AMGEN INC
Form 10-Q
November 06, 2009
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant s telephone number, including area code)

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

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

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

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

As of November 2, 2009, the registrant had 1,012,138,434 shares of common stock, $0.0001 par value, outstanding.

Table of Contents

AMGEN INC.

INDEX

		Page No.
PART I - FINANCIAL INFORMATION		**1**
Item 1.	FINANCIAL STATEMENTS	1
CONDENSED CONSOLIDATED STATEMENTS OF INCOME		1
CONDENSED CONSOLIDATED BALANCE SHEETS		2
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS		3
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS		4
Item 2.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	25
Item 4.	CONTROLS AND PROCEDURES	42
PART II - OTHER INFORMATION		**43**
Item 1.	LEGAL PROCEEDINGS	43
Item 1A.	RISK FACTORS	43
Item 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	65
Item 6.	EXHIBITS	65
SIGNATURES		66
INDEX TO EXHIBITS		67

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)

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Revenues:				
Product sales	$ 3,736	$ 3,784	$ 10,608	$ 11,013
Other revenues	76	91	225	239
Total revenues	3,812	3,875	10,833	11,252
Operating expenses:				
Cost of sales (excludes amortization of certain acquired intangible assets presented below)	545	677	1,553	1,738
Research and development	647	729	1,973	2,232
Selling, general and administrative	932	900	2,640	2,678
Amortization of certain acquired intangible assets	74	74	221	221
Other charges	9	12	63	306
Total operating expenses	2,207	2,392	6,450	7,175
Operating income	1,605	1,483	4,383	4,077
Interest expense, net	139	133	436	419
Interest and other income, net	74	62	182	264
Income before income taxes	1,540	1,412	4,129	3,922
Provision for income taxes	154	291	455	795
Net income	$ 1,386	$ 1,121	$ 3,674	$ 3,127
Earnings per share:				
Basic	$ 1.36	$ 1.06	$ 3.60	$ 2.91
Diluted	$ 1.36	$ 1.05	$ 3.58	$ 2.90

Shares used in calculation of earnings per share:				
Basic	1,016	1,058	1,020	1,075
Diluted	1,022	1,064	1,025	1,079

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

Table of Contents

AMGEN INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In millions, except per share data)

(Unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,577	$ 1,774
Marketable securities	10,436	7,778
Trade receivables, net	2,331	2,073
Inventories	2,155	2,075
Other current assets	1,475	1,521
Total current assets	19,974	15,221
Property, plant and equipment, net	5,743	5,879
Intangible assets, net	2,674	2,988
Goodwill	11,335	11,339
Other assets	1,214	1,000
Total assets	$ 40,940	$ 36,427
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 613	$ 504
Accrued liabilities	3,290	3,382
Current portion of other long-term debt	1,000	1,000
Total current liabilities	4,903	4,886
Convertible notes	4,447	4,257
Other long-term debt	6,089	4,095
Other non-current liabilities	2,643	2,304
Commitments and contingencies		
Stockholders equity:		
Common stock and additional paid-in capital; $0.0001 par value; 2,750 shares authorized; outstanding - 1,016 shares in 2009 and 1,047 shares in 2008	26,853	26,441
Accumulated deficit	(4,042)	(5,673)
Accumulated other comprehensive income	47	117
Total stockholders equity	22,858	20,885
Total liabilities and stockholders equity	$ 40,940	$ 36,427

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

Table of Contents

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

(Unaudited)

	Nine months ended September 30,	
	2009	**2008**
Cash flows from operating activities:		
Net income	$ 3,674	$ 3,127
Depreciation and amortization	792	799
Stock-based compensation expense	209	195
Other items, net	146	69
Changes in operating assets and liabilities, net of acquisitions:		
Trade receivables, net	(258)	16
Inventories	(60)	(22)
Other current assets	(33)	(29)
Accounts payable	43	136
Accrued income taxes	33	88
Other accrued liabilities	(66)	(125)
Deferred revenue	33	337
Net cash provided by operating activities	4,513	4,591
Cash flows from investing activities:		
Purchases of property, plant and equipment	(386)	(494)
Cash paid for acquisitions, net of cash acquired	-	(50)
Purchases of marketable securities	(10,889)	(7,794)
Proceeds from sales of marketable securities	7,026	5,002
Proceeds from maturities of marketable securities	1,340	625
Other	46	93
Net cash used in investing activities	(2,863)	(2,618)
Cash flows from financing activities:		
Repurchases of common stock	(1,997)	(1,568)
Repayment of debt	-	(1,000)
Net proceeds from issuance of debt	1,980	992
Net proceeds from issuance of common stock in connection with the Company s equity award programs	146	114
Other	24	(13)
Net cash provided by (used in) financing activities	153	(1,475)
Increase in cash and cash equivalents	1,803	498
Cash and cash equivalents at beginning of period	1,774	2,024

Cash and cash equivalents at end of period	$ 3,577	$ 2,522

See accompanying notes, including Note 1 for discussion of required retrospective adoption of a new accounting standard effective January 1, 2009, applicable to our convertible debt.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 and nine months ended September 30, 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 result not necessarily indicative of results for the full fiscal year.

