AMGEN INC
Form 10-Q
November 07, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

Form 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2008

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Commission file number 000-12477

Amgen Inc.

(Exact name of registrant as specified in its charter)

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

(805) 447-1000

(Registrant s telephone number, including area code)

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

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

Large accelerated filer x	Accelerated filer ¨	Non-accelerated filer ¨	Smaller reporting company ¨ (Do not check if a smaller reporting company)

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

As of October 31, 2008, the registrant had 1,059,520,930 shares of common stock, $0.0001 par value, outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In millions, except per share data)

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 3,784	$ 3,524	$ 11,013	$ 10,693
Other revenues	91	87	239	333
Total revenues	3,875	3,611	11,252	11,026
Operating expenses:				
Cost of sales (excludes amortization of acquired intangible assets presented below)	677	792	1,738	1,942
Research and development	729	776	2,232	2,444
Selling, general and administrative	900	730	2,678	2,360
Amortization of acquired intangible assets	74	76	221	224
Write-off of acquired in-process research and development	-	590	-	590
Other charges	12	254	306	543
Total operating expenses	2,392	3,218	7,175	8,103
Operating income	1,483	393	4,077	2,923
Interest and other income and (expense), net	(12)	(21)	19	(20)
Income before income taxes	1,471	372	4,096	2,903
Provision for income taxes	313	171	861	572
Net income	$ 1,158	$ 201	$ 3,235	$ 2,331

Earnings per share:				
Basic	$ 1.09	$ 0.19	$ 3.01	$ 2.07
Diluted	$ 1.09	$ 0.18	$ 3.00	$ 2.06
Shares used in calculation of earnings per share:				
Basic	1,058	1,086	1,075	1,127
Diluted	1,064	1,090	1,079	1,133

See accompanying notes.

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AMGEN INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In millions, except per share data)

(Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,522	$ 2,024
Marketable securities	7,235	5,127
Trade receivables, net	2,114	2,101
Inventories	2,004	2,091
Other current assets	1,745	1,698
Total current assets	15,620	13,041
Property, plant and equipment, net	5,972	5,941
Intangible assets, net	3,095	3,332
Goodwill	11,340	11,240
Other assets	971	1,085
	$ 36,998	$ 34,639
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 538	$ 378
Accrued liabilities	3,413	3,801
Current portion of other long-term debt	1,000	2,000
Total current liabilities	4,951	6,179
Deferred tax liabilities	346	480
Convertible notes	5,081	5,080
Other long-term debt	5,095	4,097
Other non-current liabilities	1,693	934
Contingencies		
Stockholders equity:		
Common stock and additional paid-in capital;	25,348	24,976
$0.0001 par value; 2,750 shares authorized;		
outstanding - 1,059 shares in 2008 and		

1,087 shares in 2007		
Accumulated deficit	(5,519)	(7,160)
Accumulated other comprehensive income	3	53
Total stockholders equity	19,832	17,869
	$ 36,998	$ 34,639

See accompanying notes.

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AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

(Unaudited)

	Nine months ended September 30,	
	2008	**2007**
Cash flows from operating activities:		
Net income	$ 3,235	$ 2,331
Write-off of acquired in-process research and development	-	590
Depreciation and amortization	799	900
Asset impairments	16	392
Other items, net	140	379
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	16	(15)
Inventories	(22)	(114)
Other current assets	(29)	(68)
Accounts payable	136	(119)
Accrued income taxes	88	(934)
Deferred revenue	337	-
Other accrued liabilities	(125)	529
Net cash provided by operating activities	4,591	3,871
Cash flows from investing activities:		
Purchases of property, plant and equipment	(494)	(1,033)
Cash paid for acquisitions, net of cash acquired	(50)	(698)
Purchases of marketable securities	(7,794)	(4,236)
Proceeds from sales of marketable securities	5,002	4,431
Proceeds from maturities of marketable securities	625	278
Other	93	(37)
Net cash used in investing activities	(2,618)	(1,295)
Cash flows from financing activities:		
Net proceeds from issuance of common stock in connection with equity award programs	114	244
Repurchases of common stock	(1,568)	(5,000)
Repayment of debt	(1,000)	(1,702)
Proceeds from issuance of notes, net	992	3,982
Other	(13)	6
Net cash used in financing activities	(1,475)	(2,470)

Increase in cash and cash equivalents	498	106
Cash and cash equivalents at beginning of period	2,024	1,283
Cash and cash equivalents at end of period	$ 2,522	$ 1,389

See accompanying notes.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2008

(Unaudited)

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2008 and 2007 is unaudited but includes all adjustments (consisting of only normal recurring adjustments, unless otherwise indicated), which Amgen Inc., including its subsidiaries (referred to as Amgen, the Company, we, our or us), considers necessary for a fair presentation of the results of operations for those periods. Interim result not necessarily indicative of results for the full fiscal year.

The condensed consolidated financial statements should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2007.

Principles of consolidation

The condensed consolidated financial statements include the accounts of Amgen as well as its wholly owned subsidiaries. We do not have any significant interests in any variable interest entities. All material intercompany transactions and balances have been eliminated in consolidation.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Inventories

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out (FIFO) method. During the three months ended September 30, 2008, we wrote-off $84 million of inventory resulting from a strategic decision to change manufacturing processes. During the three months ended September 30, 2007, we wrote-off $90 million of excess inventory principally due to changing regulatory and reimbursement environments. Inventories consisted of the following (in millions):

	September 30, 2008	December 31, 2007
Raw materials	$ 139	$ 173
Work in process	1,434	1,246
Finished goods	431	672

	$ 2,004	$ 2,091	

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property, plant and equipment, net

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation of $4.0 billion and $3.6 billion as of September 30, 2008 and December 31, 2007, respectively.

Goodwill

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

Fair value measurement

The Company adopted the provisions of the Financial Accounting Standards Board s (FASB s) Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157), effective January 1, 2008, for its financial assets and liabilities. The FASB delayed the effective date of SFAS 157 until January 1, 2009, with respect to the fair value measurement requirements for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the exit price) in an orderly transaction between market participants at the measurement date. The adoption of SFAS 157 did not have a material impact on the Company s consolidated financial statements.

In determining the fair value of its financial assets and liabilities, the Company uses various valuation approaches. SFAS 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access

Level 2 Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly

Level 3 Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company s available-for-sale securities, substantially all of which are fixed income investments, are comprised of U.S. Treasury securities, obligations of U.S. government agencies, money market funds, corporate debt securities, other interest bearing securities and publicly traded equity investments. U.S. Treasury securities, money market funds and publicly traded equity investments are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized in Level 1. Obligations of U.S. government agencies, corporate debt securities and other interest bearing securities are valued using quoted market prices of recent transactions or are benchmarked to transactions of very similar securities. When observable price quotations are not available, cash flow models are used to incorporate benchmark yields and issuer spreads. Obligations of U.S. government agencies, corporate debt securities and other interest bearing securities are categorized in Level 2.

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

The following fair value hierarchy table presents information about each major category of the Company s financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2008 (in millions):

	Fair value measurement at reporting date using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Balance as of September 30, 2008
Assets:				
Available-for-sale securities	$ 3,629	$ 6,029	$ -	$ 9,658
Derivatives	-	67	-	67
Total	$ 3,629	$ 6,096	$ -	$ 9,725
Liabilities:				
Derivatives	$ -	$ 44	$ -	$ 44
Total	$ -	$ 44	$ -	$ 44

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

Product sales

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

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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Research and development costs

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

Selling, general and administrative costs

Selling, general and administrative (SG&A) expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel; outside marketing and legal expenses; overhead and facilities costs and other general and administrative costs. In connection with a co-promotion agreement, we and Wyeth market and sell ENBREL in the United States and Canada and Wyeth is paid a share of the related profits, as defined. The share of ENBREL s profits owed to Wyeth (the Wyeth profit share expense) is included in SG&A expenses. For the three and nine months ended September 30, 2008, the Wyeth profit share expense was $298 million and $886 million, respectively. For the three and nine months ended September 30, 2007, the Wyeth profit share expense was $245 million and $719 million, respectively.

Earnings per share

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

Our 2011 Convertible Notes and 2013 Convertible Notes are considered Instrument C securities as defined by Emerging Issues Task Force (EITF) Issue No. 90-19 *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*. Therefore, only the shares of common stock potentially issuable with respect to the excess of the notes conversion value over their principal amount, if any, are considered as dilutive potential common shares

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for purposes of calculating diluted EPS. For the three and nine months ended September 30, 2008 and 2007, the conversion values for our convertible notes were less than the related principal amounts and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS.

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

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,158	$ 201	$ 3,235	$ 2,331
Shares (Denominator):				
Weighted-average shares for basic EPS	1,058	1,086	1,075	1,127
Effect of dilutive securities	6	4	4	6
Weighted-average shares for diluted EPS	1,064	1,090	1,079	1,133
Basic EPS	$ 1.09	$ 0.19	$ 3.01	$ 2.07
Diluted EPS	$ 1.09	$ 0.18	$ 3.00	$ 2.06

Recent accounting pronouncements

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF 07-5). Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative as outlined in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity s stock. EITF 07-5 provides guidance on how to determine if equity-linked instruments (or embedded features) such as warrants to purchase our stock, our convertible notes and convertible note hedges are considered indexed to our stock. EITF 07-5 is effective for the financial statements issued for fiscal years and interim periods within those fiscal years, beginning after December 15, 2008 and will be applied to outstanding instruments as of the beginning of the fiscal year in which it is adopted. Upon adoption, a cumulative effect adjustment will be recorded, if necessary, based on amounts that would have been recognized if this guidance had been applied from the issuance date of the affected instruments. We are currently determining the impact that EITF 07-05 will have on our financial statements, if any.

In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement* (FSP APB 14-1) that changes the method of accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion, including our convertible debt securities (see Note 5, *Financing arrangements*). We will adopt FSP APB 14-1 in the first quarter of 2009 and retrospectively apply this change to prior periods, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities will be bifurcated and accounted for separately in a manner that will result in recognizing interest expense on these securities at effective rates reflective of what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities will be included in the paid-in-capital section of stockholders equity on our Consolidated Balance Sheet and, accordingly, the initial carrying values of these debt securities will be reduced. Our net income for financial reporting purposes will 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. We are currently determining the impact FSP APB 14-1 will have on our financial statements. We expect it will have a material adverse impact on our past and future reported financial results but will have no impact on past or future cash flows.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

2. Restructuring

On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoietic stimulating agent (ESA) products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. Our ESA products have and may continue to face regulatory and reimbursement challenges, including the potential for further revisions to product labels and loss of or restrictions on reimbursement coverage. In addition, the restructuring plan is also, to a lesser degree, the result of various challenges facing certain of our other products.

Through September 30, 2008, we have completed a majority of the actions initially included in our restructuring plan. Key components of our restructuring plan initially included: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases primarily for certain R&D facilities that will not be used in our operations. Through September 30, 2008, the total cost incurred with respect to these actions was $790 million. We have recently identified certain additional initiatives designed to further assist in improving our cost structure, including outsourcing certain non-core business functions, most notably certain of our information systems infrastructure services, as well as abandoning leases for certain additional facilities that will no longer be used in our operations. The estimated cost of these additional initiatives is $50 million to $100 million. As a result of the actual costs incurred to date and the addition of the recently identified initiatives, the total charges expected to be incurred in connection with our restructuring plan, including related implementation costs, has been increased to $850 million to $925 million, as compared to our prior estimate of $775 million to $825 million. We currently estimate that all remaining costs will be incurred through 2009. Such cost estimates and amounts incurred are net of amounts recovered from our ENBREL co-promotion partner, Wyeth.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following tables summarize the charges (credits) recorded during the three and nine months ended September 30, 2008 and 2007 related to the restructuring plan by type of activity (in millions):

	Separation costs	Asset impairments	Accelerated depreciation	Other	Total
Three months ended September 30, 2008					
Other charges	$ -	$ 1	$ -	$ 7	$ 8
Interest and other income and (expense), net	-	-	-	9	9
	$ -	$ 1	$ -	$ 16	$ 17
Three months ended September 30, 2007					
Cost of sales (excludes amortization of acquired intangible assets)	$ (1)	$ 4	$ 110	$ -	$ 113
R&D	(17)	35	-	-	18
SG&A	(9)	-	-	(83)	(92)
Other charges	104	71	-	79	254
	$ 77	$ 110	$ 110	$ (4)	$ 293
Nine months ended September 30, 2008					
Cost of sales (excludes amortization of acquired intangible assets)	$ -	$ 1	$ -	$ -	$ 1
R&D	3	-	-	-	3
SG&A	-	-	-	(1)	(1)
Other charges	4	15	-	20	39
Interest and other income and (expense), net	-	-	-	9	9
	$ 7	$ 16	$ -	$ 28	$ 51
Nine months ended September 30, 2007					
Cost of sales (excludes amortization of acquired intangible assets)	$ (1)	$ 4	$ 110	$ -	$ 113
R&D	(17)	35	-	-	18
SG&A	(9)	-	-	(83)	(92)
Other charges	107	357	-	79	543
	$ 80	$ 396	$ 110	$ (4)	$ 582

As noted above, since the inception of our restructuring plan through September 30, 2008, we have incurred $790 million of the estimated $850 million to $925 million of charges expected to be incurred. The charges incurred through September 30, 2008 include $185 million of separation costs, $424 million of asset impairments, $148 million of accelerated depreciation, $33 million of other charges, which primarily include $139 million of loss accruals for leases and $9 million with respect to the loss accrued on the disposal of certain less significant marketed products and related assets, including primarily inventory, offset by $115 million of cost recoveries from Wyeth.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Separation costs	Other	Total
Restructuring reserves as of January 1, 2008	$ 97	$ 102	$ 199
Expense	7	26	33
Payments	(97)	(15)	(112)
Restructuring reserves as of September 30, 2008	$ 7	$ 113	$ 120

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

3. Related party transactions

We own a 50% interest in KA, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA s profits or losses in Selling, general and administrative in the Condensed Consolidated Statements of Income. During the three and nine months ended September 30, 2008, our share of KA s profits was $22 million and $53 million, respectively. During the three and nine months ended September 30, 2007, our share of KA s profits was $18 million and $40 million, respectively. At September 30, 2008 and December 31, 2007, the carrying value of our equity method investment in KA was $345 million and $292 million, respectively, and is included in non-current Other assets in the Condensed Consolidated Balance Sheets. KA s revenues consist of royalty income related to its licensed technology rights. All of our rights to manufacture and market certain products including darbepoetin alfa, pegfilgrastim, granulocyte colony-stimulating factor (G-CSF) and recombinant human erythropoietin are pursuant to exclusive licenses from KA, which we currently market under the brand names Aranesp®, Neulasta®, NEUPOGEN® and EPOGEN®, respectively. KA receives royalty income from us, as well as Kirin, J&J and F. Hoffmann-La Roche Ltd. (Roche) under separate product license agreements for certain geographic areas outside of the United States. During the three and nine months ended September 30, 2008, KA earned royalties from us of $85 million and $243 million, respectively. During the three and nine months ended September 30, 2007, KA earned royalties from us of $83 million and $253 million, respectively. These amounts are included in Cost of sales (excludes amortization of acquired intangible assets) in the Condensed Consolidated Statements of Income. At September 30, 2008 and December 31, 2007, we owed KA $3 million and $91 million, respectively, which was included in Accrued liabilities in the Condensed Consolidated Balance Sheets.

KA s expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and nine months ended September 30, 2008, we earned revenues from KA of $41 million and $100 million, respectively, for certain R&D activities performed on KA s behalf. During the three and nine months ended September 30, 2007, we earned revenues from KA of $39 million and $144 million, respectively. These amounts are included in Other revenues in the Condensed Consolidated Statements of Income.

4. Income taxes

The effective tax rates for the three and nine months ended September 30, 2008 are lower than the statutory rate primarily as a result of indefinitely invested earnings of our foreign operations which are taxed at a lower rate than the statutory rate. The effective tax rate for the three months ended September 30, 2007 is higher than the statutory rate primarily as a result of the write-off of non tax-deductible, acquired IPR&D expense in

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

connection with the acquisitions of Alantos Pharmaceuticals Holding, Inc. (Alantos) and Ilypsa, Inc. (Ilypsa) partially offset by indefinitely invested earnings of our foreign operations. The effective tax rate for the nine months ended September 30, 2007 is different from the statutory rate primarily as a result of these same factors as well as the favorable resolution of our federal income tax examination for prior years, which was recorded in the second quarter of 2007. 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. We are no longer subject to U.S. federal income tax examinations for years ending on or before December 31, 2004 or to California state income tax examinations for years ending on or before December 31, 2003.

