

AMGEN INC
Form 10-Q
August 09, 2007
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 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
(State or other jurisdiction of
incorporation or organization)

One Amgen Center Drive,

Thousand Oaks, California
(Address of principal executive offices)

(805) 447-1000

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

91320-1799
(Zip Code)

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(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of August 6, 2007, the registrant had 1,086,741,500 shares of common stock, \$0.0001 par value, outstanding.

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PART I FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

The information in this report for the three and six months ended June 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 and 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)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Revenues:				
Product sales	\$ 3,604	\$ 3,491	\$ 7,169	\$ 6,618
Other revenues	124	113	246	203
Total revenues	3,728	3,604	7,415	6,821
Operating expenses:				
Cost of sales (excludes amortization of acquired intangible assets presented below)	558	493	1,150	1,045
Research and development	817	788	1,668	1,443
Selling, general and administrative	860	840	1,630	1,529
Amortization of acquired intangible assets	74	87	148	174
Write-off of acquired in-process research and development		1,101		1,101
Other items	289		289	
Total operating expenses	2,598	3,309	4,885	5,292
Operating income	1,130	295	2,530	1,529
Interest and other income, net	7	21	1	101
Income before income taxes	1,137	316	2,531	1,630
Provision for income taxes	118	302	401	615
Net income	\$ 1,019	\$ 14	\$ 2,130	\$ 1,015
Earnings per share:				
Basic	\$ 0.90	\$ 0.01	\$ 1.86	\$ 0.85
Diluted	\$ 0.90	\$ 0.01	\$ 1.84	\$ 0.84
Shares used in calculation of earnings per share:				
Basic	1,129	1,173	1,147	1,188
Diluted	1,134	1,185	1,155	1,202

See accompanying notes.

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

	June 30, 2007	December 31, 2006
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 1,727	\$ 1,283
Marketable securities	3,579	4,994
Trade receivables, net	2,163	2,124
Inventories	2,206	1,903
Other current assets	1,521	1,408
Total current assets	11,196	11,712
Property, plant and equipment, net	5,970	5,921
Intangible assets, net	3,539	3,747
Goodwill	11,265	11,302
Other assets	1,001	1,106
	\$ 32,971	\$ 33,788
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 542	\$ 555
Accrued liabilities	3,587	4,589
Convertible notes		1,698
Other debt	100	100
Total current liabilities	4,229	6,942
Deferred tax liabilities	413	367
Convertible notes	5,080	5,080
Other long-term debt	6,132	2,134
Other non-current liabilities	648	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 1,089 shares in 2007 and 1,166 shares in 2006	24,576	24,155
Accumulated deficit	(8,093)	(5,203)
Accumulated other comprehensive (loss) income	(14)	12
Total stockholders' equity	16,469	18,964
	\$ 32,971	\$ 33,788

See accompanying notes.

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

	Six Months Ended June 30,	
	2007	2006
Cash flows from operating activities:		
Net income	\$ 2,130	\$ 1,015
Write-off of acquired in-process research and development		1,101
Depreciation and amortization	526	476
Asset impairment	286	
Other items, net	334	91
Changes in operating assets and liabilities:		
Trade receivables, net	(39)	(249)
Inventories	(252)	(193)
Other assets	(65)	41
Accounts payable	(12)	88
Accrued income taxes	(737)	154
Other accrued liabilities	112	50
Net cash provided by operating activities	2,283	2,574
Cash flows from investing activities:		
Purchases of property, plant and equipment	(727)	(458)
Cash paid for acquisition of Abgenix, Inc., net of cash acquired		(1,888)
Purchases of marketable securities	(2,154)	(1,546)
Proceeds from sales of marketable securities	3,382	1,414
Proceeds from maturities of marketable securities	184	527
Other	(25)	(91)
Net cash provided by (used in) investing activities	660	(2,042)
Cash flows from financing activities:		
Repurchases of common stock	(5,000)	(1,250)
Repayment of convertible notes	(1,702)	(1)
Repayment of debt assumed in Abgenix, Inc. acquisition		(653)
Proceeds from issuance of notes, net	3,981	
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	205	225
Other	17	40
Net cash used in financing activities	(2,499)	(425)
Increase in cash and cash equivalents	444	107
Cash and cash equivalents at beginning of period	1,283	1,840

Cash and cash equivalents at end of period	\$ 1,727	\$ 1,947
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See accompanying notes.

Table of Contents**AMGEN INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****June 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 six months ended June 30, 2007 and 2006 is unaudited but includes all adjustments (consisting only of normal recurring accruals, 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. Inventories consisted of the following (in millions):

	June 30, 2007	December 31, 2006
Raw materials	\$ 231	\$ 205
Work in process	1,359	1,090
Finished goods	616	608
	\$ 2,206	\$ 1,903

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 June 30, 2007). Intangible assets primarily consist of acquired product technology rights of \$2,956 million, net of accumulated amortization of \$1,459 million, 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 technology used in research and development (R&D) with alternative future uses (acquired R&D technology rights), primarily the XenoMouse® technology acquired in the Abgenix, Inc. (Abgenix) acquisition. Amortization of the acquired R&D technology rights is included in Research and development in the Condensed Consolidated Statements of Operations. Amortization of other intangible assets is principally included in Cost of sales (excludes amortization of acquired intangible assets) and Selling, general and administrative expense in the Condensed Consolidated Statements of Operations. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

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

Product sales

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

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

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

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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 June 30, 2006, we wrote off \$1,101 million of acquired IPR&D related to the Abgenix acquisition. Acquired IPR&D is considered part of total R&D expense.

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 2032 Modified Convertible Notes, 2011 Convertible Notes, 2013 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.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Income (Numerator):				
Net income for basic and diluted EPS	\$ 1,019	\$ 14	\$ 2,130	\$ 1,015
Shares (Denominator):				
Weighted-average shares for basic EPS	1,129	1,173	1,147	1,188
Effect of Dilutive Securities	5	12	8	14
Weighted-average shares for diluted EPS	1,134	1,185	1,155	1,202
Basic earnings per share	\$ 0.90	\$ 0.01	\$ 1.86	\$ 0.85
Diluted earnings per share	\$ 0.90	\$ 0.01	\$ 1.84	\$ 0.84

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.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

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 3, Income taxes for further discussion.

2. 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 six months ended June 30, 2007, our share of KA s profits was \$15 million and \$22 million, respectively. During the three and six months ended June 30, 2006, our share of KA s profits was \$16 million and \$28 million, respectively. At June 30, 2007 and December 31, 2006, the carrying value of our equity method investment in KA was \$263 million and \$241 million, respectively, and is included in non-current Other assets in the Condensed Consolidated Balance Sheets. KA s revenues consist of royalty income related to its licensed technology rights. All of our rights to manufacture and market certain products including darbepoetin alfa, pegfilgrastim, granulocyte colony-stimulating factor (G-CSF) and recombinant human erythropoietin are pursuant to exclusive licenses from KA, which we currently market certain of these products under the brand names Aranesp[®], Neulasta[®], NEUPOGEN[®] and EPOGEN[®], respectively. KA receives royalty income from us, as well as Kirin, Johnson & Johnson and F. Hoffmann-La Roche Ltd. (Roche) under separate product license agreements for certain geographic areas outside of the United States. During the three and six months ended June 30, 2007, KA earned royalties from us of \$85 million and \$170 million, respectively. During the three and six months ended June 30, 2006, KA earned royalties from us of \$82 million and \$156 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 six months ended June 30, 2007, we earned revenues from KA of \$49 million and \$105 million, respectively, for certain R&D activities performed on KA s behalf. During the three and six months ended June 30, 2006, we earned revenues from KA of \$35 million and \$63 million, respectively. These amounts are included in Other revenues in the Condensed Consolidated Statements of Operations.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

3. Income taxes

The effective tax rates for the three and six months ended June 30, 2007 are different from the statutory rate primarily as a result of the favorable resolution of our federal tax examination for prior years and indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our controlled foreign corporations 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 examined 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 three months ended June 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 six months ended June 30, 2007, the gross amount of our UTBs increased approximately \$250 million as a result of tax positions taken during the current year, and decreased approximately \$450 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 June 30, 2007, we believe that it was reasonably possible that our liabilities for UTBs may decrease by \$100 million to \$275 million within the succeeding twelve months due to potential tax settlements as well as the resolution of other issues identified during the examination process.

Table of Contents**AMGEN INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (Continued)****4. Financing arrangements**

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

	June 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	236	235
Total borrowings	11,312	9,012
Less current portion	100	1,798
Total non-current debt	\$ 11,212	\$ 7,214

2008 Floating Rate Notes, 2017 Notes and 2037 Notes

In May 2007, we issued \$2.0 billion aggregate principal amount of floating rate notes due in 2008 (the 2008 Floating Rate Notes), \$1.1 billion aggregate principal amount of notes due in 2017 (the 2017 Notes) and \$0.9 billion 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 a fixed rate of 5.85% and 6.375%, respectively. The 2017 Notes and 2037 Notes may be redeemed, 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 \$2,253 million aggregate principal amount of these convertible notes for their then-accreted value of \$1,702 million 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)****5. Stockholders equity***Stock repurchase programs*

The following table reflects a summary of activity under our stock repurchase programs for the six months ended June 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
Total	82.7(1)	\$ 5,000	59.6	\$ 4,250

(1) The total number of shares repurchased during the three and six 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 3, 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 June 30, 2007, \$1,539 million was available for stock repurchases under our stock repurchase program authorized by the Board of Directors in December 2006. In July 2007, the Board 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 six months ended June 30, 2007, total comprehensive income was \$987 million and \$2,104 million, respectively. During the three and six months ended June 30, 2006, total comprehensive income was \$5 million and \$977 million, respectively.

6. 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.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

7. Other items

Due to the various challenges faced by certain of our key products, in particular Aranesp[®] and EPOGEN[®], which are discussed in more detail in the Overview section of Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A), we commenced a global review of the Company's business plans to identify opportunities to improve our cost structure in response to any resulting declines in revenues.

As part of these efforts and in connection with the preparation of our financial statements for the three months ended June 30, 2007, we have decided to make changes to various ongoing capital projects. These decisions were 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 decisions included a re-scoping of our 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, the Company recorded charges for asset impairment of \$286 million and related costs of \$3 million during the three months ended June 30, 2007. These charges are included in other operating expenses in the Condensed Consolidated Statement of Operations.

8. Subsequent events

Alantos Pharmaceutical Holding, Inc.

On July 16, 2007, we completed the acquisition of Alantos Pharmaceutical Holding, Inc. (Alantos), which will be 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 agreed to pay cash of approximately \$300 million to acquire via merger all of the outstanding shares of Alantos. Alantos' operations will be included in our condensed consolidated financial statements commencing July 16, 2007. In connection with the acquisition, we will write-off the estimated fair value of Alantos' IPR&D during the three months ended September 30, 2007.

Ilypsa, Inc.

On July 18, 2007, we completed the acquisition of Ilypsa, Inc. (Ilypsa), which will be 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 agreed to pay cash of approximately \$420 million to acquire via merger all of the outstanding shares of Ilypsa. Ilypsa's operations will be included in our condensed consolidated financial statements commencing July 18, 2007. In connection with the acquisition, we will write-off the estimated fair value of Ilypsa's IPR&D during the three months ended September 30, 2007.

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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 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.

We primarily earn revenues and income and generate cash from sales of human therapeutic products in the areas of supportive cancer care, nephrology, inflammation and, beginning in the third quarter 2006, oncology when we received U.S. Food and Drug Administration (FDA) approval and launched Vectibix (panitumumab), our first cancer therapeutic. For the three and six months ended June 30, 2007, total revenues were \$3.7 billion and \$7.4 billion, respectively. For the three and six months ended June 30, 2007, net income and diluted earnings per share were \$1.0 billion and \$2.1 billion and \$0.90 per share and \$1.84 per share, respectively. As discussed in more detail below, the results of our operations for the three and six months ended June 30, 2007 reflect charges for asset impairment and related costs of \$289 million primarily associated with reduced capital investments as part of the

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rationalization of our worldwide network of manufacturing facilities and, to a lesser degree, moderation of the expansion of our research facilities. As of June 30, 2007, cash, cash equivalents and marketable securities were \$5.3 billion, of which approximately \$4.2 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 June 30, 2007.

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 six months ended June 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.

