory, Amgen) shall provide the Commercialization Committee a copy of its proposed commercialization plan for Dmab in the Territory for the next four Calendar Quarters for the Commercialization Committee's review, comment and approval (with Collaborator and Amgen (should Amgen be commercializing any Amgen Additional Indication in the Territory) each having its own commercialization plan (either by indication or for all indications for which it is responsible in the Territory)). In addition, should a Party seek to make material changes to an approved commercialization plan, then at least five (5) business 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.

2.12.4. *Decision Making*. The Commercialization Committee shall strive to reach consensus on decisions, taking into account the views of each committee member. In the event the committee fails to reach consensus, the committee [*] determination unless the decision relates primarily to [*], in which case the committee [*] determination.

3. GRANT OF LICENSE

3.1. Licensed Amgen Patents. Amgen hereby grants Collaborator [*] (except as otherwise expressly set forth herein (such exception to include the transition periods described in Section 4.18 (Transition in Oncology Development) and Section 15.5 (Transition Period))) right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell Dmab in the Territory for the

Collaborator Indications under the Licensed Amgen Patents. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing).

3.2. Licensed Amgen Know-How. Amgen hereby grants Collaborator [*] 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 Dmab in the Territory for the Collaborator Indications. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing).

3.3. Licensed Collaborator Patents. Collaborator hereby grants Amgen [*] right and license under the Licensed Collaborator Patents, subject to the terms and conditions hereof, solely to develop, commercialize, make, have made, use, import, sell and offer for sale [*] for all uses. Such [*]shall be subject to a retained exclusive right in the Territory during the Term solely for Collaborator to develop, commercialize, use and sell Dmab in the Territory for the Collaborator Indications. 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 Collaborator; (ii) Amgen shall be responsible for any disclosure of the Confidential Information of Collaborator by such sublicensee in violation of the provisions of Article 11 (Confidentiality and Publications); (iii) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; (iv) to the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed; and (v) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. For the avoidance of doubt, Collaborator is retaining the right to develop, commercialize, make, have made, use, import, sell and offer for sale products and services other than [*] under the Licensed Collaborator Patents and no rights with respect to products and services other than [*] are granted to Amgen hereunder.

3.4. Licensed Collaborator Know-How. Collaborator hereby grants Amgen [*] right and license, subject to the terms and conditions hereof, to utilize the Licensed Collaborator Know-How solely for the purpose of supporting its development, commercialization, manufacture, use and sale of [*]: (x) in the Territory, outside the Collaborator Indications during the Term and for all uses thereafter; and (y) outside the Territory for all uses both during the Term and thereafter. 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 Collaborator; (ii) Amgen shall be responsible for any disclosure of the Confidential Information of Collaborator by such sublicensee in violation of the provisions of Article 11 (Confidentiality and Publications); (iii) no such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder; (iv) to the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed; and (v) Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. Notwithstanding the foregoing, the license granted in this Section 3.4 (Licensed Collaborator Know-How) shall be exclusive to the extent the relevant Licensed Collaborator Know-How is developed in the course of the Collaboration.

3.5. Collaborator Sublicensing. Collaborator 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 Collaborator shall be responsible for any disclosure of the Confidential Information of Amgen by such sublicensee in violation of the provisions of Article 11 (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 Collaborator shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. No sublicense shall operate to excuse Collaborator's compliance with its obligations hereunder. Collaborator shall have the right to distribute Dmab in the Territory through reputable distributors.

3.6. Provision of Know-How. Following the Effective Date, the Parties shall cooperate to establish procedures for the provision of Licensed Amgen Know-How to Collaborator and Licensed Collaborator Know-How to Amgen. During the Term, Amgen shall use reasonable efforts to provide all material Licensed Amgen Know-How to Collaborator, and Collaborator shall use reasonable efforts to provide all material Licensed Collaborator Know-How to Amgen. In any event, each of the Parties shall provide to the other any Licensed Amgen Know-How or Licensed Collaborator Know-How (respectively) as the other Party shall reasonably request. Notwithstanding the foregoing, Amgen shall have no obligation to provide manufacturing information to Collaborator and neither Party shall have an obligation to provide information relating to any product other than Dmab.

3.7. Trademarks.

3.7.1. *Grant to Collaborator*. Amgen hereby grants Collaborator [*] (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 15.5 (Transition Period)) right and license during the Term, subject to the terms and conditions hereof, solely to develop, commercialize, use and sell Dmab in the Territory in the Collaborator Indications under the same Licensed Amgen Trademarks as used by Amgen in the corresponding indications outside the Territory. Such license shall include the right to sublicense only as set forth in Section 3.5 (Collaborator Sublicensing). Such license is subject to Amgen's retained right to utilize such Licensed Amgen Trademarks in the Territory outside Collaborator Indications. The Parties acknowledge that the use of the Licensed Amgen Trademarks in the Territory may have commercial value to Collaborator, and that Collaborator shall have the right to commercialize Dmab in the Collaborator Indications in the Territory under the same Licensed Amgen Trademarks as utilized for such indications by Amgen outside the Territory. Should the Parties desire that a different trademark be used for Collaborator 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). Upon Amgen's request, Collaborator shall include an Amgen trademark designated by Amgen to Collaborator in writing (e.g., "Amgen" or "Amgen K.K.") on all packaging, labeling, promotional and marketing materials for Dmab in equal prominence to those of Collaborator. Collaborator shall utilize those Amgen trademarks as requested by Amgen to the extent that Amgen provides the necessary trademark approvals within thirty (30) days of request by Collaborator for such approval. Amgen hereby grants Collaborator a non-exclusive right and license, with the right to sublicense as set forth in Section 3.5 (Collaborator 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*. Collaborator hereby grants Amgen a [*] license during the Term to use Licensed Collaborator Trademarks to the extent Amgen desires or may be required to utilize the same in connection with its development and commercialization of Dmab in the Territory hereunder[*]. Subject to the foregoing, such license shall include the right to sublicense [*]. Any sublicensee shall be required to enter into a written agreement obligating it to comply with the provisions of Section 3.8 (Trademark Quality Standards). No such sublicense shall operate to excuse Amgen's compliance with its obligations hereunder. To the extent that such sublicense grants rights with respect to the Territory, it shall require such sublicensee to comply with the obligations and prohibitions of this Agreement relevant to the right(s) sublicensed, and Amgen shall be responsible for a breach by such sublicensee of any such obligations or prohibitions. Upon any termination or expiration of this Agreement, Collaborator shall, upon Amgen's request but at no charge, promptly assign the Licensed Collaborator Trademarks (and the associated goodwill) to Amgen.

3.8. Trademark Quality Standards. Each Party shall (i) maintain such reasonable quality standards for the Licensed Amgen Trademarks (with respect to Collaborator) or the Licensed Collaborator 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 Collaborator) or Licensed Collaborator Trademark (with respect to Amgen) in a manner that suggests any connection with any product other than Dmab or any service; and (iii) not use or display the Licensed Amgen Trademarks (with respect to Collaborator) or the Licensed Collaborator 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 Collaborator) or Licensed Collaborator 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 Collaborator) or Licensed Collaborator Trademarks (with respect to Amgen) used in the marketing or promotion of Dmab in order to review such usage. Amgen agrees that it shall not seek

to register or obtain ownership rights in any Licensed Collaborator Trademark (or confusingly similar trademark) and Collaborator 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 Dmab outside the Territory in any indication (or confusingly similar trademark to any of the foregoing).

3.9. Retained Rights and Limitations. No rights are granted to Collaborator hereunder to Licensed Amgen Patents, Licensed Amgen Know-How or Licensed Amgen Trademarks outside the Collaborator Indications, or outside the Territory. No rights are granted to Collaborator hereunder to make or have made Dmab or any other product. No rights are granted herein to Collaborator to control the research, development or commercialization of Dmab 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.

4. DEVELOPMENT AND REGULATORY APPROVAL

4.1. Responsibility for Development in Collaborator Indications. Collaborator shall develop Dmab in Collaborator Indications in the Territory in accordance with the then-current development plan approved by the Development Committee for such Collaborator Indications. Collaborator's responsibility with respect to Collaborator Indications in the Territory shall include: (a) filing for and seeking Regulatory Approval in the name of Collaborator 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 Dmab in the Territory for a particular Collaborator Indication and any post-approval activities to be conducted for any such Collaborator 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 Collaborator in the Territory for each Collaborator Indication pursued (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 Dmab; (f) forecasting clinical manufacturing production requirements; and (g) reporting on study design, study outcome, other communications and regulatory filings to the appropriate Governmental Authority. Collaborator shall be solely responsible for its costs incurred in its development of Dmab.

4.2. Preclinical Development in Collaborator Indications. Notwithstanding the provisions of Section 4.1 (Responsibility for Development in Collaborator Indications), Amgen shall be responsible for performing (itself or through a subcontractor) any preclinical research that is required (as reasonably demonstrated by written communication from or written meeting minutes of discussions with the relevant Governmental Authority) in order to conduct development of Dmab in one or more Collaborator Indications in the Territory in accordance with this Agreement. [*]. Such research shall be conducted in

accordance with a research plan to be agreed in writing by Amgen and Collaborator. Notwithstanding the foregoing, should [*] is likely to [*], then it shall notify [*]. In such case, [*]. Upon the request of either Party, the Parties shall [*], and should such [*], then [*] in accordance with Section [*].