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

Financial Accounting Standards Board (FASB) Accounting Standards Codification

During the three months ended September 30, 2009, the FASB Accounting Standards Codification (ASC or Codification) became the authoritative source of accounting principles generally accepted in the United States (GAAP) recognized by the FASB. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, FASB staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards Updates that update the Codification. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

Change in method of accounting for convertible debt instruments

Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for convertible debt that may be partially or wholly settled in cash. 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 9, *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.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with 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.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fair value measurement

We adopted a new accounting standard that defines fair value and establishes a framework for fair value measurements effective January 1, 2008 for financial assets and liabilities and effective January 1, 2009 for non-financial assets and liabilities that are not remeasured on a recurring basis. Under this standard, fair value is generally 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 this accounting standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

During the three months ended June 30, 2009, we adopted a new accounting standard that modifies the guidance used in determining whether the impairment of a debt security is other-than-temporary. Under this accounting standard, the impairment of a debt security is considered other-than-temporary if an entity concludes that it intends to sell the impaired security, that it is more likely than not it will be required to sell the security before the recovery of its cost basis or that it does not otherwise expect to recover the entire cost basis of the security. This accounting standard also amends the presentation requirements of other-than-temporarily impaired debt securities and expands disclosure requirements in the financial statements for investments in both debt and equity securities. The adoption of this accounting standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

During the three months ended June 30, 2009, we adopted two new accounting standards that require disclosures at each interim balance sheet date of the fair value of financial instruments and valuation techniques used to determine fair value. Previously, these disclosures were only required annually. One of these accounting standards also provides additional guidance in estimating fair value when the market volume and level of activity for an asset or liability have significantly decreased and identifying circumstances that indicate a transaction may not be orderly. The adoption of these two accounting standards did not have a material impact on our condensed consolidated results of operations, financial position or cash flows.

See Note 11, *Fair value measurement*.

Derivative instruments

Effective January 1, 2009, we adopted a new accounting standard that requires disclosures about our derivative instruments and hedging activities. This standard 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 standard also requires disclosure of how derivatives and related hedged items affect our financial statements. The adoption of this standard did not have a material impact on our condensed consolidated results of operations, financial position or cash flows. See Note 12, *Derivative instruments*.

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.

Property, plant and equipment, net

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation of $4.5 billion and $4.1 billion as of September 30, 2009 and December 31, 2008, respectively.

Goodwill

Goodwill principally relates to our 2002 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 sale of the Company s products, primarily in Europe, are excluded from revenues.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Research and development costs

Research and development (R&D) costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems 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 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.

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 certain 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.

Subsequent events

During the three months ended June 30, 2009, we adopted a new accounting standard that establishes general standards for the accounting and disclosing of events that occur after the balance sheet date that are not addressed elsewhere in the Codification. This standard requires entities to disclose the date through which subsequent events have been evaluated and whether that date is the date the financial statements were issued. We have evaluated subsequent events through the date of issuance of our financial statements in this Form 10-Q.

Recent accounting pronouncements

In June 2009, the FASB issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise s involvement in the variable interest entity. This standard is effective for us for interim and annual reporting periods beginning on or after January 1, 2010. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In August 2009, the FASB issued a new accounting standard which clarifies guidance for determining the fair value of a liability when a quoted price in an active market for an identical liability is not available. This standard provides for the use of one or more valuation techniques including use of quoted prices of identical or similar liabilities when traded as assets, quoted prices of similar liabilities and other techniques consistent with the fair value measurement framework, such as the amount an entity would pay to transfer the identical liability or would receive to enter into the identical liability. This standard is effective for us for interim and

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

annual periods beginning on or after October 1, 2009. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us for annual periods beginning on or after January 1, 2011. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

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 a new accounting standard which changed the method of accounting for certain types of convertible debt and, as required by this standard, we retrospectively applied this change in accounting to all prior periods for which we had applicable outstanding convertible debt.