During the three and nine months ended September 30, 2008, the gross amount of our unrecognized tax benefits (UTBs) increased approximately $100 million and $280 million, respectively, as a result of tax positions taken during the current year. During the nine months ended September 30, 2008, the gross amount of our UTBs decreased approximately $185 million, net, related to tax positions taken in prior years, primarily as a result of an agreement with the Internal Revenue Service in the first quarter of 2008 related to certain transfer pricing positions for the years 2005 and 2006. The majority of our UTBs at September 30, 2008, if recognized, would affect our effective tax rate.

5. Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of September 30, 2008 and December 31, 2007 (in millions):

	September 30, 2008	December 31, 2007
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,500	$ 2,500
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	2,500
5.85% notes due 2017 (2017 Notes)	1,099	1,099
Floating rate notes due 2008 (2008 Floating Rate Notes)	1,000	2,000
4.00% notes due 2009 (2009 Notes)	1,000	999
4.85% notes due 2014 (2014 Notes)	1,000	1,000
6.375% notes due 2037 (2037 Notes)	899	899
6.15% notes due 2018 (2018 Notes)	499	-
6.90% notes due 2038 (2038 Notes)	498	-
Other	181	180
Total borrowings	11,176	11,177
Less current portion	1,000	2,000
Total non-current debt	$ 10,176	$ 9,177

On April 17, 2008, we filed a shelf registration statement with the Securities and Exchange Commission (SEC), which replaced our previous $1.0 billion shelf registration statement and allows us to issue an unspecified amount of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depository shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units and depository shares. Under this registration statement,

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all of the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance.

In May 2008, we increased our commercial paper program by $1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of $2.5 billion. We also have a $2.5 billion syndicated unsecured revolving credit facility which matures in November 2012 and is available for general corporate purposes, or as a liquidity backstop to our commercial paper program; however, $178 million of such commitment was provided by a subsidiary of Lehman Brothers Holdings Inc. (Lehman). Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. As a result, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. No amounts were outstanding under the commercial paper program or credit facility as of September 30, 2008.

In May 2008, we issued $500 million aggregate principal amount of notes due in 2018 (the 2018 Notes) and $500 million aggregate principal amount of notes due in 2038 (the 2038 Notes) in a registered offering. The 2018 Notes and 2038 Notes pay interest at fixed annual rates of 6.15% and 6.90%, respectively. Concurrent with the issuance of the 2018 Notes, we entered into interest rate swap agreements that effectively convert the payment of our fixed rate interest payments to variable rate interest payments over the life of the 2018 Notes. The 2018 Notes and 2038 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a make-whole amount, as defined in the indenture governing the notes. In the event of a change in control triggering event, as defined in the indenture governing the notes, we may be required to purchase for cash all or a portion of the 2018 Notes and the 2038 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $6 million and are being amortized over the life of the notes. Upon the receipt of the proceeds from the issuance of the 2018 Notes and 2038 Notes, we exercised our right to call $1.0 billion of floating rate notes due November 2008, which were retired in June 2008.

6. Stockholders equity

Stock repurchase programs

A summary of activity under our stock repurchase programs for the nine months ended September 30, 2008 and 2007 is as follows (in millions):

	2008		2007	
	Shares	Dollars	Shares	Dollars
First quarter	-	$ -	8.8	$ 537
Second quarter	32.7	1,549 (1)	73.9 (2)	4,463
Third quarter	-	19 (1)	2.5 (2)	-
Total	32.7	$ 1,568	85.2	$ 5,000

(1) The total cost of shares repurchased during the second quarter of 2008 excludes approximately $19 million paid in July 2008 in connection with the final settlement of an accelerated share repurchase program (ASR) entered into in May 2008.

(2) The total number of shares repurchased during the second quarter of 2007 excludes 2.5 million shares received in July 2007 in connection with the final settlement of an ASR entered into in May 2007.

As of September 30, 2008, $4.9 billion remained available for stock repurchases as authorized by our Board of Directors. The manner of purchases, the amount we spend, and the number of shares repurchased will vary based on a number of factors, including the stock price, blackout periods in which we are restricted from

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repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

7. Acquisition

On January 4, 2008, we completed the acquisition of Dompé, a privately held company that marketed certain of our products in Italy. This cash acquisition was accounted for as a business combination. The purchase price was approximately $162 million, which included the carrying value of our existing 49% ownership in Dompé. The purchase price paid was preliminarily allocated to net assets acquired of approximately $63 million based on their estimated fair values at the acquisition date and the excess of the purchase price over the fair values of net assets acquired of approximately $99 million was assigned to goodwill. There was no material gain or loss related to the reacquisition of marketing rights previously granted to Dompé as a result of this business combination. The results of Dompé s operations have been included in the condensed consolidated financial statements commencing January 4, 2008. Pro forma results of operations for the three and nine months ended September 30, 2008 assuming the acquisition of Dompé had taken place at the beginning of 2008 would not differ significantly from the actual reported results.

8. Other charges

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

For the three and nine months ended September 30, 2008, we recorded restructuring charges of $8 million and $39 million, respectively. For the three and nine months ended September 30, 2007, we recorded restructuring charges of $254 million and $543 million, respectively. Such expenses are included in Other charges in the Condensed Consolidated Statements of Income. (See Note 2, *Restructuring* for further discussion.)

9. Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters that are complex in nature and have outcomes that are difficult to predict. In accordance with SFAS 5, *Accounting for Contingencies,* we record accruals for such contingencies to the extent that we conclude that it is probable that a liability will be incurred and the amount of the related loss can be reasonably estimated. See Note 10, *Contingencies* to our Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2007 for further discussion of certain of our legal proceedings and other matters.

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

Transkaryotic Therapies (TKT) and Aventis Litigation

On October 2, 2008, the U.S. District Court for the District of Massachusetts (the Massachusetts District Court) entered a Memorandum and Order upholding the validity of claim 1 of the 422 patent, the sole remaining issue on remand, and entered declaratory judgment enjoining TKT and Hoechst Marion Roussel, Inc. (now Aventis Pharmaceuticals Inc.) from infringing the 422 patent, the 698 patent and the 349 patent for the life of the patents, the last of which expires in 2015.

Robert J. Swanston v. TAP Pharmaceutical Products, Inc., et al.

A hearing on defendants motion for summary judgment has been rescheduled before the Maricopa County, Arizona Superior Court for December 5, 2008.

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State of Alabama v. Abbott Laboratories, Inc. (Abbott), et al.

Two additional trials of non-Track 4 defendants (which did not include Amgen and Immunex) were held in June 2008. Following these trials, plaintiff Alabama filed a motion to set a trial date for four additional companies, including Amgen and Immunex. The Circuit Court of Montgomery County, Alabama granted the motion and set trial for Amgen and Immunex for February 2009. The plaintiff also filed a motion to consolidate the four defendants into one trial and the motion to consolidate was granted as to two of the four defendants, which did not include Amgen or Immunex.

County of Erie v. Abbott Laboratories, Inc., et al.; County of Schenectady v. Abbott Laboratories, Inc., et al.; County of Oswego v. Abbott Laboratories, Inc., et al.

The State of New York Litigation Coordinating Panel granted defendants motions to coordinate the Erie, Oswego and Schenectady County cases. The Erie County judge will hear all discovery disputes on November 13 and 14, 2008.

State of Kansas, ex rel Steve Six v. Amgen Inc. and Immunex Corporation

On November 3, 2008, the State of Kansas filed a complaint against Amgen and Immunex in the District Court of Wyandotte County, Kansas, Civil Court Division. Approximately forty other pharmaceutical manufacturers were also sued by the state. Plaintiff Kansas alleges that the manufacturers misrepresented product pricing information reported to the state by falsely inflating those prices.

Roche Matters

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

On October 2, 2008, the Massachusetts District Court entered an Order making final its ruling denying the parties post-trial motions and upholding the jury s verdict in all respects except infringement of claim 12 of the 933 patent under the Doctrine of Equivalents. The Order also stated the Massachusetts District Court s intention to enter a permanent injunction prohibiting F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH and Hoffman-La Roche, Inc. (collectively, Roche) from infringing the 422 patent, the 933 patent, the 868 patent and the 698 patent. The Massachusetts District Court then administratively closed the case awaiting resolution of the then pending appeal of the preliminary injunction. On October 6, 2008, Roche filed a Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit) of the Massachusetts District Court s October 2nd Order.

On October 8, 2008, the Federal Circuit held a hearing on Roche s appeal of the preliminary injunction and on October 10, 2008 the Federal Circuit entered an order affirming the grant of the preliminary injunction. On October 17, 2008, the Massachusetts District Court entered judgment that the patents in suit are valid, enforceable, and infringed and permanently enjoined Roche from infringing the `422 patent, the 933 patent, the 868 patent and the 698 patent for the remaining life of these patents. Also on October 17, 2008, Roche filed a supplemental notice of appeal to the Federal Circuit. On October 30, 2008, Amgen filed two post-judgment motions with the Massachusetts District Court seeking entry of supplemental findings of fact and conclusions of law. On October 31, 2008, the Massachusetts District Court entered a notice that it would not be entering any supplemental findings of fact and conclusions of law. On November 3, 2008, the Massachusetts District Court entered an order terminating Amgen s post-judgment motions.

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

On September 19, 2008, the U.S. District Court for the District of Delaware (the Delaware District Court) issued an order construing the claims of the 516 patent and granted summary judgment that ENBREL does not infringe the 516 patent. Prior to the ruling, Ariad withdrew its claims of infringement against Kineret®. Also on September 19, 2008, the Delaware District Court granted summary judgment in-part in favor of Ariad, ruling that Amgen could not prove inequitable conduct on the basis of one of its claims, but that sufficient evidence exists for a trial on inequitable conduct on Amgen s alternative bases. The Delaware District Court also dismissed Amgen s claims of invalidity on the claims of the 516 patent not asserted by Ariad to be infringed by sales of ENBREL (Ariad had asserted that only seven of the 203 patent claims were infringed), but the Delaware District Court maintained Amgen s unenforceability claims to all 203 claims of the 516 patent.

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On October 3, 2008, the Delaware District Court stayed Amgen s invalidity and unenforceability claims and entered final judgment of no infringement in favor of Amgen. The Delaware District Court declared the case administratively closed, to be reopened only by the parties after a decision on appeal. The Delaware District Court canceled the previously scheduled November trial date. On October 6, 2008, Ariad filed a notice of appeal to the Federal Circuit.

Human Genome Sciences (HGS) Litigation

HGS motion for reconsideration before the Delaware District Court was denied on August 21, 2008, and the Federal Circuit entered an order reactivating HGS appeal effective October 22, 2008.

Sensipar® Abbreviated New Drug Application (ANDA) Litigation

On October 31, 2008, the Delaware District Court entered a First Scheduling Order indicating that the case will be placed in the trial pool on May 3, 2010.

Federal Antitrust Litigation

The U.S. District Court for the District of New Jersey granted Amgen s motion to dismiss in part and denied in part, permitting plaintiffs to revise their complaint. Plaintiffs elected to voluntarily dismiss their complaint and a Stipulation of Voluntary Dismissal was filed on September 22, 2008.

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

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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 SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Words such as expect, anticipate, outlook, could, target, project, intend, plan, believe, seek, estimate, should, may, of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in *Item 1A. Risk Factors*. We have based our forward looking statements on our management s beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward looking statements. Reference is made in particular to forward looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources and trends. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

The following Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to assist the reader in understanding Amgen s business. MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and our consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2007.

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

We primarily earn revenues and income and generate cash from sales of human therapeutic products in the areas of supportive cancer care, nephrology and inflammation. Our principal products include Aranesp®, EPOGEN®, Neulasta®, NEUPOGEN® and ENBREL, all of which are sold in the United States. Aranesp® and EPOGEN® stimulate the production of red blood cells to treat anemia and belong to a class of drugs referred to as erythropoiesis-stimulating agents, or ESAs. Aranesp® is used for the treatment of anemia both in supportive cancer care and in nephrology. EPOGEN® is used to treat anemia associated with chronic renal failure (CRF). Neulasta® and NEUPOGEN®, which are used in supportive cancer care, selectively stimulate the production of neutrophils, one type of white blood cell that helps the body fight infections. ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. ENBREL blocks the biologic activity of tumor necrosis factor (TNF) by inhibiting TNF, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis and psoriasis. For both the three and nine months ended September 30, 2008, our principal products represented 94% of total worldwide product sales. Our international product sales consist principally of European sales of Aranesp®, Neulasta® and NEUPOGEN®. International product sales represented approximately 23% and 22% of total product sales for the three and nine months ended September 30, 2008, respectively. For additional information about our principal products, their

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

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business. Government authorities in the United States and in other countries regulate the manufacturing and marketing of our products and our ongoing R&D activities. The regulatory environment is evolving and there is increased scrutiny on drug safety and increased authority being granted to regulatory bodies, in particular the U.S. Food and Drug Administration (FDA), to assist in ensuring the safety of therapeutic products. Most patients receiving our principal products for approved indications are covered by either government or private payer health care programs. The reimbursement environment is also evolving with greater emphasis on cost containment. Further, as a result of the new U.S. presidential administration s plans for changes in the healthcare system, we believe that we and others in our industry will be under increased pressure to further demonstrate the safety, efficacy and economic value of our products. Therefore, sales of our principal products are and will continue to be affected by the availability and extent of reimbursement from third-party payers, including government and private insurance plans and administration of those programs. Further, safety signals or trends or adverse events or results from clinical trials or studies or meta-analyses (a meta-analysis is the review of studies using various statistical methods to combine results from previous separate, but related, studies) performed by us or by others (including our licensees or independent investigators) or from the marketed use of our products may expand safety labeling, restrict the use of our approved products or may result in additional regulatory requirements, such as requiring risk management activities, including a risk evaluation and mitigation strategy (REMS), and/or additional or more extensive clinical trials as part of postmarketing commitments (PMCs) or a pharmacovigilance program, and may negatively impact worldwide sales or reimbursement of our products. In addition, the capital and credit markets have been experiencing extreme volatility and disruption, particularly in the past several weeks. We are working to manage our business effectively despite the unprecedented conditions in the financial markets both in the United States and around the world. However, the extent and/or the duration of any potential adverse economic impact that such financial disruption may have on our third party payers, customers, suppliers and service providers is unclear.

Total product sales for the three and nine months ended September 30, 2008 increased 7% and 3% as compared to the prior year comparative periods, respectively. Product sales in the United States for the three and nine months ended September 30, 2008 totaled $2.9 billion and $8.6 billion, respectively, representing an increase of 4% for the three month period and remaining essentially unchanged for the nine month period compared to the prior year comparative periods. International product sales for the three and nine months ended September 30, 2008 totaled $855 million and $2.5 billion, respectively, reflecting increases of 20% and 16% over the prior year comparative periods. International product sales for the three and nine months ended September 30, 2008 reflect favorable foreign currency exchange rate changes of $78 million and $243 million, respectively. Excluding the impact of foreign currency exchange rate changes for the three and nine months ended September 30, 2008, worldwide product sales increased 5% and 1%, respectively, and international product sales increased 9% and 4%, respectively.