4.3. [*]. Should Collaborator determine to [*] of Dmab for the [*] (including with respect to [*] and including [*]), Collaborator shall give Amgen prompt prior written notice thereof. The Parties shall promptly meet to discuss [*] and Collaborator shall, thereafter, have the right to [*] in accordance with such [*] unless [*] that [*] that such [*] would [*] of Dmab [*]. In such event the Parties [*]. Notwithstanding the above, if such development [*], then Collaborator [*] in accordance with [*]. Prior to any such [*], and Collaborator shall [*] as requested by Amgen [*]. Notwithstanding the foregoing, should [*] is likely to [*] of Dmab [*], then Amgen shall notify Collaborator of the same. In such case, Collaborator shall [*]. Upon the request of either Party, the Parties shall meet to discuss [*] and, should the Parties [*], and should [*], [*] shall have the right to [*] in accordance with [*].

4.4. Development in Combination or Outside Territory. Collaborator shall not, without Amgen's prior express written consent, conduct any development of Dmab outside the Territory, or conduct any development of Dmab in combination with any other pharmaceutical product.

4.5. Responsibility for Development in Amgen Additional Indications. Amgen shall develop Dmab for any Amgen Additional Indication(s) then under development by Amgen in the Territory in accordance with the then-current development plan approved by the Development Committee for such indications. Amgen's responsibility with respect to Amgen Additional Indications in the Territory shall include: (a) filing for and seeking Regulatory Approval in the name of Amgen from the relevant Governmental Authorities; (b) investigating additional indications for which Dmab will be developed; (c) identifying and carrying out all major development tasks to be conducted prior to submission of filings for Regulatory Approval for Dmab for a particular indication and any post-approval activities to be conducted for any such indication; (d) identifying key development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (e) carrying out all aspects of all clinical trials necessary to obtain Regulatory Approval in the name of Amgen for each indication pursued (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; (f) performing any other additional clinical and preclinical research in support of the clinical development of Dmab; (g) forecasting clinical manufacturing production requirements; and (h) reporting on study design, study outcome, other communications and regulatory filings to the appropriate Governmental Authority. Subject to Section 4.18 (Transition in Oncology Development) and Section 8.8 (Development Cost Sharing) Amgen shall be solely responsible for its costs incurred in its development of Dmab in the Territory.

4.6. Development Outside the Territory. Amgen shall have the sole right to manage and conduct the development of Dmab outside the Territory in all indications. The foregoing is without prejudice to Collaborator's payment obligations pursuant to Section 8.8 (Development Cost Sharing).

4.7. Global Development. The Parties acknowledge that it may be in their mutual interests to integrate Collaborator's development of Dmab within the Territory into Amgen's global development plan for Dmab for a particular Collaborator Indication. The Parties agree to discuss in good faith where it may be appropriate to so include such development, and the relevant cost-sharing that will be applicable thereto. As requested by either Party, the Parties shall meet and confer in good faith as to the feasibility and potential efficiency gains of cooperating to integrate Collaborator's development of Dmab for [*] in the Territory into Amgen's global development plan for such indication. The Parties acknowledge that one ongoing study within Oncology, a study of [*], the *"Ongoing Oncology Study"*), currently includes sites both inside and outside the Territory. The Ongoing Oncology Study is a global registration trial intended to support a filing for approval in the United States and Europe, as well as in the Territory. After the Effective Date, the management of those sites shall be addressed as provided in Section 4.18 (Transition in Oncology Development), and shall be conducted strictly in accordance with Amgen's global procedures and protocol for such trial, as in effect at the relevant time, as communicated by Amgen to Collaborator (and/or any relevant contract research organization). If Amgen elects to [*] that would be likely to [*] in the Territory, the Parties will discuss [*] and will discuss [*] in the Territory.

4.8. Sharing of Regulatory Filings. Each of the Parties will disclose to the other a draft copy of any Regulatory Filing in the Territory in the original language no less than thirty (30) days prior to filing it with a Governmental Authority. Each Party will consider in good faith any comments made by the other Party with respect to such filings. Each Party shall, no less frequently than quarterly, and more often as reasonably requested by the other Party, provide to the other Party (in such format as reasonably requested) all material preclinical and clinical data arising out of or relating to Dmab in trials thereof in the Territory (and outside the Territory, for Amgen) (or such subset of such data as the Parties may agree). Each of the Parties shall maintain a database which contains all clinical trial data accumulated from all clinical trials of Dmab in the Territory (in a computer readable format reasonably requested by Amgen). Upon the request of either Party, the other Party shall provide a right of reference to any requested Regulatory Filings or Regulatory Approvals in the Territory, and Amgen shall provide the same such right of reference to Collaborator 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 Dmab as permitted hereunder (or, with respect to Amgen, manufacture of Dmab). Notwithstanding the foregoing, Amgen shall not be required to provide to Collaborator nor to allow Collaborator to access (but shall provide a right of reference as set forth in Section 4.15.3 (Amgen Cooperation) to the extent necessary) Amgen's manufacturing information with respect to Dmab or any sections of any such Regulatory Filing related thereto and neither Party shall have an obligation to provide information relating to any product other than Dmab.

4.9. Clinical Supply. Collaborator shall obtain its requirements of Dmab for use in clinical development from Amgen, and shall [*] provision of such clinical supply. Amgen shall use reasonably diligent efforts to provide Collaborator with such supply in a form materially the same as the form of clinical supply used by Amgen outside the Territory (i.e. with respect to formulation, presentation, raw materials, diluent and components). Should Collaborator request Amgen to provide clinical supply that materially varies from that used by Amgen outside the Territory, Collaborator and Amgen shall meet to discuss in good faith the best approach with respect to such request. Collaborator shall provide Amgen, at least thirty (30) days prior to the start of each Calendar Quarter, a rolling, one-year forecast for its requirements of clinical Dmab supply. Amgen shall use its reasonable efforts to satisfy such need, and shall promptly notify Collaborator of any difficulty foreseen in doing so. In such event, the Parties shall meet promptly to discuss how to best address such situation.

4.10. Quality Agreement. Promptly following the Effective Date, the quality assurance departments of Amgen and Collaborator will develop and agree upon a quality agreement governing the quality and specifications of clinical Dmab to be supplied hereunder including with respect to product quality and product complaints (to the extent not covered in a separate safety agreement entered into pursuant to Section 4.13 (Safety Agreement)) with respect to Dmab. The quality agreement will be documented in writing, and routinely updated by mutual written agreement of the Parties.

4.11. Transfer of Regulatory Filing. Promptly after the Effective Date, Amgen shall transfer to Collaborator all Regulatory Filings in the Territory with respect to Dmab in Collaborator Indications.

4.12. Transfer of Regulatory Matters. Collaborator 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 Dmab in the Territory without the prior written approval of Amgen.

4.13. Safety Agreement. Promptly following the Effective Date, the safety departments of Amgen and Collaborator 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 Dmab 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.

4.14. Adverse Event Reporting. Each Party shall inform the other Party of any adverse event with respect to Dmab of which it becomes aware in a timely manner commensurate with the seriousness of the adverse event. Each Party shall be responsible for reporting to the MHLW all adverse events with respect to Dmab (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 Dmab.

4.15. Communications.

4.15.1. *Collaborator Responsibility.* Collaborator 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 Dmab in Collaborator Indications with applicable Governmental Authorities in the Territory (other than with respect to manufacturing). Collaborator will supply to Amgen a copy of: (i) all such correspondence and communications to any such Governmental Authority at least ten (10) business 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 (10) business days of receipt of any such correspondence. Collaborator shall consider in good faith any comments or suggestions made by Amgen with respect to any such communication. Amgen shall reasonably cooperate with Collaborator in responding to any inquiry made by a Governmental Authority in the Territory regarding Dmab in Collaborator Indications, and Collaborator 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 Collaborator and any Governmental Authority, and Collaborator shall give Amgen ten (10) business days prior written notice thereof (or prompt written notice, if ten (10) business days notice is impractical). Should Collaborator be unable to solicit Amgen's participation in any such discussion (as, for example, with respect to a call or visit to Collaborator by such Governmental Authority without notice), then Collaborator shall provide Amgen prompt written notice of such communication with a summary of the discussion.

4.15.2. *Amgen Responsibility.* Amgen shall have exclusive responsibility for all correspondence and for any official communication (except as Collaborator may be required by Law or a Governmental Authority to communicate) regarding Dmab in Amgen Additional Indications with applicable Governmental Authorities in the Territory and with applicable Governmental Authorities in all indications outside the Territory. Amgen shall have exclusive responsibility for all correspondence and for any official communication with Government Authorities in and outside the Territory regarding manufacture of Dmab. With respect to the Territory, Amgen will supply to Collaborator a copy of: (i) all such correspondence and communications (other than those related to manufacturing or relating to Amgen proprietary manufacturing information) to any such Governmental Authority at least ten (10) business 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 (other than those related to manufacturing or relating to Amgen proprietary manufacturing information) from any such Governmental Authority within (10)

business days of receipt of any such correspondence. Amgen shall consider in good faith any comments or suggestions made by Collaborator with respect to any such communication. Collaborator shall be entitled to observe and participate in any discussions between Amgen and any Governmental Authority in the Territory (other than those related to manufacturing or to Amgen proprietary manufacturing information), and Amgen shall give Collaborator ten (10) business days prior written notice thereof (or prompt written notice, if ten (10) business days notice is impractical). Should Amgen be unable to solicit Collaborator'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 Collaborator prompt written notice of such communication with a summary of the discussion. With respect to correspondence and communication with Governmental Authorities outside the Territory: (i) Amgen shall use reasonable efforts to provide Collaborator copies of material written correspondence, and summaries of material non-written communication, as reasonably necessary to permit Collaborator to comply with its relevant regulatory obligations; and (ii) Amgen shall discuss with Collaborator Amgen's experience in seeking Regulatory Approvals outside the Territory and shall provide that information (including selected correspondence and materials) it reasonably believes would be helpful in Collaborator's establishment of its strategy for development and regulatory activities with respect to Dmab in the Territory (provided that Amgen shall not be required to disclose competitively sensitive information). Should Amgen fail to provide Collaborator with any of the foregoing information (other than competitively sensitive information), Collaborator shall have the right to request the same from Amgen, and Amgen shall promptly provide such correspondence or summaries to Collaborator (other than competitively sensitive information).