The following tables illustrate the impact of adopting this accounting standard on the Condensed Consolidated Statements of Income (in millions, except per share information):

	Three months ended September 30, 2009		
	Excluding the effect of the accounting standard	Effect of the accounting standard	Including the effect of the accounting standard
Operating income	$ 1,605	$ -	$ 1,605
Interest expense, net	76	63	139
Interest and other income, net	74	-	74
Income before income taxes	1,603	(63)	1,540
Provision for income taxes	178	(24)	154
Net income	$ 1,425	$ (39)	$ 1,386
Earnings per share:			
Basic	$ 1.40	$ (0.04)	$ 1.36
Diluted	$ 1.39	$ (0.03)	$ 1.36

	Three months ended September 30, 2008		
	As originally reported	Effect of the accounting standard	Revised
Operating income	$ 1,483	$ -	$ 1,483
Interest expense, net	74	59	133

Interest and other income, net	62	-	62
Income before income taxes	1,471	(59)	1,412
Provision for income taxes	313	(22)	291
Net income	$ 1,158	$ (37)	$ 1,121
Earnings per share:			
Basic	$ 1.09	$ (0.03)	$ 1.06
Diluted	$ 1.09	$ (0.04)	$ 1.05

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Nine months ended September 30, 2009		
	Excluding the effect of the accounting standard	Effect of the accounting standard	Including the effect of the accounting standard
Operating income	$ 4,383	$ -	$ 4,383
Interest expense, net	250	186	436
Interest and other income, net	182	-	182
Income before income taxes	4,315	(186)	4,129
Provision for income taxes	525	(70)	455
Net income	$ 3,790	$ (116)	$ 3,674
Earnings per share:			
Basic	$ 3.72	$ (0.12)	$ 3.60
Diluted	$ 3.70	$ (0.12)	$ 3.58

	Nine months ended September 30, 2008		
	As originally reported	Effect of the accounting standard	Revised
Operating income	$ 4,077	$ -	$ 4,077
Interest expense, net	245	174	419
Interest and other income, net	264	-	264
Income before income taxes	4,096	(174)	3,922
Provision for income taxes	861	(66)	795
Net income	$ 3,235	$ (108)	$ 3,127
Earnings per share:			
Basic	$ 3.01	$ (0.10)	$ 2.91
Diluted	$ 3.00	$ (0.10)	$ 2.90

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following tables illustrate the impact of adopting this accounting standard on the Condensed Consolidated Balance Sheets (in millions):

	September 30, 2009		
	Excluding the effect of the accounting standard	Effect of the accounting standard	Including the effect of the accounting standard
Non-current assets:			
Other assets	$ 1,227	$ (13)	$ 1,214
Non-current liabilities:			
Convertible notes	5,082	(635)	4,447
Other non-current liabilities	2,404	239	2,643
Stockholders equity:			
Common stock and additional paid-in capital	25,939	914	26,853
Accumulated deficit	(3,511)	(531)	(4,042)

	December 31, 2008		
	As originally reported	Effect of the accounting standard	Revised
Non-current assets:			
Other assets	$ 1,016	$ (16)	$ 1,000
Non-current liabilities:			
Convertible notes	5,081	(824)	4,257
Other non-current liabilities	1,995	309	2,304
Stockholders equity:			
Common stock and additional paid-in capital	25,527	914	26,441
Accumulated deficit	(5,258)	(415)	(5,673)

The effect of this accounting standard on Other non-current liabilities in the Condensed Consolidated Balance Sheets reflects the impact of deferred taxes. In addition, the effect of this accounting standard on Common stock and additional paid-in capital in the Condensed Consolidated Balance Sheets 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 this accounting standard. 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. Income taxes

The effective tax rates for the three and nine months ended September 30, 2009 and September 30, 2008 are different from the federal statutory tax rate 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. In addition, the effective tax rates for the three and nine months ended September 30, 2009 were further reduced by favorable resolution of certain matters with tax authorities for prior periods.

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.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2009, we have settled the examinations of our U.S. income tax returns with the Internal Revenue Service for certain matters for the years ended December 31, 2005 and 2006 and have remeasured our unrecognized tax benefits (UTBs) accordingly. As of September 30, 2009, we have also settled the examinations of our California state income tax returns for certain matters for the years ended December 31, 2004 and 2005 and have remeasured our UTBs accordingly.