Certain of our products, principally our marketed ESA products, have faced and will continue to face various challenges resulting from regulatory and reimbursement developments. Late in 2006 and throughout 2007, adverse safety results involving ESA products were observed in various studies that were performed by us and by others (including our licensees or independent investigators) that explored the use of ESAs in settings different from those outlined in the FDA approved label, including targeting higher hemoglobin (Hb) levels and/or use in non-approved patient populations. The results of these studies culminated in significant regulatory and reimbursement developments affecting the class of ESA products, including Aranesp® and EPOGEN®. For example, in February 2007, following the reported results from our Anemia of Cancer phase 3 study (the AoC 103 study), the United States Pharmacopoeia Dispensing Information (USP DI) Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, Aranesp® use in AoC essentially ceased. In addition, during 2007, we had discussions with the FDA and other regulatory authorities and meetings with certain of the FDA s advisory panels, namely the Oncologic Drugs Advisory Committee (ODAC), the Cardiovascular-Renal Drug Advisory Committee (CRDAC) and the Drug Safety and Risk

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Management Advisory Committee (DSaRMAC), regarding the administration of our ESA products in certain settings. These adverse safety results involving ESA products in various studies and related discussions with regulatory authorities led to several key regulatory and reimbursement developments, including safety-related revisions to ESA product labels in the United States in March and November 2007. Further, in July 2007, the Centers for Medicare and Medicaid Services (CMS) issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Related Neoplastic Conditions (the Decision Memorandum). The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia (CIA) with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy. These developments have had a material adverse impact on sales of our marketed ESA products, in particular Aranesp® sales in the U.S. supportive cancer care setting. Furthermore, our ESA products will continue to face future challenges, including those described below under *ESA Developments* and also the potential for further revisions to product labels and changes to reimbursement.

As a result of the challenges facing certain of our products and, in particular, the regulatory and reimbursement developments involving our marketed ESA products that began in 2007 and their resulting impact on our operations, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. Key components of our restructuring plan initially included: (i) worldwide staff reductions aggregating approximately 2,500 positions, (ii) rationalization of our worldwide network of manufacturing facilities in order to gain cost efficiencies while continuing to meet future commercial and clinical demand for our products and product candidates and, to a lesser degree, changes to certain R&D capital projects and (iii) abandoning leases primarily for certain R&D facilities that will not be used in our operations. Through September 30, 2008, we have completed a majority of these actions and incurred $790 million of costs. We have recently identified certain additional initiatives designed to further assist in improving our cost structure, including outsourcing certain non-core business functions, most notably certain of our information systems infrastructure services, as well as abandoning leases for certain additional facilities that will no longer be used in our operations. The estimated cost of these additional initiatives is $50 million to $100 million. As a result of the actual costs incurred to date and the addition of the recently identified initiatives, the total charges expected to be incurred in connection with our restructuring plan, including related implementation costs, has been increased to $850 million to $925 million, as compared to our prior estimate of $775 million to $825 million. We currently estimate that all remaining costs will be incurred through 2009. Such cost estimates and amounts incurred are net of amounts recovered from our ENBREL co-promotion partner, Wyeth.

The following is a discussion of select key developments affecting our business that occurred in 2008 and should be read in conjunction with *Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations* in Part I of our Form 10-Qs for the quarterly periods ended March 31, 2008 and June 30, 2008 and *Item 1. Business Key Developments* in Part I of our Annual Report on Form 10-K for the year ended December 31, 2007.

ESA Developments

On August 6, 2008, we finalized changes to the ESA product labeling based on a complete response letter, received on July 30, 2008, from the FDA to the revisions to the ESA labeling we proposed following the March 13, 2008 ODAC meeting. The revised labeling included, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels ≥ 10 grams per deciliter (g/dL) and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. Additionally, in response to the FDA s request under authority prescribed by the Food and Drug Administration Amendments Act of 2007 (the FDAAA), we have recently submitted a proposed REMS program for Aranesp® in oncology. We

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also continue to work with the FDA to finalize protocols for clinical trials to determine the effects of Aranesp® on survival and tumor outcomes.

On January 1, 2008, the CMS revisions to its Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (EMP) became effective, which require a 50% reduction in Medicare reimbursement if a patient s Hb is above 13 g/dL for three or more consecutive months. In addition, the EMP reduces the monthly dosing limits to 400,000 international units (IUs) of EPOGEN®, from 500,000 IUs, and to 1,200 micrograms (mcgs) of Aranesp®, from 1,500 mcgs. We believe that the EMP implementation in January 2008 has significantly affected physician behavior resulting in declines in dosing trends as particularly noted in the quarter of implementation. However, this dose decline subsequently stabilized but may further fluctuate in the future.

On March 5, 2008, we announced that the European Commission reached its decision to amend the product labeling for the class of ESAs, including Aranesp®. On May 15, 2008, we and other ESA marketing authorization holders participated in a closed meeting of the Scientific Advisory Group on Oncology (SAG-O). The marketing authorization holders were asked to provide an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients. These data included previously disclosed interim results from the Preoperative Epirubicin Paclitaxel Aranesp® (PREPARE) study in neo-adjuvant breast cancer therapy; follow-up data from the Gynecologic Oncology Group study (GOG-191 study) in cervical cancer, which were published in the February 2008 issue of Gynecologic Oncology; and the February 2008 meta-analysis by Bennett et al, which was published in the Journal of the American Medical Association. Scientific Advisory Groups (SAGs) are established by the European Medicines Agency (EMEA) to deliver answers, on a consultative basis, to specific questions addressed to them by the Committee for Medicinal Products for Human Use (CHMP). On June 26, 2008 the EMEA, based upon the CHMP s opinion which took into account the position expressed by the SAG-O, recommended updating the product information for ESAs with a new warning for their use in cancer patients. In July 2008, the EMEA requested that further clarity around the product information be provided by regulatory agencies in each European Member State country through the publication of a Dear Healthcare Professional Communication, following which we followed the necessary regulatory procedure to update the Aranesp® product information. In October 2008, we received notification that the Aranesp® product information update was approved by the European Commission. The product information for all ESAs was updated to advise that in some clinical situations blood transfusions should be the preferred treatment for the management of anemia in patients with cancer and that the decision to administer ESAs should be based on the benefit-risk assessment with the participation of the individual patient. This assessment should take into account the specific clinical context, including the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference.

On September 30, 2008, we announced that we had received a summary of preliminary results from the Cochrane Collaboration s independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating ESAs in cancer patients, which we submitted to the FDA and EMEA. The preliminary summary includes four components: on-study deaths and overall survival in cancer patients regardless of their specific cancer treatment (chemotherapy, radiochemotherapy, radiotherapy, anemia of cancer with no treatment, other), and on-study deaths and overall survival in patients receiving chemotherapy (the only oncologic population for which ESA treatment is indicated in current FDA-approved labeling). The analysis showed that ESAs increased on-study deaths and decreased overall survival compared to controls. Although neither of these results were statistically significant, they do not exclude the potential for adverse outcomes when ESAs are used according to the current labeling. We expect to receive the complete meta-analysis results later this year and will provide this information to regulatory authorities at that time.

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Other Regulatory Developments

On June 4, 2008, the FDA issued an Early Communication regarding the ongoing safety review of TNF blockers and the possible association between the use of these medicines and the development of lymphoma and other cancers in children and young adults and stated that it had decided to conduct further analyses to evaluate the risk and benefits of TNF blockers in pediatric patients.

Following the June 18, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) meeting, on July 24, 2008, the FDA requested additional information from us to support the supplemental biologic license application (BLA) we submitted for the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis. We continue to work with the FDA to respond to its requests and provide it with information to address additional questions related to the supplemental BLA and plans for risk management activities.

On September 4, 2008, the FDA issued a Web-Alert regarding their review of histoplasmosis and other opportunistic fungal infections in patients treated with TNF-blockers. The FDA requested that the boxed warning and warnings sections of the U.S. prescribing information (PI) and the medication guide for ENBREL (and other TNF blockers) be strengthened to include the risk of histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. We are working with the FDA to finalize the required revisions to respond to its requests.

On August 22, 2008, the FDA approved Nplate (romiplostim), the first and only platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura (ITP). Nplate , the first FDA approved peptibody protein, works by raising and sustaining platelet counts, representing a novel approach for the long-term treatment of this chronic disease. As part of the approval for Nplate™, a REMS was developed with the FDA to assure the safe use of Nplate™ while minimizing risk. The Nplate™ REMS involves, among other things, healthcare provider and patient enrollment registries, tracking of patient medical history and data and follow-up safety questionnaires to healthcare providers all of which require extensive discussion and education with healthcare providers.

Clinical Developments

Denosumab Osteoporosis

On July 25, 2008, we announced findings from the pivotal fracture trial (Study 216) evaluating our receptor activator of nuclear factor kappa B (RANK) ligand inhibitor, denosumab, in the treatment of postmenopausal osteoporosis. In this pivotal, three-year, international, phase 3 study of approximately 7,800 women with osteoporosis, patients were randomized to receive either denosumab, given by subcutaneous injection once every six months, or placebo injections. For the primary endpoint, treatment with denosumab resulted in a statistically significant reduction in the incidence of new vertebral fractures compared with placebo treatment. In addition, women receiving denosumab experienced a statistically significant reduction in the incidence of new non-vertebral and hip fractures (each a secondary endpoint) compared with those receiving placebo. The incidence and types of both adverse and serious adverse events observed in this study, including serious infections and neoplasms, were similar between the denosumab and placebo groups. The most common adverse events across both treatment arms were arthralgia, back pain, hypertension and nasopharyngitis.

On September 16, 2008 at the 2008 American Society of Bone and Mineral Research (ASBMR) annual meeting in Montreal, Canada, we presented detailed results of Study 216 evaluating

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denosumab in osteoporosis. Compared to placebo, patients who received denosumab had 68% fewer vertebral fractures (2.3% for denosumab versus 7.2% for placebo, p=0.0001), 40% fewer hip fractures (0.7% versus 1.2%, p=0.036) and 20% fewer non-vertebral fractures (6.5% versus 8.0%, p=0.011). At the meeting we also presented data regarding the incidence and types of adverse events and serious adverse events observed in the trial, which were similar between the placebo and denosumab groups.

In addition to the detailed results of Study 216, a pivotal fracture study, we presented the results of two non-pivotal phase 3 studies of denosumab in osteoporosis at the ASBMR. The first was a phase 3 head-to-head, double-blind trial known as the STAND (Study of Transitioning from AleNdronate to Denosumab) trial (Study 234). The results of this study demonstrated that subcutaneous injections of denosumab every six months achieved significantly greater increases in bone mineral density (BMD) versus those achieved with alendronate at all sites measured. For the primary endpoint, denosumab resulted in significant increases in BMD at the total hip compared with alendronate (1.9% versus 1.05%, p<0.0001). Treatment with denosumab also resulted in significant increases in BMD compared with continued alendronate treatment at all secondary endpoints including the lumbar spine, femoral neck, hip trochanter and 1/3 radius. The incidence and types of adverse events observed in the study, including neoplasm and infection, were similar between the denosumab and alendronate treatment groups. The most common adverse events across both treatment arms were back pain, arthralgia and nasal pharyngitis.

The second non-pivotal study was a head-to-head trial comparing denosumab to weekly oral alendronate, also known as the DECIDE (Determining Efficacy: Comparison of Initiating Denosumab versus Alendronate) trial (Study 141). As a part of this study, patients were given a questionnaire after 12 months of treatment to gauge preference on mode of administration as well as satisfaction with frequency of dosing of twice-yearly subcutaneous injections versus weekly oral tablet. More than three-quarters of patients in both study arms preferred subcutaneous injection over oral pills (77% versus 23%, p <0.0001). In addition, significantly more patients were more satisfied with twice-yearly dosing compared to weekly dosing (80% versus 20% placebo injection versus weekly oral alendronate, and 79% versus 21% denosumab versus weekly placebo tablet, p <0.0001 for both study groups).

Denosumab Oncology

On July 14, 2008, we announced findings from a three-year pivotal phase 3 placebo-controlled trial evaluating denosumab in the treatment of bone loss in men undergoing androgen deprivation therapy (ADT) for non-metastatic prostate cancer. In this study of more than 1,400 men, denosumab treatment produced statistically significantly greater increases in BMD at the lumbar spine (primary endpoint) and non-vertebral sites compared with placebo at multiple time points. These improvements in BMD were consistent with those seen in other denosumab studies evaluating BMD in women with breast cancer receiving aromatase inhibitor therapy, and in postmenopausal women with low bone mass. During the thirty-six month evaluation period, men receiving denosumab experienced less than half the incidence of new vertebral fractures (a secondary endpoint) compared with those receiving placebo, a statistically significant finding. Furthermore, in the denosumab arm there were fewer non-vertebral fractures over the thirty-six month period.

Other

During the three months ended September 30, 2008, we received interim results from a phase 2 study of AMG 317 in patients with moderate to severe asthma. The data showed evidence of biological activity; however, the clinical efficacy from the interim analysis did not meet our expectations. The phase 2 study will be completed this year and results will be submitted to an appropriate peer-reviewed forum.

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Competition

On October 17, 2008, the Massachusetts District Court entered judgment that the patents in suit are valid and enforceable, and would be infringed by the import, use and sale of Roche s pegylated-erythropoietin product. The Massachusetts District Court permanently enjoined Roche from infringing the 422 patent, the 933 patent, the 868 patent and the 698 patent for the remaining life of these patents.

On September 15, 2008, Ratiopharm s Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel s Biograstim® and Teva Generics (Teva) Tevagrastim®, all G-CSF biosimilar products, received marketing authorization from the European Commission. Ratiopharm launched its G-CSF biosimilar product, Ratiograstim®, in the United Kingdom in October 2008, and is expected to launch it in Germany and several other European markets in the fourth quarter of 2008. CT Arzneimittel is expected to market its G-CSF biosimilar product in Germany in the fourth quarter of 2008. Teva stated that it would begin marketing its G-CSF biosimilar product throughout Europe in 2009.

Other Developments

On September 15, 2008, we announced that we have entered into an agreement with Biovitrum AB (Biovitrum) under which Biovitrum will acquire from us the marketed biologic therapeutic products Kepivance® (palifermin) and Stemgen® (ancestim), and will also obtain from us a worldwide exclusive license to Kineret® (anakinra) for its current approved indication. In connection with entering into this agreement, we recorded a $9 million loss accrual on the disposal in the three months ended September 30, 2008. This amount is included in Interest and other income and (expense), net in the Condensed Consolidated Statements of Income.

For the three and nine months ended September 30, 2008, net income was $1.2 billion and $3.2 billion, respectively, and diluted earnings per share was $1.09 per share and $3.00 per share, respectively. As of September 30, 2008, cash, cash equivalents and marketable securities were $9.8 billion, of which approximately $7.7 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds were repatriated for use in our U.S. operations, we would be required to pay additional U.S. federal and state income taxes at the applicable marginal tax rates. Our total debt outstanding was $11.2 billion as of September 30, 2008, of which $1.0 billion is scheduled to mature on November 28, 2008.

There are also many economic and industry-wide factors that affect our business generally and uniquely, including, among others, those relating to increased complexity and cost of R&D due, in part, to greater scrutiny of clinical trials with respect to safety which may lead to fewer treatments being approved by the FDA or other regulatory bodies and/or safety-related label changes for approved products; increasingly intense competition for marketed products and product candidates; reimbursement changes; healthcare provider prescribing behavior, regulatory or private healthcare organization medical guidelines and reimbursement practices; complex and expanding regulatory requirements; and intellectual property protection. See *Item 1. Business* in Part I of our Annual Report on Form 10-K for the year ended December 31, 2007 and *Item 1A. Risk Factors* in Part II herein for further information on these economic and industry-wide factors and their impact and potential impact on our business.

Reimbursement

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Generally, in Europe and other countries outside the United States, the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products

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may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Further, adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand the safety information in the labeling for our approved products and may negatively impact worldwide reimbursement for our products. On July 30, 2007, CMS issued its Decision Memorandum and on January 14, 2008, issued changes to its Medicare National Coverage Determinations Manual, effective for claims with dates of service on or after July 30, 2007, with an implementation date of April 7, 2008. A discussion of the Decision Memorandum follows below. (See also *Item 1A. Risk Factors Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.*)

Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare programs payment policies for drugs and biologicals are subject to various laws and regulations. Beginning in January 1, 2005 under the Medicare Prescription Drug Improvement and Modernization Act (the MMA), in the physician clinic setting and January 1, 2006, in the hospital outpatient and dialysis settings, Aranesp®, Neulasta® and NEUPOGEN® have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its average sales price (ASP) (sometimes referred to as ASP+6%). Effective January 1, 2008, Medicare payment in the hospital outpatient setting reimburses each product at 105% of its ASP and CMS has the regulatory authority to further reduce the outpatient hospital payment formula in future years. For example, effective January 1, 2009, CMS, in its Outpatient Prospective Payment System Final Rule for 2009, released on October 30, 2008, set the payment rate in the hospital outpatient setting at ASP+4% for 2009. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product s ASP is calculated and reported to CMS on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP based payment rate for Aranesp® that will be in effect for the fourth quarter of 2008 will be based in part on certain historical sales and sales incentive data for Aranesp® from July 1, 2007 through June 30, 2008. CMS publishes the ASPs for products in advance of the quarter in which they go into effect.

