

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**Form 10-Q**

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

For the quarterly period ended March 31, 2009

OR

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

Commission file number 000-12477

**Amgen Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**91320-1799**  
(Zip Code)

**(805) 447-1000**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

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

As of May 4, 2009, the registrant had 1,012,372,068 shares of common stock, \$0.0001 par value, outstanding.

---

---

AMGEN INC.

INDEX

	Page No.
<b>PART I</b>	<b><a href="#">FINANCIAL INFORMATION</a></b>
Item 1.	<a href="#">Financial Statements</a>
	1
	<a href="#">Condensed Consolidated Statements of Income – Three months ended March 31, 2009 and 2008</a>
	1
	<a href="#">Condensed Consolidated Balance Sheets – March 31, 2009 and December 31, 2008</a>
	2
	<a href="#">Condensed Consolidated Statements of Cash Flows – Three months ended March 31, 2009 and 2008</a>
	3
	<a href="#">Notes to Condensed Consolidated Financial Statements</a>
	4
Item 2.	<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>
	23
Item 4.	<a href="#">Controls and Procedures</a>
	38
<b>PART II</b>	<b><a href="#">OTHER INFORMATION</a></b>
Item 1.	<a href="#">Legal Proceedings</a>
	39
Item 1A.	<a href="#">Risk Factors</a>
	39
Item 2.	<a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>
	65
Item 6.	<a href="#">Exhibits</a>
	65
	<a href="#">Signatures</a>
	66
	<a href="#">Index to Exhibits</a>
	67

## PART I - FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

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

	Three months ended March 31,	
	2009	2008 "Revised" *
Revenues:		
Product sales	\$ 3,238	\$ 3,537
Other revenues	70	76
Total revenues	<u>3,308</u>	<u>3,613</u>
Operating expenses:		
Cost of sales (excludes amortization of acquired intangible assets presented below)	477	546
Research and development	633	694
Selling, general and administrative	798	874
Amortization of acquired intangible assets	74	74
Other charges	5	10
Total operating expenses	<u>1,987</u>	<u>2,198</u>
Operating income	1,321	1,415
Interest and other income (expense), net	<u>(89)</u>	<u>(35)</u>
Income before income taxes	1,232	1,380
Provision for income taxes	<u>213</u>	<u>280</u>
Net income	<u>\$ 1,019</u>	<u>\$ 1,100</u>
Earnings per share:		
Basic	\$ 0.99	\$ 1.01
Diluted	\$ 0.98	\$ 1.01
Shares used in calculation of earnings per share:		
Basic	1,032	1,089
Diluted	1,037	1,092

See accompanying notes.

\* See Note 1 for discussion of required retrospective adoption of a new accounting standard applicable to our convertible debt.

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

	<b>March 31, 2009</b>	<b>December 31, 2008 "Revised" *</b>
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 2,777	\$ 1,774
Marketable securities	7,601	7,778
Trade receivables, net	2,009	2,073
Inventories	2,080	2,075
Other current assets	1,609	1,521
Total current assets	16,076	15,221
Property, plant and equipment, net	5,804	5,879
Intangible assets, net	2,882	2,988
Goodwill	11,336	11,339
Other assets	1,282	1,000
	<u>\$ 37,380</u>	<u>\$ 36,427</u>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities:		
Accounts payable	\$ 687	\$ 504
Accrued liabilities	2,986	3,382
Current portion of other long-term debt	1,000	1,000
Total current liabilities	4,673	4,886
Convertible notes	4,320	4,257
Other long-term debt	6,088	4,095
Other non-current liabilities	2,332	2,304
Contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital; \$0.0001 par value; 2,750 shares authorized; outstanding - 1,011 shares in 2009 and 1,047 shares in 2008	26,526	26,441
Accumulated deficit	(6,659)	(5,673)
Accumulated other comprehensive income	100	117
Total stockholders' equity	19,967	20,885
	<u>\$ 37,380</u>	<u>\$ 36,427</u>

See accompanying notes.

\* See Note 1 for discussion of required retrospective adoption of a new accounting standard applicable to our convertible debt.

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

	Three months ended March 31,	
	2009	2008 "Revised" *
<b>Cash flows from operating activities:</b>		
Net income	\$ 1,019	\$ 1,100
Depreciation and amortization	267	266
Stock-based compensation expense	59	59
Other items, net	-	(7)
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	64	(93)
Inventories	22	18
Other current assets	(123)	35
Accounts payable	44	118
Accrued income taxes	176	112
Other accrued liabilities	(668)	(323)
Deferred revenue	(1)	297
Net cash provided by operating activities	<u>859</u>	<u>1,582</u>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(117)	(170)
Cash paid for acquisitions, net of cash acquired	-	(48)
Purchases of marketable securities	(3,580)	(1,468)
Proceeds from sales of marketable securities	3,426	2,126
Proceeds from maturities of marketable securities	425	208
Other	(15)	49
Net cash provided by investing activities	<u>139</u>	<u>697</u>
<b>Cash flows from financing activities:</b>		
Repurchases of common stock	(1,997)	-
Net proceeds from issuance of debt	1,980	-
Net proceeds from issuance of common stock in connection with the Company's equity award programs	21	28
Other	1	(7)
Net cash provided by financing activities	<u>5</u>	<u>21</u>
Increase in cash and cash equivalents	1,003	2,300
Cash and cash equivalents at beginning of period	<u>1,774</u>	<u>2,024</u>
Cash and cash equivalents at end of period	<u>\$ 2,777</u>	<u>\$ 4,324</u>

See accompanying notes.

\* See Note 1 for discussion of required retrospective adoption of a new accounting standard applicable to our convertible debt.

**AMGEN INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2009**  
**(Unaudited)**

**1. Summary of significant accounting policies**

*Business*

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

*Basis of presentation*

The financial information for the three months ended March 31, 2009 and 2008 is unaudited but includes all adjustments (consisting of only normal recurring adjustments, unless otherwise indicated), which Amgen Inc., including its subsidiaries (referred to as “Amgen,” “the Company,” “we,” “our” or “us”), considers necessary for a fair presentation of the results of operations for those periods. Interim results are not necessarily indicative of results for the full fiscal year.

The condensed consolidated financial statements should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2008.

*Change in method of accounting for convertible debt instruments*

Effective January 1, 2009, we adopted Financial Accounting Standards Board’s (“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”) and, as required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt. Under this method of accounting, the debt and equity components of our convertible notes are bifurcated and accounted for separately. The equity components of our convertible notes, including our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, are included in “Common stock and additional paid-in capital” in the Condensed Consolidated Balance Sheets, with a corresponding reduction in the carrying values of these convertible notes as of the date of issuance or modification, as applicable. The reduced carrying values of our convertible notes are being accreted back to their principal amounts through the recognition of non-cash interest expense. This results in recognizing interest expense on these borrowings at effective rates approximating what we would have incurred had we issued nonconvertible debt with otherwise similar terms. See Note 2, “*Change in method of accounting for convertible debt instruments*” and Note 6, “*Financing arrangements.*”

*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.

*Collaborative arrangements*

Effective January 1, 2009, we adopted the provisions of Emerging Issues Task Force (“EITF”) Issue No. 07-1, “*Accounting for Collaborative Agreements*” (“EITF 07-1”). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which include certain arrangements we have entered into regarding the research and development (“R&D”), manufacture and/or commercialization of products and product candidates.

Under EITF 07-1, a collaborative arrangement is defined as a contractual arrangement that involves a joint operating activity. These arrangements involve two (or more) parties who are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

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

We evaluate whether an arrangement is a collaborative arrangement under EITF 07-1 at its inception based on the facts and circumstances specific to the arrangement. We reevaluate whether an arrangement qualifies or continues to qualify as a collaborative arrangement under EITF 07-1 whenever there is a change in either the roles of the participants or the participants' exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor. For arrangements that are determined to be collaborative arrangements under EITF 07-1, we report costs incurred and revenue generated from transactions with third parties (that is, parties that do not participate in the arrangement) in accordance with EITF Issue No. 99-19 "*Reporting Revenue Gross as a Principal versus Net as an Agent*" ("EITF 99-19"). For those collaborative arrangements where it is determined that we are the principal participant, costs incurred and revenue generated from third parties are recorded on a gross basis in our financial statements.

The adoption of EITF 07-1 did not have a material impact on our condensed consolidated results of operations, financial position or cash flows. See Note 3, "*Collaborative arrangements.*"

*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.

*Fair value measurement*

We adopted the provisions of the 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 and effective 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 our condensed consolidated results of operations, financial position or cash flows.

*Derivative instruments*

Effective January 1, 2009, we adopted the provisions of the FASB's SFAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities – an amendment of FASB Statement No. 133*" ("SFAS 161") for our derivative instruments. SFAS 161 requires that the objectives for using derivative instruments be disclosed to better convey the purpose of derivative use in terms of the risks that we are intending to manage. This new standard also requires disclosure of how derivatives and related hedged items affect our financial statements. The adoption of SFAS 161 did not have a material impact on our condensed consolidated results of operations, financial position or cash flows. See Note 10, "*Derivative instruments.*"

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

*Inventories*

Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out (“FIFO”) method. Inventories consisted of the following (in millions):

	<u>March 31,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
Raw materials	\$ 120	\$ 112
Work in process	1,417	1,519
Finished goods	543	444
	<u>\$ 2,080</u>	<u>\$ 2,075</u>

*Property, plant and equipment, net*

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation of \$4.3 billion and \$4.1 billion as of March 31, 2009 and December 31, 2008, respectively.

*Goodwill*

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

*Product sales*

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

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

We have the exclusive right to sell Epoetin alfa for dialysis, certain diagnostics and all non-human, non-research uses in the United States. We sell Epoetin alfa under the brand name EPOGEN®. We granted to Ortho Pharmaceutical Corporation (which has assigned its rights under the product license agreement to Ortho Biotech Products, L.P. (“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*

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’ costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of Kirin-Amgen Inc. (“KA”), and costs and cost recoveries associated with



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

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 is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 3, “*Collaborative arrangements.*”

*Selling, general and administrative costs*

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

SG&A expenses include costs and cost recoveries associated with collaborative arrangements. Net payment or reimbursement of SG&A costs for collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 3, “*Collaborative arrangements.*”

*Earnings per share*

Basic earnings per share (“EPS”) is based upon the weighted-average number of common shares outstanding. Diluted EPS is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options, restricted stock (including restricted stock units) and other equity awards under our employee compensation plans and potential issuance of stock upon the assumed conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified 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. For further information regarding our convertible notes, see Note 6, “*Financing arrangements.*”

Our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes are considered Instrument C securities as defined by EITF 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 or accreted value, if any, are considered as dilutive potential common shares for purposes of calculating diluted EPS. For the three months ended March 31, 2009 and 2008, the conversion values for our convertible notes were less than the related principal amounts or accreted value and, accordingly, no shares were assumed to be issued for purposes of computing diluted EPS. For further information regarding our convertible notes, see Note 6, “*Financing arrangements.*”

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

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

	Three months ended March 31,	
	2009	2008
<b>Income (Numerator):</b>		
Net income for basic and diluted EPS	\$ 1,019	\$ 1,100
<b>Shares (Denominator):</b>		
Weighted-average shares for basic EPS	1,032	1,089
Effect of dilutive securities	5	3
Weighted-average shares for diluted EPS	1,037	1,092
Basic EPS	\$ 0.99	\$ 1.01
Diluted EPS	\$ 0.98	\$ 1.01

For the three months ended March 31, 2009 and 2008, there were employee stock options, calculated on a weighted average basis, to purchase 46 million and 52 million shares, respectively, with exercise prices greater than the average market prices of common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. In addition, shares which may be issued upon conversion of our convertible debt or upon exercise of our warrants are not included above as their impact on diluted EPS would have been anti-dilutive. Shares which may be issued under our 2007 performance award program were also excluded because conditions under the program were not met as of either period.

*Recent accounting pronouncements*

In April 2009, the FASB issued FSP SFAS No. 115-2, “*Recognition and Presentation of Other-Than-Temporary Impairments*” (“FSP SFAS 115-2”), which will be effective for interim and annual periods ending after June 15, 2009. FSP SFAS 115-2 modifies the guidance to determine whether the impairment of a debt security is other-than-temporary. This new standard also amends the presentation and disclosure requirements of other-than-temporarily impaired debt and equity securities in the financial statements. We are currently evaluating the potential impact of FSP SFAS 115-2 on our financial statements.

**2. Change in method of accounting for convertible debt instruments**

As discussed in Note 1, “*Summary of significant accounting policies - Change in method of accounting for convertible debt instruments,*” effective January 1, 2009, we adopted FSP APB 14-1 and, as required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt.

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

The following illustrates the impact of adopting FSP APB 14-1 on the Condensed Consolidated Income Statements for the three months ended March 31, 2009 and 2008 and on the Condensed Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008 (in millions, except per share information):

**Three months ended March 31, 2009**

	<b>Excluding the effect of FSP APB 14-1</b>	<b>Effect of FSP APB 14-1</b>	<b>Including the effect of FSP APB 14-1</b>
Operating income	\$ 1,321	\$ -	\$ 1,321
Interest and other income (expense), net	(28)	(61)	(89)
Income before income taxes	1,293	(61)	1,232
Provision (benefit) for income taxes	236	(23)	213
Net income	<u>\$ 1,057</u>	<u>\$ (38)</u>	<u>\$ 1,019</u>
Earnings per share:			
Basic	\$ 1.03	\$ (0.04)	\$ 0.99
Diluted	\$ 1.02	\$ (0.04)	\$ 0.98

**Three months ended March 31, 2008**

	<b>As originally reported</b>	<b>Effect of FSP APB 14-1</b>	<b>“Revised”</b>
Operating income	\$ 1,415	\$ -	\$ 1,415
Interest and other income (expense), net	22	(57)	(35)
Income before income taxes	1,437	(57)	1,380
Provision (benefit) for income taxes	301	(21)	280
Net income	<u>\$ 1,136</u>	<u>\$ (36)</u>	<u>\$ 1,100</u>
Earnings per share:			
Basic	\$ 1.04	\$ (0.03)	\$ 1.01
Diluted	\$ 1.04	\$ (0.03)	\$ 1.01

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

	<b>March 31, 2009</b>		
	<b>Excluding the effect of FSP APB 14-1</b>	<b>Effect of FSP APB 14-1</b>	<b>Including the effect of FSP APB 14-1</b>
<b>Non-current assets:</b>			
Other assets	\$ 1,297	\$ (15)	\$ 1,282
<b>Non-current liabilities:</b>			
Convertible notes	5,082	(762)	4,320
Other non-current liabilities	2,046	286	2,332
<b>Stockholders' equity:</b>			
Common stock and additional paid-in capital	25,612	914	26,526
Accumulated deficit	(6,206)	(453)	(6,659)
	<b>December 31, 2008</b>		
	<b>As originally reported</b>	<b>Effect of FSP APB 14-1</b>	<b>"Revised"</b>
<b>Non-current assets:</b>			
Other assets	\$ 1,016	\$ (16)	\$ 1,000
<b>Non-current liabilities:</b>			
Convertible notes	5,081	(824)	4,257
Other non-current liabilities	1,995	309	2,304
<b>Stockholders' equity:</b>			
Common stock and additional paid-in capital	25,527	914	26,441
Accumulated deficit	(5,258)	(415)	(5,673)

The effect of FSP APB 14-1 on other non-current liabilities reflects the impact of deferred taxes. In addition, the effect of FSP APB 14-1 on common stock and additional paid-in capital reflects, principally, the impact of the equity component of our convertible debt partially offset by deferred taxes.