For the three and six months ended June 30, 2007, product sales, which are mainly comprised of our principal products, represented 97% of total revenues. Total product sales for the three and six months ended June 30, 2007 grew 3% and 8%, respectively, principally driven by demand for ENBREL and Neulasta[®]. Total product sales growth for the three and six months ended June 30, 2007 was adversely impacted by Aranesp[®] sales. In particular, for the three months ended June 30, 2007, U.S. Aranesp[®] sales declined 19% primarily reflecting a decrease in demand as discussed in more detail below. We believe that future product sales growth will be more difficult than in previous years since, as discussed below, certain of our principal products, principally Aranesp[®] and EPOGEN[®], face various challenges primarily arising from clinical trial results that led to regulatory activities, including revisions to labeling and loss of reimbursement coverage for certain of our products, and the potential for further label and reimbursement changes, and legislative reviews. In addition, increased competition, including additional approved indications for existing competitive products, is also presenting challenges to certain of our principal products, as discussed below.

In particular, our products used to treat anemia, Aranesp[®] and EPOGEN[®], have and are continuing to experience significant regulatory and legislative challenges. Aranesp[®] and EPOGEN[®] belong to a class of drugs used to treat anemia referred to as erythropoiesis-stimulating agents, or ESAs. Aranesp[®] is used primarily in the United States and in Europe for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN[®] is used in the United States to treat anemia associated with chronic kidney disease. Due to negative safety results of various 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, our anemia products, and Aranesp[®] in particular in the oncology setting, have experienced significant regulatory challenges. For example:

In February 2007, the United States Pharmacopoeia Dispensing Information (USP DI) Drug Reference Guides removed Aranesp[®] for use in the treatment of Anemia of Cancer (AoC). Thereafter, nearly all Medicare contractors stopped reimbursing for Aranesp[®] use in AoC patients.

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On March 9, 2007, the FDA approved updated safety information, including a boxed warning, in the prescribing information for the class of ESAs, including Aranesp® and EPOGEN®.

Sales growth slowed for Aranesp® in the United States in the latter part of the three months ended March 31, 2007 and declined significantly in the three months ended June 30, 2007 principally driven by a decrease in demand. This decrease in demand primarily reflects customer reaction in the oncology setting to these label and reimbursement changes. In addition, in Europe, there has been slight dosing conservatism in oncology, in the three months ended June 30, 2007, in part, as a result of recent developments in the United States.

Further, 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 sets the coverage policy for Medicare and other government beneficiaries who account for approximately 50% of cancer patients receiving Aranesp®. We are in continuing discussions with CMS regarding the Decision Memorandum and are in the process of evaluating the impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp® and currently believe that the majority of cancer patients who receive treatment with Aranesp® are initiated at hemoglobin (Hb) levels above 10g/dL and maintain Hb levels above 10g/dL with continued therapy. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10g/dL, we believe that such restriction will change the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, dose and duration of therapy. We expect this restriction on reimbursement of ESAs in the Decision Memorandum would have a material adverse effect on our sales of Aranesp®, and our business and results of operations. Additionally, we believe that the Decision Memorandum may be followed and implemented by some private payers. See the Reimbursement section, which follows for further discussion of the Decision Memorandum.

In addition, the outcome of recent and pending developments could have a material adverse impact on future product sales in the United States or internationally, as applicable, for Aranesp® and/or EPOGEN® as they may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement practices.

For example, the following could further impact future Aranesp® sales:

On May 10, 2007, the Oncologic Drugs Advisory Committee (ODAC) met to discuss the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. The ODAC is an advisory committee of external experts who advise the FDA about the safety and efficacy of drug products for use in treating cancer patients. This committee is advisory only and FDA officials are not bound or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels. The ODAC recommended that more restrictions be added to ESA labels and that additional clinical trials be conducted by companies with currently approved ESAs, including us, although no specific restrictions or studies were recommended at the ODAC meeting. Although not required, the FDA will likely take into consideration the recommendations by the ODAC and will decide what updates to the ESA labels are necessary and whether additional clinical trials for ESAs should be conducted and how those trials should be designed. As a result of these recent developments, we are in discussions with the FDA and are working to arrive at new class labeling for ESAs in the oncology setting in the United States.

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The FDA has stated that it intends to hold a joint meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease, which may lead to label changes.

The European Scientific Advisory Group and the Committee for Medicinal Products for Human Use (CHMP) recently held meetings to review the safety and labeling of ESAs made by us, Johnson & Johnson, Shire Pharmaceuticals Group (Shire) and Roche in both the nephrology and oncology settings. We expect labeling changes to apply to all members of the ESA class consistently and expect that the new labels will be announced sometime towards the end of 2007.

For example, the following could further impact future EPOGEN[®] sales:

The above-described joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, which may lead to label changes in the renal setting.

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 IUs of EPOGEN[®] from 500,000 IUs.

On April 12, 2007 after a review of existing guidelines, the National Kidney Foundation (NKF) distributed to the nephrology community a draft of the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline and Clinical Practice Recommendations for Anemia Management in Chronic Kidney Disease (proposed KDOQI guidelines). In the proposed KDOQI guidelines, the NKF recommends what factors should be considered in selecting a Hb target and states that the selected Hb target should generally be in the range of 11.0 to 12.0 g/dL.

Legislative actions, such as The Children's Health and Medicare Protection Act of 2007 proposed legislation (the Proposed CHAMP Legislation) released by the U.S. House of Representatives Committees on Ways & Means and Energy & Commerce on July 24, 2007, which would reduce ESA payments to large dialysis organizations to average sales price (ASP) +2% in 2008 and 2009.

Our anemia products and certain other principal products are also facing a number of competitive challenges as well. For example:

Roche is developing a pegylated erythropoietin molecule (peg-EPO) product for the United States for which they have filed a biologic license application (BLA) with the FDA. On May 18, 2007, Roche announced that the FDA had issued an approvable letter for their peg-EPO product for the treatment of anemia associated with chronic renal failure, including

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patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the CRDAC has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, upon regulatory approval, despite our ongoing lawsuit and their acknowledgment of our U.S. erythropoietin patents (see Item 1. Legal Proceedings *Roche Matters* in Part II herein). In addition, Roche's peg-EPO product, MIRCERA received approval by the European Commission on July 26, 2007 to treat anemia associated with chronic kidney disease and is expected to be launched in certain European Union (EU) countries in the third quarter of 2007.

Shire launched Dynepo (Epoetin delta), a competing erythropoietin product, in Germany in March 2007. Dynepo is expected to be launched in certain other EU countries throughout the remainder of 2007.

The first biosimilar erythropoietin products which would compete with Aranesp® may be approved in the EU in the third quarter of 2007 and could be available shortly thereafter. The first biosimilar G-CSF products, which would compete with Neulasta® and NEUPOGEN®, may be approved in the EU sometime in 2008, and could be available soon thereafter.

ENBREL operates in an extremely competitive environment as evidenced by the number of competitive products, including HUMIRA®, Remicade®, Orelia®, Rituxan®, Raptiva® and Amevive®. Although these competing products have helped to grow both the rheumatology and dermatology segments, they have also resulted in ENBREL experiencing share loss in both of these segments. Further, as a result of safety concerns related to patient survival, we previously announced that we had discontinued Vectibix treatment in our Panitumumab Advanced Colorectal Cancer Evaluation (PACCE) trial, a non-registration-enabling trial evaluating the addition of Vectibix to standard chemotherapy and Avastin® (bevacizumab) for the treatment of first-line metastatic colorectal cancer. We are in continuing discussions with the FDA with respect to the Vectibix label, and expect to provide additional prominence to data from the PACCE trial. The language is still in development, discussions with the FDA are on-going and any label change is subject to FDA approval. Our registrational studies to explore the utility of Vectibix in combination with chemotherapy in first and second line metastatic colorectal cancer continue and are not being modified at this time as a result of the PACCE trial. Further, on May 25, 2007, the CHMP adopted a negative opinion with respect to the approval of Vectibix™ in the EU to treat patients with metastatic colorectal cancer whose disease has progressed on or following all standard chemotherapy regimens. In accordance with European regulations, we have requested a re-examination of the CHMP opinion as part of the EU regulatory process.

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

As a result of these challenges, we have commenced a global review of the Company's business plans to identify opportunities to improve our cost structure in response to any resulting declines in revenues. In connection with these efforts, we have begun taking certain actions to moderate our operating expense growth. In addition, we will refocus spending on critical R&D and operational priorities and seek greater efficiencies in how we conduct our business while continuing to make significant innovative R&D investments and build the framework for the Company's future growth.

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As part of these efforts, we have decided to make changes to various ongoing capital projects. These decisions were 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 decisions included a re-scoping of our 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, the Company recorded charges for asset impairment and related costs of \$289 million during the three months ended June 30, 2007. These charges are included in other operating expenses in the Condensed Consolidated Statement of Operations.

We are continuing our review of the Company's operations and depending, in part, on the outcome of certain future developments, including the impact of CMS' Decision Memorandum related to the use of ESAs in oncology and the results of the upcoming joint meeting of the CRDAC and Drug Safety and Risk Management Advisory Committee, we may be required to take further actions to reduce costs. As a result, we may incur additional related charges in the near term, certain of which may be material.

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2007	2006	Change	2007	2006	Change
Operating Income	\$ 1,130	\$ 295	283%	\$ 2,530	\$ 1,529	65%

Operating income as a percentage of product sales was 31% and 8% for the three months ended June 30, 2007 and 2006, respectively. For the six months ended June 30, 2007 and 2006, operating income as a percentage of product sales was 35% and 23%, respectively. Operating income for the three and six months ended June 30, 2006 was 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. We have 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. Based on current business trends, we expect to see further growth in R&D expense in 2007, but not to the same extent experienced in 2006, in order to support the increased number and expense of studies to advance our late-stage pipeline, including previously initiated mega-trials, as well as the continued advancement of earlier stage compounds. However, as a result of recent regulatory and legislative challenges discussed above, we have and will continue to assess the optimal level of our R&D investment. To the extent future sales are negatively impacted as a result of these challenges, we may be required to adjust our R&D investment plans.

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On July 16, 2007, we completed our acquisition of Alantos, which will be 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 agreed to pay cash of approximately \$300 million to acquire via merger 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 will be 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 agreed to pay cash of approximately \$420 million to acquire via merger 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 chronic kidney disease patients on hemodialysis.

There are also many economic and industry-wide factors that affect our business generally and uniquely, including, among others, those relating to increased complexity and cost of R&D due, in part, to greater scrutiny of clinical trials with respect to safety which may lead to fewer treatments being approved by the FDA or other regulatory bodies and/or safety-related label changes for approved products; increasingly intense competition for marketed products and product candidates; reimbursement changes; healthcare provider prescribing behavior, regulatory or private healthcare organization medical guidelines and reimbursement practices; complex and expanding regulatory requirements; and intellectual property protection. See Item 1. Business in Part I of our Annual Report on Form 10-K for the year ended December 31, 2006 and

Item 1A. Risk Factors in Part II herein for further information on these economic and industry-wide factors and their impact and potential impact on our business.

Reimbursement

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Generally, in Europe and other countries outside the United States, the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Further, adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand safety labeling for our approved products and may negatively impact worldwide reimbursement for our products. On May 14, 2007, CMS issued its Proposed National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the Proposed NCD) and on July 30, 2007, issued its Decision Memorandum. We are in the process of evaluating 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 Item 1A. Risk Factors *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or 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.* in Part II herein.) In addition, Senator Charles Grassley from the United States Senate Finance Committee sent letters to the FDA, CMS and to us expressing interest in the use of ESAs in cancer and End Stage Renal Disease (ESRD)

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patients and has requested meetings with each of the three. To the extent that there is resulting legislation or changes in CMS or FDA policy as a result of Senator Grassley's concerns, such changes could have a material or adverse effect on the use of our ESA products.

Most patients receiving Aranesp[®], Neulasta[®] and NEUPOGEN[®] for approved indications are covered by both government and private payer healthcare programs. Government healthcare programs are governed by the Medicare Prescription Drug Improvement and Modernization Act (the MMA) which was enacted into law in December 2003 and became effective January 1, 2005. Since January 1, 2005, in the physician clinic setting and since January 1, 2006, in the hospital outpatient setting, Aranesp[®], Neulasta[®] and NEUPOGEN[®] have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its ASP (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP for Aranesp[®] that will be in effect for the third quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp[®] from June 1, 2006 through May 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 had to revise our interpretation and methodology of such interpretation to reflect such calculation changes both prospectively and retroactively. Partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN[®] was reduced for the third quarter of 2007. Prior to January 1, 2006, Medicare's hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized the average wholesale price (AWP) as the basis of Medicare Part B payment for covered outpatient drugs and biologics administered in the hospital outpatient setting. From 2003 to 2005, CMS applied an equitable adjustment such that the Aranesp[®] reimbursement rate was based on the AWP of PROCRI[®], Johnson & Johnson's recombinant human erythropoietin product marketed in the United States, using a dose conversion ratio. In 2006 and 2007, CMS did not apply an equitable adjustment to tie the reimbursement rate for Aranesp[®] to PROCRI[®]. On July 16, 2007, CMS released its 2008 OPPS proposed rule that did not propose to apply an equitable adjustment to the reimbursement rate for Aranesp[®] to PROCRI[®], however, CMS has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp[®] in future years.