In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the End Stage Renal Disease (ESRD) Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement methodology is established by federal law and is monitored and implemented by CMS. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. Beginning in the third quarter of 2007, based on its ongoing assessment for payment of Part B drugs, CMS instituted a single payment limit for Epoetin alfa (EPOGEN® and PROCRIT®) in all provider settings. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician clinic setting, dialysis facility and hospital outpatient setting. These calculations are regularly reviewed for completeness and based on such review, we have revised our reported ASPs to reflect calculation changes both prospectively and retroactively. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN® was reduced for the third quarter of 2007.

Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to a revised EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and appropriate hematocrit outcomes of dialysis patients. The EMP was revised, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient s Hb is above 13 g/dL for three or more consecutive months. In addition, the revised EMP reduces the monthly dosing limits to 400,000

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IUs of EPOGEN®, from 500,000 IUs, and to 1,200 mcgs of Aranesp®, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN® sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. However, this dose decline subsequently stabilized but may further fluctuate in the future.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005, 2006, 2007 and for the first three quarters of 2008 were not significantly impacted by the reimbursement changes resulting from the MMA. However, additional provisions of the MMA and other regulations or legislation affecting reimbursement that have gone or may go into effect could affect our product sales in the future. For example, on July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms including a broader payment bundle for dialysis services and drugs which will require CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. The new bundled rate will include dialysis services covered under the current composite rate, all ESAs and other intravenous injectable drugs and oral equivalent forms used in dialysis. The bundled reimbursement rate will be phased in over a four-year period in equal increments starting in 2011. It is possible that providers could elect to move to a full Medicare bundled payment in 2011. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011 which subjects facilities to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, which include anemia management and dialysis adequacy. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We are in the process of evaluating the new Medicare legislation on our business and cannot predict the full impact a bundled payments system would have on sales of EPOGEN® or Aranesp® used in the treatment of persons receiving outpatient dialysis services.

In addition, in response to CMS considering and rejecting changes to the ASP calculation methodology for accounting for discounts in multi-product contracts in the 2007 Medicare Physician Fee Schedule Final Rule, MedPAC released its second Congressionally-mandated report on December 29, 2006 on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Under the ASP system, we allocate our discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Referencing a MedPAC December 2006 report, CMS proposed in the Medicare Physician Fee Schedule Proposed Rule for 2008 revising the methodology for calculating ASP to require the reallocation of price concessions of drugs sold under bundled arrangements, described by CMS in part as an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement. In the Medicare Physician Fee Schedule Final Rule for 2008, CMS stated that it was not finalizing the proposed regulatory change at this time, based on comments recommending a delay and raising concerns about the proposal. The agency also clarified that in the absence of specific guidance, manufacturers may continue to make reasonable assumptions in the calculation of ASP, consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices. The agency stated that it will continue to monitor this issue and may provide more specific guidance in the future. In the Medicare Physician Fee Schedule Final Rule for 2009 released on October 30, 2008, the agency did not address the topic of bundled price concessions.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the March 9, 2007 label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a national coverage analysis (NCA) which is generally CMS first step toward developing a national coverage determination (NCD). Generally, a NCD is a national

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policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. On July 30, 2007, CMS issued its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions. The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy.

We believe this restriction on reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, based on our knowledge, although no private payers have implemented the Decision Memorandum to date, many private payers have implemented the restrictions included in the Decision Memorandum. Further, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage.

In addition, the FDA held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. On July 31, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process and which included as potential topics the use of ESAs in ESRD and chronic kidney disease (CKD). CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD and we cannot predict whether ESAs in the renal setting will be the subject of a future NCD, however, any final NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in Decision Memorandum for treatment of anemia in oncology with ESAs, would negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. In addition, on August 22, 2008 our platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic ITP, Nplate™, was approved by the FDA and falls within the thrombopoiesis stimulating agents (platelet growth factors) topic that was also included on CMS July 31, 2008 potential future NCD topic list. We cannot predict whether Nplate™ will be the subject of a future NCD.

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, has increased the level of Medicaid rebates paid by us.

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Results of Operations

Product sales

For the three and nine months ended September 30, 2008 and 2007, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2008	2007	Change	2008	2007	Change
Aranesp®	$ 845	$ 818	3%	$ 2,431	$ 2,787	(13)%
EPOGEN®	634	602	5%	1,810	1,851	(2)%
Neulasta®/NEUPOGEN®	1,192	1,100	8%	3,479	3,159	10%
ENBREL	893	821	9%	2,685	2,374	13%
Sensipar®	161	122	32%	444	335	33%
Vectibix®	41	41	0%	107	137	(22)%
Other	18	20	(10)%	57	50	14%
Total product sales	$ 3,784	$ 3,524	7%	$ 11,013	$ 10,693	3%
Total U.S.	$ 2,929	$ 2,809	4%	$ 8,560	$ 8,572	0%
Total International	855	715	20%	2,453	2,121	16%
Total product sales	$ 3,784	$ 3,524	7%	$ 11,013	$ 10,693	3%

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, contracting and pricing strategies, wholesaler and end-user inventory management practices, patient population growth, fluctuations in foreign currency exchange rates, new product launches and indications, competitive products, product supply and acquisitions.

Total product sales for the three and nine months ended September 30, 2008 increased 7% and 3% as compared to the prior year comparative periods, respectively. Product sales in the United States for the three and nine months ended September 30, 2008 totaled $2.9 billion and $8.6 billion, respectively, representing an increase of 4% for the three month period and remaining essentially unchanged for the nine month period compared to the prior year comparative periods. International product sales for the three and nine months ended September 30, 2008 totaled $855 million and $2.5 billion, respectively, reflecting increases of 20% and 16% over the prior year comparative periods. International product sales for the three and nine months ended September 30, 2008 reflect favorable foreign currency exchange rate changes of $78 million and $243 million, respectively. Excluding the impact of foreign currency exchange rate changes for the three and nine months ended September 30, 2008, worldwide product sales increased 5% and 1%, respectively, and international product sales increased 9% and 4%, respectively.

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Aranesp®

For the three and nine months ended September 30, 2008 and 2007, total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2008	2007	Change	2008	2007	Change
Aranesp® - U.S.	$ 458	$ 460	0%	$ 1,290	$ 1,692	(24)%
Aranesp® - International	387	358	8%	1,141	1,095	4%
Total Aranesp®	$ 845	$ 818	3%	$ 2,431	$ 2,787	(13)%

U.S. sales of Aranesp® in the three months ended September 30, 2008 benefited from a $54 million change in the accounting estimate related to its product sales returns reserve. Excluding the positive impact of the change in accounting estimate, U.S. sales of Aransep® decreased 12% compared to the three months ended September 30, 2007. This decrease in U.S. Aranesp® sales reflects the negative impact on demand, primarily in the supportive cancer care setting, of physician conformance to regulatory and reimbursement changes which principally occurred in the second half of 2007 and additional product label changes which occurred on August 6, 2008, as well as a slight decline in share. The decline in demand in the three months ended September 30, 2008 was partially offset by an increase in the average net sales price. The regulatory and reimbursement developments include in particular, (i) the CMS Decision Memorandum issued in July 2007, which significantly restricted Medicare reimbursement for use of Aranesp® in CIA and which we believe has also negatively impacted Aranesp® use in CIA for patients covered by private insurance plans, (ii) the loss of Aranesp® for use in the treatment of AoC in 2007 and (iii) the August 6, 2008, March 7, 2008, November 8, 2007 and March 9, 2007 product safety-related label changes in the United States. During the latter part of the three months ended December 31, 2007 and during the nine months ended September 30, 2008, underlying Aranesp® demand remained relatively stable, but in September 2008 we began to see a slight reduction in weekly sales which we believe is related to the early effect of the August 6, 2008 label revision on utilization patterns. We believe that Aranesp® sales in the United States, primarily in the supportive cancer care setting, will likely further decline as a result of the August 6, 2008 label revision, our new contracts entered into with our customers and the proposed REMS that we recently submitted to the FDA.

The decrease in U.S. Aranesp® sales for the nine months ended September 30, 2008, reflects the negative impact of the above noted regulatory and reimbursement developments as well as a slight decline in share, partially offset by an increase in the average net sales price and the positive impact of changes in the estimate of its product sales returns reserve.

The increase in international Aranesp® sales for the three and nine months ended September 30, 2008 is due to changes in foreign currency exchange rates, which positively impacted sales by approximately $35 million and $116 million, respectively. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales for the three and nine month periods decreased 2% and 6%, respectively, reflecting the impact of pricing pressures and ESA dosing conservatism. Through September 30, 2008, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total international Aranesp® segment share.

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

regulatory developments, including those resulting from:

- ESA product labeling changes in the United States on August 6, 2008, as the FDA directed;
- risk management activities, including a REMS, undertaken by us or required by the FDA or other regulatory authorities;
- product labeling changes occurring on March 5, 2008 in Europe for the class of ESAs, including Aranesp®, by the European Commission and the potential for further changes resulting from the EMEA s recommendation that the ESA product information be updated with a new warning for their use in cancer patients;
- future product label changes;

reimbursement developments, including those resulting from:

- government s and/or third-party payer s reaction to recent or future product label changes;
- current or future cost containment pressures by third-party payers, including governments and private insurance plans;

adverse events or results from clinical trials or studies or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), which have and could further impact product safety labeling, negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;

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

our ability to maintain worldwide segment share and differentiate Aranesp® from current and potential future competitive products, including J&J s Epoetin alfa product marketed in the United States and certain other locations outside of the United States and other competitors products outside of the United States, including biosimilar products that have been or are expected to be launched in the future;

our current and future contracting and related pricing strategies;

patient population growth; and

development of new treatments for cancer and future chemotherapy treatments. For example, targeted therapies and other treatments that are less myelosuppressive may require less Aranesp®;

certain of which could have a material adverse impact on future sales of Aranesp®.

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

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EPOGEN®

For the three and nine months ended September 30, 2008 and 2007, total EPOGEN® sales were as follows (dollar amounts in millions):

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2008	2007	Change	2008	2007	Change
EPOGEN® - U.S.	$ 634	$ 602	5%	$ 1,810	$ 1,851	(2)%

EPOGEN® sales for the three months ended September 30, 2008 increased 5% primarily due to an increase in demand, reflecting an increase in the average net sales price, favorable changes in wholesaler inventory levels and revised estimates of dialysis demand (primarily spillover) for prior quarters. Increased demand due to patient population growth was offset by a decline in dose/utilization within certain settings. The decrease of 2% in EPOGEN® sales for the nine months ended September 30, 2008 was primarily due to a decrease in demand, reflecting a decrease in the average net sales price, unfavorable wholesaler inventory changes and revised estimates of dialysis demand (primarily spillover) for prior quarters. Spillover is a result of the Company s contractual relationship with J&J (see Note 1, *Summary of significant accounting policies Product sales* to the Condensed Consolidated Financial Statements for further discussion).

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

reimbursement developments, including those resulting from:

- changes in healthcare providers prescribing behavior resulting in dose fluctuations due to the CMS revisions to its EMP, which became effective January 1, 2008;
- the federal government s reaction to recent or future product label changes;
- changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid;

regulatory developments, including those resulting from:

- future product label changes;
- risk management activities, including a REMS, undertaken by us or required by the FDA;

governmental or private organization regulations or guidelines relating to the use of our product, including changes in medical guidelines and legislative actions;

adverse events or results from clinical trials or studies or meta-analyses performed by us, including our pharmacovigilance clinical trials, or by others (including our licensees or independent investigators), which have and could further impact product safety labeling, negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;

cost containment pressures from the federal and state governments on healthcare providers;

our current and future contracting and related pricing strategies;

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changes in future patient population growth or dose/utilization; and

development of new modalities to treat anemia associated with CRF;

certain of which could have a material adverse impact on future sales of EPOGEN®.

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

Neulasta®/NEUPOGEN®

For the three and nine months ended September 30, 2008 and 2007, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2008	2007	Change	2008	2007	Change
Neulasta® - U.S.	$ 633	$ 598	6%	$ 1,850	$ 1,744	6%
NEUPOGEN® - U.S.	223	232	(4)%	667	636	5%
U.S. Neulasta®/NEUPOGEN® - Total	856	830	3%	2,517	2,380	6%
Neulasta® - International	219	165	33%	620	472	31%
NEUPOGEN® - International	117	105	11%	342	307	11%
International Neulasta®/NEUPOGEN® - Total	336	270	24%	962	779	23%
Total Worldwide Neulasta®/NEUPOGEN®	$ 1,192	$ 1,100	8%	$ 3,479	$ 3,159	10%

The increase in U.S. sales of Neulasta®/NEUPOGEN® for the three and nine months ended September 30, 2008 primarily reflects an increase in demand for Neulasta® driven by an increase in the average net sales price. The increase in demand for the three months ended September 30, 2008 was partially offset by a decline in units sold, which we believe was primarily due to stocking by end users of our products, including healthcare providers such as physicians or their clinics and hospitals, which occurred in the three months ended June 30, 2008.

The increase in international Neulasta®/NEUPOGEN® sales for the three and nine months ended September 30, 2008 reflects changes in foreign currency exchange rates, which positively impacted combined international sales by $33 million and $97 million, respectively, as well as increased demand driven by continued conversion from NEUPOGEN® to Neulasta®. Excluding the favorable impact of foreign currency exchange rate changes, international Neulasta®/NEUPOGEN® sales increased 12% and 11% over the three and nine months ended September 30, 2007, respectively.

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

penetration of existing segments;

competitive products or therapies, including biosimilar products that have been or may be approved in the European Union (EU) and be available shortly thereafter. For example, in September 2008, Ratiopharm s Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel s Biograstim® and Teva s Tevagrastim®, all G-CSF biosimilar products, received marketing authorization from the European Commission. Ratiopharm has launched its G-CSF biosimilar product, Ratiograstim®, in the United Kingdom in October 2008, and is expected to launch it in Germany and several other European markets in the fourth quarter of 2008. CT Arzneimittel is

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expected to market its G-CSF biosimilar product in Germany in the fourth quarter of 2008. Teva stated that it would begin marketing its G-CSF biosimilar product throughout Europe in 2009.

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

adverse events or results from clinical trials or studies or meta-analyses performed by us or by others (including our licensees or independent investigators), which could expand safety labeling and may negatively impact healthcare provider prescribing behavior, use of our products, regulatory or private healthcare organization medical guidelines and reimbursement practices;

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

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

our current and future contracting and related pricing strategies;

patient population growth; and

development of new treatments for cancer and future chemotherapy treatments. For example, targeted therapies and other treatments that are less myelosuppressive may require less Neulasta®/NEUPOGEN®.

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

ENBREL

For the three and nine months ended September 30, 2008 and 2007, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2008	2007	Change	2008	2007	Change
ENBREL - U.S.	$ 838	$ 777	8%	$ 2,531	$ 2,247	13%
ENBREL - International	55	44	25%	154	127	21%
Total ENBREL	$ 893	$ 821	9%	$ 2,685	$ 2,374	13%

ENBREL sales growth for the three months ended September 30, 2008 reflects higher demand due to increases in both average net sales price and patients. ENBREL sales growth in the three months ended September 30, 2008 was affected by share declines in the United States compared to the three months ended September 30, 2007 due to increased competitive activity. However, sales growth continued in both rheumatology and dermatology, and ENBREL continues to maintain a leading position in both segments.

ENBREL sales growth for the nine months ended September 30, 2008 reflects higher demand due to increases in both average net sales price and patients and an initial wholesaler inventory stocking of approximately $120 million resulting from the shift to a wholesaler distribution model in the three months ended March 31, 2008. During the three months ended March 31, 2008, ENBREL s distribution model was converted from primarily being drop shipped directly to pharmacies to a wholesaler distribution model similar to our other products in the United States. We believe that this estimated initial wholesaler inventory stocking is within the expected normal inventory range. ENBREL sales growth in the nine months ended September 30, 2008 was affected by share declines in the United States compared to the nine months ended September 30, 2007 due to increased competitive activity.