As a result of the accounting change, our accumulated deficit as of January 1, 2008, increased from \$7.2 billion as originally reported, to \$7.4 billion after applying FSP APB 14-1. There was no impact resulting from this accounting change on our cash flows from operating activities, investing activities or financing activities as reflected in the Condensed Consolidated Statements of Cash Flows.

### **3. Collaborative arrangements**

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and product candidates. These collaborations generally provide for non-refundable, upfront license fees, R&D and commercial performance milestone payments, cost sharing, royalty payments and/or profit sharing. Our collaboration agreements with third parties are performed on a "best efforts" basis with no guarantee of either technological or commercial success. Each collaboration is unique in nature and our significant arrangements are discussed below.

#### *Wyeth*

Amgen and Wyeth are in a collaboration agreement to co-promote ENBREL in the United States and Canada. The rights to market ENBREL outside of the United States and Canada are reserved to Wyeth. Under the co-promotion agreement, a management committee comprised of equal representation from Amgen and Wyeth is responsible for overseeing the marketing and sales of ENBREL, including strategic planning, the approval of an annual marketing plan and product pricing. Wyeth and Amgen share in the agreed upon selling

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

and marketing expenses approved by the joint management committee. In addition, we pay Wyeth a percentage of the annual gross profits on our ENBREL sales, which reflect the sharing of manufacturing costs in the United States and Canada attributable to all approved indications for ENBREL on a scale that increases as gross profits increase, however, we maintain a majority share of ENBREL profits.

We also have a global supply agreement with Wyeth related to the manufacture, supply and allocation of bulk supplies of ENBREL. Under this agreement, we and Wyeth share the total worldwide bulk supply of ENBREL produced by our Rhode Island manufacturing facility, the manufacturing facility of Boehringer Ingelheim Pharma KG (“BI Pharma”) in Germany and Wyeth’s manufacturing facility in Ireland.

In accordance with EITF 99-19, we have determined that we are the principal participant in the collaboration with Wyeth to market ENBREL in the United States and Canada. Accordingly, we record sales of ENBREL to third parties on a gross basis. For the three months ended March 31, 2009 and 2008, ENBREL sales aggregated \$758 million and \$951 million, respectively.

During the three months ended March 31, 2009 and 2008, the Wyeth profit share expense was \$248 million and \$305 million, respectively, and is included in “Selling, general and administrative” in the Condensed Consolidated Statements of Income. In addition, cost recoveries from Wyeth for their share of the selling and marketing co-promotion were \$15 million and \$16 million for the three months ended March 31, 2009 and 2008, respectively, and are included in “Selling, general and administrative” in the Condensed Consolidated Statements of Income.

*Daiichi Sankyo Company, Limited*

We are in a collaboration and license agreement with Daiichi Sankyo Company, Limited (“Daiichi Sankyo”), which provides them the exclusive rights to develop and commercialize denosumab in Japan in postmenopausal osteoporosis, oncology and additional indications. As part of the agreement, Amgen received exclusive worldwide rights to certain Daiichi Sankyo intellectual property to the extent applicable to denosumab. Daiichi Sankyo assumed all development costs in Japan and reimburses Amgen for certain worldwide development costs. During the three months ended March 31, 2009 and 2008, cost recoveries from Daiichi Sankyo were \$14 million and \$11 million, respectively, and are included in “Research and development” in the Condensed Consolidated Statements of Income.

*Takeda Pharmaceutical Company Limited*

We are in a collaboration agreement with Takeda Pharmaceutical Company Limited (“Takeda”), which provides them the exclusive rights to develop and commercialize for the Japanese market up to 12 clinical stage molecules, including Vectibix<sup>®</sup>, from our pipeline across a range of therapeutic areas, including oncology and inflammation. Pursuant to the terms of the agreement, Takeda reimburses Amgen for certain worldwide development costs for the clinical stage molecules. We have the right to participate in the promotion of these products in Japan. In addition, we entered into a collaboration agreement with Takeda for the worldwide development and commercialization of motesanib. Each party has the right to participate in the co-promotion and/or commercialization of motesanib in the other party’s territory. Both Amgen and Takeda provide funding for the development of motesanib outside of Japan with each company responsible for a defined percentage of the total development costs. During the three months ended March 31, 2009 and 2008, cost recoveries from Takeda were \$25 and \$26 million, respectively, and are included in “Research and development” in the Condensed Consolidated Statements of Income. In addition, during the three months ended March 31, 2008, we received an upfront license fee payment of \$300 million from Takeda. This license fee payment is being recognized as revenue over 20 years. Included in “Other revenues” in the Condensed Consolidated Statements of Income is approximately \$4 million and \$3 million for the three months ended March 31, 2009 and 2008, respectively, relating to this milestone payment.

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

*Other Collaborations*

In addition, we have other collaborations, not disclosed above, that are not material individually or in the aggregate.

**4. Related party transactions**

We own a 50% interest in KA, a corporation formed in 1984 with Kirin Holdings Company, Limited (“Kirin”) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA’s profits or losses in “Selling, general and administrative” in the Condensed Consolidated Statements of Income. During the three months ended March 31, 2009 and 2008, our share of KA’s profits was \$19 million and \$14 million, respectively. As of March 31, 2009 and December 31, 2008, the carrying value of our equity method investment in KA, net of dividends paid, was \$375 million and \$356 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 from Kirin, J&J and F. Hoffmann-La Roche Ltd. (“Roche”) under separate product license agreements for certain geographic areas outside of the United States. During the three months ended March 31, 2009 and 2008, KA earned royalties from us of \$71 million and \$75 million, respectively. These amounts are included in “Cost of sales (excludes amortization of acquired intangible assets)” in the Condensed Consolidated Statements of Income. As of March 31, 2009, KA owed us \$9 million, which was included in “Other current assets” in the Condensed Consolidated Balance Sheets. At December 31, 2008, we owed KA \$82 million, which was included in “Accrued liabilities” in the Condensed Consolidated Balance Sheets.

KA’s expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three months ended March 31, 2009 and 2008, we earned revenues from KA of \$29 million and \$32 million, respectively, for certain R&D activities performed on KA’s behalf. These amounts are included in “Other revenues” in the Condensed Consolidated Statements of Income.

**5. Income taxes**

The effective tax rates for the three months ended March 31, 2009 and March 31, 2008 are different from the statutory rates primarily as a result of indefinitely invested earnings of our foreign operations. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be invested indefinitely outside the United States.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely audited by the tax authorities in those jurisdictions. Significant disputes can arise with these tax authorities involving issues of the timing and amount of deductions, the use of tax credits 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.

The Internal Revenue Service (“IRS”) is currently examining our U.S. income tax returns for the years ended December 31, 2005 and 2006. This examination is currently anticipated to be completed in 2009. As of March 31, 2009, the IRS has proposed certain audit adjustments. The Company is currently evaluating those proposed adjustments to determine if it agrees. If accepted, the Company does not anticipate that the adjustments would result in a material adverse impact to our consolidated financial position, results of operations or cash flows.

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

During the three months ended March 31, 2009, the gross amount of our unrecognized tax benefits (“UTBs”) increased approximately \$90 million as a result of tax positions taken during the current year. The majority of our UTBs at March 31, 2009, if recognized, would affect our effective tax rate.

As of March 31, 2009, we believe that it is reasonably possible that our gross liabilities for UTBs may decrease by \$100 million to \$275 million within the succeeding twelve months due to potential tax settlements.

**6. Financing arrangements**

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of March 31, 2009 and December 31, 2008 (in millions):

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$ 2,239	\$ 2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,000	1,970
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	1,000	1,000
5.70% notes due 2019 (2019 Notes)	998	-
6.40% notes due 2039 (2039 Notes)	995	-
6.375% notes due 2037 (2037 Notes)	899	899
6.15% notes due 2018 (2018 Notes)	499	499
6.90% notes due 2038 (2038 Notes)	498	498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)	81	81
Other	100	100
<b>Total borrowings</b>	<b>11,408</b>	<b>9,352</b>
Less current portion	1,000	1,000
<b>Total non-current debt</b>	<b>\$ 10,408</b>	<b>\$ 8,352</b>

*2019 Notes and 2039 Notes*

In January 2009, we issued \$1.0 billion aggregate principal amount of notes due in 2019 (the “2019 Notes”) and \$1.0 billion aggregate principal amount of notes due in 2039 (the “2039 Notes”) in a registered offering. The 2019 Notes and 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and 2039 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. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. The total debt discount on issuance and debt issuance costs were \$7 million and \$13 million, respectively, and are being amortized over the life of the notes.

*Convertible notes*

Effective January 1, 2009, we adopted FSP APB 14-1 and, as required by this new standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt (see Note 2, “*Change in method of accounting for convertible debt instruments*”). Under this method of accounting, the debt and equity components of our convertible notes are bifurcated and accounted for separately. The equity components of our convertible notes, including our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, are included in “Common stock and additional paid-in

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

capital” in the Condensed Consolidated Balance Sheets, with a corresponding reduction in the carrying values of these convertible notes as of the date of issuance or modification, as applicable. The reduced carrying values of our convertible notes are being accreted back to their principal amounts through the recognition of non-cash interest expense. This results in recognizing interest expense on these borrowings at effective rates approximating what we would have incurred had we issued nonconvertible debt with otherwise similar terms.

The 2011 Convertible Notes and the 2013 Convertible Notes were issued at par and pay interest at a rate of 0.125% and 0.375%, respectively. The discounts associated with these notes resulting from the adoption of FSP APB 14-1 are being amortized over periods that end on the scheduled maturity dates of these notes and result in effective interest rates of approximately 6.24% for the 2011 Convertible Notes and approximately 6.35% for the 2013 Convertible Notes. For the three months ended March 31, 2009 and 2008, interest expense for the 2011 Convertible Notes and 2013 Convertible Notes was approximately \$1 million and \$2 million, respectively, based on the contractual coupon rates. For the three months ended March 31, 2009 and 2008, amortization of the discount for the 2011 Convertible Notes was approximately \$33 million and \$31 million, respectively. For the three months ended March 31, 2009 and 2008, amortization of the discount for the 2013 Convertible Notes was \$29 million and \$27 million, respectively.

The 2011 Convertible Notes and the 2013 Convertible Notes may, subject to certain conditions, be converted based on a conversion rate of 12.5247 and 12.5814 shares, respectively, per \$1,000 principal amount of notes (which represents a conversion price of approximately \$79.84 and \$79.48 per share, respectively). Upon conversion, a holder would receive the conversion value, as defined, in: (i) cash equal to the lesser of the principal amount of the note or the conversion value and (ii) shares of our common stock, cash or a combination of common stock and cash, at our option, to the extent the conversion value exceeds the principal amount of the note. As of March 31, 2009, these notes were not convertible and the principal values exceeded the conversion values.

The principal balances, unamortized discounts and net carrying amounts of the liability components and the equity components for our 2011 Convertible Notes and 2013 Convertible Notes as of March 31, 2009 and December 31, 2008 are as follows (in millions):

	Liability component			Equity component
	Principal balance	Unamortized discount	Net carrying amount	Net carrying amount
<b>March 31, 2009</b>				
2011 Convertible Notes	\$ 2,500	\$ 261	\$ 2,239	\$ 643
2013 Convertible Notes	\$ 2,500	\$ 500	\$ 2,000	\$ 829
<b>December 31, 2008</b>				
2011 Convertible Notes	\$ 2,500	\$ 294	\$ 2,206	\$ 643
2013 Convertible Notes	\$ 2,500	\$ 530	\$ 1,970	\$ 829

The 2032 Modified Convertible Notes were issued in 2005 in exchange for zero-coupon, 30-year convertible notes that we issued in 2002. Like the notes for which they were exchanged, no interest is currently being paid on the 2032 Modified Convertible Notes. These notes were issued at a discount from their principal amount (prior to the adoption of FSP APB 14-1). The reduced carrying value is being accreted back to the principal amount based on a contractual interest rate of 1.125% over the life of the notes. In March 2007, substantially all of the holders of the 2032 Modified Convertible Notes exercised their option to put these convertible notes to us. The additional discount on the 2032 Modified Convertible Notes recognized pursuant to the retrospective application of FSP APB 14-1 (in excess of the discount recognized under the contractual terms of these securities) was amortized as non-cash interest expense prior to the holders putting these convertible notes to us. We continue to recognize interest expense for the amortization of the discount based on the



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

contractual rate for the 2032 Modified Convertible Notes that remain outstanding. Such amounts were not material for the three months ended March 31, 2009 and 2008.

Holders of the remaining outstanding 2032 Modified Convertible Notes may, subject to certain conditions, convert each of their notes based on a conversion rate of 8.8601 shares of common stock. The conversion price per share of the convertible notes as of any day will equal the accreted value on that day, divided by the conversion rate, or \$87.28, as of March 31, 2009. If converted, the 2032 Modified Convertible Notes will be settled in cash for an amount equal to the lesser of the accreted value of the 2032 Modified Convertible Notes at the conversion date or the conversion value, as defined, and shares of common stock, if any, to the extent the conversion value exceeds the amount paid in cash. As of March 31, 2009, these notes were not convertible and the accreted value exceeded the amount that would have been received upon conversion. As of March 31, 2009 and December 31, 2008, the equity component for the 2032 Modified Convertible Notes was approximately \$29 million.

## 7. Stockholders' equity

### *Stock repurchase programs*

A summary of activity under our stock repurchase programs for the three months ended March 31, 2009 and 2008 is as follows (in millions):

	2009		2008	
	Shares	Dollars	Shares	Dollars
First quarter	37.5	\$ 1,997	-	\$ -

As of March 31, 2009, \$2.2 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 variety of factors, including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

## 8. Restructuring

On August 15, 2007, we announced a plan to restructure our worldwide operations in order to improve our cost structure. This restructuring plan was primarily the result of regulatory and reimbursement developments that began in 2007 involving erythropoiesis-stimulating agent ("ESA") products, including our marketed ESA products Aranesp® and EPOGEN®, and the resulting impact on our operations. Key components of our restructuring plan initially included: (i) worldwide staff reductions, (ii) rationalization of our worldwide network of manufacturing facilities 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. Subsequently, we 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. Through March 31, 2009, we have completed all of the actions and incurred all related costs initially included in our restructuring plan. As of March 31, 2009, we currently estimate that we will incur an additional \$45 million to \$90 million of costs, including related implementation costs, with respect to the subsequently identified initiatives.

