

AMGEN INC  
Form 10-Q  
May 11, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**Form 10-Q**

(Mark One)

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

**For the quarterly period ended 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)  
**(805) 447-1000**

**91320-1799**  
(Zip Code)

(Registrant's telephone number, including area code)

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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.

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**Table of Contents****PART I - FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****AMGEN INC.****CONDENSED CONSOLIDATED STATEMENTS OF INCOME****(In millions, except per share data)****(Unaudited)**

	<b>Three months ended March 31,</b>		
	<b>2009</b>	<b>2008 Revised</b>	<b>*</b>
<b>Revenues:</b>			
Product sales	\$ 3,238	\$ 3,537	
Other revenues	70	76	
 Total revenues	 3,308	 3,613	
 <b>Operating expenses:</b>			
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	 1,987	 2,198	
 Operating income	 1,321	 1,415	
Interest and other income (expense), net	(89)	(35)	
 Income before income taxes	 1,232	 1,380	
Provision for income taxes	213	280	
 Net income	 \$ 1,019	 \$ 1,100	
 <b>Earnings per share:</b>			
Basic	\$ 0.99	\$ 1.01	
Diluted	\$ 0.98	\$ 1.01	

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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.

**Table of Contents****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
	\$ 37,380	\$ 36,427
<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

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\$	37,380	\$	36,427
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See accompanying notes.

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

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

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008 Revised *</b>
Cash flows from operating activities:		
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	859	1,582
Cash flows from investing activities:		
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	139	697
Cash flows from financing activities:		
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	5	21
Increase in cash and cash equivalents	1,003	2,300
Cash and cash equivalents at beginning of period	1,774	2,024



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Cash and cash equivalents at end of period	\$ 2,777	\$ 4,324
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See accompanying notes.

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

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**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.



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**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*.

**Table of Contents****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):

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

*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*

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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

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**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*.

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

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

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<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
<b>Basic EPS</b>		
	\$ 0.99	\$ 1.01
<b>Diluted EPS</b>		
	\$ 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.



**Table of Contents****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	\$ 1,057	\$ (38)	\$ 1,019
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

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Net income	\$ 1,136	\$ (36)	\$ 1,100
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## Earnings per share:

Basic	\$ 1.04	\$ (0.03)	\$ 1.01
Diluted	\$ 1.04	\$ (0.03)	\$ 1.01

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## AMGEN INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

March 31, 2009

	Excluding the effect of FSP APB 14-1	Effect of FSP APB 14-1	Including the effect of FSP APB 14-1
<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)

December 31, 2008

	As originally reported	Effect of FSP APB 14-1	Revised
<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**

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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

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**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®, 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.

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**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.

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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>
<b>Less current portion</b>	<b>1,000</b>	<b>1,000</b>
<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



**Table of Contents****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

**December 31, 2008**

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

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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

**Table of Contents****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):

	<b>2009</b>		<b>2008</b>	
	<b>Shares</b>	<b>Dollars</b>	<b>Shares</b>	<b>Dollars</b>
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

**Table of Contents****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
	\$ 5	\$ -	\$ 14	\$ 19

**Three months ended March 31, 2008**

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
	\$ 6	\$ 3	\$ 3	\$ 12

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)
	\$ 6	\$ 144	\$ 150

Restructuring reserves as of March 31, 2009

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
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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:**

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

**Fair value measurement using:****December 31,  
2008**

<b>Quoted prices in active markets for identical assets</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant unobservable inputs (Level 3)</b>
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## (Level 1)

<b>Assets:</b>				
Available-for-sale securities	\$ 3,575	\$	5,927	\$ - \$ 9,502
Derivatives	-		415	- 415
Total	\$ 3,575	\$	6,342	\$ - \$ 9,917
<b>Liabilities:</b>				
Derivatives	\$ -	\$	66	\$ - \$ 66
Total	\$ -	\$	66	\$ - \$ 66



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**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.

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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):

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

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):

Derivatives not designated as hedging  instruments under SFAS 133	Location of gain/(loss)  recognized in income	Amount of gain/(loss) recognized in income

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Foreign exchange contracts	Interest and other income (expense), net	\$	14
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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):

	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
<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*

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*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.

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**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

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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.

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**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.





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

#### *Forward looking statements*

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

#### **Overview**

The following 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

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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%.

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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<sup>TM</sup> (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*

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*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,**

	<b>2009</b>	<b>2008</b>	<b>Change</b>
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)%

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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

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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):

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

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:



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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;

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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 Services ( 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

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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

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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):

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

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;

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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

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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<sup>TM</sup> (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;

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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

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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.

**Table of Contents****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):

	March 31,	December 31,
	2009	2008
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):

	March 31,	December 31,
	2009	2008
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):

**Three months ended March 31,****2009****2008**

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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

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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.



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**Item 4. CONTROLS AND PROCEDURES**

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

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**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 ( EMEA ) in European countries and similar regulatory bodies in Canada and Australia. Currently, we are required in the United States and in foreign countries to obtain approval from those countries' regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to 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

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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,

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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

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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 PROCIT® (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.* )

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*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 produc*