4.15.3. *Amgen Cooperation – Manufacturing Information*. Upon Collaborator's request, Amgen will reasonably cooperate with Collaborator 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 Dmab by Amgen for supply to Collaborator; provided, however, that Amgen's obligation to provide Collaborator with manufacturing and process information is limited to the circumstance where the information is reasonably required for Collaborator 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 Collaborator 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).

4.16. Recalls. The Parties shall exchange their internal standard operating procedures as to product recalls (*"SOPs"*) reasonably promptly after the Effective Date and thereafter reasonably promptly after such SOPs are approved or modified. If either Party becomes aware of information about quantities of Dmab supplied by Amgen to Collaborator which may not conform to the specifications for Dmab then in effect, or for which there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, or for which Dmab itself is 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 subsection 4.16.1 (Collaborator Right) or 4.16.2 (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 subsection 4.16.1 (Collaborator Right) or 4.16.2 (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 Collaborator only to the extent necessary for Collaborator 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) if such provision will satisfy such requirement (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 4.16.1 (Collaborator Right) or 4.16.2 (Amgen Right) shall promptly comply with such order with written notice to the other Party.

4.16.1. *Collaborator Right*. Collaborator shall have the sole right to control a Recall of Dmab in Collaborator Indications in the Territory. Collaborator shall maintain complete and accurate records of any Recall it has the right to control pursuant to this Section 4.16 (Recalls) for such periods as may be required by Law, but in any event for no less than [*].

4.16.2. *Amgen Right*. Amgen shall have the sole right to control a Recall of Dmab outside Collaborator Indications in the Territory (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 4.16 (Recalls) for such periods as may be required by Law, but in any event for no less than [*].

4.17. 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 Dmab in the Territory.

4.18. Transition in Oncology Development. Notwithstanding anything in this Agreement to the contrary, the Parties shall cooperate with respect to the conduct of the Ongoing Oncology Study in the Territory as follows: The Parties have [*] to the Ongoing Oncology Study [*] such Ongoing Oncology Study [*] and the Parties both recognize

[*] Amgen shall [*] the Ongoing Oncology Study. To the extent Amgen is [*] Collaborator, [*] of the Ongoing Oncology Study [*]. If [*], Amgen and Collaborator shall [*]. Amgen shall have the right to continue to [*] until Amgen and Collaborator [*]. From and after the Effective Date, Collaborator shall [*] the Sites [*] and [*] as may be agreed hereunder (including the [*]). As provided in Section 4.7 (Global Development), the Ongoing Oncology Study shall be conducted strictly in accordance with Amgen's global development plan and protocols for such trials, as in effect at the relevant time, as communicated by Amgen to Collaborator [*].

5. COMMERCIALIZATION

5.1. Operational Control in Collaborator Indications. Collaborator shall have operational responsibility for commercialization of Dmab in the Territory in Collaborator Indications. Collaborator shall commercialize Dmab in all Collaborator Indications in the Territory in accordance with the then-current commercialization plan approved by the Commercialization Committee. Collaborator shall promote and commercialize Dmab using only professional and well-trained employees of Collaborator, and shall not utilize a contract sales organization in connection with Dmab without Amgen's prior written approval. Subject to the foregoing, with respect to Collaborator Indications in the Territory, Collaborator'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 4.15.1 (Collaborator Responsibility)); (c) creation of promotional materials regarding Dmab which are intended for distribution to Third Parties (including medical professionals) and to Collaborator'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 and collecting prescription tracking, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Collaborator shall be solely responsible for its costs incurred in its commercialization of Dmab.

5.2. Amgen Co-Promotion Right. Amgen shall have the right, upon [*] written notice [*] to co-promote Dmab in one or more Collaborator Indications in the Territory at any time [*]. Collaborator shall provide Amgen any information reasonably requested by Amgen to allow Amgen to consider whether to exercise such option. Should Amgen elect to co-promote Dmab in one or more Collaborator Indications in the Territory, it shall elect to provide up to [*] percent ([*]%) 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 Collaborator's commercialization activities hereunder. Collaborator shall pay Amgen [*]. Amgen shall have the right to terminate its co-promotion activities by ninety (90) days notice to Collaborator, and the Parties shall cooperate to transition such activities to Collaborator 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. Operational Control in Amgen Additional Indications. Amgen shall have operational responsibility for commercialization of Dmab in the Territory in any Amgen Additional Indications in accordance with the then-current commercialization plan approved by the Commercialization Committee. Amgen shall promote and commercialize Dmab using only professional and well-trained employees of Amgen, and shall not utilize a contract sales organization in connection with Dmab without Collaborator's prior written approval. Subject to the foregoing, with respect to any Amgen Additional Indications being commercialized in the Territory, Amgen'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 Collaborator shall have the right to participate in any discussions with Governmental Authorities with respect to labeling in accordance with Section 4.15.2 (Amgen Responsibility)); (c) creation of promotional materials regarding Dmab which are intended for distribution to Third Parties (including medical professionals) and to Amgen'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 and collecting prescription tracking, call reporting, handling data regarding sales to hospitals and other end users and handling all other customer service-related functions. Except as set forth in Section 5.2 (Amgen Co-Promotion Right), Amgen shall be solely responsible for its costs incurred in its commercialization of Dmab.

5.4. Commercialization Outside the Territory. Amgen shall be solely responsible for the commercialization of Dmab for all indications outside the Territory and the costs thereof, and Collaborator shall have no rights with respect thereto.

5.5. Compliance with Laws, Regulations and Guidelines. Each Party agrees to comply with Law with respect to the development and commercialization of Dmab in the Territory. Neither Party shall be required to undertake any activity relating to the commercialization of Dmab in the Territory that it believes, in good faith, may violate any Law.

5.6. Cooperation Generally. Subject to the oversight of the Commercialization Committee, the Parties shall cooperate generally with respect to the commercialization of Dmab in the Territory.

6. COLLABORATOR AND AMGEN ADDITIONAL INDICATIONS

6.1. Reasonably Diligent Efforts. Collaborator shall use Reasonably Diligent Efforts to develop, obtain Regulatory Approval for and commercialize Dmab in all Collaborator Indications in the Territory, and it shall be a material breach of this Agreement for Collaborator to fail to do so. The Parties acknowledge that [*]. With respect to the development of Dmab [*], Reasonably Diligent Efforts shall be [*].

6.2. Additional Indications.

6.2.1. *Amgen Developed Indications*. Within ninety (90) days of Amgen's written request, Collaborator shall inform Amgen in writing of whether or not it intends to develop and commercialize Dmab in the Territory in an indication which is then subject to clinical development by Amgen outside the Territory, but other than a Collaborator Indication. Amgen shall provide Collaborator with all information reasonably requested by Collaborator reasonably necessary to enable Collaborator to make such determination. Should Collaborator elect in writing to do so during such ninety (90) day period, then such indication shall, from that point forward, be a Collaborator Indication. Should Collaborator notify Amgen that it does not intend to so develop and commercialize Dmab for such indication (or fail to timely respond to Amgen's request), then such indication shall become an *"Amgen Additional Indication."*

6.2.2. *Collaborator Proposed Indications*. Should Collaborator wish to develop or commercialize Dmab in the Territory in an indication other than a Collaborator Indication or an Amgen Additional Indication, it shall request Amgen's written approval thereof and the Parties shall discuss in good faith expansion of the definition of Collaborator Indications to include such indication. Collaborator 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 approve the expansion of such definition unless Amgen reasonably believes that [*]. Should the Parties so agree in writing, then such indication shall, from such point forward, be a Collaborator Indication. Any such approved development shall be subject to [*]. Collaborator shall not [*].

7. MANUFACTURE AND SUPPLY

7.1. Manufacturing Rights. No rights are granted to Collaborator hereunder to manufacture Dmab or to obtain Dmab from any entity other than Amgen or its designee. Collaborator shall not manufacture Dmab or obtain Dmab from any entity other than Amgen or its designee.

7.2. Supply Agreement. The Parties (or their Affiliates) intend to enter into a supply agreement for the commercial supply of Dmab (materially consistent with the Supply Agreement Term Sheet Schedule attached hereto) subsequent to the Effective Date, and shall, upon the request of either Party, negotiate in good faith to do so. In the event of any conflict between this Agreement and such supply agreement, this Agreement shall control.

7.3. 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 Dmab provided to Collaborator by Amgen pursuant to the supply agreement to be entered into by the Parties pursuant to Section 7.2 (Supply Agreement) (including with respect to the use of any contract manufacturer to produce such Dmab). Collaborator 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 Collaborator in connection with such cooperation.

8. PAYMENT

8.1. License Payments by Collaborator. In consideration of the rights granted by Amgen to Collaborator hereunder, Collaborator shall make the following payments to Amgen;

8.1.1. *License Fee.* Collaborator shall pay Amgen a non-refundable, non-creditable license fee in the amount of $20,000,000 within ten (10) days after the Effective Date.

