

AMGEN INC  
Form 10-Q  
November 09, 2007  
Table of Contents

---

**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 **(I.R.S. Employer**  
**incorporation or organization)** **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

## Edgar Filing: AMGEN INC - Form 10-Q

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

---

**Table of Contents**

**AMGEN INC.**

**INDEX**

	<b>Page No.</b>
<b>PART I FINANCIAL INFORMATION</b>	
Item 1. <u>Financial Statements</u>	1
<u>Condensed Consolidated Statements of Operations Three and nine months ended September 30, 2007 and 2006</u>	2
<u>Condensed Consolidated Balance Sheets September 30, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Cash Flows Nine months ended September 30, 2007 and 2006</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
Item 4. <u>Controls and Procedures</u>	40
<b>PART II OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	41
Item 1A. <u>Risk Factors</u>	45
Item 2. <u>Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	70
Item 5. <u>Other Information</u>	70
Item 6. <u>Exhibits</u>	70
<u>Signatures</u>	71
<u>Index to Exhibits</u>	72

**Table of Contents**

**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.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Revenues:</b>				
Product sales	\$ 3,524	\$ 3,503	\$ 10,693	\$ 10,121
Other revenues	87	109	333	312
<b>Total revenues</b>	<b>3,611</b>	<b>3,612</b>	<b>11,026</b>	<b>10,433</b>
<b>Operating expenses:</b>				
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	
<b>Total operating expenses</b>	<b>3,218</b>	<b>2,290</b>	<b>8,103</b>	<b>7,582</b>
<b>Operating income</b>	<b>393</b>	<b>1,322</b>	<b>2,923</b>	<b>2,851</b>
Interest and other income and (expense), net	(21)	39	(20)	140
<b>Income before income taxes</b>	<b>372</b>	<b>1,361</b>	<b>2,903</b>	<b>2,991</b>
Provision for income taxes	171	259	572	874
<b>Net income</b>	<b>\$ 201</b>	<b>\$ 1,102</b>	<b>\$ 2,331</b>	<b>\$ 2,117</b>
<b>Earnings per share:</b>				
Basic	\$ 0.19	\$ 0.94	\$ 2.07	\$ 1.79
Diluted	\$ 0.18	\$ 0.94	\$ 2.06	\$ 1.77
<b>Shares used in calculation of earnings per share:</b>				
Basic	1,086	1,167	1,127	1,181
Diluted	1,090	1,178	1,133	1,194

See accompanying notes.

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

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
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.



**Table of Contents****AMGEN INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In millions)****(Unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities:</b>		
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
<b>Changes in operating assets and liabilities:</b>		
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
<b>Net cash provided by operating activities</b>	<b>3,871</b>	<b>4,147</b>
<b>Cash flows from investing activities:</b>		
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)
<b>Net cash used in investing activities</b>	<b>(1,295)</b>	<b>(3,929)</b>
<b>Cash flows from financing activities:</b>		
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
<b>Net cash used in financing activities</b>	<b>(2,470)</b>	<b>(767)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>106</b>	<b>(549)</b>
Cash and cash equivalents at beginning of period	1,283	1,840
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,389</b>	<b>\$ 1,291</b>



Edgar Filing: AMGEN INC - Form 10-Q

See accompanying notes.

**Table of Contents****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):

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

**Table of Contents****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<sup>®</sup> 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<sup>®</sup> (darbepoetin alfa), EPOGEN<sup>®</sup> (Epoetin alfa), Neulasta<sup>®</sup> (pegfilgrastim)/NEUPOGEN<sup>®</sup> (Filgrastim) and Enbrel<sup>®</sup> (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<sup>®</sup>. 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.

**Table of Contents****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, 2007		Nine Months Ended September 30, 2007	
<b>Income (Numerator):</b>				
Net income for basic and diluted EPS	\$ 201	\$ 1,102	\$ 2,331	\$ 2,117
<b>Shares (Denominator):</b>				
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

**Table of Contents****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.

**Table of Contents****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):

	Separation Costs	Asset Impairments	Accelerated Depreciation	Other	Total
<b>Three Months Ended September 30, 2007</b>					
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

	Separation Costs	Asset Impairments	Accelerated Depreciation	Other	Total
<b>Nine Months Ended September 30, 2007</b>					
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

**Table of Contents****AMGEN INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**Table of Contents****AMGEN INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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<sup>®</sup>, Neulasta<sup>®</sup>, NEUPOGEN<sup>®</sup> and EPOGEN<sup>®</sup>, 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.