Through March 31, 2009, we have incurred \$906 million of costs related to the above-noted actions. The charges included \$193 million of separation costs, \$467 million of asset impairments, \$148 million of accelerated depreciation and \$98 million of other net charges, which primarily include \$161 million of loss accruals for leases, \$10 million loss on the disposal of certain less significant marketed products, \$23 million for implementation costs associated with certain restructuring initiatives and \$19 million of other charges, offset by

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

\$115 million of cost recoveries from Wyeth.

The following tables summarize the charges (credits) recorded during the three months ended March 31, 2009 and 2008 related to the above-noted actions by type of activity (in millions):

<b>Three months ended March 31, 2009</b>	<b>Separation costs</b>	<b>Asset impairments</b>	<b>Other</b>	<b>Total</b>
Selling, general and administrative	\$ -	\$ -	\$ 14	\$ 14
Other charges	5	-	-	5
	<u>\$ 5</u>	<u>\$ -</u>	<u>\$ 14</u>	<u>\$ 19</u>
<b>Three months ended March 31, 2008</b>				
Cost of sales (excludes amortization of acquired intangible assets)	\$ -	\$ 1	\$ -	\$ 1
Research and development	2	-	-	2
Selling, general and administrative	-	-	(1)	(1)
Other charges	4	2	4	10
	<u>\$ 6</u>	<u>\$ 3</u>	<u>\$ 3</u>	<u>\$ 12</u>

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

	<b>Separation costs</b>	<b>Other</b>	<b>Total</b>
Restructuring reserves as of January 1, 2009	\$ 4	\$ 162	\$ 166
Expense	5	14	19
Payments	(3)	(32)	(35)
Restructuring reserves as of March 31, 2009	<u>\$ 6</u>	<u>\$ 144</u>	<u>\$ 150</u>

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

**9. Fair value measurement**

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

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

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

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

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

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of March 31, 2009 and December 31, 2008 (in millions):

	Fair value measurement using:			March 31, 2009
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
<b>Assets:</b>				
Available-for-sale securities	\$ 3,846	\$ 6,487	\$ -	\$ 10,333
Derivatives	-	344	-	344
Total	<u>\$ 3,846</u>	<u>\$ 6,831</u>	<u>\$ -</u>	<u>\$ 10,677</u>
<b>Liabilities:</b>				
Derivatives	\$ -	\$ 61	\$ -	\$ 61
Total	<u>\$ -</u>	<u>\$ 61</u>	<u>\$ -</u>	<u>\$ 61</u>

	Fair value measurement using:			December 31, 2008
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
<b>Assets:</b>				
Available-for-sale securities	\$ 3,575	\$ 5,927	\$ -	\$ 9,502
Derivatives	-	415	-	415
Total	<u>\$ 3,575</u>	<u>\$ 6,342</u>	<u>\$ -</u>	<u>\$ 9,917</u>
<b>Liabilities:</b>				
Derivatives	\$ -	\$ 66	\$ -	\$ 66
Total	<u>\$ -</u>	<u>\$ 66</u>	<u>\$ -</u>	<u>\$ 66</u>

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

There were no material remeasurements to fair value during the three months ended March 31, 2009, of assets and liabilities that are not measured at fair value on a recurring basis.

**10. Derivative instruments**

The Company is exposed to certain risks related to its business operations. The primary risks that we managed by using derivatives are foreign exchange rate risk and interest rate risk. We use financial instruments, including foreign currency forward, foreign currency option and interest rate swap contracts, to reduce our risk to these exposures. We do not use derivatives for speculative trading purposes and are not a party to leveraged derivatives.

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Condensed Consolidated Balance Sheets. Fair value is determined in accordance with SFAS 157 (see Note 9, "*Fair value measurement*"). The accounting for changes in the fair value of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and, further, on the type of hedging relationship. For derivatives designated as hedges under SFAS No. 133 "*Accounting for Derivative Instruments and Hedging Activities*" ("SFAS 133"), we formally assess, both at inception and periodically thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges under SFAS 133 are adjusted to fair value through current earnings.

We enter into foreign currency forward and option contracts to protect us against possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with sales denominated in Euros. Increases or decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by corresponding increases and decreases in our international operating expenses resulting from these foreign currency exchange rate movements. To further reduce our exposure to foreign currency exchange rate fluctuations on our international product sales, we enter into foreign currency forward and option contracts to hedge a portion of our projected international product sales over a three-year time horizon. As of March 31, 2009, we had outstanding foreign currency forward and options contracts, primarily Euro-based, with notional amounts of \$2.8 billion and \$402 million, respectively.

In connection with the issuance of long-term debt, we may enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable Treasury rate between the time we entered into these contracts and the time the related debt is issued. In connection with the issuance in January 2009 of our 2019 Notes and 2039 Notes, we entered into forward interest rate contracts related to a portion of these borrowings.

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

These foreign currency forward and option contracts and forward interest rate contracts are designated as cash flow hedges, and accordingly, the effective portion of gains and losses on these contracts are reported in “Accumulated other comprehensive income” in the Condensed Consolidated Balance Sheets and reclassified to earnings in the same periods during which the hedged transactions affect earnings. Information regarding our cash flow hedge contracts for the three months ended March 31, 2009 is presented in the table below (in millions):

<b>Derivatives in SFAS 133 cash flow hedging relationships</b>	<b>Amount of gain/(loss) recognized in Other Comprehensive Income ("OCI") (effective portion)</b>	<b>Location of gain/(loss) reclassified from Accumulated OCI into income (effective portion)</b>	<b>Amount of gain/(loss) reclassified from Accumulated OCI into income (effective portion)</b>
Interest rate contracts	\$ (11)	Interest and other income (expense), net	\$ -
Foreign exchange contracts	23	Product sales	19
<b>Total</b>	<b>\$ 12</b>		<b>\$ 19</b>

No portions of our cash flow hedge contracts are excluded from the assessment of hedge effectiveness, and ineffective portions of these hedging instruments resulted in less than \$1 million of expense recorded in “Interest and other income (expense), net” in the Condensed Consolidated Statement of Income for the three months ended March 31, 2009. As of March 31, 2009, the amounts expected to be reclassified into earnings over the next 12 months are approximately \$37 million of gains on foreign currency forward and option contracts and \$1 million of losses on forward interest rate contracts.

We have interest rate swap agreements, which qualify and are designated as fair value hedges, to achieve a desired mix of fixed and floating interest rate debt. The terms of the interest rate swap agreements correspond to the related hedged debt instruments and effectively convert a fixed interest rate coupon to a LIBOR-based floating rate coupon over the lives of the respective notes. As of March 31, 2009, we had interest rate swap agreements with an aggregate notional amount of \$2.6 billion on our notes due in 2009, 2014 and 2018 and on our Century Notes. For derivative instruments that are designated and qualify as a fair value hedge, the gain or loss on the derivative as well as the offsetting loss or gain on the hedged item attributable to the hedged risk are recognized in current earnings. For the three months ended March 31, 2009, we included the gain on the hedged debt of \$62 million in the same line item, “Interest and other income (expense), net” in the Condensed Consolidated Statement of Income, as the offsetting loss of \$62 million on the related interest rate swaps.

We enter into foreign currency forward contracts to reduce our exposure to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies which are not designated as hedging transactions under SFAS 133. These exposures are hedged on a month-to-month basis. As of March 31, 2009, the total notional amount of these foreign currency forward contracts was \$520 million. The following table reflects the effect of these derivative instruments on the Condensed Consolidated Statement of Income for the three months ended March 31, 2009 (in millions):

<b>Derivatives not designated as hedging instruments under SFAS 133</b>	<b>Location of gain/(loss) recognized in income</b>	<b>Amount of gain/(loss) recognized in income</b>
Foreign exchange contracts	Interest and other income (expense), net	\$ 14

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

The following table reflects the fair values of both derivatives designated as hedging instruments and not designated as hedging instruments under SFAS 133 included in the Condensed Consolidated Balance Sheet as of March 31, 2009 (in millions):

	<b>Derivative assets</b>		<b>Derivative liabilities</b>	
	<b>Balance Sheet location</b>	<b>Fair value</b>	<b>Balance Sheet location</b>	<b>Fair value</b>
<b>Derivatives designated as hedging instruments under SFAS 133:</b>				
Interest rate contracts	Other current assets/ Other non-current assets	\$ 187	Other current liabilities/ Other non-current liabilities	\$ -
Foreign exchange contracts	Other current assets/ Other non-current assets	156	Other current liabilities/ Other non-current liabilities	60
Total derivatives designated as hedging instruments under SFAS 133		343		60
<b>Derivatives not designated as hedging instruments under SFAS 133:</b>				
Foreign exchange contracts	Other current assets	1	Other current liabilities	1
Total derivatives not designated as hedging instruments under SFAS 133		1		1
Total derivatives		\$ 344		\$ 61

Our foreign exchange contracts that were in a liability position as of March 31, 2009 contain certain credit risk related contingent provisions that are triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts.

**11. 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, 2008 for further discussion of certain of our legal proceedings and other matters.

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

*Average Wholesale Price ("AWP") Litigation*

*In Re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456 (the "MDL Proceeding")*

At the April 27, 2009, fairness hearing, the U.S. District Court for the District of Massachusetts (the "Massachusetts District Court") was still not satisfied with several notice requirements and refused to grant final approval of the settlement agreement until those deficiencies are satisfied. The court scheduled a May 28, 2009 status conference where the court has indicated that it plans to discuss mediation with respect to all non-settling MDL Proceeding cases and to understand the status of each.

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

*State of Iowa v. Abbott Laboratories, Inc., et al.*

On January 22, 2009, Amgen's motion to dismiss in part regarding EPOGEN<sup>®</sup> was granted.

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

On May 7, 2009, a Rule 16 hearing on plaintiff's class certification motion occurred, but no ruling has yet been issued.

*State of Arizona, etc., et al. v. Abbott Laboratories, Inc., et al.*

On May 28, 2009, a status conference has been set where the Massachusetts District Court has said it plans to discuss mediation with respect to this case.

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

A hearing on defendants' motion to dismiss occurred on March 5, 2009, following which the court denied the motion.

*Roche Matters*

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

The parties have fully briefed the Roche defendants' appeal and Amgen's cross-appeal to the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit Court") of the Massachusetts District Court's final judgment and permanent injunction. Oral argument before the Federal Circuit Court covering the matters on appeal is scheduled for June 4, 2009.

*U.S. International Trade Commission ("ITC")*

On April 30, 2009 the Federal Circuit Court issued an order granting, in part, the petition for rehearing en banc filed by the ITC and the Roche defendants. In its order, the Federal Circuit Court withdrew the judgment and opinion previously entered on March 19, 2008 and entered a new judgment and opinion on April 30, 2009. The April 30, 2009 order maintained the March 19, 2008 reversal of the ITC's dismissal of the ITC investigation for non-infringement and its remand of the case back to the ITC for further proceedings to determine if patent infringement has occurred.

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

Oral argument before the Federal Circuit Court on Ariad's appeal of the judgment of the U.S. District Court for the District of Delaware (the "Delaware District Court") was held on May 6, 2009.

*Human Genome Sciences ("HGS") Litigation*

The parties have fully briefed HGS's appeal to the Federal Circuit Court of the Delaware District Court's judgment in the 35 U.S.C. § 146 action of Interference No. 105,240. Oral argument before the Federal Circuit Court remains to be scheduled by the court.

*Sensipar<sup>®</sup> Abbreviated New Drug Application ("ANDA") Litigation*

On April 3, 2009, Teva Pharmaceutical Industries Limited ("Teva") and Barr Pharmaceuticals Inc. ("Barr") each filed a motion for leave to amend their respective answer, defenses and counterclaims to include, for example, allegations of unenforceability of the patents-in-suit. In addition, Teva's amendment, if allowed, would include a counterclaim against Amgen for infringement of U.S. Patent No. 7,449,603. Amgen, NPS Pharmaceuticals ("NPS") and Brigham and Women's Hospital ("BWH") opposed these motions by brief filed on April 23, 2009. The motions have been fully briefed by the parties and a hearing on the motions has been set by the court for May 14, 2009.

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

*Federal Securities Litigation – In re Amgen Inc. Securities Litigation*

On March 4, 2009, plaintiff filed its motion for class certification before the U.S. District Court for the Central District of California (the “California Central District Court”), Amgen filed its response on April 29, 2009 and Plaintiff’s reply will be due on May 13, 2009. A hearing on the motion is scheduled for June 15, 2009.

*State Derivative Litigation – Birch v. Sharer, et al.*

On February 25, 2009, the case was reassigned to a judge in the Complex Department of the Los Angeles County Superior Court and the initial status conference has been scheduled for May 13, 2009.

*ERISA Litigation*

Oral argument before the U.S. Court of Appeals for the 9<sup>th</sup> Circuit on the plaintiffs’ appeal of the California Central District Court’s dismissal of the plaintiffs’ claims occurred on May 8, 2009.

*Third-Party Payers Litigation*

Amgen filed its motion to dismiss the amended and consolidated multi-district litigation complaint on March 6, 2009, and the California Central District Court has scheduled a hearing on the motion for May 26, 2009.

*Qui Tam Actions*

A United States government filing in the Massachusetts District Court concerning the partially unsealed complaint filed pursuant to the Qui Tam provisions of the Federal Civil False Claims Act and on behalf of 17 named states and the District of Columbia under their respective State False Claims Acts (the “Massachusetts Qui Tam Action”) became public on or about May 7, 2009. The filing states that the relator in the Massachusetts Qui Tam Action is a former Amgen employee. Further, the filing represents that, in addition to the Massachusetts Qui Tam Action, there are currently nine other actions under the False Claim Act (“Qui Tam Actions”) pending under seal against Amgen, including eight pending in the U.S. District Court for the Eastern District of New York and one pending in the U.S. District Court for the Western District of Washington. While the Massachusetts Qui Tam Action has been partially unsealed, the other nine Qui Tam Actions remain under seal and have not been provided to Amgen. In the filing made public on May 7, 2009, the U.S. government represents that these ten Qui Tam Actions allege that Amgen engaged in a wide variety of illegal marketing practices with respect to various Amgen products and that these are joint civil and criminal investigations being conducted by a wide variety and large number of federal and state agencies.

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

**12. Subsequent event**

On May 6, 2009, the stockholders approved the Amgen Inc. 2009 Equity Incentive Plan (the “2009 Plan”) for non-employee members of our Board of Directors, the employees and consultants of Amgen, its subsidiaries and affiliates. After May 6, 2009, no further awards may be made under our existing equity plans. The 2009 Plan authorizes the issuance of 100,000,000 shares, subject to reduction for awards granted under our existing plans after December 31, 2008 through May 6, 2009. To the extent any awards granted under existing plans after December 31, 2008 or any awards granted under the 2009 Plan expire, or are forfeited without the issuance of shares, or are settled for cash in lieu of shares, the shares subject to such awards will be added back into the pool of available shares in accordance with the terms of the 2009 Plan.



**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*Forward looking statements*

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

**Overview**

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to assist the reader in understanding the business of Amgen. 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, 2008.

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. ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. Our international product sales consist principally of European sales of Aranesp®, Neulasta® and NEUPOGEN®. International product sales represented approximately 23% and 21% of total product sales for the three months ended March 31, 2009 and 2008, respectively.