8.1.2. *Milestone Payments.* In addition to the license fee, Collaborator shall pay Amgen the following non-refundable, non-creditable development and commercial milestone payments as set forth below, in each case within thirty (30) days after the occurrence of the corresponding event:

Milestone Event	Payment Amount
[*]	$ [*]
[*]	$ [*]
[*]	$ [*]

8.2. License Payments by Amgen. In consideration of the licenses granted by Collaborator to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How) hereunder, Amgen shall make the following payments to Collaborator:

8.2.1. *License Fee*. Amgen shall pay Collaborator a non-refundable, non-creditable license fee in the amount of $[*] within ten (10) days after the substantial completion of the transfer from Collaborator to Amgen of the documents, filings and other information, certificates, instruments and documents related to the Licensed Collaborator Patents as required pursuant to Section 10.2.1.

8.2.2. *Milestone Payments*. Amgen shall pay Collaborator the following non-refundable, non-creditable milestone payments as set forth below, in each case within thirty (30) days after the first occurrence of the following events with respect to Dmab:

Milestone Event	Payment Amount
The sooner to occur of: (i) Regulatory Approval of Dmab [*]; and (ii) Regulatory Approval of Dmab [*].	$ [*]
The sooner to occur of: (i) Regulatory Approval of Dmab [*] in [*]; and (ii) Regulatory Approval of Dmab [*] in [*].	$ [*]

8.2.3. *Maintenance Payments*. In order to maintain the license rights granted by Collaborator to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), Amgen shall be required to make maintenance fee payments as set forth in the table below. Should Amgen fail to make any such payment when due, Collaborator shall have the right to terminate the licenses granted to Amgen pursuant to such Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How) by thirty (30) days written notice to Amgen, as Collaborator's sole and exclusive remedy with respect to such failure to pay. Such termination shall be automatically effective as of the thirty-first (31st) day following Amgen's receipt of such notice unless Amgen has cured by making the required payment within such thirty (30) day period, in which case such termination notice shall be of no force or effect. As of the effective date of termination of Amgen's licenses pursuant to such Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), Amgen's payment obligations pursuant to this Section 8.2 (License Payments by Amgen) shall terminate.

Maintenance Payment Amount	Payment Due Date
$ [*]	[*]
$ [*]	[*]
$ [*]	[*]

8.2.4. *Payments Survive.* The Parties acknowledge that Amgen's payment obligations pursuant to this Section 8.2 (License Payments by Amgen) are in consideration of Collaborator's grants of license to Amgen pursuant to Sections 3.3 (Licensed Collaborator Patents) and 3.4 (Licensed Collaborator Know-How), which licenses are perpetual and irrevocable (except as set forth in Section 8.2.3 (Maintenance Payments)) and which survive any termination of this Agreement. The payment obligations of this Section 8.2 (Amgen Payments) shall therefore likewise survive any such termination or expiration of this Agreement (without prejudice to Collaborator's termination rights pursuant to Section 8.2.3 (Maintenance Payments); and without prejudice to the last sentence of Section 8.2.3 (Maintenance Payments)).

8.3. Royalty Payments.

8.3.1. *Collaborator Payments to Amgen*. Collaborator shall pay Amgen the following royalty amounts with respect to annual Collaborator Net Sales during the Term:

Annual Net Sales Amount	Royalty Percentage
That portion of aggregate annual Collaborator Net Sales (across all indications) less than $[*]	[*]%
That portion of aggregate annual Collaborator Net Sales (across all indications) equal to or in excess of $[*]	[*]%

8.3.2. *Calculation of Royalty Tiers*. A fiscal year beginning on April 1st and ending on March 31st shall be used for the purposes of calculating annual Collaborator Net Sales in the determination of royalty amounts payable pursuant to Section 8.3.1 (Collaborator Payments to Amgen).

8.3.3. *Amgen Payments to Collaborator.* Amgen shall pay Collaborator [*]% of Amgen Net Sales during the Term as royalty amounts.

8.3.4. *No Royalty on Amgen Sales Outside Territory*. For the avoidance of doubt, no royalty and, except as expressly provided in Section 8.2.2 (Milestone Payments), no other payments shall be owed by Amgen to Collaborator with respect to development, receipt of any Regulatory Approval, or sales of Dmab by or on the account of Amgen, its Affiliates or licensees outside the Territory for any indication.

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

8.5. Calculation of Net Sales. In calculating Net Sales:

8.5.1. *Free Products.* Any disposal of Dmab at no charge for, or use of Dmab 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.

8.5.2. *Bundled Products*. Where Dmab is sold in a Bundle, then for the purposes of calculating the Net Sales under this Agreement, such Dmab 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 Dmab 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 Dmab 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 Dmab.

8.6. Reports. Beginning with the Calendar Quarter after the First Commercial Sale of Dmab in the Territory and thereafter for each Calendar Quarter in which royalties are payable until the expiration of the Payor Party's obligation to pay royalties hereunder, royalty payments and reports of the sale of Dmab for each Calendar Quarter will be calculated and delivered by the Payor Party to the Payee Party under this Agreement within forty-five (45) days of the end of each such Calendar Quarter. In addition, such reports for the first Calendar Quarter of each Calendar Year shall be delivered by the Payor Party to the Payee Party within five (5) business days of the end of such Calendar Quarter using the best estimate of the Payor Party, with a final report (and the accompanying royalty payments) sent no later than forty-five (45) days of the end of such Calendar Quarter. Each payment of royalties will be accompanied by a report of Net Sales of Dmab stating: (a) Net Sales of Dmab by or on behalf of the Payor Party during the applicable Calendar Quarter (detailed with gross invoiced amounts, deductions and Net Sales); and (b) a calculation of the royalty payment due from the Payor Party hereunder for such Calendar Quarter. Any reports which contain currency conversions shall provide the details and background information used to calculate such conversions.

8.7. No Wrongful Reductions. The Payor Party shall not attempt to reduce compensation rightly due to the Payee Party hereunder by shifting compensation otherwise payable to the Payor Party from a Third Party with respect to Dmab to another product or service for which no royalties are payable by it hereunder.

8.8. Development Cost Sharing. In addition to the other payments referenced herein, Collaborator shall pay to Amgen a share of Amgen Development Costs including those for the third Calendar Quarter of 2007 and thereafter:

8.8.1. *Amounts*. Collaborator'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 8.8.2 (Maximum Payments):

Calendar Year	Collaborator Share
2007-2009	[*]%
2010 and thereafter	[*]%

8.8.2. *Maximum Payments*. Notwithstanding the foregoing, Collaborator's payment obligations pursuant to this Section 8.8 (Development Cost Sharing) shall be subject to a maximum payment as set forth below for each Calendar Year (each, an *"Annual Maximum")*. In addition, total, aggregate amounts payable by Collaborator pursuant to this Section 8.8 (Development Cost Sharing) shall not exceed $[*] (the *"Aggregate Maximum"*). In the event the amount otherwise payable in a Calendar Quarter (*"Q1; Q2; Q3* or *Q4"*, as appropriate) would exceed: [*] (the *"Quarterly Maximum"*) then Collaborator shall pay only such Quarterly Maximum. Since there will be only two quarterly payments by Collaborator in 2007 (due to the Effective Date of this Agreement occurring

during Q3 of 2007), the Quarterly Maximum for Q3 of 2007 shall be [*] of the Annual Maximum for 2007, and the Quarterly Maximum for Q4 of 2007 shall be the Annual Maximum for 2007 less the amount paid by Collaborator pursuant to this section for Q3 of 2007. No [*] the Annual Maximum for a particular Calendar Year nor [*] the Quarterly Maximum for a particular Calendar Quarter shall [*]. No amounts in excess of the Aggregate Maximum shall be payable by Collaborator pursuant to this Section 8.8 (Development Cost Sharing).

Calendar Year	Annual Maximum
2007	$ [*]
2008	$ [*]
2009	$ [*]
Aggregate Maximum	$ [*]

8.8.3. *Reports.* Within thirty (30) days of the end of each Calendar Quarter, Amgen shall provide Collaborator with a report specifying in reasonable detail the Amgen Development Costs incurred or paid by Amgen in such Calendar Quarter, as well as any other costs for which Amgen is entitled reimbursement hereunder (such as those incurred pursuant to Section 4.18 (Transition in Oncology Development)). In addition, for the first Calendar Quarter of each Calendar Year Amgen shall provide Collaborator a non-binding estimate of Collaborator's share of Amgen Development Costs, as well as any other costs for which Amgen is entitled reimbursement hereunder (such as those incurred pursuant to Section 4.18 (Transition in Oncology Development)) for such Calendar Quarter within five (5) business days of the end of such Calendar Quarter. Amgen Development Costs may be attributed by Amgen to either the Calendar Quarter in which they are paid or incurred, but no amount shall be attributed to more than one Calendar Quarter.

8.8.4. *Payments.* Collaborator shall pay Amgen its share of Amgen Development Costs in accordance with Section 8.10 (Payment Method) within thirty (30) days of receiving Amgen's report pursuant to Section 8.8.3 (Reports). For the avoidance of doubt, except as expressly set forth in Section 15.3.3 (Development Cost Share), Collaborator's payment obligation with respect to Amgen Development Costs shall remain in effect until the Aggregate Maximum has been paid in full.

8.8.5. *Example.* The Development Costs Example Schedule sets forth an example of the calculation of Collaborator's share of Amgen Development Costs.

8.9. No Other Compensation. Other than as explicitly set forth (and as applicable) in this Agreement, neither Party shall be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other under this Agreement.

8.10. Payment Method. All payments made hereunder between the Parties shall be made in U.S. Dollars except as set forth in Section 8.13 (Blocked Currency). The Payor Party shall pay all sums due hereunder by check, wire transfer, or electronic funds transfer

(EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.15 (Withholding) and Section 8.16 (VAT)).