During the three and nine months ended September 30, 2009, the gross amount of our UTBs increased approximately $80 million and $225 million, respectively, as a result of tax positions taken during the current year. During the three and nine months ended September 30, 2009, the gross amount of our UTBs increased approximately $37 million as a result of tax positions taken during prior periods. During the three and nine months ended September 30, 2009, the gross amount of our UTBs decreased approximately $140 million and $310 million, respectively, primarily as a result of resolving certain tax matters related to prior periods. The majority of our UTBs as of September 30, 2009, if recognized, would affect our effective tax rate.

4. 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.

Upon conversion of our 2011 Convertible Notes, 2013 Convertible Notes and 2032 Modified Convertible Notes, the principal amount or accreted value would be settled in cash and the excess of conversion value over the principal amount or accreted value may be settled in cash and/or shares of common stock. 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 and nine months ended September 30, 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 9, *Financing arrangements*.

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

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Income (Numerator):				
Net income for basic and diluted EPS	$ 1,386	$ 1,121	$ 3,674	$ 3,127
Shares (Denominator):				
Weighted-average shares for basic EPS	1,016	1,058	1,020	1,075
Effect of dilutive securities	6	6	5	4
Weighted-average shares for diluted EPS	1,022	1,064	1,025	1,079
Basic EPS	$ 1.36	$ 1.06	$ 3.60	$ 2.91
Diluted EPS	$ 1.36	$ 1.05	$ 3.58	$ 2.90

For the three and nine months ended September 30, 2009, there were employee stock options, calculated on a weighted average basis, to purchase 31 million and 43 million shares, respectively, with exercise prices greater than the average market prices of our common stock for these periods that are not included in the computation of diluted EPS as their impact would have been anti-dilutive. For the three and nine months ended September 30, 2008, there were employee stock options, calculated on a weighted average basis, to purchase 35 million and 47 million shares, respectively, with exercise prices greater than the average market prices of our 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 in any of the periods presented above as their impact on diluted EPS would have been anti-dilutive. Shares which may be

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

issued under our 2007 and 2009 performance award programs were also excluded for the applicable periods because conditions under the programs were not met.

5. Related party transactions

We own a 50% interest in KA, a corporation formed in 1984 with Kirin Holdings Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA s profits or losses in Selling, general and administrative in the Condensed Consolidated Statements of Income. During the three and nine months ended September 30, 2009, our share of KA s profits was $13 million and $49 million, respectively. During the three and nine months ended September 30, 2008, our share of KA s profits was $22 million and $53 million, respectively. As of September 30, 2009 and December 31, 2008, the carrying value of our equity method investment in KA, net of dividends received, was $405 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 and nine months ended September 30, 2009, KA earned royalties from us of $85 million and $237 million, respectively. During the three and nine months ended September 30, 2008, KA earned royalties from us of $85 million and $243 million, respectively. These amounts are included in Cost of sales (excludes amortization of certain acquired intangible assets) in the Condensed Consolidated Statements of Income. As of September 30, 2009, KA owed us $4 million, which was included in Other current assets in the Condensed Consolidated Balance Sheet. At December 31, 2008, we owed KA $82 million, which was included in Accrued liabilities in the Condensed Consolidated Balance Sheet.

KA s expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and nine months ended September 30, 2009, we earned revenues from KA of $27 million and $81 million, respectively, for certain R&D activities performed on KA s behalf. During the three and nine months ended September 30, 2008, we earned revenues from KA of $41 million and $100 million, respectively, for certain R&D activities performed on KA s behalf. These amounts are included in Other revenues in the Condensed Consolidated Statements of Income.

6. 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. As of September 30, 2009, we have substantially completed all of the actions and incurred all related costs included in our restructuring plan and subsequently identified initiatives.

Through September 30, 2009, we have incurred $952 million of costs related to the above-noted actions. The charges included $214 million of separation costs, $476 million of asset impairments, $148 million of accelerated depreciation and $114 million of other net charges, which primarily include $165 million of loss accruals for leases, $10 million loss on the disposal of certain less significant marketed products, $35 million for implementation costs associated with certain cost saving initiatives and $19 million of other charges, offset by $115 million of cost recoveries from Pfizer Inc. (Pfizer) (formerly Wyeth).