Aranesp® and EPOGEN® stimulate the production of red blood cells to treat anemia and belong to a class of drugs referred to as 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® selectively stimulate the production of neutrophils, one type of white blood cell that helps the body fight infections. ENBREL blocks the biologic activity of tumor necrosis factor ("TNF") by inhibiting its binding to TNF receptors, a substance induced in response to inflammatory and immunological responses, such as rheumatoid arthritis and psoriasis. For the three months ended March 31, 2009 and 2008, our principal products represented 93% and 95%, respectively, of worldwide product sales. For additional

## [Table of Contents](#)

information about our principal products, their approved indications and where they are marketed, see “*Item 1. Business – Marketed Products and Selected Product Candidates*” in Part I of our Annual Report on Form 10-K for the year ended December 31, 2008.

We operate in a highly regulated industry and various U.S. and foreign regulatory bodies have substantial authority over how we conduct our business in those countries. 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, which may lead to fewer products being approved by the FDA or other regulatory bodies or additional safety-related requirements or restrictions on the use of our products.

Most patients receiving our principal products for approved indications are covered by either government or private payer healthcare programs, which are placing greater emphasis on cost containment, including requiring that the economic value of products be clearly demonstrated. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products and private insurers may be influenced by government reimbursement methodologies. 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. Additionally, ongoing healthcare reform efforts could result in long-term changes to coverage and reimbursement that may also have a significant impact on our business. For example, the 2008 U.S. general elections resulted in a renewed focus on healthcare issues, and key elected and appointed officials have proposed significant reform to the U.S. healthcare system that would impact reimbursement of our products. In addition, a number of states are considering legislative proposals that would significantly alter their healthcare systems. 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, trends, adverse events or results from clinical trials, 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.

Worldwide product sales for the three months ended March 31, 2009 decreased 8% compared to the prior year comparative period. Product sales in the United States for the three months ended March 31, 2009 totaled \$2.5 billion, representing a decrease of 10% compared to the prior year comparative period. This decrease reflects, in part, approximately \$120 million of benefit to ENBREL sales in the three months ended March 31, 2008 related to the initial wholesaler inventory stocking resulting from a change in ENBREL’s distribution model. During the three months ended March 31, 2008, ENBREL’s distribution model was converted from being primarily drop shipped to pharmacies to a wholesaler distribution model similar to our other products. International product sales for the three months ended March 31, 2009 totaled \$736 million, reflecting a decrease of 2% compared to the prior year comparative period. The decrease in international product sales for the three months ended March 31, 2009 reflects unfavorable foreign currency exchange rate changes of \$69 million. Excluding the impact of foreign currency exchange rate changes, worldwide product sales decreased 7% and international product sales increased 7% for the three months ended March 31, 2009. Worldwide product sales for the three months ended March 31, 2009 also reflect the divestiture of certain of our less significant products in the latter part of 2008. Worldwide sales of these products were \$18 million for the three months ended March 31, 2008. Excluding the impact of the change in the ENBREL distribution model, the change in foreign currency exchange rates and the divestiture of certain of our less significant products, worldwide product sales would have declined by approximately 3%.

## [Table of Contents](#)

For the three months ended March 31, 2009, net income was \$1,019 million compared to \$1,100 million for the three months ended March 31, 2008, representing a decrease of 7%. Diluted earnings per share were \$0.98 per share and \$1.01 per share for the three months ended March 31, 2009 and 2008, respectively, representing a decrease of 3%.

The following is a discussion of selected key factors that have impacted and may continue to impact our business in 2009.

### *Economic Environment*

Sales of our products and our results of operations for the three months ended March 31, 2009 were adversely affected by the current unprecedented global economic conditions. The negative impact on our business has been particularly evident in the United States where this economic downturn and, in part, the associated increase in unemployment, has resulted in a significant increase in the number of individuals whose private insurance coverage has been reduced or eliminated and/or who have assumed a larger portion of healthcare costs previously covered by their employers and/or who have reduced their out-of-pocket medical expenditures for various reasons, including high co-pays or unmet insurance deductibles. While it is not possible to accurately estimate the impact or extent of these developments, we believe that the current economic conditions have led to changes in patient behavior and spending patterns that have negatively affected usage of certain of our products, particularly products with higher co-pays, such as ENBREL. Such changes in behavior may include delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies and/or foregoing health insurance coverage.

In addition to its effects on patients, the economic downturn may have also increased cost sensitivities among medical providers in the United States, such as oncology clinics, particularly in circumstances where providers may experience challenges in the collection of patient co-pays or be forced to absorb treatment costs as a result of coverage decisions or reimbursement terms. Moreover, the current economic conditions appear to have caused our wholesale distributors to lower their levels of inventory on hand, which we believe they have done to reduce their carrying costs and improve their results of operations. These inventory reductions also contributed to lower sales of certain of our products for the three months ended March 31, 2009.

Generally, sales of our products in the United States for the three months ended March 31 have been slightly lower relative to the immediately preceding three month period, which we believe to be due, in part, to various factors relating to wholesaler and customer buying patterns; including holiday-driven wholesaler and customer stocking, contract-driven customer buying and patients purchasing products later in the year after satisfying their annual insurance deductibles. As a result, demand for our products and wholesale distributor inventory levels in the United States are typically negatively impacted in the three months ended March 31. These effects have generally not been significant when comparing product sales in the three months ended March 31 with product sales for the corresponding three month period of the prior year. However, due to the current unprecedented economic environment discussed above, we believe that the effect of the above-noted factors on demand and wholesaler inventories in the three months ended March 31, 2009 has been amplified such that they have also adversely impacted our product sales in the three months ended March 31, 2009 when compared to the three months ended March 31, 2008.

Depending on the severity and duration of these economic conditions and their resulting impact on our business or on third-party payers, including governments and private insurance plans, wholesale distributors, customers, service providers and suppliers, our future product sales and results of operations may continue to be negatively impacted.

## Table of Contents

### *ESA Developments*

Our ESA products have had and will continue to face future challenges, in particular, Aranesp® in the U.S. supportive cancer care setting. For example, on August 6, 2008, we revised the ESA product labeling, as the FDA directed, 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 Oncologic Drugs Advisory Committee (“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 hemoglobin (“Hb”) levels  $\geq 10$  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. Furthermore, we are moving forward with a new randomized, double-blind, placebo-controlled, Phase 3 non-inferiority study evaluating overall survival when comparing advanced non-small cell lung cancer (“NSCLC”) patients on Aranesp® to patients receiving placebo (“Study 782”) as part of our Aranesp® pharmacovigilance program. We are currently identifying clinical sites for Study 782 and plan to begin patient enrollment this year. 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 submitted a proposed REMS and continue to work closely with the FDA to develop a REMS program for the class of ESA products. The components of the REMS approved by the FDA could be different for the use of ESAs in the oncology and nephrology indications. We believe that a REMS program for our ESA products could have a material adverse impact on the future sales of Aranesp®, especially in the U.S. supportive cancer care setting. Additionally, future Aranesp® sales could also be materially adversely impacted by further changes in reimbursement, including as a result of future regulatory developments.

### *Competition*

Certain of our marketed products are under increased competitive pressures, including from biosimilar and other products in Europe, which compete or are expected to compete with Aranesp®, Neulasta® and NEUPOGEN®, as well as our marketed products in the United States, including ENBREL. For example, we have experienced and expect to continue to experience increased competition throughout Europe, including from a number of biosimilar erythropoietin products, which compete with Aranesp®. In addition, a number of G-CSF biosimilar products have received or are expected to receive marketing authorization from the European Commission, and have been or are expected to be launched and compete with Neulasta® and NEUPOGEN®. Further, in the United States, ENBREL will continue to face increased competition primarily due to the expected launch of new products, including competition from J&J’s Simponi™ (golimumab), which was approved by the FDA in April 2009.

### *Other*

Over the past several years, we have taken various actions to improve our cost structure, including a restructuring of our worldwide operations which we announced in August 2007. Subsequently, we identified various other initiatives designed to further assist in improving our cost structure. As of March 31, 2009, we have completed all of the actions and incurred all related costs initially included in our 2007 restructuring plan and have approximately \$45 million to \$90 million of costs remaining to be incurred with respect to the subsequently identified initiatives. Further, as a result of the recent economic downturn, we have also taken certain other actions to increase cost efficiencies and to reduce discretionary expenditures in order to allow us to continue to invest in our pipeline of product candidates, including denosumab, provide support for key products and assure product quality. Depending on the severity and duration of the current economic downturn, we may be required to take further actions to improve our cost structure.

As of March 31, 2009, cash, cash equivalents and marketable securities were \$10.4 billion, of which approximately \$8.0 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 (see “Item 1A. Risk Factors - Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and

## [Table of Contents](#)

activities could have a material adverse effect on our financial results.” in Part II herein). Our total debt outstanding was \$11.4 billion as of March 31, 2009, of which \$1.0 billion is due in November 2009, which we expect to repay without incurring additional indebtedness.

There are many factors that affect us and our industry in general, 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; increasing restrictions on the use of our 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, 2008 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.

## Results of Operations

### Product sales

For the three months ended March 31, 2009 and 2008, worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
Aranesp®	\$ 626	\$ 761	(18)%
EPOGEN®	565	554	2%
Neulasta®/NEUPOGEN®	1,073	1,086	(1)%
ENBREL	758	951	(20)%
Sensipar®	148	133	11%
Other	68	52	31%
Total product sales	\$ 3,238	\$ 3,537	(8)%
Total U.S.	\$ 2,502	\$ 2,788	(10)%
Total International	736	749	(2)%
Total product sales	\$ 3,238	\$ 3,537	(8)%

Product sales are influenced by a number of factors, some of which may impact sales of certain of our existing products more significantly than others, 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. In addition, general economic conditions may effect, and/or in some cases amplify, certain of these factors with a corresponding impact on our product sales.

Worldwide product sales for the three months ended March 31, 2009 decreased 8% compared to the prior year comparative period. Product sales in the United States for the three months ended March 31, 2009 totaled \$2.5 billion, representing a decrease of 10% compared to the prior year comparative period. This decrease reflects, in part, approximately \$120 million of benefit to ENBREL sales in the three months ended March 31, 2008 related to the initial wholesaler inventory stocking resulting from a change in ENBREL’s distribution model. During the three months ended March 31, 2008, ENBREL’s distribution model was converted from being primarily drop shipped to pharmacies to a wholesaler distribution model

## [Table of Contents](#)

similar to our other products. International product sales for the three months ended March 31, 2009 totaled \$736 million, reflecting a decrease of 2% compared to the prior year comparative period. The decrease in international product sales for the three months ended March 31, 2009 reflects unfavorable foreign currency exchange rate changes of \$69 million. Excluding the impact of foreign currency exchange rate changes, worldwide product sales decreased 7% and international product sales increased 7% for the three months ended March 31, 2009. Worldwide product sales for the three months ended March 31, 2009 also reflect the divestiture of certain of our less significant products in the latter part of 2008. Worldwide sales of these products were \$18 million for the three months ended March 31, 2008. Excluding the impact of the change in the ENBREL distribution model, the change in foreign currency exchange rates and the divestiture of certain of our less significant products, worldwide product sales would have declined by approximately 3%.

### *Aranesp®*

For the three months ended March 31, 2009 and 2008, total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
Aranesp® - U.S.	\$ 292	\$ 405	(28)%
Aranesp® - International	334	356	(6)%
Total Aranesp®	\$ 626	\$ 761	(18)%

U.S. Aranesp® sales in the three months ended March 31, 2009 were negatively impacted by \$12 million from changes in accounting estimates related to accruals for sales incentives related to prior period sales. In addition, U.S. Aranesp® sales during the three months ended March 31, 2008 were positively impacted by \$22 million due to a change in the accounting estimate related to product sales return reserves. Excluding the impact of these changes in accounting estimates, U.S. sales of Aranesp® declined 21% in the three months ended March 31, 2009. The decrease in U.S. Aranesp® sales was principally driven by a decline in demand, reflecting the negative impact, primarily in the supportive cancer care setting, of additional safety-related product label changes which occurred in August 2008, and, to a lesser extent, loss of segment share. The decline in sales during the three months ended March 31, 2009 was slightly offset by favorable changes in wholesaler inventories.

International Aranesp® sales for the three months ended March 31, 2009 decreased 6% due to the negative impact of changes in foreign currency exchange rates, which aggregated approximately \$29 million, partially offset by an increase in demand. Excluding the impact of foreign currency exchange rate changes, international Aranesp® sales increased 2% for the three months ended March 31, 2009. For the three months ended March 31, 2009, the ESA segment in Europe has declined primarily due to price erosion, partially offset by growth in patient population. Through March 31, 2009, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total international Aranesp® segment share.

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

- regulatory developments, including those resulting from:
  - i the proposed REMS for the class of ESAs, which we are discussing with the FDA, or other risk management activities undertaken by us or required by the FDA or other regulatory authorities;
  - i future product label changes;

## [Table of Contents](#)

- reimbursement developments, including those resulting from:
  - i government's and/or third-party payer's reaction to regulatory developments, including the proposed REMS, which we are discussing with the FDA, and recent or future product label changes;
  - i current or future cost containment pressures by third-party payers, including governments and private insurance plans;
- severity and duration of the current global economic downturn;
- 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 contracting and related pricing strategies;
- patient population growth; and
- development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

Certain of the above factors could have a material adverse impact on future sales of Aranesp®.

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

### *EPOGEN®*

For the three months ended March 31, 2009 and 2008, total EPOGEN® sales were as follows (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
EPOGEN® - U.S.	\$ 565	\$ 554	2%

EPOGEN® sales for the three months ended March 31, 2009 increased 2%, primarily due to an increase in demand. This increase in demand was principally due to patient population growth and an increase in average net sales price, partially offset by changes in customer purchasing patterns. EPOGEN® demand also benefited from a dose recovery in the three months ended March 31, 2009 compared to the three months ended March 31, 2008. On January 1, 2008, the Centers for Medicare and Medicaid Service's ("CMS") Erythropoietin Monitoring Policy ("EMP") became effective resulting in declines in dosing trends, which was particularly noted in the first quarter of implementation. This dose decline subsequently moderated but may continue to

fluctuate; however, for the three months ended March 31, 2009, it has resulted in higher dosing relative to the three months ended March 31, 2008.

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

- reimbursement developments, including those resulting from:
  - i changes in healthcare providers’ prescribing behavior resulting in dose fluctuations due to the CMS’ revisions to its EMP, which became effective January 1, 2008;
  - i the federal government’s reaction to regulatory developments, including recent or future product label changes;
  - i changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid;
  - i cost containment pressures from the federal and state governments on healthcare providers;
- regulatory developments, including those resulting from:
  - i future product label changes;
  - i risk management activities, including a REMS, undertaken by us or required by the FDA;
- severity and duration of the current global economic downturn;
- governmental or private organization regulations or guidelines relating to the use of our products, including changes in medical guidelines and legislative actions;
- adverse events or results from clinical trials or studies 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;
- our contracting and related pricing strategies;
- changes in future patient population growth or dose/utilization; and
- development of new modalities to treat anemia associated with CRF.