8.11. Change in Accounting Periods. From time to time, either Party may change its company-wide (or Territory-wide) accounting and financial reporting practices from Calendar Quarters and Calendar Years to fiscal quarters and fiscal years or vice versa. If a Party notifies the other of a change in its accounting and financial reporting practices from Calendar Quarters and Calendar Years to fiscal quarters and fiscal years or vice versa, then thereafter, beginning with the period specified in the notice, the payment, reporting and other obligations of such Party hereunder related to Calendar Quarters and Calendar Years shall be deemed satisfied by compliance therewith in accordance with the new reporting periods (fiscal reporting periods or calendar reporting periods, as the case may be) instead of the previously utilized reporting periods. The Parties shall cooperate in good faith to minimize any disruption caused by any such change. Notwithstanding the foregoing, any change in Collaborator's accounting periods shall not affect the timing or amount of Collaborator's payment obligations pursuant to Section 8.8 (Development Cost Sharing).

8.12. Audits. The Payor Party shall keep complete and accurate records pertaining to the development and sale of Dmab in the Territory in sufficient detail to permit the Payee 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 8.12 (Audits)) to inspection for [*] following the end of the period to which they pertain. The Payee Party shall have the right, at its own expense, to have an independent, certified public accountant, selected by such Payee Party review the records of the Payor Party upon reasonable notice (which shall be no less than thirty (30) days prior written notice) and during regular business hours. Upon request, the accountant shall execute a confidentiality agreement reasonably required by the Payor Party. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. The Payee Party's audit rights with respect to any Calendar Year shall expire [*] after the end of such year and the books and records for any particular Calendar Year shall only be subject to one (1) audit. Should the inspection lead to the discovery of a discrepancy to the Payee Party's detriment, then the Payor Party shall pay to the Payee 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 Payor Party's detriment, then the Payee Party shall pay to the Payor Party the amount of the discrepancy without interest. The Payee Party shall pay the full cost of the inspection unless the discrepancy is to the Payee Party's detriment and is greater than [*] percent ([*]%) of the amount actually paid for the audited period, in which case the Payor Party shall pay the cost of such inspection.

8.13. Blocked Currency. If at any time legal restrictions in the Territory prevent the prompt remittance of any payments with respect to sales therein, the Payor Party shall have the

right and option to make such payments by depositing the amount thereof in local currency to the Payee Party's account in a bank or depository in the Territory.

8.14. Taxes. All Taxes levied on account of a payment made by a Payor Party to a Payee Party pursuant to this Agreement will be the responsibility of and paid by the Payee Party or shall be subject to the withholding and remittance provisions of Section 8.15 (Withholding).

8.15. Withholding. In the event that Laws require a Payor Party to withhold Taxes with respect to any payment to be made by such Party to the Payee Party pursuant to this Agreement, the Payor Party will withhold such Taxes from the amount due and furnish the Payee Party with proof of payment of such Taxes. The Payor Party will provide reasonable assistance to the Payee Party in its efforts to claim an exemption of Taxes, obtain a refund of Taxes withheld, or obtain a credit with respect to such Taxes paid. In order for the Payee Party to secure an exemption from, or a reduction in, any withholding of Taxes, the Payee Party shall provide to the Payor Party such forms as reasonably required for each type of payment to be made pursuant to the Agreement for which an exemption from, or a reduction in, any withholding of Taxes is claimed. Each Party shall provide the other any cooperation reasonably requested to minimize any withholding obligation (e.g., by providing the necessary tax forms upon request).

8.16. VAT. All payments due a Payee Party from a Payor Party pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by the Payor Party upon receipt of a valid VAT invoice).

8.17. 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 8.17 (Late Payment) shall in no way limit any other remedies available to either Party.

8.18. Third Party Royalties. Except as expressly set forth in Sections 8.15 (Withholding) and 8.16 (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. SETTLEMENT OF PATENT DISPUTES

9.1. Settlement. The Parties hereby intend that this Agreement fully and finally dispose, compromise and settle any and all patent disputes between Collaborator and its Affiliates, and its and their successors and assigns, and Amgen and its Affiliates, and its and their successors and assigns, with respect to the Settled Patents. [*] In consideration of this settlement, the Parties hereby agree as follows: Collaborator covenants that neither it, its Affiliates nor sublicensees, nor its or their successors or assigns will [*] the Territory. Collaborator, for itself, its Affiliates and each of its and their successors and assigns, hereby [*] the Territory. Amgen covenants that neither it, its Affiliates nor sublicensees, nor any of its or their successors or assigns will initiate or file, or request, assist or cause any Third Party to [*] the Territory. Amgen, for itself, its Affiliates and each of its and their successors and assigns, hereby [*] the Territory. The foregoing [*] in this Section 9.1 (Settlement) are subject to the Parties' respective rights to control preparation, filing (including filing for correction of claims or specifications),

prosecution, maintenance, defense (including responses to patent office communications, office actions, oppositions, interferences and challenges) and enforcement of the Settled Patents as specified in Article 10 (Intellectual Property) (following expiration or termination of this Agreement, as may be modified by the provisions of Article 15 (Term and Termination)), and the exercise of a Party's rights in accordance with Article 10 (Intellectual Property) (as may be so modified following expiration or termination of this Agreement) shall not be deemed a breach of the [*] under this Section 9.1 (Settlement).

10. INTELLECTUAL PROPERTY

10.1. 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 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 or license 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).

10.2. Transition and Cooperation.

10.2.1. *Transition*. [*] The Parties shall cooperate to promptly transition such documents, filings and other information, execute all agreements, certificates, instruments and documents, and take such other actions, in each case as necessary or reasonably requested by the other Party to effectuate such transition of control consistent with this Article 10 (Intellectual Property).

10.2.2. *Cooperation*. Each Party shall provide the Party in control [*] and the controlling Party shall reimburse the assisting Party's reasonable, documented out-of-pocket expenses incurred in connection therewith. Without limiting the foregoing, if reasonably necessary for standing or to satisfy other requirements to file, pursue or maintain an action in accordance with this Article 10 (Intellectual Property), a non-controlling Party will join such action at the controlling Party's request, and the controlling Party shall reimburse the non-controlling Party's reasonable, documented out-of-pocket expenses incurred in connection therewith. Each Party shall, upon the request of the other Party, execute all agreements, certificates, instruments and documents necessary to enable the requesting Party to evidence, register, protect or perfect its rights hereunder, including short-form licenses and other documents necessary to register its licenses with the United States Patent and Trademark Office, and corresponding offices in other countries.

10.3. Prosecution and Maintenance.

10.3.1.*In Territory.*

10.3.1.1. *Collaborator* [*] *Prosecution*. Collaborator shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Collaborator, 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) in the Territory [*] at Collaborator's expense, as well as preparation and filing for any patent term extensions or similar protections therefor.[*]

10.3.1.2. *Amgen* [*] *Prosecution.* [*] Amgen may, upon written notice to Collaborator and at Amgen's sole cost, control 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 related thereto) of such item within the Territory Patents and Trademarks thereafter in accordance with this Section 10.3.1.2 (Amgen [*] Prosecution) (any item so assumed, an "*Amgen Assumed Item*"). Amgen shall control, itself or through outside counsel reasonably acceptable to the Parties and directed by Amgen, 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 related thereto) of Amgen Assumed Items in the Territory, at Amgen's expense, as well as preparation and filing for any patent term extensions or similar protections therefor.[*].

10.3.2. *Outside Territory*. Amgen shall control and be solely responsible for the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance, defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) and all other actions with respect to its patent rights, trademark rights and other intellectual property outside the Territory, at its sole cost and expense. Amgen shall control and be solely responsible for the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance, defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) related thereto) and all other actions with respect to [*].

10.4. Defense and Settlement of Third Party Claims. If a Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, sale or importation [*] by a Party (the "*Defending Party*"), the Defending Party shall have the sole right to defend against any such assertions at its sole cost. If such Third Party asserts that a patent right or other right owned by it is infringed by the manufacture, use, sale or

importation [*] by both of the Parties, then the Parties shall meet and confer, and both Parties shall have the sole right to defend against any such assertions with respect to its activities at their respective sole cost. The other Party shall assist the Defending Party and cooperate in any such litigation at the Defending Party's request, and the Defending Party shall reimburse such other Party any reasonable, documented, out-of-pocket costs incurred in connection therewith. Subject to such control, the other Party may join any defense and settlement pursuant to this Section 10.4 (Defense and Settlement of Third Party Claims), with its own counsel at its sole cost. Regardless of which Party is the Defending Party (or if both Parties are a Defending Party), the Defending Party shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, the Defending Party shall keep the other Party advised of all material communications, actual and prospective filings or submissions regarding such action, and shall provide the other Party copies of and an opportunity to review and comment on any such communications, filings and submissions. [*] The Defending Party shall not settle or consent to the entry of any judgment in any enforcement action hereunder without the other Party's prior written consent, not to be unreasonably withheld or delayed. Each Party shall keep the other reasonably informed of all claims and actions governed by this Section 10.4 (Defense and Settlement of Third Party Claims).

10.5. Enforcement.

10.5.1. *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.

10.5.1.1. *Collaborator* [*] *Enforcement.* [*]

10.5.1.2. *Amgen* [*] *Enforcement.* [*]

10.5.2. *Outside Territory*. [*]

10.6. Allocation of Recoveries. All Recoveries shall first be applied to reimbursement of the unreimbursed legal fees and expenses reasonably incurred by the Parties in the action from which such Recovery was received on a pro rata basis. Any Recoveries that are left over after such reimbursement shall be allocated between the Parties [*] percent ([*]%) to Collaborator and [*] percent ([*]%) to Amgen. Amgen shall have the sole right to retain any and all recoveries with respect to the enforcement of any Amgen intellectual property or proprietary right, Licensed Collaborator Patents, Licensed Collaborator Know-How or Joint Patents outside the Territory. After any termination or expiration of this Agreement, Amgen shall have the right to retain one hundred percent (100%) of any Recoveries left over after reimbursement of costs.