In the United States, dialysis providers are primarily reimbursed for EPOGEN[®] by the federal government through the ESRD Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement rate is established by federal law and is monitored and implemented by CMS. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN[®] and Aranesp[®], is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. On May 18, 2007, CMS released a notice, based on its ongoing assessment for payment of Part B drugs, that there would be a single payment limit for Epoetin alfa (EPOGEN[®] and PROCRI[®]) beginning in the third quarter of 2007. Further, on July 24, 2007, the U.S. House of Representatives Committees on Ways & Means and Energy & Commerce released the Proposed CHAMP Legislation which would reduce ESA payment to large dialysis organizations to ASP+2% in 2008 and 2009. Although we cannot predict the payment levels of EPOGEN[®] in future quarters, a decrease in the reimbursement rate for EPOGEN[®] may have a material adverse effect on our business and results of operations.

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Since April 1, 2006, the ESRD Program reimbursement has been subject to a revised Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. This policy, EMP, was revised, effective October 1, 2006, to provide that if a patient's Hb is greater than 13 g/dL, providers are instructed to reduce the patient's EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient's EPOGEN® and Aranesp® dose and the provider does not submit medical documentation to support maintaining a patient's Hb above 13 g/dL, reimbursement will be reduced to the level it would have been had the provider reduced dosage by 25%. On July 20, 2007, CMS published revisions to the EMP, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient's Hb is above 13 g/dL for three or more consecutive months and a reduction of the monthly dosing limits to 400,000 IUs of EPOGEN® from 500,000 IUs, and to 1,200 mcgs of Aranesp® from 1,500 mcgs.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA. While we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For example, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN®. The demonstration project was scheduled to start in January 2006, but has been delayed with no announced start date. However, the Proposed CHAMP Legislation would bundle payment to large dialysis organizations (LDOs) for dialysis services, including but not limited to composite rate services, ESAs, other drugs and labs common in dialysis, and home dialysis training beginning in 2010. The Proposed CHAMP Legislation also requires that aggregate payment be reduced by 4% in 2010, and allows CMS four years to phase in bundling to non-LDO providers. 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, we cannot predict what impact a bundled payments system would have on sales of EPOGEN® or Aranesp® used in the treatment of persons receiving outpatient dialysis services.

In addition, on December 29, 2006, the Medicare Payment Advisory Commission (MedPAC) released its second Congressionally-mandated report on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Under the ASP system, the Company allocates its discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Referencing MedPAC's December 2006 report, CMS proposed in the Medicare Physician Fee Schedule Proposed Rule for 2008 revising the methodology for calculating ASP to require the reallocation of price concessions of drugs sold under bundled arrangements, described by CMS in part as an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or

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biological or other drugs or biologicals or some other performance requirement. As it is premature to speculate on how CMS will finalize the proposed methodology, we cannot predict the potential impact this revised methodology may have on our business.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the 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 chemotherapy-induced anemia;

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 criteria:

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;

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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 > 1g/dL (hematocrit > 3%). However, if after the first 4 weeks the Hb is > 10g/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 criteria 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 NCD, including Myelodysplastic syndrome (MDS).

The Decision Memorandum sets the coverage policy for Medicare and other government beneficiaries who account for approximately 50% of cancer patients receiving Aranesp®. We are in continuing discussions with CMS regarding the Decision Memorandum and are in the process of evaluating the impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp® and currently believe that the majority of cancer patients who receive treatment with Aranesp® are initiated at Hb levels above 10g/dL and maintain Hb levels above 10g/dL with continued therapy. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10g/dL, we believe that such restriction will change the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, dose and duration of therapy. We expect this restriction on reimbursement of ESAs in the Decision Memorandum would have a material adverse effect on our sales of Aranesp®, and our business and results of operations. Additionally, we believe that the Decision Memorandum may be followed and implemented by some private payers.

In addition, the FDA has stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease. We cannot predict what action the FDA may take as a result of such committee meeting or what impact it may have on our sales of our ESAs and on our business. Although the revisions to the EMP 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 the Proposed NCD for treatment of anemia in oncology with ESAs, would negatively effect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations.

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Further, the Deficit Reduction Act of 2005 (DRA) included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that became effective on January 1, 2006, will increase the level of Medicaid rebates paid by us. We are currently in the process of further evaluating the impact of the DRA and are uncertain as to the potential full 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 price concessions in the Medicare Physician Fee Schedule Proposed Rule for 2008. Given its recent release, we are in the process of evaluating what impact the final rule will have on our business.

Results of Operations*Product sales*

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2007	2006	Change	2007	2006	Change
Aranesp®	\$ 949	\$ 1,055	(10)%	\$ 1,969	\$ 1,948	1%
EPOGEN®	624	613	2%	1,249	1,217	3%
Neulasta®/NEUPOGEN®	1,041	1,005	4%	2,059	1,901	8%
ENBREL	823	724	14%	1,553	1,382	12%
Sensipar®	108	79	37%	213	140	52%
Vectibix	45		n/a	96		n/a
Other	14	15	(7)%	30	30	0%
Total product sales	\$ 3,604	\$ 3,491	3%	\$ 7,169	\$ 6,618	8%
Total U.S.	\$ 2,879	\$ 2,861	1%	\$ 5,763	\$ 5,432	6%
Total International	725	630	15%	1,406	1,186	19%
Total product sales	\$ 3,604	\$ 3,491	3%	\$ 7,169	\$ 6,618	8%

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.

Product sales growth for the three and six months ended June 30, 2007 was principally driven by increased demand for ENBREL and Neulasta®. Total product sales growth for the three and six months ended June 30, 2007 was adversely impacted by Aranesp® sales. In particular, for the three months ended June 30, 2007, U.S. Aranesp® sales declined 19% primarily reflecting a decrease in demand as a result of customer reaction to certain label and reimbursement changes. International product sales for the

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three and six months ended June 30, 2007 were favorably impacted by \$41 million and \$83 million, respectively, from foreign currency exchange rate changes. Excluding the favorable impact of foreign currency exchange rate changes, international product sales increased 9% and 12% over the three and six months ended June 30, 2006, respectively.

Aranesp[®]

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	2006	Change	2007	2006	Change
Aranesp [®] U.S.	\$ 578	\$ 713	(19)%	\$ 1,232	\$ 1,309	(6)%
Aranesp [®] International	371	342	8%	737	639	15%
Total Aranesp[®]	\$ 949	\$ 1,055	(10)%	\$ 1,969	\$ 1,948	1%

The decrease in U.S. Aranesp[®] sales for the three and six months ended June 30, 2007 was principally driven by a decline in demand. Additionally, to a lesser degree, U.S. sales were adversely impacted by unfavorable wholesaler inventory changes which were offset by end-user inventory build. The decline in demand primarily reflects customer reaction in the oncology setting to the ESA safety-related label change and the reimbursement change related to the discontinued Medicare reimbursement of Aranesp[®] for use in the treatment of AoC, which occurred primarily in the latter half of the first quarter of 2007, as discussed above in the *Overview* section. The impact of these label and reimbursement changes was not fully reflected in sales in the three months ended March 31, 2007 given the timing of their development.

The increase in international Aranesp[®] sales for the three months ended June 30, 2007 was primarily due to changes in foreign exchange which positively impacted sales by approximately \$21 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp[®] sales for the three month period increased 2%. International sales for the three months ended June 30, 2007 also reflect increased demand in the European nephrology segment partially offset by slight dosing conservatism in the European oncology segment. Although we are maintaining our competitive share position in oncology in Europe, the slight dosing conservatism may have been influenced, in part, by recent developments in the United States. The increase in international sales for the six months ended June 30, 2007 was favorably impacted by foreign currency exchange rate changes of \$45 million. Excluding the impact of foreign currency exchange rate changes, international Aranesp[®] sales for the six month period increased 8%. International sales for the six months ended June 30, 2007 also reflect certain segment growth and share gains, largely occurring during the first quarter of 2007.

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

reimbursement changes for ESAs resulting from CMS Decision Memorandum issued on July 30, 2007. The Decision Memorandum sets the coverage policy for Medicare and other government beneficiaries who account for approximately 50% of cancer patients receiving Aranesp[®]. We are in continuing discussions with CMS regarding the Decision Memorandum and are in the process of evaluating the impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp[®] and currently believe that the majority of cancer patients who receive treatment with Aranesp[®] are initiated at Hb levels above 10g/dL and maintain Hb levels above 10g/dL with continued therapy. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10g/dL, we believe that such restriction will change the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, dose and duration of therapy. We expect this restriction on reimbursement of ESAs in the Decision Memorandum would have a material adverse effect on our sales of Aranesp[®], and our business and results of operations. Additionally, we believe that the Decision Memorandum may be followed and implemented by some private payers;

adverse events or results from clinical trials or studies performed by us or by others, which have and could further impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices. For example, as discussed in more

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detail above in the Overview section, negative safety results for various studies performed by us and by third-parties, including our AoC 103 Study, involving off-label usage of ESAs have resulted in the following:

discontinued reimbursement for Aranesp® by nearly all Medicare contractors in the treatment of AoC;

product safety label changes in the United States for the class of ESAs, including Aranesp® and EPOGEN®, and potential for additional label changes resulting from:

- * 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. We are in discussions with the FDA and are working to arrive at new class labeling for ESAs in the oncology setting in the United States;
- * an FDA scheduled joint meeting of the CRDAC and Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease; and
- * the European Scientific Advisory Group and the CHMP recently held meetings to review the safety and labeling of ESAs made by us, Johnson & Johnson, Shire and Roche in both the European nephrology and oncology settings. We expect labeling changes to apply to all members of the ESA class consistently and expect that the new labels will be announced sometime towards the end of 2007.

changes in healthcare provider prescribing behavior or use of our product, such as more conservative dosing;

governmental or private organization regulations or guidelines relating to the use of our products;

reimbursement and cost containment pressures by third-party payers, including governments and private insurance plans;

an increasingly competitive environment of products or therapies, which in 2007 in the United States could potentially include competition in the nephrology segment from Roche's peg-EPO product, which Roche has indicated they intend to bring to the U.S. market upon regulatory approval despite our ongoing lawsuit and their acknowledgment of our U.S. erythropoietin patents (see Item 1. Legal Proceedings *Roche Matters* in Part II herein) and in the EU includes or could potentially include Shire's erythropoietin product, Dynepo™, launched in Germany in March 2007 and expected to be launched in certain other EU countries throughout the remainder of 2007, Roche's peg-EPO product, MIRCERA®,

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approved in the EU on July 26, 2007 and expected to be launched in certain EU countries in the third quarter of 2007 and biosimilar products which may be approved in the third quarter of 2007 and launched shortly thereafter;

our ability to differentiate Aranesp[®] from current and potential future competition;

pricing strategies; and
any or all of which could have a material adverse impact on future sales of Aranesp[®].

(See 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 six months ended June 30, 2007 and 2006, total EPOGEN[®] sales were as follows (in millions):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	2006	Change	2007	2006	Change
EPOGEN [®] U.S	\$ 624	\$ 613	2%	\$ 1,249	\$ 1,217	3%

EPOGEN[®] sales for the three and six months ended June 30, 2007 increased primarily due to patient population growth, 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), and favorable wholesaler inventory changes, partially offset by changes in customer purchasing patterns. EPOGEN[®] sales for the three months ended June 30, 2007 were also negatively impacted by low single digit 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:

adverse events or results from clinical trials or studies performed by us or by others, which have and could further impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices. For example, as discussed in more detail above in the Overview section, negative safety results for various studies performed by us and by third-parties, involving off-label usage of ESAs have resulted in the following:

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;

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product safety label changes in the United States for the class of ESAs, including Aranesp® and EPOGEN®, and the potential for additional label changes resulting from an FDA scheduled joint meeting of the CRDAC and Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease;

the potential for changes in medical guidelines resulting from the NKF issuance of the proposed KDOQI guidelines, which recommend what factors should be considered in selecting a Hb target and state that the selected Hb target should generally be in the range 11.0 to 12.0 g/dL;

changes in healthcare provider prescribing behavior or use of our product, such as more conservative dosing behavior;

governmental or private organization regulations or guidelines relating to the use of our products;

changes in reimbursement rates or a change in the basis for reimbursement by the federal government;

the possibility of competition from Roche's peg-EPO, which Roche has indicated they plan to bring to the U.S. nephrology market in 2007, upon regulatory approval despite our ongoing lawsuit and their acknowledgment of our U.S. erythropoietin patents (see Item 1. Legal Proceedings - *Roche Matters* in Part II herein);

cost containment pressures from the federal government on healthcare providers;

pricing strategies; and
any or all of which could have a material adverse impact on future sales of EPOGEN®.