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.



## [Table of Contents](#)

### Neulasta®/NEUPOGEN®

For the three months ended March 31, 2009 and 2008, total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
Neulasta® - U.S.	\$ 594	\$ 569	4%
NEUPOGEN® - U.S.	202	223	(9)%
U.S. Neulasta®/NEUPOGEN® - Total	796	792	1%
Neulasta® - International	183	187	(2)%
NEUPOGEN® - International	94	107	(12)%
International Neulasta®/NEUPOGEN® - Total	277	294	(6)%
Total Neulasta®/NEUPOGEN®	\$ 1,073	\$ 1,086	(1)%

The increase in U.S. sales of Neulasta®/NEUPOGEN® for the three months ended March 31, 2009 was due primarily to an increase in demand, slightly offset by unfavorable changes in wholesaler inventories. The increase in demand was driven by a mid single digit increase in average net sales price, partially offset by a decline in units sold.

The decline in international Neulasta®/NEUPOGEN® sales for the three months ended March 31, 2009 was due to the negative impact of changes in foreign currency exchange rates, which aggregated approximately \$29 million, partially offset by an increase in demand driven by the continued conversion from NEUPOGEN® to Neulasta®. Excluding the impact of foreign currency exchange rate changes, combined international Neulasta®/NEUPOGEN® sales increased 4% for the three months ended March 31, 2009.

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

- severity and duration of the current global economic downturn;
- the availability, extent and access to reimbursement by government and third-party payers;
- penetration of existing segments;
- competitive products or therapies, including biosimilar products that have been or may be approved and launched in the European Union (“EU”);
- 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 impact product 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 contracting and related pricing strategies;
- patient population growth; and

## [Table of Contents](#)

- development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

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 months ended March 31, 2009 and 2008, total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
ENBREL - U.S.	\$ 712	\$ 904	(21)%
ENBREL - International	46	47	(2)%
Total ENBREL	\$ 758	\$ 951	(20)%

The decline in ENBREL sales was driven primarily by unfavorable changes in wholesaler inventory and, to a lesser extent, a decline in demand, primarily in the dermatology setting due to share erosion. During the three months ended March 31, 2008, ENBREL’s distribution model was converted from being primarily drop shipped to pharmacies to a wholesaler distribution model similar to our other products. As a result, sales of ENBREL in the three months ended March 31, 2008 were benefited by approximately \$120 million related to the initial wholesaler inventory stocking resulting from this change in the distribution model. Excluding this positive impact to 2008 sales and the estimated decline in wholesaler inventory levels during the three months ended March 31, 2009, ENBREL sales declined approximately 5% in the three months ended March 31, 2009 compared to the prior year, primarily due to a decline in demand. The decline in demand was principally due to a decrease in units sold, partially offset by an increase in the average net sales price. ENBREL sales were affected by a significantly slower rate of growth in the TNF segment in both rheumatology and dermatology and increased competitive activity. ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

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

- the effects of competing products or therapies, including new competitive products coming to market, such as J&J’s Simponi™ (golimumab) and CNTO 1275 (ustekinumab) and, in part, our ability to differentiate ENBREL based on a combination of its safety profile and efficacy;
- severity and duration of the current global economic downturn;
- the availability, extent and access to reimbursement by government and third-party payers;
- 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;

## [Table of Contents](#)

- 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 impact product safety labeling and may negatively impact healthcare provider prescribing behavior, use of our product, regulatory or private healthcare organization medical guidelines and reimbursement practices;
- 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;
- our contracting and related pricing strategies;
- patient population growth; and
- penetration of existing segments.

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.

### *Selected operating expenses*

The following table summarizes selected operating expenses for the three months ended March 31, 2009 and 2008 (dollar amounts in millions):

	Three months ended		
	March 31,		
	2009	2008	Change
Operating expenses:			
Cost of sales (excludes amortization of acquired intangible assets)	\$ 477	\$ 546	(13)%
% of product sales	15%	15%	
Research and development	\$ 633	\$ 694	(9)%
% of product sales	20%	20%	
Selling, general and administrative	\$ 798	\$ 874	(9)%
% of product sales	25%	25%	
Amortization of acquired intangible assets	\$ 74	\$ 74	0%
Other charges	\$ 5	\$ 10	(50)%

### *Cost of sales*

Cost of sales, which excludes the amortization of acquired intangible assets, decreased 13% for the three months ended March 31, 2009 primarily driven by lower sales volume and a more favorable product mix.

### *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’ costs and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs incurred under R&D arrangements with our corporate partners, such as activities performed on behalf of KA, and costs and cost recoveries 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

## [Table of Contents](#)

R&D costs for R&D collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 3, “*Collaborative arrangements*” to the Condensed Consolidated Financial Statements for further discussion.

R&D expenses decreased 9% for the three months ended March 31, 2009, which was primarily attributable to decreases of \$38 million in clinical trial costs including those associated with our denosumab registration studies due to completion of enrollment and lower clinical trial costs for motesanib associated with the delay of the NSCLC trial. In addition, there was an \$18 million reduction in staff-related costs.

### *Selling, general and administrative*

SG&A expenses are primarily comprised of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses 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 is included in SG&A expenses. See Note 3, “*Collaborative arrangements*” to the Condensed Consolidated Financial Statements for further discussion.

For the three months ended March 31, 2009, the 9% decrease in SG&A was due to the lower expenses during the three months ended March 31, 2009 associated with the Wyeth profit share expense of \$57 million, lower staff-related costs of \$28 million, lower global enterprise resource planning (“ERP”) system related expenses of \$14 million following the implementation of our new ERP system and lower litigation expenses of \$12 million, partially offset by higher product promotional expenses of \$29 million and higher restructuring costs of \$15 million. For the three months ended March 31, 2009 and 2008, the Wyeth profit share expense was \$248 million and \$305 million, respectively. Excluding Wyeth profit share expense, SG&A expenses decreased 3% compared to the three months ended March 31, 2008.

### *Interest and other income (expense), net*

Interest and other income (expense), net was \$89 million and \$35 million of expense for the three months ended March 31, 2009 and 2008, respectively. This change was primarily due to lower gains on investments of \$28 million and lower interest income of \$18 million, principally due to lower portfolio investment returns.

### *Income taxes*

Our effective tax rate for the three months ended March 31, 2009 was 17.3% compared to 20.3% for the corresponding period of the prior year. The decrease in our effective tax rate was primarily due to: (i) the inclusion of the benefit of the federal research and experimentation (“R&E”) tax credit in the three months ended March 31, 2009 (the federal R&E credit was not in effect during 2008 until it was retroactively reinstated during the three months ended December 31, 2008) and (ii) a benefit in the three months ended March 31, 2009 relating to adjustments to previously established deferred taxes due to changes in California tax law effective for future periods.

See Note 5, “*Income taxes*” to the Condensed Consolidated Financial Statements for further discussion.

### *Recent accounting pronouncements*

In April 2009, the FASB issued FSP SFAS 115-2, which will be effective for interim and annual periods ending after June 15, 2009. FSP SFAS 115-2 modifies the guidance to determine whether the impairment of a debt security is other-than-temporary. This new standard also amends the presentation and disclosure requirements of other-than-temporarily impaired debt and equity securities in the financial statements. We are currently evaluating the potential impact of FSP SFAS 115-2 on our financial statements.

**Financial Condition, Liquidity and Capital Resources**

The following table summarizes selected financial data. The amounts reflect the adoption of FSP APB 14-1 (see Note 2, “*Change in method of accounting for convertible debt instruments*” to the Condensed Consolidated Financial Statements for further discussion of our adoption of FSP APB 14-1 during the three months ended March 31, 2009)(in millions):

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
Cash, cash equivalents and marketable securities	\$ 10,378	\$ 9,552
Total assets	37,380	36,427
Current debt	1,000	1,000
Non-current debt	10,408	8,352
Stockholders' equity	19,967	20,885

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 program 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 and equity markets. In addition, we currently expect that we will repay the \$1.0 billion of our 4.00% notes due in November 2009 without incurring additional indebtedness.

*Cash, cash equivalents and marketable securities*

Of the total cash, cash equivalents and marketable securities at March 31, 2009, approximately \$8.0 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 (see “*Item 1A. Risk Factors - Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and activities could have a material adverse effect on our financial results.*” in Part II herein).

## [Table of Contents](#)

### *Financing arrangements*

The following table reflects our long-term borrowings under our various financing arrangements as of March 31, 2009 and December 31, 2008. The following carrying values reflect the adoption of FSP APB 14-1 (in millions):

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
0.125% convertible notes due 2011 (2011 Convertible Notes)	\$ 2,239	\$ 2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,000	1,970
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	1,000	1,000
5.70% notes due 2019 (2019 Notes)	998	-
6.40% notes due 2039 (2039 Notes)	995	-
6.375% notes due 2037 (2037 Notes)	899	899
6.15% notes due 2018 (2018 Notes)	499	499
6.90% notes due 2038 (2038 Notes)	498	498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)	81	81
Other	100	100
<b>Total borrowings</b>	<b>11,408</b>	<b>9,352</b>
Less current portion	1,000	1,000
<b>Total non-current debt</b>	<b>\$ 10,408</b>	<b>\$ 8,352</b>

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of March 31, 2009. 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 6, "Financing arrangements" to the Condensed Consolidated Financial Statements for further discussions of our long-term borrowings and Note 2, "Change in method of accounting for convertible debt instruments" to the Condensed Consolidated Financial Statements for further discussion of our adoption of FSP APB 14-1 during the three months ended March 31, 2009.

### *Cash flows*

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

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net cash provided by operating activities	\$ 859	\$ 1,582
Net cash provided by investing activities	139	697
Net cash provided by financing activities	5	21

### *Operating*

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the three months ended March 31, 2009 decreased approximately \$723 million, primarily due to the prior year receipt of \$300 million for an upfront milestone payment related to our licensing agreement with Takeda, lower net income and timing of receipt of payments for certain corporate partner receivables. The prior year receipt of the \$300 million upfront milestone

## [Table of Contents](#)

payment is included in the “Changes in deferred revenue” in the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2008.

### *Investing*

Cash provided by investing activities during the three months ended March 31, 2009 decreased primarily due to lower net proceeds from investing activities in marketable securities. Net proceeds from investing activities in marketable securities were \$271 million for the three months ended March 31, 2009 compared to \$866 million for the three months ended March 31, 2008. Capital expenditures totaled \$117 million during the three months ended March 31, 2009, compared to \$170 million during the corresponding period of the prior year. The capital expenditures during the three months ended March 31, 2009 were primarily associated with manufacturing capacity expansions in Puerto Rico and other site development. The capital expenditures during the three months ended March 31, 2008 were primarily associated with manufacturing capacity expansions in Puerto Rico and Fremont, other site developments and investment in our global ERP system. We currently estimate 2009 spending on capital projects and equipment to be approximately \$650 million.

### *Financing*

In January 2009, we issued \$1.0 billion aggregate principal amount of notes due in 2019 (the “2019 Notes”) and \$1.0 billion aggregate principal amount of notes due in 2039 (the “2039 Notes”) in a registered offering. The 2019 Notes and 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and 2039 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. Upon the occurrence of a change in control triggering event, as defined, we may be required to purchase for cash all or a portion of the 2019 Notes and the 2039 Notes at a price equal to 101% of the principal amount of the notes plus accrued interest. The total debt discount on issuance and debt issuance costs were \$7 million and \$13 million, respectively, and are being amortized over the life of the notes.

During the three months ended March 31, 2009, we repurchased 37.5 million shares of our common stock at a total cost of \$2.0 billion. During the three months ended March 31, 2008, we did not repurchase any shares of our common stock. In July 2007, the Board of Directors authorized us to repurchase up to \$5.0 billion of common stock. As of March 31, 2009, we had \$2.2 billion available for stock repurchases as authorized by our Board of Directors. 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. 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.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock. Employee stock option exercises provided \$21 million and \$28 million of cash during the three months ended March 31, 2009 and 2008, 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.

**Item 4. CONTROLS AND PROCEDURES**

We maintain “disclosure controls and procedures,” as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen’s Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to Amgen’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and, in reaching a reasonable level of assurance, Amgen’s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen’s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen’s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2009.

Management determined that, as of March 31, 2009, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## PART II - OTHER INFORMATION

### Item 1. LEGAL PROCEEDINGS

See Note 11, “Contingencies” 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, 2008.

### Item 1A. RISK FACTORS

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

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

We and certain of our licensees and partners conduct research, preclinical testing and clinical trials for our product candidates and marketed products for both their existing indications as well as for new and/or expanded indications. In addition, we manufacture and contract manufacture, and certain of our licensees and partners manufacture our products and product candidates, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the European Agency for the Evaluation of Medical Products (“EMA”) 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 refuse 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. In 2007, the FDAAA was signed into law 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, reputational harm and increased product liability risk.

We expect that regulatory reform efforts currently under discussion by U.S. policymakers may include changes to applicable laws and regulations that could have a significant impact on our business. Regulatory agencies could change existing, or promulgate new, regulations at any time that could affect our ability to obtain or maintain approval of our existing or future products and/or require significant additional costs to obtain or maintain such approvals. We are unable to predict when and whether any changes to regulatory

## [Table of Contents](#)

policy affecting our business could occur, and such changes could have a material adverse impact on our business, operations and financial condition.

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, is increasingly costly to maintain. With the occurrence of a number of high profile safety events relating to certain pharmaceutical products, regulatory authorities, and, in particular, the FDA, members of Congress, the U.S. Government Accountability Office, Congressional committees, private health/science foundations and organizations, medical professionals, including physicians and investigators, and the general public are increasingly concerned about potential or perceived safety issues associated with pharmaceutical and biological products, whether under study for initial approval or already marketed. For example, in 2007 we received letters from 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, promotion of our ESAs and other products, our 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 developments could have a material adverse effect on the use of our ESA products that are the subject of such developments.