10.7. Patent Term Extensions. Each Party shall provide reasonable assistance to the other Party (Amgen to Collaborator with respect to Licensed Amgen Patents and Collaborator to Amgen with respect to Licensed Collaborator Patents) in connection with obtaining SPCs to Licensed Amgen Patents and Licensed Collaborator Patents consistent with the rights of the other Party to control such matters as specified in Section 10.3 (Prosecution and Maintenance). To the extent reasonably and legally required in order to obtain any such SPC in a particular country, each Party shall make available to the

other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the SPC in such country.

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

10.9. Patent Marking. Dmab marketed and sold by Collaborator hereunder shall be marked with appropriate patent numbers or indicia of Licensed Amgen Patents, to the extent permitted by Law in the Territory. Dmab marketed and sold by Amgen hereunder in the Territory shall be marked with appropriate patent numbers or indicia of Licensed Collaborator Patents, to the extent permitted by Law in the Territory.

11. CONFIDENTIALITY AND PUBLICATIONS

11.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] ([*]) years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "*Confidential Information*"). Collaborator 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 Competing 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:

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

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

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

11.1.4. was independently developed by the receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or

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

11.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement: (a) in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, including the right to grant licenses or sublicenses as permitted hereunder, 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 related to 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 Dmab, 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.

11.3. 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, Collaborator 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 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 five (5) business days' notice to the other Party and reasonably considering comments provided by such other Party within three (3) business days after such notice).

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

11.5. Publications.

11.5.1. [*] *Right.* Collaborator shall have the [*] right to publish with respect to Dmab in Collaborator Indications in publications based in the Territory and to make scientific presentations on Dmab in Collaborator Indications within the Territory. Amgen shall have the [*] right to publish in publications based in the Territory and to make scientific presentations on Dmab in the Territory, in each case only with respect to Dmab in Amgen Additional Indications. Amgen shall have the [*] right to publish in publications based outside the Territory and to make scientific presentations on Dmab outside the Territory, in each case in all indications. Any proposed publication by Collaborator outside the Territory and any proposed publication by Amgen outside Amgen Additional Indications within the Territory (each such publication a *"*[*] *Publication"*) shall be made only to the extent approved by each of the Parties pursuant to Sections 11.5.2 (Other Publications) and 11.5.3 (Oversight and Review).

11.5.2. *Other Publications.* The Parties shall regularly consult and confer with respect to a global publication strategy for Dmab, with the understanding that Collaborator shall be solely responsible for shaping and determining the publication strategy with respect to the Territory, and Amgen solely responsible for shaping and determining the publication strategy outside the Territory, but [*]

11.5.3. *Oversight and Review.* Except as required by Law or court order, any publication or presentation concerning the activities to be conducted in the Territory hereunder, including studies or clinical trials carried out by a Party

under this Agreement, shall be subject to the oversight, guidelines and approval of the Development Committee. Unless otherwise mutually agreed upon by the Parties, the Party desiring to publish or present any publication or presentation concerning the activities to be conducted in the Territory hereunder (the "*Publishing Party*") (A) shall transmit to the other Party (the "*Reviewing Party*") for review and comment a copy of the proposed publication or presentation, at least thirty (30) days prior to the submission of the proposed publication or presentation to a Third Party; (B) shall postpone the publication or presentation for up to an additional sixty (60) 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; (C) 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 (D) shall consider all reasonable comments made by the Reviewing Party to the proposed publication or presentation. [*]

11.6. 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: (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.

12. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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

12.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor to its knowledge as of the Effective Date violate any Law. The person or

persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate action;

12.1.3. To its knowledge, as of the Effective Date no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or shall be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed concurrently herewith, 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;

12.1.4. Each Party represents and warrants that it has not been debarred or the subject of debarment proceedings by any Governmental Authority. Neither Party shall knowingly use in connection with the research, development, manufacture or commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been debarred or the subject of debarment proceedings by any regulatory agency;

12.1.5. Each Party covenants to carry out its activities hereunder in compliance with Law;

12.1.6. Each Party covenants to not misappropriate any trade secret(s) of a Third Party in connection with the performance of its activities hereunder;

12.1.7. Each Party represents and warrants that it has not granted as of the Effective Date, and during the Term shall not grant, any right to any Third Party relating to any Licensed Amgen Patent, Licensed Amgen Trademark or Licensed Amgen Know-How (with respect to Amgen) or any Licensed Collaborator Patent, Licensed Collaborator Trademark or Licensed Collaborator Know-How (with respect to Collaborator) that conflicts with the rights granted to the other Party hereunder;

12.1.8. [*]

12.2. Amgen Additional Representations and Warranties. In addition to Section 12.1 (Mutual Representations, Warranties and Covenants), Amgen hereby represents and warrants to Collaborator that Amgen has in place policies and procedures designed to ensure that Amgen Development Data is generated in compliance with Law.

12.3. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (Representations, Warranties and Covenants), COLLABORATOR 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, THE LICENSED COLLABORATOR PATENTS, LICENSED COLLABORATOR TRADEMARKS, LICENSED COLLABORATOR 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.

13. LIMITATIONS OF LIABILITY; INSURANCE

13.1. Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 13.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 14 (Indemnification), (ii) breach of Section 4.4 (Development in Combination or Outside Territory), 11.1 (Confidentiality; Exceptions), 11.2 (Authorized Disclosure), or (iii) gross negligence or intentional misconduct of a Party.

13.2. Insurance. During the Term and for six (6) years thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry in the Territory (or reasonable self-insurance sufficient to provide materially the same level and type of protection).

14. INDEMNIFICATION

14.1. Indemnity. Subject to the remainder of this Article 14 (Indemnification), Collaborator shall defend, indemnify, and hold harmless Amgen, its Affiliates, and their respective directors, officers, employees and agents (collectively, *"Amgen Indemnitees"*), at Collaborator'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 Collaborator 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 (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 Collaborator, or its Affiliates or agents, (ii) a breach by Collaborator of this Agreement, (iii) a violation of Law by Collaborator, or its Affiliates or agents, or (iv) Collaborator's, its Affiliate's or its licensee's (other than Amgen, its Affiliates or its licensees) development or commercialization of Dmab but excluding such Losses to the extent they arise from (w), (x), (y) or (z) below. Subject to the remainder of this Article 14 (Indemnification), Amgen shall defend, indemnify, and hold harmless Collaborator, its Affiliates, and their respective directors, officers, employees and agents (collectively, *"Collaborator Indemnitees"*), at Amgen's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any

Collaborator Indemnitees until such time as Amgen has acknowledged and assumed its indemnification obligation hereunder with respect to a claim) arising out of any Claim brought against any Collaborator Indemnitee by a Third Party to the extent such Losses result from (w) the negligence or willful misconduct of Amgen, or its Affiliates or agents, (x) a breach by Amgen of this Agreement, (y) a violation of Law by Amgen, or its Affiliates or agents, or (z) Amgen's, its Affiliate's or its licensee's (other than Collaborator, its Affiliates or its licensees) development or commercialization of Dmab, but excluding such Losses to the extent they arise from (i), (ii), (iii) or (iv) above.

14.2. Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Collaborator Indemnitee or an Amgen Indemnitee (the *"Indemnified Party"*) may seek indemnification under this Article 14 (Indemnification), the Indemnified Party shall promptly notify the other Party (the *"Indemnifying Party"*) of the Claim or Loss and, when known, the facts constituting the basis for the Claim; provided, however, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 14.2 (Claim for Indemnification) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. 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 11 (Confidentiality and Publications).

15. TERM AND TERMINATION

15.1. Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect until the expiration or termination of the Term, at which point it shall terminate, unless sooner terminated in accordance with this Article 15 (Term and Termination). In the event either Party wishes to continue to collaborate on commercialization of Dmab in the Territory after the Term, such Party shall deliver a notice to the other Party at least eighteen (18) months prior to the expiration of the Term and the Parties shall discuss in good faith a potential extension to this Agreement.

15.2. Termination. The Parties shall have the right to terminate this Agreement as follows:

15.2.1. *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 ninety (90) days after the receipt of such notice, then the other Party shall be permitted to terminate this Agreement by written notice given within ninety (90) days of the end of such ninety (90) day cure period and effective upon delivery.

15.2.2. *Termination for Challenge*. Amgen shall have the right to terminate this Agreement by written notice to Collaborator should Collaborator, 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.

15.2.3. *Termination for Change of Control.* Collaborator shall give Amgen written notice within five (5) days of the public announcement or disclosure of any proposed Change of Control of Collaborator. In the event of the occurrence of any Change of Control of Collaborator, Amgen shall have the right to terminate this Agreement upon [*] written notice.

15.2.4. [*]. From and after the [*], in the event that [*].

15.2.5. *Termination for* [*]. Should Collaborator elect [*] in its notice given pursuant to [*], this Agreement shall terminate twelve (12) months from its provision of such notice (or such shorter period as Amgen may specify following receipt of such notice).