In addition, EPOGEN® sales could be favorably impacted by underlying demand in the free-standing dialysis centers, which we believe will remain consistent with the annual patient population growth of approximately 3% and the lessened impact of conversion to Aranesp® in the U.S. hospital dialysis clinics, which we believe stabilized in mid-2006.

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

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	2006	Change	2007	2006	Change
Neulasta® U.S.	\$ 573	\$ 579	(1)%	\$ 1,146	\$ 1,076	7%
NEUPOGEN® U.S.	200	206	(3)%	404	397	2%
U.S. Neulasta®/NEUPOGEN® Total	773	785	(2)%	1,550	1,473	5%
Neulasta® International	161	122	32%	307	233	32%
NEUPOGEN® International	107	98	9%	202	195	4%
International Neulasta®/NEUPOGEN® Total	268	220	22%	509	428	19%
Total Worldwide Neulasta®/NEUPOGEN®	\$ 1,041	\$ 1,005	4%	\$ 2,059	\$ 1,901	8%

The decline in U.S. sales of Neulasta®/NEUPOGEN® for the three months ended June 30, 2007 primarily reflects unfavorable wholesaler inventory changes and increased sales discounts that offset growth in unit demand. The increase in international Neulasta®/NEUPOGEN® sales for the three months ended June 30, 2007 was driven by the continued conversion to Neulasta® and changes in foreign exchange, which positively impacted second quarter international sales by \$16 million. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 15%.

The increase in U.S. Neulasta®/NEUPOGEN® sales for the six months ended June 30, 2007 was principally driven by demand for Neulasta® due to segment growth. Segment growth is attributable to increase in patients, in part, due to the continued increase of Neulasta® in first cycle use as well as a higher net sales price. The increase in international Neulasta®/NEUPOGEN® sales for the six months ended June 30, 2007 was driven by the continued conversion to Neulasta® from NEUPOGEN® and changes in foreign currency exchange rate changes, which positively impacted the six months ended June 30, 2007 sales by \$32 million. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 11%.

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

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

competitive products or therapies, including biosimilar products that may be approved in the EU sometime in 2008 and be available shortly thereafter;

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;

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governmental or private organization regulations or guidelines relating to the use of our products;

reimbursement by third-party payers, including governments and private insurance plans;

cost containment pressures from governments and private insurers on healthcare providers;

pricing strategies;

penetration of existing segments; and

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

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

ENBREL

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

	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2007	2006	Change	2007	2006	Change
ENBREL U.S.	\$ 777	\$ 685	13%	\$ 1,470	\$ 1,314	12%
ENBREL International	46	39	18%	83	68	22%
Total ENBREL	\$ 823	\$ 724	14%	\$ 1,553	\$ 1,382	12%

ENBREL sales growth for the three and six months ended June 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 six months ended June 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.

We believe sales growth for the remainder of 2007 will be principally driven by growth in the rheumatology and dermatology segments.

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 and, in part, our ability to differentiate ENBREL based on its safety profile and efficacy;

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segment growth;

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;

the availability, extent and access to reimbursement by government and third-party payers;

cost containment pressures from governments and private insurers on healthcare providers; and

pricing strategies.

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

Selected operating expenses

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2007	2006	Change	2007	2006	Change
Product sales	\$ 3,604	\$ 3,491	3%	\$ 7,169	\$ 6,618	8%
Operating expenses:						
Cost of sales (excludes amortization of acquired intangible assets)	\$ 558	\$ 493	13%	\$ 1,150	\$ 1,045	10%
% of product sales	15%	14%		16%	16%	
Research and development	\$ 817	\$ 788	4%	\$ 1,668	\$ 1,443	16%
% of product sales	23%	23%		23%	22%	
Selling, general and administrative	\$ 860	\$ 840	2%	\$ 1,630	\$ 1,529	7%
% of product sales	24%	24%		23%	23%	
Amortization of acquired intangible assets	\$ 74	\$ 87	(15)%	\$ 148	\$ 174	(15)%
Write-off of acquired in-process research and development	\$	\$ 1,101	(100)%	\$	\$ 1,101	(100)%
Other items	\$ 289		100%	\$ 289		100%

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Cost of sales, which excludes the amortization of acquired intangible assets (see Condensed Consolidated Statements of Operations), increased 13% and 10%, respectively, for the three and six months ended June 30, 2007. The increase for the three and six months ended June 30, 2007 was primarily driven by product mix, primarily ENBREL, which is more costly to manufacture, increased sales volume and an increase in inventory reserves due to expiry risk associated with declining demand in some smaller products and excess inventory related to the introduction of a new product presentation. The increase in the six months ended June 30, 2007 was also due to the write-off of a semi-completed manufacturing asset that will not be used due to a change in manufacturing strategy.

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 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 increased 4% and 16%, respectively, for the three and six months ended June 30, 2007 primarily to support the increased number and expense of studies to advance the Company's late-stage pipeline, including previously initiated mega-trials, as well as the continued advancement of earlier stage compounds. During the three months ended June 30, 2007, staff-related costs and clinical trial and manufacturing costs increased approximately \$19 million and \$17 million, respectively. During the six months ended June 30, 2007, staff-related costs and clinical trial and manufacturing costs increased approximately \$81 million and \$110 million, respectively.

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. SG&A increased 2% and 7%, respectively, for the three and six months ended June 30, 2007. The increase in the three and six months ended June 30, 2007 primarily reflects the Wyeth profit share related to ENBREL. During the three and six months ended June 30, 2007 outside marketing expenses in support of our principal products, including Wyeth profit share related to ENBREL, increased by approximately \$28 million and \$92 million, respectively.

Amortization of acquired intangible assets

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

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 expensed as incurred. In the three months ended June 30, 2006, we wrote off \$1,101 million of acquired IPR&D related to the Abgenix acquisition.

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Other items

Due to the various challenges faced by certain of our key products, in particular our ESA products, which are discussed above in the Overview section, we have commenced a global review of the Company's business plans to identify opportunities to improve our cost structure in response to any resulting declines in revenues. In connection with these efforts, we have begun taking certain actions to moderate our operating expense growth. In addition, we will refocus spending on critical R&D and operational priorities and seek greater efficiencies in how we conduct our business while continuing to make significant innovative R&D investments and build the framework for the Company's future growth.

As part of these efforts, we have decided to make changes to various ongoing capital projects. These decisions were 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 decisions included a re-scoping of our 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, the Company recorded charges for asset impairment and related costs of \$289 million during the three months ended June 30, 2007. These charges are included in other operating expenses in the Condensed Consolidated Statement of Operations.

We are continuing our review of the Company's operations and depending, in part, on the outcome of certain future developments, including the impact of CMS Decision Memorandum related to the use of ESAs in oncology and the results of the upcoming joint meeting of the CRDAC and Drug Safety and Risk Management Advisory Committee, we may be required to take further actions to reduce costs. As a result, we may incur additional related charges in the near term, certain of which may be material.

Interest and other income, net

Interest and other income, net for the three months ended June 30, 2007 was \$7 million of income compared to \$21 million of income for the three months ended June 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, net for the six months ended June 30, 2007 was \$1 million of income compared to \$101 million of income for the six months ended June 30, 2006. The decrease was principally attributable to the write-off of \$51 million of deferred financing and related costs during the first quarter of 2007 resulting from the repayment of the convertible debt and the increased interest expense related to the issuance of \$4.0 billion of debt in May 2007.

Income taxes

Our effective tax rates for the three and six months ended June 30, 2007 were 10.4% and 15.8%, respectively, compared with 95.6% and 37.7%, respectively, for the same periods last year. Our effective tax rates for the three and six months ended June 30, 2007 have decreased primarily due to the write-off of acquired IPR&D cost in connection with the acquisition of Abgenix in the second quarter of 2006 and the favorable resolution of our prior years' federal examination in the second quarter of 2007. The resolution of prior years' tax matters recognized in the three months ended June 30, 2007 impacted the effective tax rates for the three and six months ended June 30, 2007 by (10.6%) and (4.8%), respectively. See Note 3, Income taxes to the Condensed Consolidated Financial Statements for further discussion.

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Recent and proposed accounting pronouncements

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

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

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

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

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

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

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

In July 2007, the FASB voted unanimously to reconsider the current 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. The FASB indicated it will expose for public comment a proposed FASB Staff Position (*FSP*) that would change the method of accounting for such securities and would require the proposed method to be retrospectively applied. The FSP 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 such a security would be bifurcated and accounted for separately in a manner that reflects the issuer's economic interest cost. While the effect on us of this expected proposal cannot be quantified unless and until the

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FASB finalizes its guidance, we expect that under this proposal, 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. This 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. Therefore, if the expected 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.

We cannot predict the outcome of the expected FASB proposal. 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):

	June 30, 2007	December 31, 2006
Cash, cash equivalents and marketable securities	\$ 5,306	\$ 6,277
Total assets	32,971	33,788
Current debt	100	1,798
Non-current debt	11,212	7,214
Stockholders' equity	16,469	18,964

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future, as well as to support our stock repurchase programs and other business initiatives, including acquisitions and licensing activities.

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at June 30, 2007, approximately \$4.2 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.

Table of Contents*Financing arrangements*

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

	June 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	236	235
Total borrowings	11,312	9,012
Less current portion	100	1,798
Total non-current debt	\$ 11,212	\$ 7,214

Certain of our financing arrangements contain non-financial covenants and as of June 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+ by Standard & Poor's and A2 by Moody's Investors Service, Inc. (Moody's). On May 23, 2007, Standard & Poor's confirmed its rating of A+ for the Company's outstanding notes, but placed the rating on credit watch with negative implications. Moody's also confirmed its rating of A2 for the Company's outstanding notes, but revised the Company's rating outlook to negative from stable. See Note 4, Financing arrangements to our Condensed Consolidated Financial Statements for further discussion of the transactions during the quarter ended June 30, 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 each of our financing arrangements.

Cash flows

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

	Six months ended June 30, 2007	2006
Net cash provided by operating activities	\$ 2,283	\$ 2,574
Net cash provided by (used in) investing activities	660	(2,042)
Net cash used in financing activities	(2,499)	(425)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the six months ended June 30, 2007 decreased from the prior year six months ended due to increased disbursements from the timing of payments in the ordinary course of business partially offset by higher receipts from customers. (See Condensed Consolidated Statements of Cash Flows.)

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Investing

Capital expenditures totaled \$727 million during the six months ended June 30, 2007, compared with \$458 million during the same period last year. The capital expenditures during the six months ended June 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.

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

As discussed above in the Overview section, we incurred an asset impairment charge of approximately \$286 million in the three months ended June 30, 2007 primarily associated with reduced capital investments as part of the rationalization of our worldwide network of manufacturing facilities and, to a lesser degree, moderation of the expansion of our research facilities. We currently estimate 2007 spending on capital projects and equipment to increase slightly compared to the prior year as we continue to increase our manufacturing operations globally, although not to the extent previously planned, and proceed with the implementation of our ERP system. The most significant of these expenditures are expected to be incurred with the further expansion of our Puerto Rico and Fremont manufacturing operations.

On July 16, 2007, we completed our acquisition of Alantos and pursuant to the merger agreement, we agreed to pay cash of approximately \$300 million. On July 18, 2007, we completed our acquisition of Ilypsa and pursuant to the merger agreement, we agreed to pay cash of approximately \$420 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 \$0.9 billion 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 \$2,253 million aggregate principal amount of Convertible Notes at their then-accreted value for \$1,702 million in cash, or approximately 96%, of the outstanding balance of these notes.

During the six months ended June 30, 2007 and 2006, we repurchased 82.7 million and 59.6 million shares of our common stock, respectively, at a total cost of \$5,000 million and \$4,250 million, respectively. The total number of shares repurchased during the six 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. As of June 30, 2007, we had \$1,539 million available for stock repurchases under our stock repurchase program authorized by the

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Board of Directors in December 2006. In July 2007, the Board 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 \$205 million and \$225 million of cash during the six months ended June 30, 2007 and 2006, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of our stock relative to the exercise price of such options.