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

- the effects of competing products or therapies, which may include new indications for existing products and new competitive products coming to market, such as J&J s CNTO 1275 (ustekinumab) and CNTO 148 (golimumab) and, in part, our ability to differentiate ENBREL based on its safety profile and efficacy;
- recent or future product label changes;
- risk management activities, including a REMS, undertaken by us or required by the FDA or other regulatory authorities;
- growth in the rheumatology and dermatology segments;
- the outcome of the FDA s review of the supplemental BLA for the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis;
- the availability, extent and access to reimbursement by government and third-party payers;
- adverse events or results from clinical trials or studies or meta-analyses performed by us or by others (including our licensees or independent investigators), which could expand safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- governmental or private organization regulations or guidelines relating to the use of our product;
- cost containment pressures from governments and private insurers on healthcare providers;
- current and future contracting and related pricing strategies;
- patient population growth; and
- penetration of existing and new segments, including potential expanded indications.

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

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Selected operating expenses

The following table summarizes selected operating expenses for the three and nine months ended September 30, 2008 and 2007 (dollar amounts in millions):

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2008	2007	Change	2008	2007	Change
Product sales	$ 3,784	$ 3,524	7%	$ 11,013	$ 10,693	3%
Operating expenses:						
Cost of sales (excludes amortization of acquired intangible assets)	$ 677	$ 792	(15)%	$ 1,738	$ 1,942	(11)%
% of product sales	18%	22%		16%	18%	
Research and development	$ 729	$ 776	(6)%	$ 2,232	$ 2,444	(9)%
% of product sales	19%	22%		20%	23%	
Selling, general and administrative	$ 900	$ 730	23%	$ 2,678	$ 2,360	13%
% of product sales	24%	21%		24%	22%	
Amortization of acquired intangible assets	$ 74	$ 76	(3)%	$ 221	$ 224	(1)%
Write-off of acquired in-process research and development	$ -	$ 590	(100)%	$ -	$ 590	(100)%
Other charges	$ 12	$ 254	(95)%	$ 306	$ 543	(44)%

Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see Condensed Consolidated Statements of Income), decreased 15% for the three months ended September 30, 2008 primarily driven by prior year restructuring costs, principally accelerated depreciation, which totaled $113 million. Absent the impact of the restructuring costs, costs of sales was relatively unchanged from the prior year as higher sales volume was offset by lower inventory reserves, lower excess capacity charges and lower ENBREL manufacturing costs. Cost of Sales for the nine months ended September 30, 2008 decreased 11% primarily as the result of charges incurred in the nine months ended September 30, 2007 including the above-mentioned restructuring charges and the write-off of a semi-completed manufacturing asset. Cost of sales for the nine months ended September 30, 2008 also reflects lower inventory reserves and lower excess capacity charges than the nine months ended September 30, 2007.

Research and development

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

R&D expenses for the three and nine months ended September 30, 2007 include $18 million of restructuring costs, comprised of $35 million in charges related to asset impairments offset by a $17 million benefit associated with the reversal of previously accrued expenses for bonuses and stock-based compensation awards, which were forfeited as a result of the employees termination. During the three months ended September 30, 2008, there were no R&D restructuring related costs. For the nine months ended September 30, 2008, restructuring related R&D costs totaled $3 million. See Note 2, *Restructuring* to the Condensed Consolidated Financial Statements for further discussion.

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R&D expenses decreased 6% for the three months ended September 30, 2008 due to lower clinical trial costs of $39 million; a decrease of $22 million in merger related expenses; the above noted decline in restructuring related costs of $18 million and the net benefit derived from our licensing activities, including our transaction with Takeda Pharmaceutical Company Limited (Takeda) in Japan, totaling $11 million, partially offset by $15 million of higher staff related costs. Our clinical trial costs were lower in the three months ended September 30, 2008 primarily due to the completion of enrollment of our large denosumab clinical trials and the related significant costs associated with site initiation and patient enrollment no longer being incurred, partially offset by the increased clinical costs for our emerging pipeline.

R&D expenses decreased 9% for the nine months ended September 30, 2008, which was primarily attributable to $100 million of decreased staff related costs; $88 million of lower clinical trial costs; $82 million of cost recoveries derived from licensing transactions, primarily with Daiichi Sankyo Company and Takeda in Japan; $24 million of decreased merger related expenses and $15 million in reduced restructuring related costs, partially offset by a $100 million expense in the nine months ended September 30, 2008 for the upfront payment associated with the Kyowa Hakko collaboration. Clinical trial costs decreased as some of our large clinical trials completed enrollment, as discussed above.

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 and legal expenses; overhead and facilities costs and other general and administrative costs. In connection with a co-promotion agreement, we and Wyeth market and sell ENBREL in the United States and Canada and Wyeth is paid a share of the related profits, as defined. The share of ENBREL s profits owed to Wyeth (the Wyeth profit share expense) is included in SG&A expenses.

For the three and nine months ended September 30, 2007, we recorded $92 million in cost recoveries for certain restructuring charges, principally with respect to accelerated depreciation, in connection with our co-promotion agreement with Wyeth totaling $83 million, and $9 million of benefit associated with the reversal of previously accrued expenses for bonuses and stock-based compensation awards, which were forfeited as a result of the employees termination. During the three months ended September 30, 2008, there were no SG&A restructuring related costs. For the nine months ended September 30, 2008, restructuring related SG&A costs totaled $1 million. See Note 2, *Restructuring* to the Condensed Consolidated Financial Statements for further discussion.

For the three months ended September 30, 2008, the 23% increase in SG&A was due to the above noted recoveries of restructuring related costs in the prior year and higher expenses during the three months ended September 30, 2008 for Wyeth profit share expense and staff related costs of $53 million and $45 million, respectively, partially offset by lower litigation expense of $28 million. For the three months ended September 30, 2008 and 2007, the Wyeth profit share expense was $298 million and $245 million, respectively.

For the nine months ended September 30, 2008, the 13% increase in SG&A was due to the above noted recoveries of restructuring related costs in the prior year and, higher expenses for the nine months ended September 30, 2008 for Wyeth profit share expense and staff related costs of $167 million and $99 million, respectively, partially offset by lower litigation expense of $35 million. For the nine months ended September 30, 2008 and 2007, the Wyeth profit share expense was $886 million and $719 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.

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Other charges

As discussed in Note 2, *Restructuring* to the Condensed Consolidated Financial Statements, on August 15, 2007, we announced plans to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. As a result of this restructuring plan, we recorded the following charges during the three and nine months ended September 30, 2008: (i) staff separation costs of $0 and $4 million, respectively, (ii) asset impairment charges of $1 million and $15 million, respectively, and (iii) other charges of $7 million and $20 million, respectively, primarily related to loss accruals for leases for certain facilities that will not be used in our business.

In conjunction with the above noted restructuring activities, we recorded the following charges during the three and nine months ended September 30, 2007: (i) staff separation costs of $104 and $107 million, respectively and (ii) asset impairment charges of $71 million and $357 million, respectively. In addition, we recorded other charges of $79 million during the three and nine months ended September 30, 2007 primarily related to loss accruals for leases for certain R&D facilities that will not be used in our business.

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

Interest and other income and (expense), net

Interest and other income and (expense), net for the three months ended September 30, 2008 was $12 million of expense compared to $21 million of expense for the three months ended September 30, 2007. This change is primarily due to higher interest income of $17 million, primarily due to higher cash balances and lower interest expense of $19 million, primarily due to lower interest rates, partially offset by the loss accrued in the three months ended September 30, 2008 on the sale of certain less significant marketed products and related assets of $9 million, which was part of our restructuring plan.

Interest and other income and (expense), net for the nine months ended September 30, 2008 was $19 million of income compared to $20 million of expense for the nine months ended September 30, 2007. This change is primarily due to the write-off of $51 million of deferred financing and related costs in March 2007 resulting from the repayment of certain of our convertible debt, an increase in net realized gains of approximately $48 million primarily due to the rebalancing of investments in our marketable securities portfolio, an increase in interest income of approximately $27 million primarily due to higher average cash balances, partially offset by incremental interest expense of approximately $59 million primarily related to the issuance of $4.0 billion of debt in May 2007 and $1.0 billion of debt in May 2008, and $9 million related to the loss accrued on the sale of certain less significant marketed products and related assets.

Income taxes

Our effective tax rates for the three and nine months ended September 30, 2008 were 21.3% and 21.0%, respectively, compared with 46.0% and 19.7%, respectively, for the same periods last year. The decrease in our effective tax rate for the three months ended September 30, 2008 compared to the same period last year was primarily due to the non-deductible, acquired IPR&D expense incurred in connection with the acquisitions of Alantos and Ilypsa in 2007, partially offset by expiration of the federal research and experimentation tax credit (R&D credit) on December 31, 2007. The increase in our effective tax rate for the nine months ended September 30, 2008 compared to the same period last year was primarily due to the favorable resolution of our prior year s federal income tax examination in the second quarter of 2007, expiration of federal R&D credit for 2008 that was not extended prior to September 30, 2008, partially offset by the non-deductible, acquired IPR&D expense incurred in connection with Alantos and Ilypsa in 2007.

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

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Recent accounting pronouncements

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF 07-5). Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative as outlined in SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity s stock. EITF 07-5 provides guidance on how to determine if equity-linked instruments (or embedded features) such as warrants to purchase our stock, our convertible notes and convertible note hedges are considered indexed to our stock. EITF 07-5 is effective for the financial statements issued for fiscal years and interim periods within those fiscal years, beginning after December 15, 2008 and will be applied to outstanding instruments as of the beginning of the fiscal year in which it is adopted. Upon adoption, a cumulative effect adjustment will be recorded, if necessary, based on amounts that would have been recognized if this guidance had been applied from the issuance date of the affected instruments. We are currently determining the impact that EITF 07-05 will have on our financial statements, if any.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement* (FSP APB 14-1) that changes the method of accounting for convertible debt securities that require or permit settlement in cash either in whole or in part upon conversion, including our convertible debt securities (see Note 5, *Financing arrangements* to the Condensed Consolidated Financial Statements). We will adopt FSP APB 14-1 in the first quarter of 2009 and retrospectively apply this change to prior periods, as required by this new standard. Under this new method of accounting, the debt and equity components of our convertible debt securities will be bifurcated and accounted for separately in a manner that will result in recognizing interest expense on these securities at effective rates reflective of what we would have incurred had we issued nonconvertible debt with otherwise similar terms. The equity component of our convertible debt securities will be included in the paid-in-capital section of stockholders equity on our Consolidated Balance Sheet and, accordingly, the initial carrying values of these debt securities will be reduced. Our net income for financial reporting purposes will 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. We are currently determining the impact FSP APB 14-1 will have on our financial statements. We expect it will have a material adverse impact on our past and future reported financial results but will have no impact on past or future cash flows.

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

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Financial Condition, Liquidity and Capital Resources

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

	September 30, 2008	December 31, 2007
Cash, cash equivalents and marketable securities	$ 9,757	$ 7,151
Total assets	36,998	34,639
Current debt	1,000	2,000
Non-current debt	10,176	9,177
Stockholders equity	19,832	17,869

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future. In addition, we plan to opportunistically pursue our stock repurchase programs and other business initiatives, including acquisitions and licensing activities. Our liquidity needs can be met through a variety of sources, including: cash provided by operating activities, sale of marketable securities, borrowings through commercial paper and/or our syndicated credit facility and other debt markets and equity markets. Our current financial position, liquidity and credit ratings should allow us to access the capital markets. However, due to the recent extreme volatility and disruption in the capital markets, we expect to be opportunistic in our timing for raising financing in the future. We have cash available to retire our remaining $1.0 billion of floating rate notes due on November 28, 2008 (following the redemption of $1.0 billion of such notes in June 2008). In addition, we anticipate that our business will generate sufficient cash for us to have flexibility to repay $1.0 billion of our 4.00% notes due November 2009 without incurring additional indebtedness.

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at September 30, 2008, approximately $7.7 billion was generated from operations in foreign tax jurisdictions and is intended for use in our foreign operations. If these funds were repatriated for use in our U.S. operations, we would be required to pay additional U.S. federal and state income taxes at the applicable marginal tax rates.

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Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of September 30, 2008 and December 31, 2007 (in millions):

	September 30, 2008	December 31, 2007
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,500	$ 2,500
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	2,500
5.85% notes due 2017 (2017 Notes)	1,099	1,099
Floating rate notes due 2008 (2008 Floating Rate Notes)	1,000	2,000
4.00% notes due 2009 (2009 Notes)	1,000	999
4.85% notes due 2014 (2014 Notes)	1,000	1,000
6.375% notes due 2037 (2037 Notes)	899	899
6.15% notes due 2018 (2018 Notes)	499	-
6.90% notes due 2038 (2038 Notes)	498	-
Other	181	180
Total borrowings	11,176	11,177
Less current portion	1,000	2,000
Total non-current debt	$ 10,176	$ 9,177

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

In May 2008, we increased our commercial paper program by $1.3 billion, which provides for unsecured, short-term borrowings of up to an aggregate of $2.5 billion. We also have a $2.5 billion syndicated unsecured revolving credit facility which matures in November 2012 and is available for general corporate purposes, or as a liquidity backstop to our commercial paper program; however, $178 million of such commitment was provided by a subsidiary of Lehman. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. As a result, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. No amounts were outstanding under the commercial paper program or credit facility as of September 30, 2008.

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of September 30, 2008. None of our financing arrangements contain any financial covenants. Our outstanding convertible notes and our other outstanding long-term notes are rated A+ with a stable outlook by Standard & Poor s, A3 with a stable outlook by Moody s Investors Service, Inc. and A with a stable outlook by Fitch, Inc.

See Note 5, *Financing arrangements* to our Condensed Consolidated Financial Statements for further discussions of the transactions during the nine months ended September 30, 2008 and *Recent accounting pronouncements* for a discussion of future impacts to the accounting for our convertible debt.

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Cash flows

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

	Nine months ended September 30,	
	2008	2007
Net cash provided by operating activities	$ 4,591	$ 3,871
Net cash used in investing activities	(2,618)	(1,295)
Net cash used in financing activities	(1,475)	(2,470)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2008 increased primarily due to the receipt of $300 million for an upfront milestone payment related to our licensing agreement with Takeda, which is included in the Changes in deferred revenue in the Condensed Consolidated Statements of Cash Flows, increased cash receipts from the sale of our products, lower payments in the ordinary course of business and lower tax payments, partially offset by payments for legal settlements totaling $283 million.

Investing

Cash used in investing activities during the nine months ended September 30, 2008 increased primarily due to the net purchases of marketable securities partially offset by a decrease in capital expenditures. Net purchases of marketable securities were $2.2 billion in the nine months ended September 30, 2008 compared to net receipts of $473 million for the nine months ended September 30, 2007. Capital expenditures totaled $494 million during the nine months ended September 30, 2008, compared with $1.0 billion during the same period in the prior year. The capital expenditures during the nine months ended September 30, 2008 were primarily associated with manufacturing capacity expansions in Puerto Rico, Fremont and other site developments and investment in our global enterprise resource planning (ERP) system and other information systems projects. The capital expenditures during the nine months ended September 30, 2007 were primarily associated with manufacturing capacity and site expansions in Puerto Rico and other locations and investment in our global ERP system and other information systems projects. We currently estimate 2008 spending on capital projects and equipment to be approximately $750 million.

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

Financing

In May 2008, we issued $500 million aggregate principal amount of notes due in 2018 (the 2018 Notes) and $500 million aggregate principal amount of notes due in 2038 (the 2038 Notes) in a registered offering. The 2018 Notes and 2038 Notes pay interest at fixed annual rates of 6.15% and 6.90%, respectively. Concurrent with the issuance of the 2018 Notes, we entered into interest rate swap agreements that effectively convert the payment of our fixed rate interest payments to variable rate interest payments over the life of the 2018 Notes. The 2018 Notes and 2038 Notes may be redeemed at any time at our option, in whole or in part, at 100% of the principal amount of the notes being redeemed plus accrued and unpaid interest, if any, and a make-whole amount, as defined in the indenture governing the notes. In the event of a change in control triggering event, as defined in the indenture governing the notes, we may be required to purchase for cash all or a portion of the 2018 Notes and the 2038 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. Debt issuance costs totaled approximately $6 million and are being amortized over the life of the notes.