**Table of Contents****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
<b>Total borrowings</b>	<b>11,313</b>	<b>9,012</b>
<b>Less current portion</b>	<b>136</b>	<b>1,798</b>
<b>Total non-current debt</b>	<b>\$ 11,177</b>	<b>\$ 7,214</b>

*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.



**Table of Contents****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.

---

**Table of Contents**

**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.

---

**Table of Contents**

**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, 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

---

**Table of Contents**

(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<sup>®</sup> sales, which were substantially offset by a decrease in Aranesp<sup>®</sup> sales. In particular for the three and nine months ended September 30, 2007, U.S. Aranesp<sup>®</sup> 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<sup>®</sup> and EPOGEN<sup>®</sup>, 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<sup>®</sup> and EPOGEN<sup>®</sup>, belong to a class of drugs referred to as erythropoiesis-stimulating agents, or ESAs. Aranesp<sup>®</sup> is used primarily in the United States and in Europe for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> for use in the treatment of Anemia of Cancer ( AoC ). Thereafter, virtually all Medicare contractors have stopped reimbursing for Aranesp<sup>®</sup> use in AoC patients. In addition, to a lesser degree, there has been a decline in Aranesp<sup>®</sup> 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<sup>®</sup> and EPOGEN<sup>®</sup>.

On May 10, 2007, the Oncologic Drugs Advisory Committee ( ODAC ) met to discuss the safety/efficacy profile of ESAs, including Aranesp<sup>®</sup> and EPOGEN<sup>®</sup>. 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

---

**Table of Contents**

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

---

**Table of Contents**

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<sup>®</sup> and EPOGEN<sup>®</sup>/PROCRI<sup>®</sup>T 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<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup>, discussed above, we believe that EPOGEN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> sales, on November 8, 2007, we announced updates to the Aranesp<sup>®</sup> and EPOGEN<sup>®</sup>/PROCRI<sup>®</sup>T package inserts in collaboration with the FDA and J&JPRD and related developments, which recognize input from the CRDAC/DSaRMAC meeting.



---

## Table of Contents

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

Roche's pegylated-erythropoietin (peg-EPO) product, MIRCERA<sup>®</sup>, which will compete with Aranesp<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>. This product, under the brand names Binocrit<sup>®</sup> (Epoetin alfa), Epoetin alfa Hexal<sup>®</sup> (Epoetin alfa) and Abseamed<sup>®</sup> (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<sup>®</sup> and Neulasta<sup>®</sup>, 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<sup>®</sup>, Remicade<sup>®</sup>, Orencia<sup>®</sup>, Rituxan<sup>®</sup>, Raptiva<sup>®</sup> and Amevive<sup>®</sup>, 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 standard chemotherapy and Avastin<sup>®</sup> (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<sup>®</sup> 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

---

**Table of Contents**

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.

**Table of Contents**

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

	Three Months Ended			Nine Months Ended		
	September 30,			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<sup>®</sup> 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

**Table of Contents**

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<sup>®</sup>, 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<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> was reduced for the third quarter of 2007. Prior to January 1, 2006, Medicare's hospital outpatient prospective payment system ( OPSS ), 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<sup>®</sup> reimbursement rate was based on the AWP of PROCRIT<sup>®</sup>, 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<sup>®</sup> to PROCRIT<sup>®</sup>. On November 1, 2007, CMS released its 2008 OPSS final rule that does not apply an equitable adjustment to the reimbursement rate for Aranesp<sup>®</sup> to PROCRIT<sup>®</sup>, 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<sup>®</sup> in future years.

**Table of Contents**

In the United States, dialysis providers are primarily reimbursed for EPOGEN<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup>, 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<sup>®</sup> and PROCRI<sup>®</sup>). Although we cannot predict the payment levels of EPOGEN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup> (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<sup>®</sup> and Aranesp<sup>®</sup> dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> 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<sup>®</sup>, from 500,000 IUs, and to 1,200 micrograms ( mcgs ) of Aranesp<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> or Aranesp<sup>®</sup> 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

---

**Table of Contents**

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%);

## Edgar Filing: AMGEN INC - Form 10-Q

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;

---

**Table of Contents**

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 reinstatement 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



**Table of Contents**

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			Nine Months Ended		
	September 30, 2007	September 30, 2006	Change	September 30, 2007	September 30, 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.