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 or 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 of the products within particular therapeutic areas, 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 coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.*”)

Certain specific labeling or label changes of our 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 with respect to any of our products by regulatory agencies, an increased rate or number of previously-identified safety-related events, 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. Label changes may also be required as a result of new legislation. Under new FDA legislation implemented in 2006, the Physician’s Labeling Rule (“PLR”) requires changes to the existing format of U.S. product package inserts for human prescription drug and biological products with the intent of making product information more easily accessible. The PLR requires revised standards of content and format of labeling and provides timelines for when new and previously approved products must comply with the new regulations. 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 U.S. labels for 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 “ – *Our ESA products continue to be under review and receive scrutiny by regulatory authorities, and further regulatory action or adverse clinical trial or meta-analysis results could adversely impact the use, sales and reimbursement of our ESAs.*”) 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,

## [Table of Contents](#)

2008, we participated in a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee (“DODAC”) to review data supporting the supplemental Biologics License Application (“BLA”) submitted by us for the use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis, who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy 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 regarding the use of ENBREL in pediatric patients with chronic moderate to severe plaque psoriasis. We cannot predict what the result of the FDA’s analysis of TNF-blockers and the development of lymphoma or other cancers in children and young adults may be, nor can we speculate on the effect of that analysis on the supplemental BLA. On March 26, 2009, the FDA announced details of a May 12-13, 2009, public workshop entitled, “Developing a Consolidated Pediatric Rheumatology Observational Registry,” which it plans to conduct in order to seek constructive input from key stakeholders in the pediatric rheumatology community, the pharmaceutical industry and the public to explore the value and feasibility of developing a consolidated “cross-product” pediatric rheumatology observational registry. We have been invited to participate and to present input based on our experience in conducting a large Phase 4 registry that has evaluated for up to three years nearly 600 children with Juvenile Idiopathic Arthritis (“JIA”) who have been treated with ENBREL, methotrexate, or the combination of methotrexate and ENBREL. At the public workshop, the FDA is also expected to share its views on the use of product-specific post-marketing registries to capture long-term safety data of drug and biological products administered to patients with JIA. Further revisions to the ENBREL label or other actions by the FDA, including additional advisory committee meetings, could have a material adverse 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 additional 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 the 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 the ability of healthcare providers to prescribe, dispense or use our products, 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 effect on our ability to launch our affected products 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 with and education of healthcare providers. This requirement has placed Nplate® at a disadvantage versus other products used for the same indication where no REMS requirement exists. Additionally, following the FDA web-alert on September 4, 2008 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 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. In December 2008, we agreed with the FDA on the required revisions to the U.S. PI, and we continue to work with the FDA to finalize the requested updates to the ENBREL REMS. Our efforts to comply with the requirements of our existing REMS and any additional REMS or other risk management activities required of us in the future could restrict or otherwise impact our existing promotional activities for our other products as well. In addition, we have ongoing PMC studies for all of our marketed products. 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 the oncology setting, and we continue to work closely with the FDA to develop a REMS program for

## Table of Contents

the class of ESA products under authority prescribed by the FDAAA. We have submitted a proposed REMS in response to the FDA's requests, although we cannot predict what risk management activities the FDA may require of us, and the components of the REMS could be different for the use of ESAs in the oncology and nephrology indications. A REMS program for our ESA products 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, the original 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. Our conditional approval of Vectibix® in the EU is reviewed annually by the European Committee for Medicinal Products for Human Use, and in December 2008 we agreed as a condition of the renewal of the conditional approval to conduct an additional clinical trial in the existing approved indication. If results from clinical trials as part of a PMC, pharmacovigilance program or comparable agreement with regulatory authorities 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.

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 or product quality issues suggest 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 voluntarily recalled two manufacturing lots of EPOGEN® and our licensee, Ortho Biotech, voluntarily recalled one manufacturing lot of PROCRI® (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, trends, 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 result 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 coverage and reimbursement from third-party payers, and to the extent that access to and 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.”)

## [Table of Contents](#)

*Our ESA products continue to be under review and receive scrutiny by regulatory authorities, and further regulatory action or adverse clinical trial or meta-analysis results could adversely impact the use, sales and reimbursement of our ESAs.*

As a result of adverse safety results involving ESA products that were observed beginning in 2006 in various studies exploring the use of ESAs in settings different from those outlined in the FDA-approved label, our ESA products have been the subject of ongoing review and scrutiny from regulatory authorities over the past several years. In the United States, we have engaged and continue to engage in discussions with the FDA regarding the benefit/risk profile of ESAs, which have resulted and could result in future changes to ESA labeling and usage. For example, on July 30, 2008, we received a complete response letter from the FDA to the revisions to the ESA labeling we proposed earlier in the year. The letter proposed, 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  $\geq 10$  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 revised the ESA labeling on August 6, 2008, as the FDA directed, and have experienced a reduction in our ESA sales, in particular Aranesp® sales in the U.S. supportive cancer care setting, since that time. Although we cannot predict what further impact the revised ESA labels may have on our business, the revised ESA labeling or any future labeling changes, including any required in connection with our ongoing discussions with the FDA regarding the conversion of the format of our ESA U.S. labels in accordance with the PLR, 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. We continue to work closely with the FDA to develop a REMS program for the class of ESA products under authority prescribed by FDAAA. (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.*”) In addition, we are moving forward with Study 782 as part of our Aranesp® pharmacovigilance program. We are currently identifying clinical sites for Study 782 and plan to begin patient enrollment this year. (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.*”)

In addition, regulatory authorities outside the United States have also reviewed and scrutinized the use of our ESA products. 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®, which set 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. Subsequently, on June 26, 2008, the EMEA recommended updating the product information for ESAs with a new warning for their use in cancer patients, which was approved by the European Commission in October 2008. 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 a 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 revised 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.

Moreover, 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 the EMEA. These results were also presented by the Cochrane Haematological Malignancies Group in December at the 2008 American Society of Hematology Congress, and a final manuscript was published in May 2009. This Cochrane meta-analysis of patient level data from previous

## [Table of Contents](#)

studies corroborates prior analyses indicating that the use of ESAs may increase the risk of death in cancer patients. The studies in the analysis all predate the current label, which advises using the least amount of ESA necessary to avoid transfusion. The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. PI (Hazard Ratio (“HR”): 1.08 [95% Confidence Interval (“CI”) 0.99-1.18]). The ESA treatment arm had increased on-study deaths (HR: 1.17 [95% CI 1.06-1.30]) and decreased overall survival (HR: 1.06 [95% CI 1.00-1.12]) compared to controls. The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. The ESA treatment arm had increased on-study deaths (HR: 1.10 [95% CI 0.98-1.24]) and decreased overall survival (HR: 1.04 [95% CI 0.97-1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label. Additionally, we are awaiting data from our Trial to Reduce Cardiovascular Events with Aranesp® Therapy, or TREAT, study, a large 4,000 patient multi-center, randomized, double-blind, placebo-controlled phase 3 trial designed to determine the impact of anemia therapy with Aranesp® on mortality and non-fatal cardiovascular events in patients with chronic kidney disease (“CKD”), anemia and type 2 diabetes, and we expect to present the data in the second half of 2009. Although we cannot predict the results of meta-analyses or the outcomes of ongoing clinical trials, or the extent to which regulatory authorities may require additional labeling changes as a result of these or other trials, we cannot exclude the possibility that adverse results from clinical trials or future analyses 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 products or product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking or to support our existing label. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate or the extent of the safety concerns, post-marketing issues and/or exposure to patients and therefore, we may spend several years and incur substantial expense in completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, the rate of occurrence of the clinical trial events being studied, 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, India, East Asia and some Central and South American countries either through

## [Table of Contents](#)

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 [www.amgen.com](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. Delays may sometimes be substantial. 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, we delayed our phase 3 trial in first-line NSCLC, which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. Following initiation of the trial, in November 2008, we and our development partners announced that enrollment in this phase 3 trial had been temporarily suspended following a planned safety data review of 600 patients by the study's independent Data Monitoring Committee ("DMC"). The study's DMC also recommended that patients with squamous NSCLC immediately discontinue motesanib therapy but did not recommend discontinuation of motesanib therapy for patients with non-squamous NSCLC. In February 2009, the DMC recommended the trial resume enrollment of patients with non-squamous NSCLC, and we are currently preparing to reinstate enrollment in this patient population following an FDA-approved revision to the study protocol. 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.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. For example, we are moving forward with Study 782 as part of our Aranesp® pharmacovigilance program. We are currently identifying clinical sites for Study 782 and plan to begin patient enrollment this year. The addition of this or other clinical trials to our pharmacovigilance program and any additional clinical trials we initiate, including those 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.

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.

## [Table of Contents](#)

*Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and 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. It is possible that applicable statutes, such as the Medicare Prescription Drug Improvement and Modernization Act, could be modified or new legislation or regulation introduced in 2009 or later that could include a focus on reducing drug costs and change coverage and reimbursement methodologies for government healthcare programs that could have a significant impact on our business. Although we cannot predict when legislation or regulation affecting reimbursement from third-party payers may be proposed or enacted in the future or the specific effect any such legislation or regulation would have on our business, any such legislation or regulations changing and/or reducing the coverage and reimbursement of our products or the way our products are used or prescribed may cause our sales to decrease and our revenues to decline.

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. For example, on January 14, 2008, CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice. A more detailed 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.*”)

An increasing focus on cost containment by public and private insurers has resulted, and could result in the future, in lower reimbursement rates for our products. Most patients receiving our principal products 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. Effective January 1, 2009 in the hospital outpatient setting, most of our products are reimbursed under a Medicare Part B payment methodology that reimburses each product at 104% of its average sales price (“ASP”) (sometimes referred to as “ASP+4%”). The rate of reimbursement in the hospital outpatient setting has been reduced twice since the inception of ASP-based payment in this setting, with reimbursement rates set at ASP+5% for 2008 and ASP+6% from 2006 to 2007. CMS has the regulatory authority to alter or maintain the Medicare payment rates for Part B drugs and biologicals in the future for the hospital outpatient setting. Effective January 1, 2005, in the physician office setting, Aranesp®, Neulasta® and NEUPOGEN® are reimbursed under a Medicare Part B payment methodology that reimburses each product at ASP+6%. A product's ASP is calculated and reported to CMS on a quarterly basis and 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 second quarter of 2009 is based in part on certain historical sales and sales incentive data for Aranesp® from January 1, 2008 through December 31, 2008. ASP-based reimbursements of products under Medicare may, in some circumstances, be below the cost that medical providers paid for such products, which could adversely affect sales of our products.

In the dialysis setting, our products may also be subject to downward pressure on reimbursement rates. 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



## [Table of Contents](#)

implemented by CMS. Currently, the ESRD reimbursement rate for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is set at ASP+6%. Although we cannot predict the payment levels of EPOGEN® in future quarters or the extent to which Medicare payments for dialysis drugs may be modified by future federal regulation or legislation, a decrease in the reimbursement rate for EPOGEN® may have a material adverse effect on our business and results of operations. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician office setting, dialysis facility setting and hospital outpatient setting. These calculations are regularly reviewed for completeness and based on such review, and 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 an EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and 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 reduced 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. 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. While this dose decline subsequently stabilized in 2008, it may further fluctuate in the future, which could have a material adverse effect on sales of EPOGEN® and our business and results of operations.

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, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including ESAs, intravenous iron, and intravenous vitamin D, as well as "oral equivalent" forms of these intravenous drugs. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. It is possible that some 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. Beginning in 2012, facilities would be subject to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, including performance standards related to 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 potential impact of the new Medicare legislation on our business and at this time cannot predict the impact a bundled payment system for outpatient dialysis might have on sales of EPOGEN® or Aranesp®.

We face risks relating to the calculation of ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. CMS further defines the statutory formula through regulations and other CMS guidance. However, the statute, regulations, and CMS guidance do not define specific methodologies for all aspects of the calculation of ASP. For example, in the Medicare Physician Fee Schedule Final Rule for 2008, CMS did not finalize a proposed methodology for treatment of bundled price concessions, stating that in the absence of specific guidance, manufacturers may make "reasonable assumptions" in their calculation of ASP, consistent with the general requirements and the intent of the Medicare statute, federal regulations and their customary business practices. While Amgen believes that any assumptions it employs in its ASP calculation methodology satisfy this reasonable assumption standard, such assumptions require us to apply judgment and are subject to CMS review, and CMS or other third parties may not agree with our assessment as to the reasonableness of our assumptions. CMS stated that it will continue to monitor this issue and may provide more specific guidance in the future. Any such specific guidance could result in a change in our ASP calculation methodology, which, if significant, could have a material adverse effect on our results of operations.

## [Table of Contents](#)

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 FDA labeling 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, an NCD is a national policy statement granting, limiting or excluding Medicare coverage for a specific medical item or service. On May 14, 2007, CMS issued a proposed NCD that was open for public comment through June 13, 2007. On July 30, 2007, CMS issued its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions, and established Medicare coverage parameters for FDA-approved ESA use in oncology.

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, to our knowledge, although no private payers have fully implemented the Decision Memorandum to date, many private payers have implemented the portions of the restrictions included in the Decision Memorandum, most commonly the provisions that reflect the prescriber package insert. 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 we believe that it may continue to impact us in the future.

In addition, the FDA held a joint meeting of the Cardiovascular-Renal Drug Advisory Committee and the Drug Safety and Risk Management Advisory Committee on September 11, 2007 to evaluate safety data on ESA use in renal disease. On July 30, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process, which included as potential topics the use of ESAs in ESRD and CKD. Also included in the initial potential future NCD topic list is the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate®. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD, or for thrombopoiesis stimulating agents, and we cannot predict whether either ESAs in the renal setting or thrombopoiesis stimulating agents 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, could negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations.

If, and when, reimbursement rates or availability for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales, which could have a material adverse effect on us and our results of operations. For example, the use of EPOGEN® in the United States in connection with treatment for ESRD is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration, 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 discontinued coverage for Aranesp® for anemia of cancer (“AoC”). (See “— *Guidelines and recommendations published by various organizations can reduce the use of our products.*”) 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

## [Table of Contents](#)

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.

Further, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Additionally, we expect that healthcare reform efforts could include long-term changes to coverage and reimbursement that may have a significant impact on our business. The 2008 U.S. general elections resulted in a renewed focus on healthcare issues, and key elected and appointed officials have proposed significant reform to the U.S. healthcare system that would impact reimbursement of our products. These proposals include provisions affecting both public programs and privately-financed health insurance arrangements. Many of these proposals attempt to increase the number of insured by raising the eligibility levels for public programs and, in some cases, requiring individuals and employers to purchase health coverage. In addition, a number of states, including California, Colorado, Connecticut, New York, and Pennsylvania, are considering legislative proposals that would significantly alter their health care systems. Collectively, such proposals may introduce structural changes to the existing reimbursement system, including changes affecting the role of federal and state governments in healthcare reimbursement; the organization of Medicare and/or Medicaid; the process of contracting with physicians, hospitals and/or other healthcare providers; physician reimbursement methods and payment rates; coverage determinations; mandated benefits; minimum medical expenditures; claim payments and processing; and drug utilization and patient safety efforts.

*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 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 patents listed for the product. For example, on July 25, 2008, we, NPS and BWH filed a lawsuit against Teva and Barr for infringement of four Sensipar® patents. The lawsuit is based on ANDAs 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 10, "Contingencies" to the Consolidated Financial Statements in our 2008 Form 10-K and in Note 11, "Contingencies" to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities; be required to enter into third-party licenses for the infringed product or technology or be 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, romiplostim and our product candidates. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab and romiplostim products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), Enbrel® (etanercept), Sensipar®/Mimpara® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim),

respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States.

In recent years, policymakers have proposed reforming U.S. patent laws and regulations. For example, patent reform legislation was introduced in both houses of Congress in 2009, and the Senate Judiciary Committee approved a patent reform bill on April 2, 2009. In general, the proposed legislation attempts to address issues surrounding the enforceability of patents and the increase in patent litigation by, among other things, changing the way damages for patent infringement are calculated, establishing new procedures for challenging patents and establishing different methods for invalidating patents. While we cannot predict what form any new patent reform laws or regulations ultimately may take, final legislation could introduce new substantive rules and procedures for challenging patents, and certain reforms that make it easier for competitors to challenge our patents could have a material adverse effect on our business.