Contractual Obligations

We adopted FIN 48 on January 1, 2007 (see Note 1, Summary of significant accounting policies *Recent accounting pronouncements* to the Condensed Consolidated Financial Statements for further discussion). On the date of adoption, the current liabilities for UTBs (net of federal benefit on state taxes) and related accrued interest totaled approximately \$705 million. As of June 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 \$400 million on June 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.

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Item 4. CONTROLS AND PROCEDURES

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

Management determined that, as of June 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.

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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 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.

Israel Bio-Engineering Project Litigation (IBEP)

On June 18, 2007, the U.S. Supreme Court denied IBEP's petition for a writ of certiorari, resulting in a final resolution of this litigation in Amgen's favor.

Average Wholesale Price Litigation

In the Multi-District Litigation (the MDL) Proceeding, the counties filed an amended complaint, and a hearing on the motions to dismiss the amended complaint is set for July 26, 2007.

Commonwealth of Kentucky v. Alpharma, Inc., et al.

The judge has set a trial date of May 15, 2009 for scheduling purposes.

Roche Matters

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

On June 5, 2007, the United States District Court for the District of Massachusetts (the District Court) entered the parties' Joint Stipulation for Dismissal of Amgen's Claim for Declaratory Judgment of Infringement of U.S. Patent No. 5,621,080. During June and July of 2007, the parties filed the following motions for summary judgment:

1. On June 11, 2007, F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH and Hoffman-La Roche, Inc. (collectively, Roche) filed its Motion for Summary Judgment of Non-Infringement of Claim 1 of Patent No. 422 and Claims 9 and 12 of Patent No. 933.
2. On June 11, 2007, Roche filed its Motion for Summary Judgment that Claim 1 of the 422 Patent is Invalid Under 35 U.S.C. § 112.
3. On June 11, 2007, Roche filed its Motion for Summary Judgment that Claim 10 of the 933 Patent is Invalid on the Grounds of Failure to Comply with Claim Differentiation Under § 112, paragraph 4.
4. On June 12, 2007, Roche filed its Motion for Summary Judgment that the Claims of Patents-In-Suit Are Invalid For Double Patenting Over Amgen's 016 Patent by F. Hoffmann-LaRoche LTD, Roche Diagnostics GmbH, Hoffmann LaRoche Inc.

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5. On June 14, 2007, Roche filed its Motion for Summary Judgment that the Asserted Claims of the 933 Patent are Invalid for Indefiniteness and Lack of Written Description.
6. On June 14, 2007, Amgen filed its Motion for Summary Judgment of No Obviousness-Type Double Patenting.
7. On June 15, 2007, Amgen filed its Motion for Summary Judgment of Infringement of 422 Claim 1, 933 Claim 3, and 698 Claim 6.
8. On June 15, 2007, Amgen filed its Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims.
9. On June 20, 2007, Amgen filed its Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled.
10. On June 22, 2007, Roche filed its Motion for Summary Judgment that Claim 7 of Patent No. 5,756,349 is Invalid Under 35 U.S.C. § 112 and is Not Infringed.
11. On June 22, 2007, Amgen filed its Motion for Summary Judgment of No Inequitable Conduct.
12. On July 3, 2007, Roche filed its Motion for Summary Judgment that Claim 1 of 422 is Invalid for Indefiniteness and Lack of Written Description.
13. On July 3, 2007, Roche filed its Motion for Summary Judgment that Amgen is Estopped from Asserting Infringement Under the Doctrine of Equivalents of the Asserted Claims of the 933 and 422 Patents.
14. On July 3, 2007, Roche filed its Motion for Summary Judgment that Amgen is Estopped from Asserting Infringement Under the Doctrine of Equivalents of the Asserted Claims of the 698 and 868 Patents.

On July 3, 2007, the District Court issued a written decision with respect to claim construction. At a July 17, 2007 hearing, the District Court denied from the bench five of Roche's motions for summary judgment, consisting of numbered items 1-5 listed above, relating to non-infringement and invalidity. The Court also denied Amgen's Motion for Summary Judgment of No Inequitable Conduct, item 11 above. The Court has not yet decided the remaining motions, items 6-10 and 12-14. The Court also ruled that Roche's antitrust claim will be tried in December of 2007 after the other claims and the jury trial on the patent case will commence on September 4, 2007 and continue until no later than October 17, 2007.

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

On May 30, 2007, Ariad filed a Motion for Leave to file Amended Counterclaims to assert Additional Claims for infringement of U.S. Patent Nos. 6,150,090 and 5,804,374. Amgen opposed Ariad's motion. The Court scheduled trial for November 2008.

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On May 21, 2007, *Rosenfield v. Amgen Inc. et. al.*, and on June 18, 2007, *Public Employees Retirement Association of Colorado v. Amgen Inc., et. al* securities class action lawsuits were filed against Amgen Inc., Kevin W. Sharer, Willard H. Dere, Richard D. Nanula, Dennis M. Fenton, Roger M. Perlmutter, Brian M. McNamee, George J. Morrow, Edward V. Fritzky, Gilbert S. Omenn and Franklin P. Johnson, Jr., (the Individual Defendants) in the United States District Court for the Central District of California (the California Central District Court). The complaint alleges that Amgen and the Individual Defendants made false statements that resulted in a fraudulent scheme and course of business operated as a fraud or deceit on purchasers of Amgen publicly traded securities in that: (i) they temporarily deceived the investing public regarding Amgen's prospects and business; (ii) they artificially inflated the prices of Amgen's publicly traded securities; and (iii) they caused plaintiffs and other members of the class to purchase Amgen publicly traded securities at inflated prices. The complaint also makes off-label marketing allegations and allegations as to a failure to disclose negative results of clinical studies. Amgen has not been served with the complaint. Plaintiffs seek class certification, compensatory damages, legal fees and other relief deemed proper. All of the individual securities class action lawsuits filed with the California Central District Court will be consolidated and an amended complaint will be filed by August 30, 2007.

Derivative class actions

On May 10, 2007, the derivative lawsuit of *Michael Schreiman v. Amgen Inc. et. al.* was filed in Superior Court of the State of California, Ventura County (the Superior Court) and names Amgen Inc., Kevin W. Sharer, Dennis M. Fenton, Richard D. Nanula, David Baltimore, Frank J. Biondi, Jr., Jerry D. Choate, Frederick W. Gluck, Frank C. Herringer, Gilbert S. Omenn, Judith C. Pelham, J. Paul Reason and Leonard D. Schaeffer, as defendants (the State Defendants). The complaint alleges the same claims and requests the same relief as in three other shareholder derivative complaints previously filed in the Superior Court. The complaint alleges that the State Defendants breached their fiduciary duties, wasted corporate assets, were unjustly enriched and violated the California Corporations Code. Plaintiffs allege that the State Defendants failed to disclose and/or misrepresented results of Aranesp® clinical studies, marketed both Aranesp® and EPOGEN® for off-label uses and that these actions or inactions as well as the Amgen market strategy caused damage to the Company resulting in several inquiries, investigations and lawsuits that are costly to defend. The complaints also allege insider trading by the State 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 June 5, 2007 the *United Food & Commercial Workers Central Pennsylvania and Regional Health & Welfare Fund v. Amgen Inc.*, on June 7, 2007 the *Vista Healthplan Inc. v. Amgen Inc.*, and on June 14, 2007, the *Painters District Council No. 30 Health & Welfare Fund v. Amgen. Inc.* putative class action lawsuits were filed by third-party payors against Amgen in the California Central District Court. In each action, the plaintiff alleges that Amgen marketed its anemia medicines, EPOGEN® and Aranesp®, for off-label uses, or uses that are not approved by the FDA, and claims that, as a result, the plaintiff paid for unwarranted prescriptions. Specifically, the complaints allege that Amgen promoted EPOGEN® and Aranesp® for: treating cancer patients who are not on chemotherapy; treating quality of life symptoms associated with anemia, such as fatigue; and reaching Hb targets above the FDA-approved level. Each plaintiff asserts claims under California's consumer protection statutes and for breach of implied warranty and unjust enrichment and plaintiffs seek to represent a nationwide class of individuals and entities.

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 European Medicines Agency (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.

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), the United States Senate Committee on Finance, private health/science foundations and organizations, medical professionals, including physicians and investigators, and the general public are increasingly concerned about potential or perceived safety issues associated with pharmaceutical and biological products, whether under study for initial approval or already marketed. For example, on March 20, 2007, we received a letter from Chairmen Dingell and Stupak of the House Subcommittee on Oversight and Investigation, Committee on Energy and Commerce posing questions around ESA studies, promotions of ESAs, communications with the FDA and sales to physicians. We also received a letter from the United States Senate Committee on Finance on May 16, 2007, requesting a briefing to discuss the issues and concerns reported in the media as to the marketing and safety of ESAs and our cooperation with the FDA. It has also been reported that Representative Peter Stark, who chairs the House Ways & Means Health Subcommittee, sent a Dear Colleague letter to other members of Congress requesting that they join his quest to overhaul Medicare reimbursement policy to curb ESA overuse due to safety concerns. Further on June 26, 2007, Representative Stark convened a meeting of the House Ways and

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Means Health Subcommittee at which ESRD program changes and bundled payment for dialysis services and drugs, among other topics, were discussed. 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. (See *Before we commercialize and sell any of our product candidates, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*)

Adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand safety labeling for our approved products and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private health organization medical guidelines and reimbursement for our products. (See *Guidelines and recommendations published by various organizations can reduce the use of our products. and Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.*) For example on March 9, 2007, based upon data from our AoC 103 Study, Johnson & Johnson's Correction of Hemoglobin and Outcomes In Renal Insufficiency (CHOIR) study, and preliminary data from the third-party investigator Danish Head and Neck Cancer (DAHANCA) 10 Study, among others, the FDA approved updated safety information, including a boxed warning, in the prescribing information for the class of ESAs, including Aranesp® and EPOGEN®. The boxed warning notes that ESAs, when administered to target a Hb of greater than 12 g/dL: i) increased the risk for death and serious cardiovascular events; ii) shortened time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy; and iii) shortened overall survival and increased deaths attributed to disease progression at four months in patients with metastatic breast cancer receiving chemotherapy. Physicians were advised in the boxed warning to use the lowest dose of ESAs that will gradually increase the Hb concentration to the lowest level sufficient to avoid the need for red blood cell transfusions, and not to exceed 12 g/dL. The European Scientific Advisory Group and the CHMP recently held meetings to review the safety and labeling of ESAs made by us, Johnson & Johnson, Shire and Roche in both the nephrology and oncology settings. We expect labeling changes to apply to all members of the ESA class consistently and expect that the new labels will be announced some time towards the end of 2007. Further, the FDA held a meeting of the ODAC on May 10, 2007, at which the panel discussed the safety/efficacy profile of ESAs, including Aranesp® and EPOGEN®. (See *The results of the May 10, 2007 ODAC panel meeting on ESAs are likely to result in the FDA requiring us to perform additional clinical trials and/or change the labeling of our ESAs.*)

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 metastatic colorectal cancer. The PACCE trial investigated a treatment regimen that used dual biologics combined with oxaliplatin- or irinotecan-based chemotherapy. 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 had previously informed investigators and regulatory authorities about safety information from a planned interim safety analysis of the PACCE trial which showed an increased incidence of grade 3 severe events of diarrhea, dehydration and infections in the Vectibix™-treated patients and additionally an increased incidence of pulmonary embolism was observed in patients who received Vectibix™ compared with those who did not. We are in continuing discussions with the FDA with respect to the Vectibix™ label, and expect to provide

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additional prominence to data from the PACCE trial. The language is still in development, discussions with the FDA are on-going and any label change is subject to FDA approval. Further, on May 25, 2007, the CHMP adopted a negative opinion with respect to the approval of Vectibix™ in the EU to treat patients with metastatic colorectal cancer whose disease has progressed on or following all standard chemotherapy regimens. In accordance with European regulations, we have requested re-examination of the CHMP opinion as part of the EU regulatory process.

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, we previously initiated a voluntary recall of the Neulasta® SureClick pre-filled pen in Europe because of the potential risk to patients of receiving an incomplete dose and we have previously 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. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

If we or others identify side effects or other safety concerns before or after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, reformulation of our products may be required or other risk management activities may be imposed by regulators, additional clinical trials may be required, changes in labeling of our products, changes in guidelines and reimbursement and changes to or re-approvals of our manufacturing facilities may be required, any of which could have a material adverse effect on sales of the affected products and on our business and results of operations. (See *Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.*) Regulatory agencies such as the FDA could require us to engage in risk management activities, 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. For example, the Vectibix prescribing information includes a boxed warning from the FDA on dermatologic toxicities and severe infusion reactions as part of an evolving FDA labeling to the anti-epidermal growth factor receptor (EGFr) class. 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

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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.