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Upon the receipt of the proceeds from the issuance of the 2018 Notes and 2038 Notes, we exercised our right to call $1.0 billion of floating rate notes due November 2008, which were retired in June 2008.

During the nine months ended September 30, 2008, we repurchased 32.7 million shares of our common stock at a total cost of $1.6 billion, in connection with an ASR entered into in May 2008. During the nine months ended September 30, 2007, we repurchased 85.2 million shares of our common stock at a total cost of $5.0 billion, in connection with an ASR entered into in May 2007. As of September 30, 2008, we had $4.9 billion available for stock repurchases as authorized by our Board of Directors. The manner of purchases, amount we spend and the number of shares repurchased will vary based on a number of factors including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions. Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock. Employee stock option exercises provided $114 million and $244 million of cash during the nine months ended September 30, 2008 and 2007, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of our stock relative to the exercise price of such options.

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

In May 2007, we issued $2.0 billion aggregate principal amount of floating rate notes due in 2008, $1.1 billion aggregate principal amount of 5.85% notes due in 2017 and $900 million aggregate principal amount of 6.375% notes due in 2037. The 2008 Floating Rate Notes bear interest at a rate per annum, equal to LIBOR plus 0.08%, which is 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 an ASR entered into in May 2007.

Contractual Obligations

On October 22, 2008, we entered into an agreement with International Business Machines Corporation (IBM) for information systems infrastructure services including electronic messaging systems, networks, helpdesk support for end users, physical information technology support, servers hosting applications, information systems hardware refresh, and evolution of methods, processes and technologies being used to provide information systems infrastructure services. The term of the agreement is five years with three one-year renewal options by us, for a total of an eight year term. The cost to us for the five year term is estimated to be $500 million with a full eight year term estimated to be $800 million.

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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 September 30, 2008.

Management determined that, as of September 30, 2008, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 9, *Contingences* to the Condensed Consolidated Financial Statements for a discussion which is limited to certain recent developments concerning our legal proceedings. This discussion should be read in conjunction with Note 10, *Contingencies* to our Consolidated Financial Statements in Part IV of our Annual Report on Form 10-K for the year ended December 31, 2007.

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties facing our business. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

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

We and certain of our licensees and partners conduct research, preclinical testing and clinical trials for our product candidates and marketed products for both their existing indications as well as for new and/or expanded indications. In addition, we manufacture and contract manufacture, and certain of our licensees and partners manufacture our products and product candidates, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the EMEA in European countries and similar regulatory bodies in Canada and Australia. Currently, we are required in the United States and in foreign countries to obtain approval from those countries regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to fail to approve commencement of, suspend or terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, mandate product withdrawals and require changes in labeling (including eliminating certain therapeutic indications) of our products. On September 27, 2007, President Bush signed into law the FDAAA, significantly adding to the FDA s authority including allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk; (ii) mandate labeling changes to products, at any point in a product s lifecycle, based on new safety information and (iii) require sponsors to implement a REMS for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on distribution or use of a product. Failure to comply with the new requirements, if imposed on a sponsor by the FDA under the FDAAA, could result in significant civil monetary penalties. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

In our experience, obtaining regulatory approval has been and continues to be increasingly difficult and costly and takes many years, and, after it is obtained, remains costly to maintain. With the occurrence of a number of high profile safety events with certain pharmaceutical products, regulatory authorities, and, in particular, the FDA, members of Congress, the U.S. Government Accountability Office (GAO), Congressional

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

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

Certain specific labeling or label changes of approved products or product candidates may be necessary or required for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns by regulatory agencies, the discovery of significant problems or safety signals or trends with a similar product that implicates an entire class of products, subsequent concerns about the sufficiency of the data or studies underlying the label or changes to the underlying safety/efficacy analysis related to results from clinical trials or meta-analysis of clinical trials or clinical data performed by us or others. In addition, before or after any of our products are approved for commercial use, regulatory bodies could decide that the product labels need to include certain warning language as part of an evolving label change to a particular class of products. For example, in March and November 2007, and in March and August 2008, the labels of the class of ESA products, including Aranesp® and EPOGEN®, were updated to include revised boxed warnings, restrictions on the use of ESAs in specific therapeutic areas and other safety-related product labeling changes. (See *Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.*) On March 17, 2008, we and Wyeth announced updates to the FDA approved labeling for ENBREL in which the U.S. PI now contains a boxed warning relating to the risk of infections, including tuberculosis. This information now in the boxed warning includes additional language regarding screening and monitoring patients for tuberculosis, including patients who tested negative for latent tuberculosis infection. Further, on September 4, 2008, the FDA issued a web-alert regarding their review of histoplasmosis and other opportunistic fungal infections in patients treated with TNF blockers. The FDA requested that the boxed warning and warnings sections of the U.S. PI and the medication guide for ENBREL (and other TNF blockers) be strengthened to include the risk of unrecognized histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. We are working with the FDA to finalize the required revisions to respond to its requests.

Additionally, on June 4, 2008, the FDA issued an Early Communication regarding the ongoing safety review of TNF blockers and the possible association between the use of these medicines and the development of lymphoma and other cancers in children and young adults and stated that it had decided to conduct further analyses to evaluate the risk and benefits of TNF blockers in pediatric patients. On June 18, 2008, we participated in a meeting of the DODAC to review data supporting the supplemental BLA submitted by us for

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the use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis, who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy and the DODAC recommended, with an 8-5 vote, to approve ENBREL in the treatment of chronic moderate to severe plaque psoriasis in children. On July 24, 2008, we received notification from the FDA through a Complete Response letter that the FDA would like additional information from us to support the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis. We continue to work with the FDA to respond to its requests and to provide it with information to address additional questions related to the supplemental BLA and plans for risk management activities. Although we cannot predict what the FDA s analysis of TNF blockers and the development of lymphoma or other cancers in children and young adults may lead to or speculate on the timing of the FDA s response on the supplemental BLA, further revisions to the ENBREL label or other actions by the FDA, including additional advisory committee meetings, could have a negative impact on the use and sales of ENBREL which could have a material adverse effect on our business and results of operations.

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

If we or others identify safety concerns before approval of the product or after a product is on the market, the regulatory agencies such as the FDA or EMEA may impose risk management activities upon us (including a REMS) which may require substantial costs and resources to negotiate, develop and implement, including sales force time to educate physicians on REMS requirements and compliance, and/or may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product, or for approval of a new indication. Further, risk management activities, including a REMS, required by regulatory agencies such as the FDA could also modify, restrict or otherwise impact our existing promotional activities of our other products, restrict or encumber the ability of healthcare providers to prescribe, dispense or use our products or limit patient access to our products, or affect our ability to compete against products that do not have a REMS, any of which could have a negative affect on our ability to launch our product and could have a material adverse effect on sales of the affected products and on our business and results of operations. For example, as part of the approval for Nplate™, a REMS was developed with the FDA to assure the safe use of Nplate™ while minimizing risk. The Nplate™ REMS involves, among other things, healthcare provider and patient enrollment registries, tracking of patient medical history and data and follow-up safety questionnaires to healthcare providers all of which require extensive discussion and education with healthcare providers which has limited our ability to promote Nplate™ and our other products. Further, as part of the update to the boxed warning and warnings sections of the U.S. PI and the medication guide for ENBREL, the FDA stated that it would require us and the other makers of TNF blockers to educate healthcare providers about the risk of histoplasmosis. In addition, we have ongoing PMC studies for substantially all of our marketed products other than Sensipar®. These clinical trials must be conducted by us to maintain regulatory approval and marketing authorization. For example, we have agreed with the FDA to a robust pharmacovigilance program to continue to study the safety surrounding the use of ESAs in certain cancer indications. (See *Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.*) Additionally, the approvals of Vectibix® in both the United States and EU were conditioned on us conducting additional clinical trials of the use of Vectibix® as a therapy in treating mCRC and our conditional approval of Vectibix® in the EU is currently the subject of an annual review by the CHMP. If results from clinical trials as part of a PMC or pharmacovigilance program are negative, it could result in the revocation of the marketing or conditional marketing approvals or revised labeling of our products, which could have a material adverse effect on sales of the affected products and on our business and results of operations.

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

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

Recent labeling changes or risk management activities required by regulatory authorities, as well as the results or meta-analyses of clinical trials, may adversely impact the use, sales and reimbursement of our ESAs.

On March 9, 2007, based upon data from our AoC 103 Study, J&J s Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study, and preliminary data from the third-party investigator Danish Head and Neck Cancer (DAHANCA) 10 Study, among others, the FDA approved updated safety information, including a boxed warning, in the labeling for the class of ESAs, including Aranesp® and EPOGEN®. On May 10, 2007, the ODAC held a panel meeting to discuss the safety/efficacy profile of ESA use in oncology. Responding to questions posed by the FDA, the ODAC recommended that more restrictions be added to ESA labeling and that additional clinical trials be conducted by companies with currently approved ESAs, including us, although no specific restrictions or studies were recommended at the ODAC meeting. The committee is advisory and FDA officials are not bound to or limited by its recommendations although, the FDA has commonly followed the recommendations of its advisory panels. The FDA also held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. On November 8, 2007, in recognition of the input from the May 2007 ODAC and September 2007 joint

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CRDAC/DSaRMAC meetings, we announced additional updates to the Aranesp® and EPOGEN®/PROCRIT® labeling which reflected ongoing interactions with the FDA regarding the safety and benefit/risk profile of ESAs and included modifications to the boxed warnings of the ESA labeling. Additionally, based on safety data from the PREPARE interim study results in neo-adjuvant breast cancer and the data from the GOG-191 study in cervical cancer, on March 7, 2008, we announced that the FDA approved updated safety information, including the boxed warning in the labeling information for the class of ESAs, including Aranesp® and EPOGEN®. On March 13, 2008, the FDA held a follow-up ODAC panel meeting to discuss cumulative data, including recent study results, on the risks of ESAs when used in the oncology setting.

On July 30, 2008, we received a complete response letter from the FDA to the revisions to the ESA labeling we proposed following the March 13, 2008 ODAC meeting. The letter included, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels ≥ 10 g/dL and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL. We finalized the ESA labeling on August 6, 2008, as the FDA directed. Although we cannot predict what impact the final ESA labels would have on our business, the final ESA labeling could have a material adverse impact on the reimbursement, use and sales of our ESA products, which would have a material adverse effect on our business and results of operations.

Additionally, we continue to work closely with the FDA to develop a REMS program for Aranesp® in oncology under authority prescribed by the FDAAA. We have submitted a proposed REMS responsive to the FDA s requests, although we cannot predict what risk management activities the FDA may require of us. A REMS program for Aranesp® could have a material adverse impact on the reimbursement, use and sales of our ESA products, which would have a material adverse effect on our business and results of operations. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market* and *Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products*.) We also continue to work with the FDA to finalize protocols for clinical trials to determine the effects of Aranesp® on survival and tumor outcomes. The addition of these clinical trials to our pharmacovigilance program and any additional clinical trials required by the FDA could result in substantial additional expense, and their outcomes could result in additional label restrictions or the loss of regulatory approval for an approved indication, each of which may have a material adverse effect on our business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our ESA products. (See *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*)

Further on March 5, 2008, we announced that the European Commission reached its decision to amend the product labeling for the class of ESAs, including Aranesp®, based on the positive opinion from the CHMP in January 2008, which was consistent with the EMEA s October 23, 2007 press release stipulating a uniform target Hb range for all ESAs of 10 g/dL to 12 g/dL with guidance to avoid sustained Hb levels above 12 g/dL. Following the March 13, 2008 ODAC, we have continued to share additional ESA safety data with the EMEA as it has become available. On May 15, 2008, we and other ESA marketing authorization holders participated in a closed meeting of the SAG-O. The marketing authorization holders were asked to provide an overview on studies that have been initiated or conducted since July 2007, as well as any other new data that can help to elucidate recent issues on the impact of ESAs on tumor progression and survival in cancer patients. These data included previously disclosed interim results from the PREPARE study in neo-adjuvant breast cancer therapy; follow-up data from the GOG-191 study in cervical cancer, which were published in the February 2008 issue of Gynecologic Oncology; and the February 2008 meta-analysis by Bennett et al, which was published in the Journal of the American Medical Association. SAGs are established by the EMEA to deliver answers, on a

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consultative basis, to specific questions addressed to them by the CHMP. On June 26, 2008 the EMEA, based upon the CHMP s opinion which took into account the position expressed by the SAG-O, recommended updating the product information for ESAs with a new warning for their use in cancer patients. In July 2008, the EMEA requested that further clarity around the product information be provided by regulatory agencies in each European Member State country through the publication of a Dear Healthcare Professional Communication, following which we followed the necessary regulatory procedure to update the Aranesp® product information. In October 2008, we received notification that the Aranesp® product information update was approved by the European Commission. The product information for all ESAs was updated to advise that in some clinical situations blood transfusions should be the preferred treatment for the management of anemia in patients with cancer and that the decision to administer ESAs should be based on the benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context and that factors that should be considered in the assessment should include the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference. Although we cannot predict what impact the final EU ESA product information will have on our business, the reimbursement, use and sales of Aranesp® in Europe could be materially adversely affected, which would have a material adverse effect on our business and results of operations.

Further, we continue to receive results from meta-analyses or previously initiated clinical trials using ESAs. For example, on September 30, 2008, we announced that we had received a summary of preliminary results from the Cochrane Collaboration s independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating ESAs in cancer patients which we submitted to the FDA and EMEA. The preliminary summary includes four components: on-study deaths and overall survival in cancer patients regardless of their specific cancer treatment (chemotherapy, radiochemotherapy, radiotherapy, anemia of cancer with no treatment, other), and on-study deaths and overall survival in patients receiving chemotherapy (the only oncologic population for which ESA treatment is indicated in current FDA-approved labeling). The analysis showed that ESAs increased on-study deaths and decreased overall survival compared to controls. Although neither of these results were statistically significant, they do not exclude the potential for adverse outcomes when ESAs are used according to the current labeling. We expect to receive the complete meta-analysis results later this year and will provide this information to regulatory authorities at that time. Additionally, our Trial to Reduce cardiovascular Events with Aranesp Therapy (TREAT), a large 4,000 patient multi-center, randomized, double-blind, controlled phase 3 trial designed to determine the impact of anemia therapy with Aranesp® on mortality and non-fatal cardiovascular events in patients with CKD, anemia and type 2 diabetes, continues to progress. The independent data safety monitoring committee completed on October 30, 2008, a pre-specified, unblinded review of the TREAT data at a point where 80% of the targeted number of fully adjudicated events had been recorded and recommended that the study continue without modification. We also expect the interim data from the ARA-PLUS breast cancer adjuvant chemotherapy study to be presented at the San Antonio Breast Cancer Symposium in December 2008. The ARA-PLUS study is an investigator sponsored study and is part of our Aranesp® pharmacovigilance program. Although we cannot predict the results of meta-analyses or the outcomes of these clinical trials, we cannot exclude the possibility that adverse results could have a material adverse impact on the reimbursement, use and sales of our ESAs which would have a material adverse effect on our business and results of operations.

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

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought or our existing products are safe and effective for use in humans in new indications sought. Additionally, we may be required to conduct additional trials as a condition of the approval of our label or as a result of perceived or existing safety concerns. The results of these clinical trials are used as the basis to obtain regulatory approval from regulatory authorities such as the FDA. Clinical trials are experiments conducted using our product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking or to support our existing label. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate or the extent of the safety concerns, post-

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marketing issues and/or exposure to patients and therefore, we may spend several years and incur substantial expense in completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, availability of clinical study material and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals, associated delays in product candidates reaching the market and revisions to existing product labels. In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some Central and South American countries either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and regulatory diverse clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially adversely affected. Additional information on our clinical trials can be found on our website at (http://www.amgen.com). (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.)