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following tables summarize the charges (credits) related to the above-noted actions by type of activity (in millions):

	Separation costs	Asset impairments	Other	Total
Three months ended September 30, 2009				
R&D	$ -	$ 3	$ -	$ 3
SG&A	-	-	6	6
Other charges	(3)	-	4	1
	$ (3)	$ 3	$ 10	$ 10
Three months ended September 30, 2008				
Other charges	$ -	$ 1	$ 7	$ 8
Interest and other income, net	-	-	9	9
	$ -	$ 1	$ 16	$ 17
Nine months ended September 30, 2009				
Cost of sales (excludes amortization of certain acquired intangible assets)	$ -	$ 1	$ -	$ 1
R&D	(3)	8	1	6
SG&A	(2)	-	25	23
Other charges	31	-	4	35
	$ 26	$ 9	$ 30	$ 65
Nine months ended September 30, 2008				
Cost of sales (excludes amortization of certain acquired intangible assets)	$ -	$ 1	$ -	$ 1
R&D	3	-	-	3
SG&A	-	-	(1)	(1)
Other charges	4	15	20	39
Interest and other income, net	-	-	9	9
	$ 7	$ 16	$ 28	$ 51

The following table summarizes the charges and spending relating to the above actions (in millions):

	Separation costs	Other	Total
Restructuring reserves as of January 1, 2009	$ 4	$ 162	$ 166
Expense	26	30	56
Payments	(24)	(54)	(78)

Restructuring reserves as of September 30, 2009	$ 6	$ 138	$ 144

7. Available-for-sale securities

We consider our investment portfolio and marketable equity investments available-for-sale and, accordingly, these investments are recorded at fair value with unrealized gains and losses generally recorded in other comprehensive income. For the three months ended September 30, 2009 and 2008, realized gains related to these investments were $22 million and $18 million, respectively, and realized losses related to these investments were $8 million and $26 million, respectively. For the nine months ended September 30, 2009 and 2008, realized gains related to these investments were $90 million and $94 million, respectively, and realized losses related to these investments were $63 million and $62 million, respectively. The cost of securities sold is based on the specific identification method.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair values of available-for-sale investments by type of security, contractual maturity and classification in the Condensed Consolidated Balance Sheets are as follows (in millions):

September 30, 2009	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Type of security:				
U.S. Treasury securities	$ 1,590	$ 16	$ (1)	$ 1,605
Obligations of U.S. government agencies and FDIC guaranteed bank debt	4,303	85	(1)	4,387
Corporate debt securities	3,976	96	(3)	4,069
Mortgage and asset backed securities	311	5	-	316
Other short-term interest bearing securities	3,530	-	-	3,530
Total debt securities	13,710	202	(5)	13,907
Equity securities	71	10	-	81
	$ 13,781	$ 212	$ (5)	$ 13,988

December 31, 2008	Amortized cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
Type of security:				
U.S. Treasury securities	$ 1,896	$ 58	$ (2)	$ 1,952
Obligations of U.S. government agencies and FDIC guaranteed bank debt	3,396	100	(3)	3,493
Corporate debt securities	1,432	10	(72)	1,370
Mortgage and asset backed securities	508	2	(6)	504
Other short-term interest bearing securities	2,126	-	-	2,126
Total debt securities	9,358	170	(83)	9,445
Equity securities	65	-	(8)	57
	$ 9,423	$ 170	$ (91)	$ 9,502

Contractual maturity	September 30, 2009	December 31, 2008
Maturing in one year or less	$ 4,140	$ 3,179
Maturing after one year through three years	5,895	3,724
Maturing after three years through five years	3,454	2,199
Maturing after five years	418	343
Total debt securities	13,907	9,445

Equity securities	81	57
	$ 13,988	$ 9,502

Classification in the Condensed Consolidated Balance Sheets	September 30, 2009	December 31, 2008
Cash and cash equivalents	$ 3,577	$ 1,774
Marketable securities	10,436	7,778
Other assets noncurrent	81	30
	14,094	9,582
Less cash	(106)	(80)
	$ 13,988	$ 9,502

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The primary objectives for our investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Our investment policy limits investments to certain types of debt and money market instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

We review periodically our available-for-sale securities for other-than-temporary declines in fair value below their cost basis and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. As of September 30, 2009 and December 31, 2008, the Company believes that the cost basis for our available-for-sale securities were recoverable in all material respects.

8. Inventories

Inventories consisted of the following (in millions):

	September 30, 2009	December 31, 2008
Raw materials	$ 109	$ 112
Work in process	1,565	1,519
Finished goods	481	444
	$ 2,155	$ 2,075

9. Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements (dollar amounts in millions):

	September 30, 2009	December 31, 2008
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,307	$ 2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,058	1,970
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.00% notes due 2009 (2009 Notes)	1,000	1,000
4.85% notes due 2014 (2014 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)	499	498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)	82	81
Other	100	100
Total borrowings	11,536	9,352
Less current portion	1,000	1,000

Total non-current debt	$ 10,536	$ 8,352

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 the 2039 Notes pay interest at fixed annual rates of 5.70% and 6.40%, respectively. The 2019 Notes and the 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 lives of the notes.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Convertible notes

Effective January 1, 2009, we adopted a new accounting standard that changed the method of accounting for certain types of convertible debt 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 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 this new accounting standard 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 both the three and nine months ended September 30, 2009 and 2008, interest expense for the 2011 Convertible Notes was approximately $1 million and $2 million, respectively, based on the contractual coupon rates. For both the three and nine months ended September 30, 2009 and 2008, interest expense for the 2013 Convertible Notes was approximately $2 million and $7 million, respectively, based on the contractual coupon rates.