**Table of Contents***Aranesp*<sup>®</sup>

For the three and nine months ended September 30, 2007 and 2006, total Aranesp<sup>®</sup> 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 <sup>®</sup> - U.S.	\$ 460	\$ 720	(36)%	\$ 1,692	\$ 2,029	(17)%
Aranesp <sup>®</sup> - International	358	347	3%	1,095	986	11%
<b>Total Aranesp<sup>®</sup></b>	<b>\$ 818</b>	<b>\$ 1,067</b>	<b>(23)%</b>	<b>\$ 2,787</b>	<b>\$ 3,015</b>	<b>(8)%</b>

The decrease in U.S. Aranesp<sup>®</sup> 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<sup>®</sup> in CIA and which we believe has also, to a lesser degree, negatively impacted Aranesp<sup>®</sup> 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<sup>®</sup> in AoC and, to a lesser degree, the decline in Aranesp<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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;

---

**Table of Contents**

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<sup>®</sup> 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<sup>®</sup>.

**Table of Contents**

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			Nine Months Ended		
	September 30, 2007	2006	Change	September 30, 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;



**Table of Contents**

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

## Edgar Filing: AMGEN INC - Form 10-Q

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%.



---

**Table of Contents**

The increase in U.S. Neulasta<sup>®</sup>/NEUPOGEN<sup>®</sup> sales for the nine months ended September 30, 2007 was driven by demand for Neulasta<sup>®</sup> due to segment growth and favorable changes to wholesaler inventory levels. The increase in international Neulasta<sup>®</sup>/NEUPOGEN<sup>®</sup> sales for the nine months ended September 30, 2007 was driven by the continued conversion to Neulasta<sup>®</sup> from NEUPOGEN<sup>®</sup> 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<sup>®</sup>/NEUPOGEN<sup>®</sup> sales increased 11%.

For the remainder of 2007, we believe sales growth for Neulasta<sup>®</sup>/NEUPOGEN<sup>®</sup> will depend on patient growth and further segment penetration of Neulasta<sup>®</sup> in the moderate-risk population that would benefit from its use in first and subsequent chemotherapy cycles. NEUPOGEN<sup>®</sup> competes with Neulasta<sup>®</sup> in the United States and Europe. Worldwide NEUPOGEN<sup>®</sup> sales have been adversely impacted by conversion to Neulasta<sup>®</sup>. 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<sup>®</sup>/NEUPOGEN<sup>®</sup> 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<sup>®</sup>/NEUPOGEN<sup>®</sup>, however, other future chemotherapy treatments that are more myelosuppressive, such as dose dense chemotherapy, could require more Neulasta<sup>®</sup>/NEUPOGEN<sup>®</sup>.

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

**Table of Contents***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%
<b>Total ENBREL</b>	<b>\$ 821</b>	<b>\$ 705</b>	<b>16%</b>	<b>\$ 2,374</b>	<b>\$ 2,087</b>	<b>14%</b>

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.



**Table of Contents***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<sup>®</sup> 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

**Table of Contents**

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 to 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

---

**Table of Contents**

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.

**Table of Contents***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.

**Table of Contents**

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,	December 31,
	2007	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.



**Table of Contents***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
<b>Total borrowings</b>	<b>11,313</b>	<b>9,012</b>
Less current portion	136	1,798
<b>Total non-current debt</b>	<b>\$ 11,177</b>	<b>\$ 7,214</b>

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



---

## **Table of Contents**

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

## **Table of Contents**

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.

---

**Table of Contents**

**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.

---

**Table of Contents**

*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<sup>®</sup> 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<sup>®</sup>.

*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.

---

**Table of Contents**

*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 derivative 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 derivative 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<sup>®</sup> clinical studies, marketed both Aranesp<sup>®</sup> and EPOGEN<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup>, 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<sup>®</sup> and Aranesp<sup>®</sup> 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,

**Table of Contents**

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<sup>®</sup> and EPOGEN<sup>®</sup> 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<sup>®</sup>, Neulasta<sup>®</sup> and Aranesp<sup>®</sup>. Plaintiff seeks injunctive and compensatory relief for this alleged anticompetitive behavior. Amgen has not yet been served in this action.



**Table of Contents****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*

**Table of Contents**

*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,

---

**Table of Contents**

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

---

**Table of Contents**

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<sup>®</sup> and EPOGEN<sup>®</sup>. 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

**Table of Contents**

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.

## Edgar Filing: AMGEN INC - Form 10-Q

On November 8, 2007, we announced updates to the Aranesp<sup>®</sup> and EPOGEN<sup>®</sup>/PROCRT<sup>®</sup> 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.

---

## **Table of Contents**

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

**Table of Contents**

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



**Table of Contents**

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<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> was reduced for the third quarter of 2007. Prior to January 1, 2006, Medicare's hospital OPSS, 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<sup>®</sup> reimbursement rate was based on the AWP of PROCRI<sup>®</sup>, 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<sup>®</sup> to PROCRI<sup>®</sup>. On November 1, 2007, CMS released its 2008 OPSS final rule that does not apply an equitable adjustment to the reimbursement rate for Aranesp<sup>®</sup> to PROCRI<sup>®</sup>, 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<sup>®</sup> in future years.