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigator s clinical trials of our products or product candidates that may delay the clinical program, require additional or longer trials to gain approval, prohibit regulatory approval of our product candidates or additional indications for our currently approved products, or may render the product candidate commercially unfeasible or limit our ability to market existing products in certain therapeutic areas or at all. For example, as a result of observing an increased frequency of cholecystitis (inflammation of the gall bladder) in patients treated with our late-stage product candidate motesanib diphosphate, we delayed our phase 3 trial in first-line non-small cell lung cancer, which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. Clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on an out of date standard of medical care, limiting the utility and application of such trials. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval for new product candidates, product label extensions or maintenance of our current labels on this basis. Further, clinical trials conducted by others, including our licensees, partners or independent investigators, may result in unfavorable clinical trials results that may call into question the safety of our products in off-label or on label uses that may result in label restrictions and/or additional trials.

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

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Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Generally, in Europe and other countries outside the United States, the government sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. Further, adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand the safety information in the labeling for our approved products and may negatively impact worldwide reimbursement for our products. On July 30, 2007, CMS issued its Decision Memorandum and on January 14, 2008, issued changes to its Medicare National Coverage Determinations Manual, effective for claims with dates of service on or after July 30, 2007, with an implementation date of April 7, 2008. A discussion of the Decision Memorandum follows below. (See also *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.*)

Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare programs payment policies for drugs and biologicals are subject to various laws and regulations. Beginning in January 1, 2005 under the MMA, in the physician clinic setting and January 1, 2006, in the hospital outpatient and dialysis settings, Aranesp®, Neulasta® and NEUPOGEN® have been reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its ASP (sometimes referred to as ASP+6%). Effective January 1, 2008, Medicare payment in the hospital outpatient setting reimburses each product at 105% of its ASP and CMS has the regulatory authority to further reduce the outpatient hospital payment formula in future years. For example, effective January 1, 2009, CMS, in its Outpatient Prospective Payment System Final Rule for 2009, released on October 30, 2008, set the payment rate in the hospital outpatient setting at ASP+4% for 2009. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product s ASP is calculated and reported to CMS on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP based payment rate for Aranesp® that will be in effect for the fourth quarter of 2008 will be based in part on certain historical sales and sales incentive data for Aranesp® from July 1, 2007 through June 30, 2008. CMS publishes the ASPs for products in advance of the quarter in which they go into effect.

In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the ESRD Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement methodology is established by federal law and is monitored and implemented by CMS. Effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting. Beginning in the third quarter of 2007, based on its ongoing assessment for payment of Part B drugs, CMS instituted a single payment limit for Epoetin alfa (EPOGEN® and PROCRIT®) in all provider settings. Although we cannot predict the payment levels of EPOGEN® in future quarters or whether Medicare payments for dialysis drugs may be modified by future federal legislation, a decrease in the reimbursement rate for EPOGEN® may have a material adverse effect on our business and results of operations. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician clinic setting, dialysis facility and hospital

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outpatient setting. These calculations are regularly reviewed for completeness and based on such review, we have revised our reported ASPs to reflect calculation changes both prospectively and retroactively. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN® was reduced for the third quarter of 2007.

Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to a revised EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and appropriate hematocrit outcomes of dialysis patients. The EMP was revised, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient s Hb is above 13 g/dL for three or more consecutive months. In addition, the revised EMP reduces the monthly dosing limits to 400,000 IUs of EPOGEN®, from 500,000 IUs, and to 1,200 mcgs of Aranesp®, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN® sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. However, this dose decline subsequently stabilized but may further fluctuate in the future. Further fluctuations in dosing of EPOGEN® as a result of the revised EMP are possible and could have a material adverse effect on the sales of EPOGEN® and our business and results of operations.

Changes resulting from the MMA, which beginning in 2005 lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. However, we believe that our product sales for 2005, 2006, 2007 and for the first three quarters of 2008 were not significantly impacted by the reimbursement changes resulting from the MMA. However, additional provisions of the MMA and other regulations or legislation affecting reimbursement that have gone or may go into effect could affect our product sales in the future. For example, on July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 became law with a number of Medicare and Medicaid reforms including a broader payment bundle for dialysis services and drugs which will require CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. The new bundled rate will include dialysis services covered under the current composite rate, all ESAs and other intravenous injectable drugs and oral equivalent forms used in dialysis. The bundled reimbursement rate will be phased in over a four-year period in equal increments starting in 2011. It is possible that providers could elect to move to a full Medicare bundled payment in 2011. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011 which subjects facilities to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, which include anemia management and dialysis adequacy. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. We are in the process of evaluating the new Medicare legislation on our business and cannot predict the full impact a bundled payments system would have on sales of EPOGEN® or Aranesp® used in the treatment of persons receiving outpatient dialysis services.

In addition, in response to CMS considering and rejecting changes to the ASP calculation methodology for accounting for discounts in multi-product contracts in the 2007 Medicare Physician Fee Schedule Final Rule, MedPAC released its second Congressionally-mandated report on December 29, 2006 on the impact of changes in Medicare payments for Part B Drugs specifically recommending that the Secretary of the Department of Health and Human Services clarify ASP reporting requirements to ensure that ASP calculations allocate discounts to reflect the transaction price for each drug. Under the ASP system, we allocate our discounts based on the prices paid for individual drugs, according to the terms of its contracts with physicians and other purchasers, and we believe that the resulting ASPs reflect the transaction prices for individual drugs. Referencing a MedPAC December 2006 report, CMS proposed in the Medicare Physician Fee Schedule Proposed Rule for 2008 revising the methodology for calculating ASP to require the reallocation of price concessions of drugs sold under bundled arrangements, described by CMS in part as an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement. In the Medicare Physician Fee Schedule Final Rule for 2008, CMS stated that it was not finalizing the proposed regulatory change at this time, based on comments recommending a delay and raising concerns about the proposal. The agency also clarified that in the absence of specific guidance, manufacturers may continue to make reasonable

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assumptions in the calculation of ASP, consistent with the general requirements and the intent of the Medicare statute and regulations and their customary business practices. The agency stated that it will continue to monitor this issue and may provide more specific guidance in the future. In the Medicare Physician Fee Schedule Final Rule for 2009 released on October 30, 2008, the agency did not address the topic of bundled price concessions.

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the March 9, 2007 label changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a NCA which is generally CMS first step toward developing a NCD. Generally, a NCD is a national policy statement granting, limiting or excluding Medicare coverage or reimbursement for a specific medical item or service. On July 30, 2007, CMS issued its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions. The Decision Memorandum established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for CIA with ESAs. We believe that the restrictions in the Decision Memorandum changed the way ESAs are used in clinical practice, for example, by decreasing the number of treated patients, the average ESA dose and the duration of ESA therapy.

We believe this restriction on reimbursement of ESAs in the Decision Memorandum has had and may continue to have a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, based on our knowledge, although no private payers have implemented the Decision Memorandum to date, many private payers have implemented the restrictions included in the Decision Memorandum. Further, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage. While we cannot fully predict the further impact of the Decision Memorandum on how, or under what circumstances, healthcare providers will prescribe or administer our ESAs, it had a significant impact to our business in 2007 and 2008 and believe that it may continue to impact us in the future.

In addition, the FDA held a joint meeting of the CRDAC and the DSaRMAC on September 11, 2007, which evaluated the safety data on ESA use in renal disease. On July 31, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process and which included as potential topics the use of ESAs in ESRD and CKD. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD and we cannot predict whether ESAs in the renal setting will be the subject of a future NCD, however, any final NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in Decision Memorandum for treatment of anemia in oncology with ESAs, would negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. In addition, on August 22, 2008 our platelet producer for the treatment of thrombocytopenia in splenectomized (spleen removed) and non-splenectomized adults with chronic ITP, Nplate™, was approved by the FDA and falls within the thrombopoiesis stimulating agents (platelet growth factors) topic that was also included on CMS July 31, 2008 potential future NCD topic list. We cannot predict whether Nplate™ will be the subject of a future NCD.

Further, the 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, has increased the level of Medicaid rebates paid by us. We continue to evaluate the impact of the DRA and cannot predict what impact the DRA 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 labeling and associated revisions in compendia, nearly all Medicare contractors dropped reimbursement for Aranesp® for anemia of cancer. (See *Guidelines and recommendations published by various organizations can reduce the use of our products.*) Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain and a failure to demonstrate clear clinical and/or comparative value associated with the use of a new therapeutic product as compared to existing therapeutic products or practices may result in inadequate or no reimbursement. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our products are and will be affected by government and private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and results of operations.

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies patents. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude or delay commercialization of products. We are currently, and in the future may be, involved in patent litigation. However, a patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market and we may be subject to competition during certain periods of litigation. Further, under the Hatch-Waxman Act, products approved by the FDA under a new drug application (NDA) may be the subject of patent litigation with generic competitors before the five year period of data exclusivity provided for under the Hatch-Waxman Act has expired and prior to the expiration of the patent term of product. For example, on July 25, 2008, we, NPS Pharmaceuticals and Brigham and Women s Hospital, filed a lawsuit against Teva and Barr for infringement of four Sensipar® patents. The lawsuit is based on ANDA filed by Teva and Barr which seek approval to market generic versions of Sensipar® before expiration of the patents. This lawsuit is described in Note 9, *Contingencies* to the Condensed Consolidated Financial Statements. 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, panitumumab and our other products and potential products. We market our erythropoietin, recombinant G-

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

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

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

As a result of various regulatory and reimbursement developments that began in 2007 and, in particular those affecting our marketed ESA products, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. As part of the restructuring plan, we reduced staff, made changes to certain capital projects and closed certain production operations. As a result of our restructuring plan, we have reduced costs in 2008. Our ability to maintain these savings is dependent upon various future developments, some of which are beyond our control. If we are unable to maintain all of the resulting savings or benefits to our business or other unforeseen events occur, our business and results of operations may be adversely affected. Further, if we were to experience additional changes to our business or redesign certain processes to achieve increased efficiencies, we may face further restructuring and/or reorganization activities in the future.

In addition, our reduction of staff was completed through a combination of a voluntary transition program and an involuntary reduction in force. In order to be successful and build our framework for future growth, we must continue to execute and deliver on our core business initiatives with fewer human resources and losses of intellectual capital. We must also attract, retain and motivate key employees including highly qualified management, scientific, manufacturing and sales and marketing personnel who are critical to our business. We may not be able to attract, retain or motivate qualified employees in the future and our inability to do so may adversely affect our business.

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

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

On August 30, 2007, the National Kidney Foundation (the NKF) distributed to the nephrology community final updated Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines and clinical practice recommendations for anemia in CKD. The NKF s Anemia Work

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Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, the NKF-KDOQI Anemia Work Group recommended in their 2007 Update to the NKF-KDOQI Anemia Management Guidelines that physicians target Hb in the range of 11 g/dL to 12 g/dL, and also stipulated that the target not be above 13 g/dL.

On February 2, 2007, following the reported results from our AoC 103 Study, the USP DI Drug Reference Guides removed Aranesp® in the treatment of AoC. Thereafter, Aranesp® use in AoC essentially ceased.

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

We may not be able to develop commercial products.

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

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness
- the product candidate had harmful side effects in humans or animals
- the necessary regulatory bodies, such as the FDA, did not approve our product candidate for an intended use
- the product candidate was not economical for us to manufacture and commercialize
- other parties have or may have proprietary rights to our product candidate, such as patent rights, and will not let us sell it on reasonable terms, or at all
- the product candidate is not cost effective in light of existing therapeutics
- we and certain of our licensees, partners or independent investigators may fail to effectively conduct clinical development or clinical manufacturing activities
- the regulatory pathway to approval for product candidates is uncertain or not well-defined

For example, we announced that after discussions with the FDA we have decided not to file for approval of motesanib diphosphate in refractory thyroid cancer until there is more clarity on what would constitute an appropriate regulatory filing package for that indication. We believe that

the safety concerns around our ESAs expressed by the FDA must be addressed to the agency s satisfaction before new indications or expanded labeling of our ESA products will likely be approved.

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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 in rhesus monkeys showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials and, as a part of that decision and based on thorough scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales.* ; *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*)

Our business may be affected by government investigations or litigation.

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, our business operations, government requests for information and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Note 10, *Contingencies* to the Consolidated Financial Statements in our 2007 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Litigation is inherently unpredictable, and the outcome can result in excessive verdicts and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our results of operations, financial position or cash flows.

We have received subpoenas from a number of government entities, including the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington, as well as the Attorneys General of New York and New Jersey. The federal subpoenas have been issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), while the Attorneys General subpoenas have been issued pursuant to state specific statutes relating to consumer fraud laws and state false claims acts. In general, the subpoenas request documents relating to the sales and marketing of our products, and our collection and dissemination of information reflecting clinical research as to the safety and efficacy of our ESAs. To the extent it is alleged in a proceeding that we are in violation of the various federal and state laws that govern the sales and marketing of its products, then a decision adverse to our interests could result in federal criminal liability or federal or state civil or administrative liability, and thus could result in substantial financial damages or criminal penalties that could have a material adverse effect on our results of operations, financial position or cash flows in the period in which such liabilities are incurred.

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

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

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

Our revenues and operating results may fluctuate from period to period for a number of reasons, some of which we cannot control. For example, primarily as a result of various regulatory and reimbursement developments involving ESA products that began in 2007, our anemia product sales, in particular sales of Aranesp®, for 2007 were materially adversely impacted. Even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections as some of our operating expenses are fixed in the short term and cannot be reduced within a short period of time to offset reductions in revenue. Further, primarily as a result of the various regulatory and reimbursement developments impacting ESA products, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. As of September 30, 2008, we have completed a majority of the actions initially included in our restructuring plan and have incurred approximately $790 million in charges. We have recently identified certain additional initiatives designed to further assist in improving our cost structure. The estimated cost of these additional initiatives is $50 million to $100 million. As a result of the actual costs incurred to date and the addition of the recently identified initiatives, the total charges expected to be incurred in connection with our restructuring plan, including implementation costs, is $850 million to $925 million. Our operating results have and may continue to fluctuate and be adversely impacted as a result of these restructuring charges. (See *We may experience difficulties, delays or unexpected costs and not achieve or maintain anticipated cost savings from our restructuring plan*.) In addition, in the event that the actual restructuring charges exceed our latest estimate, this may cause our operating results for a period to be below our expectations or projections. As a result of the above or other challenges, including further label revisions to our ESAs, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Changes in credit ratings issued by nationally recognized statistical ratings organizations could adversely affect our cost of financing and have an adverse effect on the market price of our securities. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to September 30, 2008, the trading price of our common stock has ranged from a high of $65.89 per share to a low of $39.97 per share.

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

- adverse developments regarding the safety or efficacy of our products
- changes in the government s or private payers reimbursement policies, particularly for supportive cancer care products, or prescribing guidelines for our products
- current volatility and disruption of the financial markets
- evolving medical care in treating cancer requiring less use of supportive cancer care products
- inability to maintain regulatory approval of marketed products or manufacturing facilities
- actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators
- business development or licensing activities

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product development or other business announcements by us or our competitors

regulatory matters or actions, such as label changes or risk management activities, including a REMS

lower than expected demand for our products or a change in product mix either or both of which may result in less than optimal utilization of our manufacturing facilities and the potential to incur excess capacity or impairment charges

changes in our product contracting and related pricing strategies

changes in wholesaler buying patterns

increased competition from new or existing products

fluctuations in foreign currency exchange rates

announcements in the scientific and research community

intellectual property and legal matters

actual or anticipated product supply constraints

broader economic, industry and market trends unrelated to our performance

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

Current levels of market volatility are unprecedented and adverse capital and credit market conditions may affect our ability to access cost-effective sources of funding and our investment in marketable securities may be subject to market, interest and credit risk that could reduce their value.

The capital and credit markets have been experiencing extreme volatility and disruption which, particularly in the past several weeks, has led to uncertainty and liquidity issues for both borrowers and investors. We currently have sufficient cash to repay our floating rate notes due November 28, 2008 and we anticipate that our business will generate sufficient cash for us to repay the $1.0 billion of our 4.00% notes due in November 2009. Historically, we have occasionally and opportunistically accessed the capital markets to support certain business activities including acquisitions, in-licensing activities, share repurchases and to refinance existing debt. In the future, we may not be able to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations.