For the three and nine months ended September 30, 2009, amortization of the discount for the 2011 Convertible Notes was approximately $34 million and $101 million, respectively. For the three and nine months ended September 30, 2008, amortization of the discount for the 2011 Convertible Notes was approximately $33 million and $96 million, respectively. For the three and nine months ended September 30, 2009, amortization of the discount for the 2013 Convertible Notes was approximately $30 million and $88 million, respectively. For the three and nine months ended September 30, 2008, amortization of the discount for the 2013 Convertible Notes was approximately $28 million and $82 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 shares of our common stock and cash, at our option, to the extent the conversion value exceeds the principal amount of the note. As of September 30, 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 of our 2011 Convertible Notes and our 2013 Convertible Notes are as follows (in millions):

	Liability component			Equity component
	Principal balance	Unamortized discount	Net carrying amount	Net carrying amount
Balance as of September 30, 2009				
2011 Convertible Notes	$ 2,500	$ 193	$ 2,307	$ 643
2013 Convertible Notes	$ 2,500	$ 442	$ 2,058	$ 829

Balance as of 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 payable on the 2032 Modified Convertible Notes. These notes were issued at a discount from their principal amount (prior to the adoption of the new accounting standard). The

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

reduced carrying value resulting from issuing these notes at a discount is being accreted back to the principal amount based on a contractual interest rate of 1.125% over the life of the notes. In March 2007, substantially all of the holders of the 2032 Modified Convertible Notes exercised their option to put these convertible notes to us. The additional discount on the 2032 Modified Convertible Notes recognized pursuant to the retrospective application of the new accounting standard (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 contractual rate for the 2032 Modified Convertible Notes that remain outstanding. Such amounts were not material for the three and nine months ended September 30, 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 our 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 $87.76, as of September 30, 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 our common stock, if any, to the extent the conversion value exceeds the amount paid in cash. As of September 30, 2009, these notes were not convertible and the accreted value exceeded the amount that would have been received upon conversion. As of September 30, 2009 and December 31, 2008, the equity component of the 2032 Modified Convertible Notes was approximately $29 million.

Other facilities

As of September 30, 2009, we have a $2.3 billion syndicated, unsecured, revolving credit facility which matures in November 2012 and is available for general corporate purposes or as a liquidity backstop to our commercial paper program. In late 2008, a participating financial institution in the credit facility, which had provided $178 million of such commitment declared bankruptcy. Subsequently, this financial institution, which is a subsidiary of Lehman Brothers Holdings, Inc. (Lehman), was removed from the credit facility and the aggregate commitment was reduced to its current level of $2.3 billion.

10. Stockholders equity

Stock repurchase programs

A summary of activity under our stock repurchase programs is as follows (in millions):

	2009		2008	
	Shares	Dollars	Shares	Dollars
First quarter	37.5	$ 1,997	-	$ -
Second quarter	-	-	32.7	1,549 (1)
Third quarter	-	-	-	19 (1)
Total	37.5	$ 1,997	32.7	$ 1,568

(1) The total cost of shares repurchased during the three months ended June 30, 2008 excludes approximately $19 million paid in July 2008 in connection with the final settlement of an accelerated share repurchase program entered into in May 2008.

As of September 30, 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.

16

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Fair value measurement

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

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

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

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

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

U.S. Treasury securities, money market funds (included within Other short-term interest bearing securities) and equity securities are valued using quoted market prices with no valuation adjustment. Accordingly, these securities are categorized in Level 1. Obligations of U.S. government agencies and FDIC guaranteed bank debt, corporate debt securities, mortgage and asset backed securities and other short-term interest bearing securities are valued using quoted market prices of recent transactions or are benchmarked to transactions of very similar securities. Accordingly, these securities are categorized in Level 2.