We also have been granted or obtained rights to patents in Europe relating to erythropoietin, G-CSF, pegfilgrastim (pegylated G-CSF), etanercept, darbepoetin alfa, cinacalcet, panitumumab and romiplostim. 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, closed certain production operations and abandoned leases primarily for certain R&D facilities that will not be used in our operations. We subsequently identified various other initiatives designed to further assist in improving our cost structure. Through March 31, 2009, we have completed all of these actions initially included in our 2007 restructuring plan and reduced our related costs and have approximately \$45 million to \$90 million of costs remaining to be incurred with respect to the initiatives we subsequently identified. Our ability to maintain these savings is dependent upon various future developments, some of which are beyond our control. We may not realize, in full or in part, all of the anticipated benefits and savings from our recent restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve or 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.

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 in challenging economic conditions with fewer human resources and losses of intellectual capital. We must also continue to 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, which could adversely affect our business.

Moreover, we may be forced to undertake further cost saving and/or restructuring initiatives in the future to achieve increased operating efficiencies, improve our competitive standing or results of operations and/or to address unfavorable economic conditions. The current economic climate has forced many U.S. companies to cut costs in order to maintain their competitive standing, including through restructurings and reorganizations. As a result of the global economic downturn, we have worked, and we continue to work, to increase cost efficiencies and to reduce discretionary expenditures, and in the event of further deterioration of the economy, we may also be required to consider further steps to improve our cost structure. Additionally, the anticipated benefits of our cost reduction initiatives are based on forecasts which could vary substantially

## [Table of Contents](#)

from actual results, and we cannot provide assurance that any such cost saving initiatives will not have a material adverse effect on 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 coverage and reimbursement from third-party payers, and to the extent that access to and 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 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 United States Pharmacopoeia Dispensing Information 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

## [Table of Contents](#)

- other parties have or may have proprietary rights relating 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 in refractory thyroid cancer until there is more clarity on what would constitute an appropriate regulatory filing package for that indication. We believe that the safety concerns around our ESAs expressed by the FDA must be addressed to the agency's satisfaction before new indications or expanded labeling of our ESA products will likely be approved.

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor ("BDNF"), Megakaryocyte Growth and Development Factor ("MGDF") and Glial Cell Lined-Derived Neurotrophic Factor ("GDNF"). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig's Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson's disease did not meet the primary study endpoint upon completion of nine months of the double-blind treatment phase of the study even though a small phase 1 pilot investigator-initiated open-label study over a three-year period appeared to result in improvements for advanced Parkinson's disease patients. Subsequently, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson's disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data 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 of GDNF 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; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.*"; "*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 2008 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Civil and criminal litigation is inherently unpredictable, and the outcome can result in excessive verdicts, fines, penalties and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, incur

## [Table of Contents](#)

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. Based on representations in a U.S. government filing that became public on or about May 7, 2009 relating to the Massachusetts Qui Tam Action, we now believe the subpoenas we received from the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington also relate to nine additional Qui Tam Actions which are purportedly pending against Amgen, including eight pending in the U.S. District Court for the Eastern District of New York and one pending in the U.S. District Court for the Western District of Washington. (See Note 10, "Contingencies" to the Consolidated Financial Statements in our 2008 Form 10-K, and Note 11, "Contingencies" to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.) The U.S. government filing further alleges that a large number of states (17) are involved in the Qui Tam investigations, led by the State of New York. These investigations are represented to be joint criminal and civil investigations.

Although we cannot predict whether additional proceedings may be initiated against us, or predict when these matters may be resolved, it is not unusual for investigations such as these to continue for a considerable period of time and to require management's attention and significant legal expense. 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 our products, a decision adverse to our interests could result in federal criminal liability and/or federal or state civil or administrative liability, and thus could result in substantial financial damages or criminal penalties and possible exclusion from future participation in the Medicare and Medicaid programs. In addition, we may see new governmental investigations of or actions against us citing novel theories of recovery. Any of these results could have a material adverse effect on our results of operations, financial position or cash flows in the period in which such liabilities are incurred.

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

Product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products that we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention, and adversely affect our reputation and the demand for our products. Amgen and Immunex have 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. 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. As a result, 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 December 31, 2008, the trading price of our common stock has ranged from a high of \$66.51 per share to a low of \$41.20 per share.

## [Table of Contents](#)

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
- severity and duration of the current global economic downturn
- development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy
- inability to maintain regulatory approval of marketed products or manufacturing facilities
- actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators
- business development or licensing activities
- product development or other business announcements by us or our competitors
- regulatory matters or actions, such as label changes or risk management activities, 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.



## [Table of Contents](#)

*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 during the latter part of 2008 and continuing into 2009, has led to uncertainty and liquidity issues for both borrowers and investors. We currently expect that we will repay the \$1.0 billion of our 4.00% notes due in November 2009 without incurring additional indebtedness. 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 Brothers Holdings Inc. (“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 Notes due 2011 and our 0.375% Convertible 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. Deterioration in the financial condition of these counterparties could adversely impact the accounting for these transactions. Further, additional bankruptcies in the financial sector could limit our ability to replace these 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 investments disclosed as cash equivalents and marketable securities on our 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.

*Current economic conditions may magnify certain risks that affect our business.*

Our operations and performance have been, and may continue to be, affected by economic conditions. 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 coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced, this could negatively impact the utilization of our products.*”) As a result of the current global economic downturn, 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.

In addition, as a result of the economic downturn, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. These economic conditions may affect patients’ ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare

## [Table of Contents](#)

insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies and/or foregoing health care insurance coverage. In addition to its effects on consumers, the economic downturn may have also increased cost sensitivities among medical providers in the United States, such as oncology clinics, particularly in circumstances where providers may experience challenges in the collection of patient co-pays or be forced to absorb treatment costs as a result of coverage decisions or reimbursement terms. Collectively, we believe that these changes have resulted and may continue to result in reduced demand for our products, which could continue to adversely affect our business and results of operations. Any resulting decrease in demand for our products could also cause us to experience excess inventory write-offs and/or excess capacity charges at certain of our manufacturing facilities.

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. Current economic conditions may adversely affect the ability of our distributors, customers and suppliers to obtain liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Further, economic conditions appear to have affected, and may continue to affect, the business practices of our wholesale distributors in a manner that contributed to lower sales of our products. For the three months ended March 31, 2009, certain of our wholesale distributors lowered their levels of inventory on hand, which we believe was done to reduce their carrying costs and improve their results of operations. In addition, although we monitor our distributors', customers' and suppliers' financial condition and their liquidity, in order to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could negatively impact 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 and clinical 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 regulatory agencies so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the regulatory agency 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 regulatory agencies 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

## [Table of Contents](#)

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 and clinical 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.

Some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. We are investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances as such raw materials may be subject to contamination and/or recall.

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 biologically derived substances 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; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.*

We currently manufacture and market all of 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® as well as our late-stage product candidate denosumab and plan to use contract manufacturers to produce a number of our other 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 and those of our third-party contract manufacturers, 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
- capacity of our facilities and those of our contract manufacturers

## [Table of Contents](#)

- facility contamination by microorganisms or viruses
- labor disputes or shortages, including the effects of an avian or pandemic flu outbreak
- compliance with regulatory requirements
- changes in forecasts of future demand
- timing and actual number of production runs
- production success rates and bulk drug yields
- timing and outcome of product quality testing

If we have problems in one or more of these or other manufacturing variables, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, 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 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, in particular denosumab, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at appropriate production capacity over the next few years, optimize manufacturing asset utilization, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance. Key manufacturing projects include: (i) construction and the related qualification and licensure of a new formulation and filling facility at our Puerto Rico site and (ii) expansion and the related qualification and licensure of our existing bulk protein facilities at our Puerto Rico site for the production of our late-stage product candidate, denosumab.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our 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 the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or 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. Additionally, we distribute a substantial volume of our commercial products through a single distribution center in Louisville, Kentucky for the United States and another in Breda, the Netherlands for Europe and the rest of the world. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers and our third-party logistics providers.

## [Table of Contents](#)

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

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

- power failures and/or other utility 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 such losses could adversely affect 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; timing of supply may also be affected by operation of our distribution and logistics centers and providers.”)

*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. (See also “— We face uncertainties related to the recently announced Wyeth / Pfizer merger.”) 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

## Table of Contents

third-party contract manufacturer of ENBREL bulk drug; accordingly, our U.S. and Canadian supply of ENBREL is currently significantly dependent on BI Pharma's production schedule for ENBREL. We would be unable to produce ENBREL in sufficient quantities to substantially offset shortages in BI Pharma's scheduled production if BI Pharma or other third-party contract manufacturers used for the formulation, fill and finish of ENBREL bulk drug were to cease or interrupt production or services or otherwise fail to supply materials, products or services to us for any reason, including labor shortages or disputes, regulatory requirements or action or contamination of product lots or product recalls.

For example, in the second quarter of 2002, the prior co-marketers with respect to ENBREL experienced a brief period where no ENBREL was available to fill new patient prescriptions, primarily due to variation in the expected production yield from BI Pharma. We cannot guarantee that an alternative third-party contract manufacturer would be available on a timely basis or at all. This in turn could materially reduce our ability to satisfy demand for ENBREL, which could materially and adversely affect our operating results.

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

*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, in the United States, Aranesp® competes with PROCIT®, which is marketed by J&J, in the supportive cancer care and pre-dialysis settings. In Europe, we face competition from the following products: (i) EPREX® and ERYPO® by Janssen-Cilag; (ii) NeoRecormon® by Roche; (iii) Retacrit™/Silapo® by Hospira Enterprises B.V. and Stada Arzneimittel AG; (iv) Binocrit®/Epoetin alfa Hexal®/Abseamed® by Sandoz GmbH/Hexal Biotech Forschungs GmbH/Medice Arzneimittel Pütter GmbH & Company KG and (v) MIRCERA® by Roche, which competes with Aranesp® in the nephrology segment only. Any products or technologies that are directly or indirectly successful in addressing anemia associated with CRF could negatively impact product sales of EPOGEN® and Aranesp®. In the United States, EPOGEN® and Aranesp® compete with each other, primarily in the U.S. hospital dialysis clinic setting.

In addition to competition from the above-noted marketed products, a number of companies are developing products that could potentially compete with Aranesp® and/or EPOGEN® in the future. Affymax Inc. and Takeda are co-developing Hematide™, an ESA for the treatment of anemia in renal patients. FibroGen is developing FG-2216 and FG-4592, orally active ESAs, for the treatment of anemia and is also studying FG-4592 for the treatment in anemia of CKD. Ratiopharm is developing a biosimilar ESA, EpoTheta, expected to launch in the EU in 2009. Additionally in December 2008, Merck & Company, Inc. ("Merck") announced the formation of a new biotech division, Merck Bioventures, which is developing a pegylated ESA (MK-2578), which they have announced they expect to launch in 2012. 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.*")

## [Table of Contents](#)

ENBREL competes in certain circumstances with products marketed by J&J, Abbott Laboratories (“Abbott”), Biogen IDEC Inc., Barr, Genentech, Inc., Bristol-Myers Squibb Corporation, Novartis AG and Sanofi-Aventis and others, as well as the generic drug methotrexate. ENBREL will now also face competition from J&J’s Simponi™ (golimumab), which was approved by the FDA in April 2009 for the treatment of moderate-to-severe rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis, and may face competition from other potential therapies being developed, including J&J’s CNTO 1275 (ustekinumab), Roche’s Actemra (tocilizumab), Abbott’s ABT-874 and UCB’s Cimzia® (PEGylated anti-TNF). 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.

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. As with Merck’s recent announcement of its intention to expand into biotechnology and with Pfizer Inc.’s (“Pfizer”) announcement of its proposed merger with Wyeth, pharmaceutical companies and generic manufacturers that have traditionally developed and marketed “small molecule” pharmaceutical products are expanding into the biotechnology field with increasing frequency, and some of these companies are seeking to develop biosimilar products that may compete with our products. Large biopharmaceutical companies may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do, and 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. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. Business combinations among our competitors may also increase competition and the resources available to our competitors.

*We currently face competition from biosimilar products, and we expect to face increasing competition from biosimilar products in the future.*

We currently face competition in Europe from biosimilar products, and we expect to face increasing competition from biosimilars in the future. Lawmakers in the United States are considering adopting a regulatory pathway for the abbreviated approval of biosimilars, and the EU has already created such a regulatory pathway. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader marketing approval for biosimilars, our products will become subject to increased competition. Expiration or successful challenge of applicable patent rights could trigger such competition, and we could face more litigation regarding the validity and/or scope of our patents.

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. 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, recommending that applicants seeking approval of such biosimilar products conduct pharmacodynamic, toxicological and clinical safety studies as well as a pharmacovigilance program. Some companies have received and other companies are seeking approval to market erythropoietin and G-CSF biosimilars in the EU, presenting additional competition for 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.*”) For example, following the expiration of the principal European patent relating to recombinant G-CSF on August 22, 2006, 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® in

## [Table of Contents](#)

September 2008. Ratiopharm launched its G-CSF biosimilar product, Ratiograstim®, in the United Kingdom and Germany in October 2008, in Denmark, the Netherlands, Norway, Spain and Switzerland in January 2009, in France in March 2009 and is expected to launch it in other European markets in 2009. Teva has stated that it would begin marketing Tevagrastim throughout Europe in 2009. In February 2009, the European Commission issued marketing authorizations for an additional G-CSF biosimilar product to Sandoz's Zarzio® and Hexal's Filgrastim Hexal®. Hexal launched its G-CSF biosimilar product, Ratiograstim®, in Germany in March 2009. If these companies' launch plans are successful, there may be two G-CSF biosimilars available in 2009 in the EU marketed by five different companies. 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 the United States, there currently is no regulatory pathway for the abbreviated approval of BLAs for biosimilars, but legislation on biosimilars may be enacted in the coming months or years. Such biosimilars would reference biotechnology products already approved under the U.S. Public Health Service Act. Under current law, potential competitors may introduce biotechnology products in the United States only by filing a complete BLA. Before biosimilar products could enter the U.S. market through an abbreviated approval process, Congress would need to pass legislation to create a new approval pathway and, depending on the specific provisions of any such legislation, and the FDA would need to promulgate associated regulations or guidance. The Obama Administration has expressed support for creation of such an approval pathway for biosimilars, including as a part of its broader healthcare reform effort, which the Administration has identified as one of its top priorities. In each of 2007, 2008 and 2009, a number of bills that would create a legal framework for approving biosimilars have been introduced by members of Congress. In addition, both the House of Representatives and Senate have held hearings on biosimilars. We cannot predict what the specific provisions of any final legislation might be or the timing of implementation of the pathway by the FDA. To the extent that an abbreviated biosimilar pathway is created through legislation in the United States, we would likely face greater competition and downward pressure on our product prices, sales and revenues, subject to our ability to enforce our patents. Further, biosimilar manufacturers with approved products in Europe may seek to quickly obtain U.S. approval if an abbreviated regulatory pathway for biosimilars is adopted.