15.2.6. [*]. In the event that Amgen and Collaborator are unable to agree to [*] that Amgen has notified Collaborator is [*]:

15.2.6.1. *Conditions*. [*] shall be [*] ([*]) year period following the Effective Date, and only until such time as [*] (i) [*]; and (ii)[*];

15.2.6.2. *Good-Faith Discussion*. Prior to [*] pursuant to this Section 15.2.6 ([*]), Collaborator and Amgen shall negotiate in good faith for a period of no less than thirty (30) days to determine [*]

15.2.6.3. *Notice; Effectiveness*. Termination pursuant to this Section 15.2.6 ([*]) shall be made by three (3) months written notice, given no later than five (5) years following the Effective Date and no later than thirty (30) days following the thirty (30) day negotiation period entered into pursuant to Section 15.2.6.2 (Good-Faith Discussion). Such notice shall be automatically effective as of the end of such three (3) month notice period unless [*] or that Collaborator shall [*] pursuant to [*], in which case such termination notice shall be of no force and effect.

15.3. Effect of Termination. Expiration or termination of this Agreement shall have the following effects:

15.3.1. *General.* In the event of any termination or expiration of this Agreement: (i) any liabilities previously accrued shall survive; (ii) Collaborator shall return to Amgen or destroy (and certify such destruction to Amgen) all Amgen Confidential Information; (iii) Collaborator shall, to the extent permitted by Law and requested by Amgen, assign any contracts related to Dmab in the Territory to Amgen or its designee (including by requesting and using good-faith efforts to obtain any required consents); (iv) Collaborator shall assign the Licensed Collaborator Trademarks to Amgen pursuant to Section 3.7.2 (Grant to Amgen); (v) Collaborator and Amgen shall continue to make payments pursuant to Section 8.3 (Royalty Payments) with respect to sales made prior to the effective date of such expiration or termination (the *"Termination Date"*) or, if later, prior to completion of the transition by Collaborator pursuant to Section 15.5 (Transition Period); (vi) the Parties shall transition responsibility for commercialization and development of Dmab to Amgen in accordance with Section 15.5 (Transition Period); (vii) the Parties shall cooperate to promptly transition sole responsibility for the prosecution, maintenance and enforcement in the Territory of Licensed Amgen Patents, Licensed Collaborator Patents and Joint Patents to Amgen; (viii) Amgen shall have the right to reacquire some or all of the inventory of Dmab, as requested by Amgen, in possession of Collaborator and its Affiliates and shall reimburse Collaborator the price paid by it for such inventory; and (ix) the Parties shall cooperate to promptly transfer ownership of all Regulatory Filings and Regulatory Approvals, and responsibility for regulatory communication held by Collaborator in the Territory to Amgen. In the event that the Parties are not permitted to transfer Regulatory Filings or Regulatory Approvals under clause (ix) above pursuant to Law, the Parties shall cooperate to establish a right of access and reference to such filings and approvals for Amgen, and Collaborator shall maintain such filings and approvals, and take any actions reasonably requested by Amgen with respect thereto, and thereafter Collaborator shall transfer ownership of all such Regulatory Filings and Regulatory Approvals to Amgen or its designee as and when it becomes permissible to do so. Amgen shall reimburse Collaborator its reasonable, out-of-pocket costs incurred as necessary for such maintenance and to perform such requested actions. 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, all regulatory filings, approvals and other proprietary information relating to Dmab shall be considered Amgen Confidential Information.

15.3.2. *Intellectual Property Licenses.* The provisions of [*] shall survive any expiration or termination of this Agreement, natural or otherwise[*]. The foregoing is without prejudice to the provisions of Section 8.2.3 (Maintenance Payments) and 8.2.4 (Payments Survive).

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

15.3.4.[*]. In the event of termination of this Agreement (not including any [*] or [*]:

15.3.4.1.the following [*] within thirty (30) days after[*], only to the extent [*] the Termination Date. For the avoidance of doubt, no such [*] shall be [*] with respect to any of the [*] which [*] the Termination Date. For the purposes of determining whether such [*] the Termination Date, filing for Regulatory Approval or First Commercial Sale by Collaborator shall be considered filing or sale by Amgen's licensee. For the avoidance of doubt, [*] pursuant to this Section 15.3.4.1.

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

15.3.4.2.only in the event of termination by Collaborator pursuant to Section 15.2.6 ([*]) then, within ninety (90) days of such termination, Amgen shall [*] in such event, taking into account all relevant factors, including, if and to the extent relevant, any or all of the following: (i)[*]. Such [*] shall reflect [*] in Japan assuming [*]. Upon [*] (Notice; Effectiveness), the Parties shall promptly meet to [*]. Should the Parties [*], then either party shall have the right to[*] of this Agreement or effectuation of the provisions of Sections 15.3 (Effect of Termination) through 15.5 (Transition Period).

15.3.5.[*]. In the event of a termination of this Agreement by Amgen pursuant to Section [*], then Amgen shall [*] taking into account all relevant factors, including, if and to the extent relevant, any or all of the following [*]. The Parties agree that [*] in accordance with [*]. For the avoidance of doubt, should the[*]. In addition, with respect to any [*]. The [*] are intended to apply to [*] and in no event shall [*] and similar provisions of this Agreement shall be applied to [*]. Upon Amgen's notice of termination pursuant to Section [*], the Parties shall [*]. Amgen shall disclose to Collaborator any [*] to the extent necessary for [*]. It is [*]. The use of [*] of this Agreement or effectuation of the provisions of Sections 15.3 (Effect of Termination) through 15.5 (Transition Period).

15.4. Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.3 (Effect of Termination), in the event of any expiration or termination of this Agreement the following provisions shall survive: [*]; Section [*]; Section 8.2 (License Payments by Amgen); Section 8.6 (Reports) (with respect to sales made during the Transition Period); Section 8.8.3 (Reports) (for the duration of Collaborator's payment obligations); Section 8.10 (Payment Method); Section 8.12 (Audits); Section 8.18 (Third Party Royalties); Section 9.1 (Settlement); Section 10.2.2 (Cooperation); Section 10.3.2 (Outside Territory); Section 10.4 (Defense and Settlement of Third Party Claims); Section 10.5.2 (Outside Territory); Section 10.6 (Allocation of Recoveries) (with respect to any action initiated prior to such expiration or termination); Section 10.7 (Patent Term Extensions); Section 10.9 (Patent Marking) (with respect to sales

made during the Transition Period); Section 11.1 (Confidentiality; Exceptions); Section 11.6 (Attorney-Client Privilege); Section 12.3 (Disclaimer of Warranties); Article 13 (Limitations of Liability; Insurance); Article 14 (Indemnification); this Article 15 (Term and Termination); and Article 16 (Miscellaneous). For the avoidance of doubt, Collaborator's [*].

15.5. Transition Period. During the twelve (12) months prior to [*], or for a twelve (12) month period following provision of notice of termination by [*] (the "*Transition Period*"), the Parties shall [*]. Collaborator shall take all actions [*] to facilitate [*], and the Parties shall [*] as reasonably necessary to [*] in the Territory. The Parties shall each be responsible for [*], provided that, in the event of [*], Amgen shall [*], and in the event of expiration in accordance with [*]. During any such [*], Amgen shall be responsible for [*], except to the extent the relevant [*] but [*] of [*], and Collaborator shall be responsible for [*] otherwise [*].

15.6. [*]. In the event that either Party [*] pursuant to Section [*] or Section [*] ([*]), then such Party shall have the right to have [*] (and, consequently, [*] pursuant to the relevant section) exclusively [*] in accordance with Section [*] or Section [*], as relevant. Such [*] shall be [*]. The [*] both parties. The [*] shall be [*]. The [*] shall be [*]. [*] shall be [*] shall only [*] in accordance with Section [*] or Section [*], and shall [*] either party. Each Party shall [*].

16. MISCELLANEOUS

16.1. 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.

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 Collaborator 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. 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 Collaborator or Amgen, 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.

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

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

16.9. Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out

the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

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

16.11. 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.

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

If to Collaborator:	Daiichi Sankyo Company, Limited 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan Attention: General Manager, Licensing Telephone: [*] Telecopy: [*]
With a copy to:	Daiichi Sankyo Company, Limited 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan Attention: General Manager, Legal Affairs Telephone: [*] Telecopy: [*]

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. 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 Collaborator 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.

16.15. 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.

16.16. Third Party Beneficiaries. Except as expressly provided with respect to Indemnitees in Article 14 (Indemnification), there are no third party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.

16.17. 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.

16.18. Reimportation. Collaborator shall undertake all steps necessary to prevent any Dmab provided to Collaborator hereunder for use or sale inside the Territory from being distributed or sold outside the Territory, except where Amgen and Collaborator 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. Collaborator

shall notify Amgen if it becomes aware of the exportation of Dmab from the Territory and discuss with Amgen the same.

****

(Signature page follows)

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

DAIICHI SANKYO COMPANY, LIMITED

By: /s/ Takashi Shoda
Name: Takashi Shoda
Title: Representative Director, President and Chief Executive Officer

AMGEN INC.

By: /s/ Kevin W. Sharer
Name: Kevin W. Sharer
[SEAL] Title: Chairman of the Board, Chief Executive Officer & President

Schedule
[*]

Schedule
Form of Press Release

News Release

AMGEN AND DAIICHI SANKYO ANNOUNCE AGREEMENT FOR DENOSUMAB IN JAPAN

Amgen Grants Daiichi Sankyo Exclusive Rights to Develop and Commercialize Denosumab in Japan

FOR IMMEDIATE RELEASE

THOUSAND OAKS, Calif. (July 11, 2007) and TOKYO (July 12, 2007) – Amgen (NASDAQ:AMGN) and Daiichi Sankyo Company, Limited (TSE:4568) today announced a collaboration and license agreement for the development and commercialization of denosumab in Japan. Denosumab is a fully human monoclonal antibody that targets RANK Ligand (an essential mediator of cells that break down bone) and is being investigated for its potential to treat and prevent a broad range of bone loss conditions including osteoporosis and bone metastases.