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

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following fair value hierarchy tables present information about each major category of the Company s financial assets and liabilities measured at fair value on a recurring basis (in millions):

	Fair value measurement at September 30, 2009 using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury securities	$ 1,605	$ -	$ -	$ 1,605
Obligations of U.S. government agencies and FDIC guaranteed bank debt	-	4,387	-	4,387
Corporate debt securities	-	4,069	-	4,069
Mortgage and asset backed securities	-	316	-	316
Other short-term interest bearing securities	3,425	105	-	3,530
Equity securities	81	-	-	81
	5,111	8,877	-	13,988
Derivatives	-	158	-	158
Total	$ 5,111	$ 9,035	$ -	$ 14,146
Liabilities:				
Derivatives	$ -	$ 181	$ -	$ 181
Total	$ -	$ 181	$ -	$ 181

	Fair value measurement at December 31, 2008 using:			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities	$ 3,575	$ 5,927	$ -	$ 9,502
Derivatives	-	415	-	415

Total	$ 3,575	$ 6,342	$ -	$ 9,917
Liabilities:				
Derivatives	$ -	$ 66	$ -	$ 66
Total	$ -	$ 66	$ -	$ 66

There were no material remeasurements to fair value during the nine months ended September 30, 2009 and 2008 of assets and liabilities that are not measured at fair value on a recurring basis.

Summary of the fair value of other financial instruments

Short-term assets and liabilities

The fair values of cash equivalents, accounts receivable and accounts payable approximate their carrying values due to the short-term nature of these financial instruments.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Notes payable

The following tables present the carrying value and fair value of our convertible notes, modified convertible notes and other long-term notes. The fair values of the convertible notes and modified convertible notes were estimated using discounted cash flow models based upon significant observable inputs (Level 2). The fair values of our other long-term notes were estimated using quoted prices, which were corroborated by market prices in active markets (Level 2) (in millions):

	September 30, 2009	
	Carrying value	Fair value
2011 Convertible Notes	$ 2,307	$ 2,454
2013 Convertible Notes	2,058	2,359
2017 Notes	1,099	1,173
2009 Notes	1,000	1,004
2014 Notes	1,000	1,067
2019 Notes	998	1,099
2039 Notes	995	1,155
2037 Notes	899	1,017
2018 Notes	499	574
2038 Notes	499	606
2032 Modified Convertible Notes	82	80
Other	100	119
Total	$ 11,536	$ 12,707

	December 31, 2008	
	Carrying value	Fair value
2011 Convertible Notes	$ 2,206	$ 2,300
2013 Convertible Notes	1,970	2,080
2017 Notes	1,099	1,140
2009 Notes	1,000	1,017
2014 Notes	1,000	994
2037 Notes	899	948
2018 Notes	499	536
2038 Notes	498	567
2032 Modified Convertible Notes	81	58
Other	100	111
Total	$ 9,352	$ 9,751

12. Derivative instruments

The Company is exposed to certain risks related to its business operations. The primary risks that we manage 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 any leveraged derivatives.

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Condensed Consolidated Balance Sheets (see Note 11, *Fair value measurement*). The accounting for changes in the fair value of a derivative instrument depends on whether it has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we 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 are adjusted to fair value through current earnings.

We are exposed to possible changes in values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with our international product sales denominated in Euros. Increases or

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

decreases in the cash flows associated with our international product sales due to movements in foreign currency exchange rates are partially offset by the 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 September 30, 2009, we had outstanding foreign currency forward and option contracts, primarily Euro-based, with notional amounts of $2.7 billion and $428 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 of our 2019 Notes and 2039 Notes in January 2009, we entered into forward interest rate contracts related to a portion of these borrowings.

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.

The following table reflects the effective portion of the gain/(loss) recognized in Other Comprehensive Income (OCI) for our cash flow hedge contracts (in millions):

Derivatives in cash flow hedging relationships	Three months ended September 30, 2009	Nine months ended September 30, 2009
Interest rate contracts	$ -	$ (11)
Foreign exchange contracts	(162)	(239)
Total	$ (162)	$ (250)

The following table reflects the location in the Condensed Consolidated Statements of Income and the effective portion of the gain/(loss) reclassified from Accumulated OCI into income for our cash flow hedge contracts (in millions):

Derivatives in cash flow hedging relationships	Statement of Income location	Three months ended September 30, 2009	Nine months ended September 30, 2009
Interest rate contracts	Interest expense, net	$ -	$ -
Foreign exchange contracts	Product sales	(9)	20
Total		$ (9)	$ 20

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, net and Interest expense, net in the Condensed Consolidated Statements of Income for both the three and nine months ended September 30, 2009. As of September 30, 2009, the amounts expected to be reclassified from Accumulated OCI into income over the next 12 months are approximately $72 million of losses 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 September 30, 2009, we had interest rate swap agreements with an aggregate notional amount of $2.5 billion on our notes due in 2009, 2014 and 2018. 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 and nine months ended September 30, 2009, we included the loss on the hedged debt of $22 million and gain on the hedged debt of $81 million, respectively, in the same line item, Interest expense, net in the Condensed Consolidated Statements of Income, as the offsetting gain of $22 million and loss of $81 million, respectively, on the related interest rate swap agreements.