Any significant concerns raised about the safety or efficacy of our products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to our manufacturing processes or to seek re-approval of our manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. The labeling of a new product, a revision of product labeling or the regulatory actions described above could be required even if there is no clearly established connection between the product and the safety or efficacy concerns that have been raised. If the labeling of a new product, a revision of product labeling or the regulatory actions described above resulted in decreased use of our products, it could have a material adverse effect on sales of the affected products and on our business and results of operations.

In addition, if regulatory authorities determine that we or our licensor or partner conducting R&D activities on our behalf have not complied with regulations in the R&D of a product candidate, new indication or information to support a current indication, then they may not approve the product candidate and we will not be able to market and sell it. If we were unable to market and sell our products or product candidates, our business and results of operations would be materially and adversely affected.

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

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought. The results of these clinical trials are used as the basis to obtain regulatory approval from government authorities such as the FDA. Clinical trials are experiments conducted using our product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate and therefore, we may spend as much as several years completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals and associated delays in product candidates reaching the market. In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some Central and South American countries either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to

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adequately manage our increasingly larger, more 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 or prohibit regulatory approval of our product candidates or additional indications for our currently approved products, or may render the product candidate commercially infeasible. Additionally, adverse events or results from clinical trials or studies performed by us or by others may expand safety labeling for our approved products and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement of our products. (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 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.*) 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 have 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. Based on current business trends, we expect to see further growth in R&D expense in 2007, but not to the same extent experienced in 2006, in order to support the increased number and expense of studies to advance our late-stage pipeline, including previously initiated mega-trials, as well as the continued advancement of earlier stage compounds. However, as a result of recent regulatory and legislative challenges, we have and will continue to assess the optimal level of our R&D investment. To the extent future sales are negatively impacted as a result of these challenges, we may be required to 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 results of the May 10, 2007 ODAC panel meeting on ESAs are likely to result in the FDA requiring us to perform additional clinical trials and/or change the labeling of our ESAs.

On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESAs, including Aranesp[®] and EPOGEN[®]. The ODAC is an advisory committee of external experts who advise the FDA about the safety and efficacy of drug

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products for use in treating cancer patients. This committee is advisory only and FDA officials are not bound or limited by its recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

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

Fifteen of the panel members voted to recommend additional restrictions on ESA labels;

The panel voted unanimously to recommend additional clinical trials be conducted to more clearly define the benefits and risks associated with the use of ESAs;

Twelve of the panel members voted to recommend additions to ESA labels to state that ESAs are not indicated for use in specific tumor types;

Fifteen of the panel members voted to recommend a defined Hb level in asymptomatic patients for initiation of treatment with ESAs; and

Sixteen panel members voted to recommend changes to ESA labels recommending discontinuation of ESA therapy following the completion of a chemotherapy regimen and reevaluation of the degree of anemia with subsequent chemotherapy regimen.

However, eleven of the seventeen panel members voted against recommending lowering the upper limit of the Hb range in the current ESA labels.

While the ODAC recommended that more restrictions be added to ESA labels and that additional clinical trials be conducted by companies with currently approved ESAs, including us, no specific restrictions or studies were recommended at the ODAC meeting. Although not required, the FDA will likely take into consideration the recommendations by the ODAC and will decide what updates to the ESA labels are necessary and whether additional clinical trials for ESAs should be conducted and how those trials should be designed. The further restrictions to the prescribing information of the ESA labels may include i) limiting use of ESAs in certain tumor types, ii) establishment of a threshold Hb level before therapy with ESAs may be initiated, and iii) limiting when and how long post-chemotherapy treatment ESAs should be used. We are in discussions with the FDA following the ODAC meeting and are working to arrive at new class labeling for ESAs in the oncology setting in the United States.

Although we cannot predict what action the FDA may take or the extent or impact of any such action, any restrictions to the labels of Aranesp[®] and EPOGEN[®] described above that may be required by the FDA are likely to negatively impact healthcare provider prescribing behavior, use of our ESA products, regulatory or private health organization medical guidelines, reimbursement and sales for our ESA products, which could have a material adverse effect on our business and results of operations. We believe that the results of the ODAC meeting have resulted in oncologists exercising increasing caution with respect to the use of ESAs in certain therapeutic areas and the acceleration of further reimbursement constraints by payers in anticipation of regulatory action, both of which could have a material adverse effect on the use and sales of Aranesp[®] and our business and the results of operations. In addition, the results of the ODAC meeting and activities by the FDA related to ESA safety may influence the review by the European Scientific Advisory Group and the CHMP of the safety and labeling of the class of ESAs. If the CHMP were to add restrictions to the labels, it is likely to have a negative impact on the use, reimbursement and sales of Aranesp[®] in Europe. Further, on May 14, 2007,

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CMS issued its Proposed NCD following the close of its NCA and review of data and comments submitted as part of the NCA which if finalized in its proposed or a similar form would have a material adverse effect on the use, reimbursement and sales of Aranesp[®], and our business and results of operations. (See *Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.*) The ODAC's recommendation for additional clinical trials of ESAs 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 effect 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.*) Further, the FDA has stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease. We cannot predict what action the FDA may take as a result of such committee meeting.

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. We are in the process of evaluating 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.*) In addition, Senator Charles Grassley from the United States Senate Finance Committee sent letters to the FDA, CMS and to us expressing interest in the use of ESAs in cancer and ESRD patients and has requested meetings with each of the three. To the extent that there is resulting legislation or changes in CMS or FDA policy as a result of Senator Grassley's concerns, such changes could have a material or adverse effect on the use of our ESA products.

Most patients receiving Aranesp[®], Neulasta[®] and NEUPOGEN[®] for approved indications are covered by both government and private payer healthcare programs. Government healthcare programs are governed by the MMA which was enacted into law in December 2003 and became effective January 1, 2005. Since January 1, 2005, in the physician clinic setting and since January 1,

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2006, in the hospital outpatient setting, Aranesp[®], Neulasta[®] and NEUPOGEN[®] have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its ASP (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product's ASP is calculated on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP for Aranesp[®] that will be in effect for the third quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp[®] from June 1, 2006 through May 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 had to revise our interpretation and methodology of such interpretation to reflect such calculation changes both prospectively and retroactively. Partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN[®] was reduced for the third quarter of 2007. Prior to January 1, 2006, Medicare's hospital OPPTS, which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized the AWP as the basis of Medicare Part B payment for covered outpatient drugs and biologics administered in the hospital outpatient setting. From 2003 to 2005, CMS applied an equitable adjustment such that the Aranesp[®] reimbursement rate was based on the AWP of PROCRI[®], Johnson & Johnson's recombinant human erythropoietin product marketed in the United States, using a dose conversion ratio. In 2006 and 2007, CMS did not apply an equitable adjustment to tie the reimbursement rate for Aranesp[®] to PROCRI[®]. On July 16, 2007, CMS released its 2008 OPPTS proposed rule that did not propose to apply an equitable adjustment to the reimbursement rate for Aranesp[®] to PROCRI[®], however, CMS has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp[®] in future years.

In the United States, dialysis providers are primarily reimbursed for EPOGEN[®] by the federal government through the ESRD Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement rate is established by federal law and is monitored and implemented by CMS. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN[®] and Aranesp[®], is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. On May 18, 2007, CMS released a notice, based on its ongoing assessment for payment of Part B drugs, that there would be a single payment limit for Epoetin alfa (EPOGEN[®] and PROCRI[®]) beginning in the third quarter of 2007. Further, on July 24, 2007, the U.S. House of Representatives Committees on Ways & Means and Energy & Commerce released the Proposed CHAMP Legislation which would reduce ESA payment to large dialysis organizations to ASP+2% in 2008 and 2009. Although we cannot predict the payment levels of EPOGEN[®] in future quarters, a decrease in the reimbursement rate for EPOGEN[®] may have a material adverse effect on our business and results of operations.

Since April 1, 2006, the ESRD Program reimbursement has been subject to a revised HMA-PM, a Medicare payment review mechanism used by CMS to audit EPOGEN[®] and Aranesp[®] (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. This policy, EMP, was revised, effective October 1, 2006, to provide that if a patient's Hb is greater than 13 g/dL, providers are instructed to reduce the patient's EPOGEN[®] and Aranesp[®] dose and report this reduction on claims using a coding

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modifier. If the provider does not reduce the patient's EPOGEN[®] and Aranesp[®] dose and the provider does not submit medical documentation to support maintaining a patient's Hb above 13 g/dL, reimbursement will be reduced to the level it would have been had the provider reduced dosage by 25%. On July 20, 2007, CMS published revisions to the EMP, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient's Hb is above 13 g/dL for three or more consecutive months and a reduction of the monthly dosing limits to 400,000 IUs of EPOGEN[®], from 500,000 IUs, and to 1,200 mcgs of Aranesp[®], from 1,500 mcgs.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005 and 2006 were not significantly impacted by the reimbursement changes resulting from the MMA. While we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products and we cannot estimate the full impact of the MMA on our business, we believe that it is likely to be significant to our business in 2007. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For example, the MMA required a demonstration project of a bundled payment system for dialysis, including separately billable drugs and EPOGEN[®]. The demonstration project was scheduled to start in January 2006, but has been delayed with no announced start date. However, the Proposed CHAMP Legislation would bundle payment to LDOs for dialysis services, including but not limited to composite rate services, ESAs, other drugs and labs common in dialysis, and home dialysis training beginning in 2010. The Proposed CHAMP Legislation also requires that aggregate payment be reduced by 4% in 2010, and allows CMS four years to phase in bundling to non-LDO providers. 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, 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. As it is premature to speculate on how CMS will finalize the proposed methodology, we cannot predict the potential impact this revised methodology may have on our business.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a NCA which is generally CMS' first step toward developing a NCD. Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or

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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 chemotherapy-induced anemia;

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 criteria:

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;

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 > 1g/dL (hematocrit > 3%). However, if after the first 4 weeks the Hb is > 10g/dL, ESA treatment is not covered;

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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;

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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 criteria 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 NCD, including MDS.

The Decision Memorandum sets the coverage policy for Medicare and other government beneficiaries who account for approximately 50% of cancer patients receiving Aranesp®. We are in continuing discussions with CMS regarding the Decision Memorandum and are in the process of evaluating the impact the Decision Memorandum will have on the use, reimbursement and sales of Aranesp® and currently believe that the majority of cancer patients who receive treatment with Aranesp® are initiated at Hb levels above 10g/dL and maintain Hb levels above 10g/dL with continued therapy. Given that the Decision Memorandum contains a coverage restriction for Hb levels greater than 10g/dL, we believe that such restriction will change the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, dose and duration of therapy. We expect this restriction on reimbursement of ESAs in the Decision Memorandum would have a material adverse effect on our sales of Aranesp®, and our business and results of operations. Additionally, we believe that the Decision Memorandum may be followed and implemented by some private payers.

In addition, the FDA has stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in renal disease. We cannot predict what action the FDA may take as a result of such committee meeting or what impact it may have on our sales of our ESAs and on our business. Although the revisions to the EMP 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 the Proposed NCD for treatment of anemia in oncology with ESAs, would negatively effect 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. We are currently in the process of further evaluating the impact of the DRA and are uncertain as to the potential full 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 price concessions in the Medicare Physician Fee Schedule Proposed Rule for 2008. Given its recent release, we are in the process of evaluating what impact the final rule will have on our business.

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If, and when, reimbursement rates or availability for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales, which could have a material adverse effect on us and our results of operations. For example, the use of EPOGEN[®] in the United States in connection with treatment for ESRD is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration (HCFA), instituted a reimbursement change for EPOGEN[®] which materially and adversely affected our EPOGEN[®] sales until the policies were revised. In addition, following the update to the ESA labels, nearly all Medicare contractors dropped reimbursement for Aranesp[®] for AoC. (See *Guidelines and recommendations published by various organizations can reduce the use of our products.*) Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain and a failure to demonstrate clear economic value associated with the use of a new therapeutic product as compared to existing therapeutic products or practices may result in inadequate or no reimbursement. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our products are and will be affected by government and private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and results of operations.