Under the terms of the agreement, Amgen has granted Daiichi Sankyo exclusive rights to develop and commercialize denosumab in Japan in post-menopausal osteoporosis and oncology with the potential for additional indications. As part of the agreement, Amgen will receive exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab.

The financial terms include an upfront payment to Amgen of $20 million. In addition, Daiichi Sankyo will assume all development costs for denosumab in Japan and will pay approximately $150 million of expected worldwide development costs for denosumab through 2009. In consideration of its intellectual property, Daiichi Sankyo is also eligible to receive milestone payments dependent on the approval of denosumab in the European Union or Japan, in two indications. In connection with its activities under the collaboration and license agreement, Daiichi Sankyo will pay royalties on annual net sales of denosumab in Japan in amounts commensurate with a major late stage product for the Japan market.

“Daiichi Sankyo is an ideal partner for denosumab,” said Kevin Sharer, Chairman and CEO of Amgen. “Daiichi Sankyo is uniquely positioned to bring this potential therapy to patients with a wide spectrum of bone-related diseases in Japan.”

“Daiichi Sankyo is thrilled to partner with a world leader in biotechnology to gain access to this important antibody product,” said Takashi Shoda, President and CEO of Daiichi Sankyo. “We believe that denosumab has the potential to be a first-in-class, leading product in Japan for multiple indications within Daiichi Sankyo’s therapeutic areas of focus. Denosumab’s potential applicability in oncology makes it an important part of the foundation for our growing oncology business.” Daiichi Sankyo has a full range of commercial capabilities, including in the primary care and hospital settings, a track record of successful large, first-in-class product launches and the financial strength to ensure appropriate investment in the product.

About Denosumab

Denosumab is a fully human monoclonal antibody that targets RANK Ligand and is being investigated for its potential to prevent and treat a broad range of bone loss conditions including osteoporosis, bone metastases, treatment-induced bone loss, multiple myeloma and bone erosions in rheumatoid arthritis. Denosumab is the first late-stage investigational therapy that specifically inhibits RANK Ligand, an essential mediator of the cells that break down bone.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science’s promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people’s lives.

To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

About Daiichi Sankyo Company, Limited

DAIICHI SANKYO COMPANY, LIMITED was established in September 2005 as the joint holding company for the DAIICHI SANKYO Group by means of a stock transfer. Business integration has proceeded steadily since then, and the integration process was completed in April 2007 with the merger of Sankyo Co. Ltd. and Daiichi Pharmaceutical Co., Ltd. into DAIICHI SANKYO. DAIICHI SANKYO is a global pharmaceutical innovator, continuously generating innovative drugs and services and maximizing its corporate value. For further details, please refer to the company Web site at www.daiichisankyo.com

Forward-Looking Statement: Amgen

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2006, and in our periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), difficulties or delays in manufacturing our products. In addition, sales of our products are affected by reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers.

CONTACT: Amgen, Thousand Oaks
Anne McNickle 805-447- 5890 (w) 323-868-5827 (mobile) (Media)
Arvind Sood, 805-447-1060 (Investors)

CONTACT: Daiichi Sankyo, Tokyo

Masaya Tamae, +81-3-6225-1126 (office)

Schedule
[*]

Schedule
Supply Agreement Term Sheet

Defined Terms	Capitalized terms used but not defined in this term sheet shall have the meanings assigned to them in the Collaboration Agreement.
Supply of Drug Product	Amgen will sell, and Collaborator will buy, Collaborator's requirements of Dmab (except for clinical supply, which is handled under the Collaboration Agreement). Supply for post-marketing studies would be dealt with in the Supply Agreement, not the Collaboration Agreement; provided that, supply for post-marketing studies which are required for obtaining a Regulatory Approval by MHLW and for which Collaborator is required by Law to provide Dmab [*] would be dealt with in the Collaboration Agreement. Supply of Dmab would be provided in [*] (*"Drug Product"*). Collaborator would be free to order any presentation [*] of Drug Product from those presentations initially used by Amgen outside the Territory or later adopted by Amgen for use outside the Territory. Supply Agreement will contemplate [*] in order to commercialize Dmab in the Territory. The Parties shall meet to discuss the need for and determine how to address such [*] with the minimum potential disruption to Amgen's manufacturing operations and its commercialization and development of Dmab outside the Territory, and Collaborator would bear all incremental costs associated with the [*].
Pricing	Pricing for Drug Product would consist of two components: [*].
Forecasts	The Supply Agreement will set forth a forecast procedure for Dmab to be provided thereunder. The forecast procedure will contemplate Collaborator's needs for reasonable flexibility in forecasting and Amgen's needs for sufficient information and certainty to reasonably enable it to timely supply Collaborator.
Orders	Orders will be placed at least 90 days in advance. Amgen will fill conforming orders, and will provide Drug Product [*] Incoterms 2000. Amgen will ensure all such Drug Product complies with the relevant specifications. The Supply Agreement shall specify the remaining shelf-life upon delivery of Drug Product.
Shortage; Allocation	In the event of any shortage of Drug Product, Amgen would allocate product such that [*].
Approvals and Licenses	Amgen will be responsible for obtaining and maintaining all necessary approvals, licenses and documentation related to the export of Drug Product. Collaborator shall be responsible for obtaining and maintaining

	all necessary approvals, licenses and documentation related to the import of Drug Product in the Territory, except that Amgen shall be responsible for obtaining and maintaining all necessary approvals and documentation related to the master file and the accreditation of foreign manufacturers in the Territory. Each Party shall provide copies thereof to the other as requested at least 60 days prior to the first scheduled delivery of Drug Product.
Testing and Non-compliance	Collaborator will have [*] days to test product for conformance with the specifications. In the event of any disagreement as to compliance with the specifications upon delivery, such matter will be determined by an independent third party. In the event of any such non-compliance, Collaborator's sole remedy will be the replacement of the non-conforming Drug Product by Amgen.
[*]	[*]
[*]	[*]
Regulatory Responsibility	Amgen will have sole regulatory responsibility for all manufacturing matters, in accordance with Section 4.15.2 of the Collaboration Agreement, and will cooperate with Collaborator with respect thereto in accordance with Section 4.15.3 thereof.
[*]	[*]
[*]	If it is determined that the manufacture of Drug Product should be [*] to Collaborator for the Collaborator Indications in the Territory (which information will be confidential and [*]. Collaborator and Amgen shall each be responsible for [*]. Collaborator shall still be required to pay Amgen [*]
Contract Manufacturer	Amgen will have the right to utilize one or more third-party contract manufacturers in the manufacture of Dmab and Drug Product, and Amgen shall provide written notice to Collaborator prior to the use of such third-party to produce Drug Product to be provided to Collaborator. Use of such third-party contract manufacturers shall not excuse Amgen's performance under the Supply Agreement and Amgen will be responsible for any breach of the Supply Agreement (subject to the relevant force majeure provisions, provided that failure of a contract manufacturer (other than for reasons which would, independently, constitute a force majeure) shall not constitute a force majeure).
Confidentiality	Confidentiality provisions would be included commensurate with those contained in the Collaboration Agreement. In addition, any information obtained in any inspections would be Amgen's confidential information, and shared within Collaborator only on a strict need-to-know basis.
Quality Agreement	Promptly following the execution of the Supply Agreement, the quality assurance departments of Amgen and Collaborator will develop and agree upon a quality agreement governing the quality and specifications of Drug

	Product to be supplied under the Supply Agreement including with respect to product quality and product complaints with respect to Dmab. The quality agreement will be documented in writing, and routinely updated.
Representations and Warranties	Each of the Parties will make standard representations and warranties regarding corporate power to enter into the agreement, binding nature of agreement and the like. Amgen will warrant that, upon delivery, the Drug Product will comply with the specifications. Collaborator will warrant that the Drug Product purchased will be used only for Collaborator Indications in the Territory, and that it will only order Drug Product as it reasonably anticipates it will need for such purpose. Collaborator will warrant that it will use reasonable commercial efforts to provide accurate forecasts. Amgen will warrant that it will ensure compliance with applicable U.S. export control laws, Collaborator will warrant that it will ensure compliance with applicable importation laws within the Territory (and U.S. export control laws, if applicable) and each Party will warrant to the other that it will ensure product integrity during any storage and transportation for which it is responsible. All other warranties by the parties will be disclaimed (including those of merchantability, fitness for a particular purpose, and non-infringement).
Insurance and Indemnity	Commensurate with Collaboration Agreement.
Term and Termination	Commensurate with Collaboration Agreement. In addition, the Supply Agreement will automatically terminate on termination of the Collaboration Agreement. Amgen would retain the right to terminate upon [*] notice in the event [*] Amgen would have no obligation to supply Drug Product to Collaborator if and for so long as Collaborator is in breach of its obligations under the Supply Agreement or Collaboration Agreement.
Miscellaneous	Commensurate with the Collaboration Agreement. The United Nations Convention for the International Sale of Goods will be disclaimed.

CERTIFICATIONS

I, Kevin W. Sharer, Chairman of the Board, Chief Executive Officer and President of Amgen Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

   (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

/s/ KEVIN W. SHARER
Kevin W. Sharer
Chairman of the Board,
Chief Executive Officer and President

CERTIFICATIONS

I, Robert A. Bradway, Executive Vice President and Chief Financial Officer of Amgen Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

   (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

/s/ ROBERT A. BRADWAY

Robert A. Bradway
Executive Vice President
and Chief Financial Officer

Certification of Chief Executive Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2007 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2007

/s/ KEVIN W. SHARER
Kevin W. Sharer
Chairman of the Board, Chief Executive Officer and President

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Certification of Chief Financial Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2007 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2007

/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.