The absence of an abbreviated approval pathway for biosimilar products may not be a complete barrier to the introduction of biosimilar-type products in the United States. For example, in February 2009, Teva announced its intention to introduce its version of NEUPOGEN® in the U.S. by filing a complete BLA under the existing statutory framework. Teva did not indicate whether it would wait for Amgen's U.S. patents on G-CSF to expire before attempting to enter the market.

*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, whereby they have agreed 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.



## [Table of Contents](#)

*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 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. (See also “— *We face uncertainties related to the recently announced Wyeth / Pfizer merger.*”)

*We face uncertainties related to the recently announced Wyeth/Pfizer merger.*

We are party to a number of agreements with Wyeth relating to the manufacturing, marketing and selling of ENBREL, including a co-promotion agreement and a global supply agreement. On January 26, 2009, Wyeth and Pfizer announced that they have entered into a definitive merger agreement under which Pfizer will acquire Wyeth in a cash-and-stock transaction approved by the boards of directors of both companies. Wyeth and Pfizer stated that the transaction is subject to a number of closing conditions, including the approval of Wyeth’s stockholders. While our agreements with Wyeth do not include a change of control provision, if the acquisition transaction is completed, our relationship with Wyeth may be affected in ways we do not anticipate, including changes in Wyeth/Pfizer management, strategy or otherwise.

*Our corporate compliance and risk mitigation programs cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and/or that we effectively manage all operational risks.*

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; timing of supply may also be affected by operation of our distribution and logistics centers and providers.*”) 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 or our agents 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. Additionally, while we have implemented numerous risk mitigation measures, we cannot guarantee that we will be able to effectively mitigate all operational risks. If we fail to effectively mitigate all operational risks, our product supply may be materially adversely affected, which could have a material adverse effect on our product sales and results of operations.

*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

---

## [Table of Contents](#)

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.

*Significant changes to U.S. federal, state and foreign tax laws and regulations that apply to our operations and activities could have a material adverse effect on our financial results.*

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on the results of operations. For example, our effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. taxes have been provided because such earnings are intended to be invested indefinitely outside the United States. Substantial reform of U.S. tax law regarding tax on certain foreign profits could result in an increase in our effective tax rate, which could have a material adverse effect on our financial results. (See also “*Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations – Financial Condition, Liquidity and Capital Resources – Cash, cash equivalents and marketable securities*” in Part I herein and Note 5, “*Income taxes*” to the Condensed Consolidated Financial Statements.)

**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

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. 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.

During the three months ended March 31, 2009, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended March 31, 2009 is as follows:

	<b>Total number of shares purchased</b>	<b>Average price paid per share</b>	<b>Total number of shares purchased as part of publicly announced programs</b>	<b>Maximum \$ value that may yet be purchased under the programs <sup>(1)</sup></b>
January 1 - January 31	4,756,300	\$ 54.27	4,756,300	\$ 3,913,206,073
February 1- February 28	18,971,409	56.67	18,970,531	2,838,058,556
March 1 - March 31	13,779,513	48.29	13,748,169	2,174,252,048
	<u>37,507,222</u> <sup>(2)</sup>	53.29	<u>37,475,000</u> <sup>(2)</sup>	

<sup>(1)</sup> In July 2007, the Board of Directors authorized us to repurchase up to an additional \$5.0 billion of our common stock. As of March 31, 2009, \$2.2 billion was available for stock repurchase under our stock repurchase program.

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Amgen Inc.  
(Registrant)

Date: May 11, 2009

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

## AMGEN INC.

## INDEX TO EXHIBITS

<b>Exhibit No.</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	Certificate of Elimination of the Certificate of Designations of the Series A Junior Participating Preferred Stock (As Eliminated December 10, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
3.5	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.)
3.6	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.)
3.7	Second Amendment to Amended and Restated Bylaws of Amgen Inc. (Filed as an exhibit to Form 8-K on December 10, 2008 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	Two Agreements of Resignation, Appointment and Acceptance in the same form as the previously filed Exhibit 4.3 hereto are omitted pursuant to instruction 2 to Item 601 of Regulation S-K. Each of these agreements, which are dated December 15, 2008, replaces the current trustee under the agreements listed as Exhibits 4.8 and 4.16, respectively, with Bank of New York Mellon. Amgen Inc. hereby agrees to furnish copies of these agreements to the Securities and Exchange Commission upon request.
4.5	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.6	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Officer's Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.8	Form of Liquid Yield Option™ Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.10	First Supplemental Indenture, dated March 2, 2005. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.11	Indenture, dated as of August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

## Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
4.12	Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.13	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.14	Officers' Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.15	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.16	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	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.)
4.20	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.)
4.21	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). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.2+	Amgen Inc. Amended and Restated Director Equity Incentive Program (As Amended and Restated December 10, 2007) (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference), forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.) and Forms of Stock Option Grant Agreement and Restricted Stock Unit Agreement for Ex-U.S. Grants (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.).
10.3+	Amgen Inc. Amended and Restated 1999 Equity Incentive Plan (As Amended and Restated of October 1, 2008). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.4+	Amgen Inc. Amended and Restated 1999 Incentive Stock Plan (As Amended and Restated October 1, 2008). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
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. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.6+	Amgen Inc. Amended and Restated Employee Stock Purchase Plan. (Filed as an exhibit to

## [Table of Contents](#)

<b>Exhibit No.</b>	<b>Description</b>
10.7+	Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.8+	First Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan, effective July 12, 2005. (Filed as an exhibit to Form 8-K on July 14, 2005 and incorporated herein by reference.)
10.9+	Second Amendment to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan, effective January 1, 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.)
10.10+	Amgen Supplemental Retirement Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.11+	Amendment and Restatement of the Amgen Change of Control Severance Plan (As Amended December 9, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.12+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.13+	Amgen Inc. Executive Nonqualified Retirement Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.14+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.15+	Amended and Restated Amgen Inc. Performance Award Program (As Amended and Restated effective October 1, 2008.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.16+	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.)
10.17	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.)
10.18	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.)
10.19	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.)
10.20	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.)
10.21	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.)
10.22	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.)
	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

## Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
	quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.23	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.)
10.24	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.)
10.25	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.)
10.26	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.)
10.27	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.)
10.28	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.29	Enbrel <sup>®</sup> Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated as of November 5, 1998 (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Annual Report on Form 10-K for the year ended December 31, 1998 on March 23, 1998 and incorporated herein by reference.)
10.30	Amendment No. 1 to the Enbrel <sup>®</sup> Supply Agreement, dated June 27, 2000, among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, (with certain confidential information deleted therefrom). (Filed as an exhibit to the Immunex Corporation Form 10-Q for the quarter ended June 30, 2000 on August 11, 2000 and incorporated herein by reference.)
10.31	Amendment No. 2 to the Enbrel <sup>®</sup> Supply Agreement, dated June 3, 2002, among Immunex Corporation, Wyeth (formerly known as American Home Products Corporation) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.32	Amendment No. 1 to Amendment No. 2 to the Enbrel <sup>®</sup> 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.)
10.33	Amendment No. 3 to the Enbrel <sup>®</sup> Supply Agreement, dated December 18, 2002, among Immunex Corporation, Wyeth (formerly, “American Home Products Corporation”) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2002 on March 10, 2003 and incorporated herein by reference.)



## Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.34	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.)
10.35	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.)
10.36	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.)
10.37	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). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.38*	Amendment No. 7 to the Enbrel® Supply Agreement, dated February 20, 2009, among Immunex Corporation, Wyeth (formerly, “American Home Products Corporation”) and Boehringer Ingelheim Pharma KG (with certain confidential information deleted therefrom).
10.39	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.)
10.40	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.)
10.41	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as of July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation, (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.42	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.)
10.43	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.)
10.44	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.)
10.45	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.)
10.46	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14,

## [Table of Contents](#)

<b>Exhibit No.</b>	<b>Description</b>
	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.)
10.47	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.)
10.48	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.)
10.49	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.)
10.50	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.)
10.51	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.)
10.52	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
10.53	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.)
10.54	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.)
10.55	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.)
10.56	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.)
10.57	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.)
10.58	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.)
10.59	Underwriting Agreement, dated May 20, 2008, among Amgen Inc. with Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representatives of the underwriters. (Filed as an exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)

## Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.60	Underwriting Agreement, dated January 13, 2009, by and among the Company and Goldman, Sachs & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
10.61	Master Services Agreement, dated October 22, 2008, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.62	Integrated Facilities Management Services Agreement, dated February 4, 2009 between Amgen Inc. and Jones Lang LaSalle Americas, Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.63+	Amgen Inc. 2009 Equity Incentive Plan. (Filed as Appendix A to Amgen Inc.'s Proxy Statement on March 26, 2009 and incorporated herein by reference.)
10.64+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.65+	Form of Stock Option Agreement for the Amgen Inc. 2009 Equity Incentive Plan. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.66+	Amgen Inc. 2009 Performance Award Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.67+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.68+	Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.69+	Form of Grant of Non-Qualified Stock Option Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.70+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 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.)

**AMENDMENT NO. 7  
TO THE  
ENBREL SUPPLY AGREEMENT**

This Amendment No. 7 to the ENBREL Supply Agreement (“Amendment No. 7”) is made this 20th day of February, 2009 (the “Amendment No. 7 Effective Date”) by and among **IMMUNEX CORPORATION**, a corporation of the State of Washington, having its principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320, U.S.A., together with its Affiliates (“Immunex”), **WYETH** (formerly known as American Home Products Corporation), a corporation of the State of Delaware having its corporate headquarters at Five Giralda Farms, Madison, New Jersey 07940, U.S.A. and acting through its Wyeth Pharmaceuticals Division (“Wyeth”), and **BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG**, (formerly doing business as “Boehringer Ingelheim Pharma KG”) a German corporation having a place of business at Birkendorfer Straße 65, 88397 Biberach an der Riss, Federal Republic of Germany (“BIP”), and amends the Enbrel Supply Agreement effective as of November 5, 1998, by and among Immunex, Wyeth, and BIP, and as amended (the “Agreement”).

WHEREAS, Immunex, Wyeth and BIP have entered into the Agreement for BIP’s supply of Enbrel® (etanercept) to Immunex and Wyeth;

WHEREAS, effective June 3, 2002, the Parties amended the Agreement through Amendment No. 2;

WHEREAS, pursuant to Amendment No. 2, the Parties amended and restated Section 5.10(a) of the Agreement to, among other things, allow Immunex and Wyeth to reduce the Maximum Request in the Agreement by no more than [\*]% per Calendar Year by providing at least [\*] months prior written notice to BIP; and

WHEREAS, the Parties desire to further amend Section 5.10(a) of the Agreement to set forth the annual Maximum Request for [\*] and [\*].

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

1. Annual Maximum Request for [\*] and [\*]. Section 5.10(a)(1) of the Agreement shall be amended and restated as follows:

Maximum Request; Annual Minimum.

(a) Maximum Request.

(1) Maximum Request. Subject to Section 5.10(c) below, beginning on [\*] and continuing through [\*], the annual Maximum Request in

Note: Redacted portions have been marked with [\*]. The redacted portions are subject to a request for confidential treatment that has been submitted to the Securities and Exchange Commission.

**Confidential**

the Agreement shall be equal to the Annual Minimum as defined in Section 5.10(b) below. Immunex and Wyeth hereby waive their ability to reduce the Maximum Request below the Annual Minimum under Section 5.1(b) hereof until an effective date of [\*] at the earliest, except to the extent otherwise permitted in Section 5.10(c) below. Subject to Section 5.10(c) below, beginning on [\*] and continuing through the end of the Supply Term (unless otherwise agreed in writing among the Parties), the Maximum Request for Calendar Years [\*] and [\*] shall be as follows:

<b>Year</b>	<b>Annual Maximum Request</b>
[*]	[*]
[*]	[*]

In addition to the Maximum Request, BIP shall be bound to provide the following Bulk Drug Substance Runs in the Original Biberach Facility to Immunex and Wyeth:

- (i) To the extent that BIP acquires any Original Additional Run or Subsequent Additional Run as a result of its Outsourcing Activities, (A) all such Original Additional Runs shall be reserved for Buyer through [\*] and (B) Buyer shall have a ROFR for any Subsequent Additional Run during Calendar Years [\*] and [\*], and such ROFR shall be exercised according to Section 24.1(d)(2) hereof.
- (ii) To the extent that BIP enters into a binding commitment, pursuant to Section 5.10(a)(2) below, to provide a number of Bulk Drug Substance Runs that exceeds the Maximum Request in a Transition Year, such commitment shall be binding on the Parties.
- (iii) BIP shall provide the Baseline Accepted Unused Capacity, as well as any Additional H84 Unused Capacity reserved by Immunex and Wyeth, in accordance with Section 5.10(a)(4) below.

2. Effect of Amendment 7 on Agreement. Except as otherwise set forth in this Amendment No. 7, all other terms and provisions of the Agreement shall remain in full force and effect. In the event of any conflict between the terms and conditions of the Agreement as amended by Amendment Nos. 1 - 6 and the terms and conditions of this Amendment No. 7, the terms and conditions of this Amendment No. 7 shall control.

Note: Redacted portions have been marked with [\*]. The redacted portions are subject to a request for confidential treatment that has been submitted to the Securities and Exchange Commission.

**Confidential**

3. Counterparts. This Amendment No. 7 may be executed in any number of counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute together one and the same instrument.

[continued on next page]

**Boehringer Ingelheim Pharma GmbH & Co. KG**

By: /S/ DR. UWE BUCHELER  
Name: Dr. Uwe Bucheler  
Title: SVP Biopharmaceuticals/Site Management  
Date: March, 26, 2009

**Boehringer Ingelheim Pharma GmbH & Co. KG**

By: /S/ DR. HANS MICHELBERGER  
Name: Dr. Hans Michelberger  
Title: VP Legal  
Date: March 26, 2009

**Immunex Corporation**

By: /S/ MADHU BALACHANDRAN  
Name: Madhu Balachandran  
Title: SVP Manufacturing  
Date: February 23, 2009

**Wyeth, acting through its Wyeth Pharmaceuticals division**

By: /S/ ROBERT A. DOUGAN  
Name: Robert A. Dougan  
Title: Sr. Vice President  
Date: March 19, 2009

**Confidential**

## CERTIFICATIONS

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

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2009

/s/ KEVIN W. SHARER

---

Kevin W. Sharer  
Chairman of the Board,  
Chief Executive Officer and President



## CERTIFICATIONS

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

1. I have reviewed this Quarterly Report on Form 10-Q of Amgen Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - (d) Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2009

/s/ ROBERT A. BRADWAY

---

Robert A. Bradway  
Executive Vice President and  
Chief Financial Officer

**Certification of Chief Executive Officer**

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2009 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 11, 2009

/s/ KEVIN W. SHARER

---

Kevin W. Sharer  
Chairman of the Board, Chief Executive  
Officer and President

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

**Certification of Chief Financial Officer**

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2009 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 11, 2009

/s/ ROBERT A. BRADWAY

---

Robert A. Bradway  
Executive Vice President  
and Chief Financial Officer

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