We have some exposure to financial institutions which have come under pressure as a result of the current credit crisis. For example, we have historically had 16 financial institutions participate in our $2.5 billion revolving credit facility including a subsidiary of Lehman, which had a $178 million commitment. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008. Although we have never drawn on our credit facilities and do not currently anticipate any need to do so, we would not anticipate the ability to access this specific commitment provided by Lehman in the future. Additionally, the conversion feature of our 0.125% Convertible Senior Notes due 2011 and our 0.375% Convertible Senior Notes due 2013 are hedged pursuant to

transactions entered into with two financial institutions. We have also entered into interest rate swap agreements for certain of our outstanding debt and routinely enter into foreign currency exchange contracts with financial institutions as counterparties. Additional bankruptcies in the financial sector could limit our ability to replace these

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transactions on favorable terms, or at all, or to manage the risks inherent in our business which could have a material adverse effect on our business and results of operations.

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

The volatility of the current financial markets may magnify certain risks that affect our business.

Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. (See *Our sales depend on 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*.) As a result of the volatility of the current financial markets, our third-party payers may delay or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement from government programs, including Medicare and Medicaid, and/or private payer healthcare programs could have a material adverse affect on the sales of our products, our business and results of operations.

Additionally, we rely upon third-parties for certain parts of our business, including licensees and partners, wholesale distributors of our products, contract clinical trial providers, contract manufacturers and single third-party suppliers. Because of the recent volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third-parties which could have a material adverse affect on our business and results of operations.

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

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

Also, certain of the raw materials required in the commercial manufacturing and the formulation of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin (HSA). We are also investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically-sourced raw materials as such raw materials may be subject to contamination and/or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials, which may be sourced from other countries, used in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. Further, any disruptions or delays by us or by third-party suppliers or partners in converting to alternatives to certain biological sources and alternative manufacturing processes or our ability to gain regulatory approval for the alternative materials and manufacturing processes could increase our associated costs or result in the recognition of an impairment in the carrying value of certain related assets, which could have a material and adverse affect on our results of operations.

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

We currently manufacture and market all our principal products, and we plan to manufacture and market many of our product candidates. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.*) We currently manufacture our products and product candidates at our manufacturing facilities located in Thousand Oaks and Fremont, California; Boulder and Longmont, Colorado; West Greenwich, Rhode Island; Bothell, Washington and Juncos, Puerto Rico. (See *We manufacture and formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products.*) Additionally, we currently use third-party contract manufacturers to produce or assist in the production of ENBREL, Sensipar®/Mimpara® and Nplate™ 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 contract manufacturers
- facility contamination by microorganisms or viruses
- labor disputes or shortages, including the effects of an avian or pandemic flu outbreak
- compliance with regulatory requirements

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changes in forecasts of future demand

timing and actual number of production runs

production success rates and bulk drug yields

timing and outcome of product quality testing

If we have problems in one or more of these or other manufacturing variables, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from 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 and license a new contract manufacturer. In order to maintain supply, mitigate risks associated with the vast majority of our formulation, fill and finish operations being performed in a single facility and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at appropriate production capacity over the next few years, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance. Key manufacturing projects include: (i) expansion of our existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate denosumab; (ii) construction, qualification and licensure of a new formulation and filling facility at our Puerto Rico site and (iii) expansion of our Fremont, California facility to support future product launches.

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

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

We currently perform all of the formulation, fill and finish for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®, some formulation, fill and finish operations for ENBREL, and all of the bulk manufacturing for Aranesp®, Neulasta® and NEUPOGEN® at our manufacturing facility in Juncos, Puerto Rico. Our global supply

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of these products is significantly dependent on the uninterrupted and efficient operation of this facility. A number of factors could adversely affect our operations, including:

- power failures
- breakdown, failure or substandard performance of equipment
- improper installation or operation of equipment
- labor disputes or shortages, including the effects of an avian or pandemic flu outbreak
- inability of third-party suppliers to provide raw materials and components
- natural or other disasters, including hurricanes
- failures to comply with regulatory requirements, including those of the FDA

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

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

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

We currently produce a substantial portion of the annual ENBREL supply at our Rhode Island manufacturing facility. However, we also depend on third parties for a significant portion of our ENBREL bulk supply as well as for some of the formulation, fill and finish of ENBREL that we manufacture. BI Pharma is our third-party contract manufacturer of ENBREL bulk drug; accordingly, our U.S. and Canadian supply of ENBREL is currently significantly dependent on BI Pharma s production schedule for ENBREL. We would be unable to produce ENBREL in sufficient quantities to substantially offset shortages in BI Pharma s scheduled production if BI Pharma or other third-party contract manufacturers used for the formulation, fill and finish of ENBREL bulk drug were to cease or interrupt production or services or otherwise fail to supply materials, products or services to us for any reason, including labor shortages or disputes, regulatory requirements or action or contamination of product lots or product recalls. For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. We cannot

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guarantee that an alternative third-party contract manufacturer would be available on a timely basis or at all. This in turn could materially reduce our ability to satisfy demand for ENBREL, which could materially and adversely affect our operating results.

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

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

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases for which our products may be indicated. For example, ENBREL competes in certain circumstances with products marketed by J&J, Abbott, Biogen IDEC Inc., Genentech, Inc., Bristol-Myers Squibb Corporation, Novartis AG and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed, including J&J s CNTO 1275 (ustekinumab) and CNTO 148 (golimumab). Additionally, in the first quarter of 2008 Abbott received approval from the FDA to market HUMIRA® as a treatment for adult patients with moderate to severe chronic plaque psoriasis and HUMIRA® now competes with ENBREL in both the rheumatology and dermatology segments and ENBREL has experienced and continues to experience share loss to competitors. Further, Aranesp® competes with J&J s PROCRIT® in the U.S. in the oncology setting and effective October 1, 2008, Amgen restructured its oncology clinic contracts which may adversely impact sales of Aranesp® which could have a material adverse effect on our business and results of operations.

Additionally, Aranesp® competes or will potentially compete in the EU with:

Product	Company	Key Countries Launched
EPREX®	J&J	EU
Neorecormon®	Roche	EU
Biosimilar Erythropoietin	Sandoz with co-marketers Hexal and Medice	Austria, Germany, UK, Netherlands, Finland, France, Ireland, Italy
Biosimilar Erythropoietin	Hospira/Stada	Germany, Austria, Greece, Ireland, Netherlands, Sweden, UK
peg-EPO/MIRCERA®	Roche	Across international countries except for Italy, Portugal, Australia

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In addition, several companies are developing potentially competing therapies. For example, Affymax Inc./Takeda are co-developing, Hematide , an erythropoietin mimetic for the treatment of anemia. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.*) Our products may compete against products that have lower prices, equivalent or superior performance, are easier to administer or that are otherwise competitive with our products.

Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. As these patents have expired, some companies have and other companies may receive approval for and market biosimilar or other products to compete with our products in the EU, presenting additional competition to our products. For example, on September 15, 2008, the European Commission issued marketing authorizations for the first G-CSF biosimilar products to Ratiopharm s Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel s Biograstim® and Teva s Tevagrastim®. Ratiopharm launched its G-CSF biosimilar product, Ratiograstim®, in the United Kingdom in October 2008, and is expected to launch it in Germany and several other European markets in the fourth quarter of 2008. CT Arzneimittel is expected to market its G-CSF biosimilar product in Germany in the fourth quarter of 2008. Teva stated that it would begin marketing its G-CSF biosimilar product throughout Europe in 2009. These G-CSF biosimilar products would compete with Neulasta® and NEUPOGEN®. We cannot predict to what extent the entry of biosimilar products or other competing products will impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU. Our inability to compete effectively could reduce sales which could have a material adverse effect on our results of operations.

In 2006, the EMEA developed and issued final regulatory guidelines related to the development and approval of biosimilar products. The final guidelines included clinical trial guidance for certain biosimilar products including erythropoietins and G-CSFs, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. In the United States, there currently is no legal approval pathway for the approval of BLAs for biosimilars. A number of events would need to occur before these products could enter the market, including passage of legislation by Congress to create a new approval pathway and, depending on the specific provisions of any such legislation, promulgation of associated regulations or guidance by the FDA. In 2007, several members of Congress expressed interest in the issue, a number of bills were introduced, the House of Representatives and the Senate held hearings on biosimilars, and the Senate Committee on HELP voted on legislation in June 2007. In 2008, additional legislation was introduced in the House of Representatives. To date, however, no final legislation has been considered or passed in either chamber of Congress. Given the continuing interest of Congress in the issue, it is possible but not likely that legislation on biosimilars will be finalized in 2008. It is unknown what type of regulatory framework, what legal provisions, and what timeframes for issuance of regulations or guidance any final legislation would contain. Until such legislation is created, we cannot predict when biosimilars could appear in the United States.

Certain of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in R&D in areas where we have products or where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical corporations may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. Business

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combinations among our competitors may also increase competition and the resources available to our competitors.

We must build the framework for our future growth, and if we fail to execute on our initiatives our business could be adversely affected.

As a result of developments in 2007 and, in particular the regulatory and reimbursement changes to our ESA products, on August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. We face a number of risks, some of which we cannot completely control. For example:

- we will need to manage complexities associated with a large and geographically diverse organization
- we will need to manage and execute large, complex and global clinical trials
- we will need to significantly expand our sales and marketing resources to launch our late-stage product candidate, denosumab
- we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply
- we have implemented a new ERP system to support our increasing complex business and business processes and need to ensure that the new system continues to operate without disruptions to our operations

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

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

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

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

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Our marketing of ENBREL is dependent in part upon Wyeth.

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

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

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

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

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

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

As of September 30, 2008, we had one outstanding stock repurchase program. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a number of factors including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions. Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. A summary of our repurchase activity for the three months ended September 30, 2008 is as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced programs	Maximum $ value that may yet be purchased under the programs [1]
July 1 - July 31	89	$ 62.07 [2]	-	$ 4,871,328,709 [2]
August 1 - August 31	8,321	63.12	-	4,871,328,709
September 1 - September 30	759	61.83	-	4,871,328,709
	9,169 [3]	63.00	- [3]	

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

(2) The total cost of shares repurchased during the three months ended September 30, 2008 includes $19,060,523 paid in July 2008 in connection with the final settlement of an ASR entered into in May 2008.

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

Item 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: November 7, 2008

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). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 14, 2007). (Filed as an exhibit to Form 8-K filed on February 20, 2007 and incorporated herein by reference.)
3.5	Amendment to Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.6	Officer s Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, establishing a series of securities entitled 8 1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Form of Liquid Yield Option Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.8	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	First Supplemental Indenture, dated March 2, 2005. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.10	Indenture, dated as of August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.11	Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.12	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.13	Officers Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.14	Registration Rights Agreement, dated as of November 18, 2004, among Amgen Inc. and Morgan Stanley & Co. Incorporated and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.15	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)

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Exhibit No.	Description
4.16	Indenture, dated as of May 6, 2005. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.17	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.125% Convertible Senior Note due 2011). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.18	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.375% Convertible Senior Note due 2013). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.19	Registration Rights Agreement, dated as of February 17, 2006, among Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JPMorgan Securities Inc., Lehman Brothers Inc., Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
4.20	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.21	The instruments defining the rights of holders of the long-term debt securities of Abgenix, Inc. and its subsidiaries are omitted pursuant to section (b)(4)(iii)(A) of Item 601 of Regulation S-K. Amgen Inc. hereby agrees to furnish copies of these instruments to the Securities and Exchange Commission upon request.
4.22	Officers Certificate of Amgen Inc. dated as of May 30, 2007, including forms of the Company s Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.23	Registration Rights Agreement, dated as of May 30, 2007, among Amgen Inc. and Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., J.P. Morgan Securities Inc. and Lehman Brothers Inc. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
10.1+*	Amgen Inc. Amended and Restated 1991 Equity Incentive Plan (As Amended and Restated October 1, 2008).
10.2+	Amgen Inc. Amended and Restated Director Equity Incentive Program (As Amended and Restated December 10, 2007) and forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated Director Equity Incentive Program. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
10.3+*	Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of October 1, 2008).
10.4+*	Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated October 1, 2008).
10.5+*	Forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for the Amgen Inc. Amended and Restated 1991 Equity Incentive Plan, the Amgen Inc. Amended and Restated 1999 Equity Incentive Plan and the Amgen Inc. Amended and Restated 1999 Incentive Stock Plan.
10.6+	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.)
10.7+	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.)
10.8+	Second Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan (As Amended and Restated July 12, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
10.9+*	Amgen Supplemental Retirement Plan (As Amended and Restated January 1, 2009.)

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Exhibit No.	Description
10.10+	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.)
10.11+	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.)
10.12+	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.)
10.13+	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.)
10.14+	Fourth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended June 1, 2004). (Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.)
10.15+	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.)
10.16+	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.)
10.17+	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.)
10.18+	Eighth Amendment to the Amgen Inc. Change of Control Severance Plan (As Amended December 15, 2006). (Filed as an exhibit to Form 10-K for the year ended December 31, 2006 on February 28, 2007 and incorporated herein by reference.)
10.19+*	Amgen Inc. Executive Incentive Plan. (As Amended and Restated January 1, 2009.)
10.20+*	Amgen Inc. Executive Nonqualified Retirement Plan. (As Amended and Restated January 1, 2009.)
10.21+*	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2009.)
10.22+*	Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated October 1, 2008.)
10.23+	Form of Performance Unit Agreement. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.24+	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.)
10.25+	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.)
10.26+	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.)
10.27+	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.)
10.28+	Restricted Stock Purchase Agreement, dated March 3, 2003, between Amgen Inc. and Brian M. McNamee. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2003 on July 30, 2003 and incorporated herein by reference.)
10.29+	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.)
10.30+	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.)
10.31+	Amendment to Promissory Note, dated August 31, 2007 to Promissory Note, dated June 27,

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Exhibit No.	Description
	2001, of Mr. Richard Nanula. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
10.32+	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.)
10.33+	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.)
10.34+	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.)
10.35+	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.)
10.36+	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.)
10.37+	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.)
10.38+	Amendment No. 13 to the Shareholders Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.39+	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.)
10.40+	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.)
10.41+	Amendment Agreement, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.)
10.42+	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.)
10.43+	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.)
10.44+	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,

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Exhibit No.	Description
	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.)
10.45	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.)
10.46	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.)
10.47	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.)
10.48	Amendment No. 1 to Amendment No. 2 to the Enbrel® Supply Agreement, dated June 23, 2008, 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, 2008 on August 8, 2008 and incorporated herein by reference.)
10.49	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.)
10.50	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.)
10.51	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.)
10.52	Amendment No. 6 to the Enbrel® Supply Agreement, dated November 27, 2007, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom) (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
10.53*	Amendment No. 2 to Amendment No. 6, dated August 26, 2008, to the Enbrel® Supply Agreement, dated November 27, 2007, among Immunex Corporation, Wyeth (formerly, American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom).
10.54	Agreement Regarding Governance and Commercial Matters, dated December 16, 2001, by and among American Home Products Corporation, American Cyanamid Company and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.55	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.)
10.56	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as

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Exhibit No.	Description
	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.)
10.57	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.)
10.58	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.)
10.59	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.)
10.60	Purchase Agreement, dated as of February 14, 2006, among Amgen Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Citigroup Global Markets Inc., JP Morgan Securities, Inc., Lehman Brothers Inc, Bear, Stearns & Co. Inc., Credit Suisse Securities (USA) LLC. (Filed as an exhibit to Form 8-K on February 21, 2006 and incorporated herein by reference.)
10.61	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International related to the 0.125% Convertible Senior Notes Due 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.62	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.)
10.63	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.)
10.64	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.)
10.65	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.)
10.66	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.)
10.67	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.)
10.68	Purchase Agreement, dated May 24, 2007, among Amgen Inc., Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated and the Initial Purchasers Names in Schedule A thereof. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.69	Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.70	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by

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Exhibit No.	Description
	reference.)
10.71	Credit Agreement, dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 8-K filed on November 2, 2007 and incorporated herein by reference.)
10.72	Multi-product License Agreement with Respect to Japan between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.73	License Agreement for motesanib diphosphate between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.74	Supply Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.75	Sale and Purchase Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.76	Variable Term Accelerated Share Repurchase Transaction dated May 28, 2008, between Amgen Inc. and Lehman Brothers, Inc. acting as Agent Lehman Brothers OTC Derivatives Inc., acting as Principal. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 8, 2008 and incorporated herein by reference.)
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.

(* = filed herewith)

(** = furnished herewith and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended)

(+ = management contract or compensatory plan or arrangement.)