In the United States, dialysis providers are primarily reimbursed for EPOGEN<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup>, 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<sup>®</sup> and PROCRI<sup>®</sup>). Although we cannot predict the payment levels of EPOGEN<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Aranesp<sup>®</sup> (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<sup>®</sup> and Aranesp<sup>®</sup> dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN<sup>®</sup> and Aranesp<sup>®</sup> 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<sup>®</sup>, from 500,000 IUs, and to 1,200 mcgs of Aranesp<sup>®</sup>, 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.

**Table of Contents**

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's 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;

---

**Table of Contents**

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 reinstatement 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

## Edgar Filing: AMGEN INC - Form 10-Q

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

**Table of Contents**

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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> which materially and adversely affected our EPOGEN<sup>®</sup> sales until the policies were revised. In addition, following the update to the ESA labels, nearly all Medicare contractors dropped reimbursement for Aranesp<sup>®</sup> 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.

---

**Table of Contents**

*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.

**Table of Contents**

<b>Product</b>		<b>General Subject Matter</b>	<b>Expiration</b>
<b>Epoetin alfa</b>	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
<b>darbepoetin alfa</b>	U.S.	Glycosylation analogs of erythropoietin proteins	5/15/2024
	Europe <sup>(1)</sup>	Glycosylation analogs of erythropoietin proteins	10/12/2010
		Glycosylation analogs of erythropoietin proteins	8/16/2014
<b>Filgrastim</b>	U.S.	G-CSF polypeptides	12/3/2013
		Methods of treatment using G-CSF polypeptides	12/10/2013
<b>pegfilgrastim</b>	U.S.	Pegylated G-CSF	10/20/2015
	Europe <sup>(1)</sup>	Pegylated G-CSF	2/8/2015
<b>etanercept</b>	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
<b>panitumumab</b>	U.S.	Human monoclonal antibodies to EGFr	5/5/2017
<b>cinacalcet HCl</b>	U.S. <sup>(2)</sup>	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 <sup>(1)</sup>	Calcium receptor-active molecules	10/23/2015

<sup>(1)</sup> 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.

<sup>(2)</sup> 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.* )

---

**Table of Contents**

*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<sup>®</sup> and Aranesp<sup>®</sup>.

The GAO issued a report on December 5, 2006 recommending that ESRD drugs and biologics, including EPOGEN<sup>®</sup>, 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<sup>®</sup>, including discussion of the delay in the MMA mandated bundled payment demonstration, and the GAO report and recommendation. Future Medicare reform legislation may



---

**Table of Contents**

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

**Table of Contents**

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.

---

**Table of Contents**

*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

**Table of Contents**

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

## Edgar Filing: AMGEN INC - Form 10-Q

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

**Table of Contents**

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



## Edgar Filing: AMGEN INC - Form 10-Q

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

**Table of Contents**

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<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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<sup>™</sup>. 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<sup>®</sup>, Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup>, some formulation, fill and finish operations for ENBREL, and all of the bulk manufacturing for Aranesp<sup>®</sup>, Neulasta<sup>®</sup> and NEUPOGEN<sup>®</sup> 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

---

**Table of Contents**

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.

**Table of Contents**

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:

<b>Product</b>	<b>Company</b>	<b>Countries</b>	<b>Timing for Launch</b>
EPREX®	Johnson & Johnson	EU	Launched
Neorecormon®	Roche	EU	Launched
			Launched
Dynepo™	Shire	Germany, UK	Q4 2007
Biosimilar Erythropoietin	Sandoz with co-	Italy, Spain, France	Launched
		Germany, UK	
		Others	
	marketers Hexal and		2008
	Medice		
Biosimilar Erythropoietin	Hospira/Stada	Germany, UK	2008
		Others	2008
peg-EPO/MIRCERA®	Roche	Germany, UK,	August-November
		Netherlands, Austria	
		Sweden, Switzerland	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.

---

**Table of Contents**

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

---

**Table of Contents**

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<sup>®</sup>, 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<sup>®</sup> 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*

**Table of Contents**

*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 effect on our results of operations.

**Table of Contents****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.





**Table of Contents**

**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

**Table of Contents**

**AMGEN INC.**

**INDEX TO EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
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, 2007. (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, 2007. (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.)

**Table of Contents**

- 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.)

**Table of Contents**

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.)

**Table of Contents**

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.)

**Table of Contents**

- 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<sup>®</sup> 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.)

**Table of Contents**

- 10.57 Amendment No. 1 to the ENBREL<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.)



**Table of Contents**

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.)