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies' patents. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patents that they may claim prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude or delay commercialization of products. We are currently, and in the future may be, involved in patent litigation. However, a patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market and we may be subject to competition during certain periods of litigation. For example, Roche is developing a peg-EPO molecule for which they have filed a BLA with the FDA and which Roche announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA[®] for the treatment of anemia associated with chronic renal failure including patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the CRDAC has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007. On November 8, 2005, we filed a lawsuit against Roche for patent infringement of six of our U.S. patents. In addition, on April 11, 2006, we filed a complaint with the U.S. International Trade Commission (ITC) requesting that the ITC institute an investigation of Roche's importation of peg-EPO. This lawsuit and matter is described in Item 1. Legal Proceedings *Roche Matters*. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007,

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upon regulatory approval, despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents. (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 expiry in the EU and our principal European patent relating to G-CSF has expired.

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

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

⁽²⁾ An application for patent term extension has been submitted and is currently pending in the United States.

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

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Neulasta® and NEUPOGEN®. While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with or may compete with the following products:

Product	Company	Countries	Timing for Launch
EPREX®	Johnson & Johnson	EU	Launched
Neorecormon®	Roche	EU	Launched
Dynepo™	Shire	Germany, UK	Launched
		Italy, Spain, France	Q3 & Q4 2007
Biosimilar Erythropoietin	Sandoz	Germany, UK	Late Q3/Early Q4 2007
		Others	2008
Biosimilar Erythropoietin	Hospira/Stada	Germany, UK	Q4 2007
		Others	2008
peg-EPO	Roche	Germany, UK, Netherlands, Switzerland	August/September 2007 (approved by European Commission on July 26, 2007)

Although, 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, biosimilar products or other products that effectively compete with our products 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.

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*

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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 April 12, 2007 the NKF distributed to the nephrology community the draft of the KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia Management in Chronic Kidney Disease. The draft guideline was open for comments from the community until April 30, 2007 prior to being finalized and published. The NKF's Anemia Working Group initiated a review of the existing guidelines following recent clinical developments, such as the publication of the results of the CHOIR and other trials. In the proposed guideline, the group recommends what factors should be considered in selecting a Hb target and states that the selected Hb target should generally be in the range 11.0 to 12.0 g/dL. Like others in the nephrology community, we are currently reviewing the new guideline and cannot predict what impact the revised guideline will have on our business but anticipate that CMS will likely consider the KDOQI guidelines as it undertakes its review of the EMP.

The GAO issued a report on December 5, 2006 recommending that ESRD drugs and biologics, including EPOGEN[®], be bundled into the Medicare dialysis composite payment rate. A day after the GAO report was released, the House Ways and Means Committee held a hearing that focused on EPOGEN[®], including discussion of the delay in the MMA mandated bundled payment demonstration, and the GAO report and recommendation. Although Congress did not take legislative action in 2006 to require bundling, the Proposed CHAMP Legislation would bundle payment for all dialysis services, including but not limited to ESAs, other drugs and labs common in dialysis, beginning in 2010.

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 an aggressive R&D program. 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

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the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness

the product candidate had harmful side effects in humans or animals

the necessary regulatory bodies, such as the FDA, did not approve our product candidate for an intended use

the product candidate was not economical for us to manufacture and commercialize

other parties have or may have proprietary rights to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all

the product candidate is not cost effective in light of existing therapeutics

we and certain of our licensors or partners may fail to effectively conduct clinical development or clinical manufacturing activities

the regulatory pathway to approval for product candidates is uncertain or not well-defined

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

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF) and Glial Cell Lined-Derived Neurotrophic Factor (GDNF). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig's Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson's disease did not meet the primary study endpoint upon completion of nine months of the double-blind treatment phase of the study even though a small phase 1 pilot investigator-initiated open-label study over a three year period appeared to result in improvements for advanced Parkinson's disease patients. Subsequently, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson's disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials and, as a part of that decision and based on thorough scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See *Difficulties, disruptions or delays in*

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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 impacted by government investigations or litigation.

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, our business operations, government requests for information and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Item 1. Legal Proceedings and are updated as required in subsequently filed Form 10-Qs. Litigation is inherently unpredictable, and the outcome can result in excessive verdicts and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our results of operations (in the case of monetary damages, in the period in which such damages are incurred).

The federal government, state governments and private payers are investigating, and many have filed actions against numerous pharmaceutical and biotechnology companies, including Amgen and Immunex, now a wholly owned subsidiary of ours, alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated AWP, which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and other payers to healthcare providers who prescribed and administered those products. A number of these actions have been brought against us and/or Immunex. Additionally, a number of states have pending investigations regarding our Medicaid drug pricing practices and the U.S. Departments of Justice and Health and Human Services have requested that Immunex produce documents relating to pricing issues. Further, certain state government entity plaintiffs in some of these AWP cases are also alleging that companies, including ours, were not reporting their best price to the states under the Medicaid program. These cases and investigations are described in Item 1. Legal Proceedings *Average Wholesale Price Litigation* and are updated as required in subsequent Form 10-Qs. Other states and agencies could initiate investigations of our pricing practices. A decision adverse to our interests on these actions and/or investigations could result in substantial economic damages and could have a material adverse effect on our results of operations in the period in which such liabilities are incurred.

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

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

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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 operating results may fluctuate from period to period for a number of reasons. For example as a result of various regulatory, legislative and competitive challenges facing certain of our principal products, in particular our ESA products, we decided to make changes to various ongoing capital projects. These decisions were primarily focused on rationalizing our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet product demand. As a result of these decisions, we recorded charges for asset impairments and related costs of \$289 million during the three months ended June 30, 2007. In addition, depending in part on the outcome of certain future developments, we may be required to take further actions to reduce costs. As a result we may incur additional related charges in the near term, certain of which may be material. Further, although we are moderating our operating expense growth in response to these challenges, some of our operating expenses are fixed in the short term and cannot be reduced within a short period of time to offset unplanned or unexpected reductions in revenue. Our ability to achieve cost savings within the timeframes that may be required is subject to significant economic, competitive and other uncertainties, some of which are beyond our control. Because of this, even a relatively small revenue shortfall may cause a period's results to be below our expectations or projections. A revenue shortfall could arise from any number of factors, some of which we cannot control. For example, as a result of the above noted challenges facing our principal products, 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 June 30, 2007, the trading price of our common stock has ranged from a high of \$76.50 per share to a low of \$53.68 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

actual or anticipated product supply constraints

business development or licensing activities

product development or other business announcements by us or our competitors

regulatory matters or actions

changes in our product pricing strategies

lower than expected demand for our products

changes in wholesaler buying patterns

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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

broader economic, industry and market trends unrelated to our performance

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

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

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

Certain raw materials necessary for commercial manufacturing and formulation of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for formulation, fill and finish of our products are provided by single-source unaffiliated third-party suppliers. Certain of these raw materials, medical devices and components are the proprietary products of these unaffiliated third-party suppliers and, in some cases, such proprietary products are specifically cited in our drug application with the FDA so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the FDA approved that other supplier. We would be unable to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including:

regulatory requirements or action by the FDA or others

adverse financial developments at or affecting the supplier

unexpected demand for or shortage of raw materials, medical devices or components

labor disputes or shortages, including the effects of an avian or pandemic flu outbreak, or otherwise

failure to comply with our quality standards which results in quality failures, product contamination and/or recall

These events could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. For example, we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility without impact on our ability to supply these products. However, we may experience these shortages in the future resulting in delayed shipments, supply constraints and/or stock-outs of our products.

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Also, certain of the raw materials required in the commercial manufacturing and the formulation of our products are derived from biological sources, including mammalian tissues, bovine serum and HSA. We are investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically-sourced raw materials as such raw materials may be subject to contamination and/or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially.

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 and Juncos, Puerto Rico (See *We 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

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timing and actual number of production runs

production success rates and bulk drug yields

timing and outcome of product quality testing

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

We manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Although we have obtained regulatory approval for our marketed products, these products and our manufacturing processes and those of our third-party contract manufacturers must undergo a potentially lengthy FDA or other regulatory approval process and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build and license a new manufacturing plant and it can take longer than three years to qualify a new contract manufacturer. In order to maintain adequate supply to keep up with demand for our products, mitigate risks associated with nearly all of the bulk manufacturing for Aranesp[®], Neulasta[®] and NEUPOGEN[®] and the vast majority of our formulation, fill and finish operations located in Puerto Rico, and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at appropriate production capacity over the next few years, expand our use of third-party contract manufacturers and maintain a state of regulatory compliance. Key manufacturing projects include: 1) expansion of existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate denosumab; 2) expansion of our Fremont, CA facility to support future product launches; and 3) construction, qualification and licensure of new formulation, fill and finish facilities at our Puerto Rico site.

If regulatory authorities determine that we or our third-party contract manufacturers or third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or our third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and third-party service providers are subject to FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and service providers may not be available on a timely basis or at all. For example, we are dependent upon a single FDA approved third-party contract manufacturer for the formulation, fill and finish of Vectibix[™]. If we or our third-party contract manufacturers and third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us for any reason, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. If we are unable to manufacture, market and sell our products, our business and results of operations would be materially and adversely affected.

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

We currently perform all of the formulation, fill and finish for EPOGEN[®], Aranesp[®], Neulasta[®] and NEUPOGEN[®], some formulation, fill and finish operations for ENBREL, and nearly all of the bulk manufacturing for Aranesp[®], Neulasta[®] and NEUPOGEN[®] at our manufacturing facility in Juncos, Puerto Rico. Our global supply of these products is significantly dependent on the uninterrupted and efficient operation of this facility. A number of factors could adversely affect our formulation, fill and finish operations, including:

power failures

breakdown, failure or substandard performance of equipment

improper installation or operation of equipment

labor disputes or shortages, including the effects of an avian or pandemic flu outbreak, or otherwise

inability of third-party suppliers to provide raw materials and components

natural or other disasters, including hurricanes

failures to comply with regulatory requirements, including those of the FDA

For example, this facility in Puerto Rico has experienced manufacturing component shortages and has had evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output. Although these experiences in Puerto Rico have not impacted our ability to supply product in the past, the same or other problems may result in our being unable to supply these products, which could adversely affect our product sales and operating results materially. Although we have obtained limited insurance to protect against certain business interruption losses, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. The extent of the coverage of our insurance could limit our ability to mitigate for lost sales and could result in such losses adversely affecting our product sales and operating results materially. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales.*)

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

We currently produce a substantial portion of annual ENBREL supply at our Rhode Island manufacturing facilities. 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

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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 the Rhode Island facilities' 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 facilities are 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 facilities, 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 facilities. If third-party formulation, fill and finish manufacturers are unable to provide sufficient capacity or are otherwise unable to provide services to us, the supply of ENBREL could be adversely affected materially.

Under a collaboration and global supply agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by Amgen's Rhode Island manufacturing facilities, 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. Aranesp® and EPOGEN® may also face competition in the U.S. from Roche's peg-EPO for which they have filed a BLA with the FDA and which Roche announced on May 18, 2007 that the FDA had issued an approvable letter for MIRCERA® for the treatment of anemia.

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associated with chronic renal failure including patients on dialysis and patients not on dialysis. Roche stated that it has received a draft label from the FDA and expects the label to be finalized after the CRDAC has issued its recommendations on the entire class of ESAs. The FDA stated that it intends to hold a joint meeting of the CRDAC and the Drug Safety and Risk Management Advisory Committee on September 11, 2007, to evaluate the safety data on ESA use in the renal disease. According to Roche's public statements, they expect to launch the molecule in the U.S. nephrology segment in 2007, upon regulatory approval, despite our ongoing lawsuit and their acknowledgement of our U.S. erythropoietin patents. (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, Aranes[®] competes or will potentially compete in the EU with:

Product	Company	Countries	Timing for Launch
EPREX [®]	Johnson & Johnson	EU	Launched
Neorecormon [®]	Roche	EU	Launched
Dynepo [™]	Shire	Germany, UK	Launched
		Italy, Spain, France	Q3 & Q4 2007
biosimilar erythropoietin	Sandoz	Germany, UK	Late Q3/Early Q4 2007
		Others	2008
biosimilar erythropoietin	Hospira/Stada	Germany, UK	Q4 2007
		Others	2008
peg-EPO	Roche	Germany, UK,	August/September 2007
		Netherlands,	(approved by European Commission on July 26,
		Switzerland	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 U.S. to treat patients with metastatic colorectal cancer, competes with Imclone's Erbitux[®]. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.*) Our products may compete against products that have lower prices, equivalent or superior performance, are easier to administer or that are otherwise competitive with our products.

Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. We believe that as these patents have expired, some companies have and other companies may receive approval for and market biosimilar products to compete with our products in the EU, presenting additional competition to our products. Although we cannot predict with certainty when the first G-CSF biosimilar products could appear on the market in the EU, we expect that the first biosimilar G-CSF product may be approved in the EU some time in 2008 and could be available shortly thereafter, and that it would compete with Neulasta[®] and NEUPOGEN[®]. We cannot predict whether or to what extent the entry of biosimilar products or other competing products would impact future Aranes[®], Neulasta[®] or NEUPOGEN[®] sales in the EU. Our inability to compete effectively could reduce sales which could have a material adverse effect on our results of operations.

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In 2006, the EMEA developed and issued final regulatory guidelines related to the development and approval of biosimilar products. The final guidelines included clinical trial guidance for certain biosimilar products including erythropoietins and G-CSFs, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In the United States, there currently is no legal approval pathway for the approval of BLAs for 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 have grown rapidly, and if we fail to adequately manage that growth our business could be adversely impacted.

We have had an aggressive growth plan that has included substantial and increasing investments in R&D, sales and marketing and facilities. We plan to continue to grow, although not to the same extent as seen in recent years. However, given the recent challenges around ESAs and certain of our other products, 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 larger and more geographically diverse organization

we will need to manage and execute larger, more complex and increasingly global clinical trials

we will need to retain our highly qualified management, scientific, manufacturing and sales and marketing personnel

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we may need to significantly expand our sales and marketing resources to launch late-stage product candidates

we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply

we will need to start up our new manufacturing facilities and enter into and manage new third-party contract manufacturing arrangements

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 manage our growth in these ways or others, such failure could result in a material adverse effect on our business and results of operations.

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

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

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

Our marketing of ENBREL will be dependent in part upon Wyeth.

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

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

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, is subject to extensive federal and state regulation in the United States and to extensive regulation in foreign countries. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.* and *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales.*) While we have developed and instituted a corporate compliance program based on what we believe to be current best practices, we cannot assure you that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. If we fail to comply with any of these regulations and/or laws a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

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

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

The EITF recently considered whether the accounting for convertible debt securities that requires or permits settlement in cash either in whole or in part upon conversion (*cash settled convertible debt securities*) should be changed, but was unable to reach a consensus and discontinued deliberations on this issue. Subsequently, in July 2007, the FASB voted unanimously to reconsider the current accounting for cash settled convertible debt securities, which includes our convertible debt securities. The FASB indicated it will expose 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 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 such a security would be bifurcated and accounted for separately in a manner that reflects the issuer's economic interest cost. While the effect on us of this expected proposal cannot be quantified unless and until the FASB finalizes its guidance, we expect that under this proposal, 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. This 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. Therefore, if the expected 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.

We cannot predict the outcome of the expected FASB proposal. 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.

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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 potential recognition of impairment in the carrying value, if any, could have a material and adverse affect 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 June 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 June 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)
April 1 - April 30	9,127,993	\$ 63.14	9,125,000	\$ 5,426,258,487
May 1 - May 31	64,799,703(2)	59.98	64,798,835(2)	1,539,425,047
June 1 - June 30	670	56.52		1,539,425,047
	73,928,366(3)	60.37	73,923,835(3)	

- (1) In December 2006, the Board authorized us to repurchase up to \$5.0 billion of common stock. In July 2007, the Board authorized us to repurchase up to an additional \$5.0 billion of common stock.
- (2) 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 (see Note 5, 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.

Table of Contents**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

- (a) The Company held its Annual Meeting of Stockholders on May 9, 2007.
- (b) Omitted pursuant to Instruction 3 to Item 4 of Form 10-Q.
- (c) The five items voted upon at the meeting were: (i) to elect four directors to a three year term of office expiring at the 2010 Annual Meeting of Stockholders (Item One), however, if Items 3 and 4 below to eliminate the classification of the Board are approved by the required vote of stockholders, then the terms of all directors, including those elected at the Annual Meeting, will end at the next annual meeting of stockholders; (ii) to ratify the selection of Ernst & Young LLP as the independent registered public accounting firm for the Company for the year ending December 31, 2007 (Item Two); (iii) to approve amendments to the Amended Certificate of Incorporation to eliminate the classification of the Board of Directors (Item Three); (iv) to approve amendments to the Bylaws to eliminate the classification of the Board of Directors (Item Four); and the Stockholder Proposals (Item Five), which consisted of Stockholder Proposal #1 relating to an animal welfare policy, and Stockholder Proposal #2 relating to a sustainability report.

The voting was as follows:

	In Favor	Against	Abstain	Broker Non-Votes
Item One				
Mr. Frank J. Biondi, Jr.	969,940,658	34,563,451		
Mr. Jerry D. Choate	990,204,732	14,736,532		
Mr. Frank C. Herring	993,038,873	11,894,007		
Dr. Gilbert S. Omenn	985,847,698	18,691,445		
Item Two	988,446,056	17,666,059	7,784,432	
Item Three	994,381,905	10,202,877	9,311,765	
Item Four	994,072,063	10,331,811	9,492,673	
Item Five				
Stockholder Proposal #1	41,625,406	629,365,767	128,873,895	214,031,479
Stockholder Proposal #2	77,457,888	603,385,504	119,021,476	214,031,679

All nominees to the Board of Directors were declared to have been elected as directors and, because stockholders also approved Items Three and Four eliminating declassification of the Board of Directors, will hold office until the 2008 Annual Meeting of Stockholders. Items Two, Three and Four were declared to have been approved. With respect to Item Five, Stockholder Proposals #s 1 and 2 were declared to have not been approved.

- (d) Not applicable.

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Item 5. OTHER INFORMATION

Due to the various challenges faced by certain of our key products, in particular our ESA products, which are discussed in the Overview section of the MD&A in Part I herein, we have commenced a global review of the Company's business plans to identify opportunities to improve our cost structure in response to any resulting declines in revenues. As part of these efforts and in connection with the preparation of our financial statements for the three months ended June 30, 2007, we have decided to make changes to various ongoing capital projects. These decisions were 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 decisions included a re-scoping of our 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, the Company recorded charges for asset impairment of \$286 million and related costs of \$3 million during the three months ended June 30, 2007. These charges are recorded as other operating expenses in the Condensed Consolidated Statement of Operations.

Item 6. EXHIBITS

- (a) *Reference is made to the Index to Exhibits included herein.*

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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: August 9, 2007

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

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AMGEN INC.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
3.2*	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007).
3.3*	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007).
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. (As Amended May 24, 2007).
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	Officers 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	Officers 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.)

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- 4.11 Indenture, dated as of August 4, 2003, between Amgen Inc. and JPMorgan Chase Bank. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
- 4.12 Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 4.13 Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 4.14 Officers Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 4.15 Registration Rights Agreement, dated as of November 18, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 4.16 Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
- 4.17 Indenture, dated as of May 6, 2005, between Amgen Inc. and LaSalle Bank National Association. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
- 4.18 Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006, between Amgen Inc. and JPMorgan Chase Bank, N.A., as trustee (including form of 0.125% Convertible Senior Note due 2011). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
- 4.19 Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 between Amgen Inc. and JPMorgan Chase Bank, N.A., as trustee (including form of 0.375% Convertible Senior Note due 2013). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
- 4.20 Registration Rights Agreement, dated as of February 17, 2006, among Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JPMorgan Securities Inc., Lehman Brothers Inc., Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
- 4.21 Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
- 4.22 The instruments defining the rights of holders of the long-term debt securities of Abgenix, Inc. and its subsidiaries are omitted pursuant to section (b)(4)(iii)(A) of Item 601 of Regulation S-K. Amgen Inc. hereby agrees to furnish copies of these instruments to the Securities and Exchange Commission upon request.
- 4.23 Officers Certificate of Amgen Inc. dated as of May 30, 2007, including forms of the Company's Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
- 4.24 Registration Rights Agreement, dated as of May 30, 2007, among Amgen Inc. and Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., J.P. Morgan Securities Inc. and Lehman Brothers Inc. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
- 10.1+ Amended and Restated 1991 Equity Incentive Plan (As Amended and Restated December 5, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)

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- 10.2+* Amgen Inc. Director Equity Incentive Program (As Amended and Restated March 7, 2007)
- 10.3+ Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements for Amgen Inc. Director Equity Incentive Program. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.4+ Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (As Amended and Restated December 5, 2005) and Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.5+ Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of December 5, 2005) and Forms of Stock Option Grant Agreements. (Filed as exhibits to Form 8-K on December 8, 2005 and incorporated herein by reference.)
- 10.6+ Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated April 1, 2006). (Filed as an exhibit to Form S-8 on April 3, 2006 and incorporated herein by reference.)
- 10.7+ Amgen Inc. Amended and Restated Employee Stock Purchase Plan. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
- 10.8+ First Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan (As Amended and Restated July 12, 2005). (Filed as an exhibit to Form 8-K on July 14, 2005 and incorporated herein by reference.)
- 10.9+ Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 12, 2004 and incorporated herein by reference.)
- 10.10+ First Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2005). (Filed as an exhibit to Form 8-K on October 20, 2005 and incorporated herein by reference.)
- 10.11+ Second Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated July 1, 2006). (Filed as an exhibit to Form 8-K on May 16, 2006 and incorporated herein by reference.)
- 10.12+ Third Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2007). (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+ 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.)
- 10.14+ 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.)
- 10.15+ 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.)
- 10.16+ 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.)
- 10.17+ 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.)

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- 10.18+ 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.)
- 10.19+ 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.)
- 10.20+ 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.)
- 10.21+ Eight 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.)
- 10.22+ Amgen Inc. Executive Incentive Plan. (Filed as Annex G to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
- 10.23+ 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.)
- 10.24+ 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.)
- 10.25+ 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.)
- 10.26+ 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.)
- 10.27+ 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.)
- 10.28+ 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.)
- 10.29+* Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated July 9, 2007).
- 10.30+* Form of Performance Unit Agreement to the Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated July 9, 2007).
- 10.31+ 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.)
- 10.32+ 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.)
- 10.33+ 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.)
- 10.34+ 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.)
- 10.35+ 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.)

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- 10.36+ 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.)
- 10.37+ 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.)
- 10.38+ 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.)
- 10.39+ 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.)
- 10.40+ Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between Amgen and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
- 10.41 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.)
- 10.42 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.)
- 10.43 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.)
- 10.44 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.)
- 10.45* Amendment No. 13 to the Shareholders Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom).
- 10.46 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.)
- 10.47 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.)
- 10.48 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.)

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- 10.49 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.)
- 10.50 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.)
- 10.51 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.)
- 10.52 ENBREL[®] Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated as of November 5, 1998 (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Annual Report on Form 10-K for the year ended December 31, 1998 on March 23, 1998 and incorporated herein by reference.)
- 10.53 Amendment No. 1 to the ENBREL[®] Supply Agreement, dated June 27, 2000, among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Form 10-Q for the quarter ended June 30, 2000 on August 11, 2000 and incorporated herein by reference.)
- 10.54 Amendment No. 2 to the ENBREL[®] Supply Agreement, dated June 3, 2002, among Immunex Corporation, Wyeth (formerly known as American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
- 10.55 Amendment No. 3 to the ENBREL[®] Supply Agreement, dated December 18, 2002, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2002 on March 10, 2003 and incorporated herein by reference.)
- 10.56 Amendment No. 4 to the ENBREL[®] Supply Agreement, dated May 21, 2004, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
- 10.57 Amendment No. 5 to the ENBREL[®] Supply Agreement, dated August 30, 2005, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation) and Boehringer Ingelheim Pharma KG. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2005 on November 9, 2005 and incorporated herein by reference.)
- 10.58 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.)

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- 10.59 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.)
- 10.60 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.)
- 10.61 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.)
- 10.62 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.)
- 10.63 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.)
- 10.64 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.)
- 10.65 Credit Agreement, dated as of July 16, 2004, among Amgen Inc., the Banks therein named, Citibank N.A., as Issuing Bank, Citicorp USA, Inc., as Administrative Agent, and Barclays Bank PLC, as Syndication Agent. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2004 on August 6, 2004 and incorporated herein by reference.)
- 10.66 First Amendment dated as of December 6, 2005, to the Credit Agreement dated as of July 16, 2004, among Amgen Inc., the Banks therein named, Citibank N.A., as Issuing Bank, Citicorp USA, Inc, as Administrative Agent, and Barclays Bank PLC, as Syndication Agent. (Filed as an exhibit to Form 8-K dated and filed on December 8, 2005 and incorporated herein by reference.)
- 10.67 Purchase Agreement, dated as of November 15, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representatives of the several initial purchasers. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
- 10.68 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.)
- 10.69 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.)

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- 10.70 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.)
- 10.71 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.)
- 10.72 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.)
- 10.73 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.)
- 10.74 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.)
- 10.75 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.)
- 10.76* 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 hereof.
- 10.77* Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International.
- 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.)