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. These exposures are hedged on a month-to-month basis. As of September 30, 2009, the total notional amount of these foreign currency forward contracts was $466 million.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table reflects the location in the Condensed Consolidated Statements of Income and amount of gain/(loss) recognized in income of the derivative instruments not designated as hedging instruments (in millions):

Derivatives not designated as hedging instruments	Statement of Income location	Three months ended September 30, 2009	Nine months ended September 30, 2009
Foreign exchange contracts	Interest and other income, net	$ (34)	$ (30)

The following table reflects the fair values of both derivatives designated as hedging instruments and not designated as hedging instruments included in the Condensed Consolidated Balance Sheet as of September 30, 2009 (in millions):

	Derivative assets		Derivative liabilities	
	Balance Sheet location	Fair value	Balance Sheet location	Fair value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets/Other non-current assets	$ 125	Accrued liabilities/Other non-current liabilities	$ -
Foreign exchange contracts	Other current assets/Other non-current assets	33	Accrued liabilities/Other non-current liabilities	181
Total derivatives designated as hedging instruments		158		181
Derivatives not designated as hedging instruments:				
Foreign exchange contracts	Other current assets	-	Accrued liabilities	-
Total derivatives not designated as hedging instruments		-		-
Total derivatives		$ 158		$ 181

Our foreign exchange contracts that were in a liability position as of September 30, 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.

13. Commitments and 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. 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, Note 11, *Contingencies* to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and Note 13, *Commitments and Contingencies* to our

Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 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

Final approval hearing of the Track Two settlement before the U.S. District Court for the District of Massachusetts (the Massachusetts District Court) was scheduled for October 21, 2009. However, plaintiffs filed for an extension of the final approval

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

hearing due to continued deficiencies in executing notices and the Massachusetts District Court rescheduled the hearing for February 2, 2010.

Roche Matters

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

On September 15, 2009, the Court of Appeals for the Federal Circuit (the Federal Circuit Court) affirmed the Massachusetts District Court s October 2, 2008 judgment that the Roche Defendants peg-EPO product, Mircera®, infringes four Amgen patents, specifically U.S. Patent No. 5,547,933 (the 933 Patent), U.S. Patent No. 5,955,422 (the 422 Patent), U.S. Patent No. 5,618,698 (the 698 Patent) and U.S. Pat No. 5,441,868 (the 868 Patent). Regarding the fifth patent-in-suit, U.S. Patent No. 5,756,349 (the 349 Patent), the Federal Circuit Court reversed the holding of non-infringement by the District Court and remanded that issue for a new trial which would allow Amgen to prove that the Roche Defendants peg-EPO product infringes that patent as well. The Federal Circuit Court also affirmed the validity of Amgen s patents except for a single issue of obviousness-type double patenting which only impacts Amgen s later expiring patents (933, 422 and 349 Patents). The Federal Circuit Court remanded this validity issue to the Massachusetts District Court for further analysis. The Federal Circuit Court left undisturbed the permanent injunction that prohibits the Roche Defendants from selling its peg-EPO product, Mircera® in the United States until expiry of the infringed patents.

On October 26, 2009, Amgen and the Roche Defendants each filed Combined Petitions For Rehearing And Rehearing En Banc with the Federal Circuit Court. Amgen requested that the Federal Circuit Court rehear its September 15th determination and affirm the District Court s judgment that Amgen is entitled to the statutory safe harbor protection against validity challenges to the 933, 422 and 349 Patents on the issue of obviousness-type double patenting. The Roche Defendants requested that the Federal Circuit Court rehear its September 15th determination that the 868 Patent and the 698 Patent were not invalid for obviousness-type double patenting in view of Amgen s now expired U.S. Patent 4,703,008 and its determination that the 933 Patent and the 422 Patent were infringed by the Roche Defendants peg-EPO product while still being valid in view of the prior art. The parties have both been invited to file responsive briefs by no later than November 10, 2009.

U.S. International Trade Commission (ITC)

On August 31, 2009, Amgen filed a motion for summary determination of violation with a request for entry of a limited exclusion order. On September 1, 2009, the Roche respondents notified the ITC that it was not opposing Amgen s motion for summary determination and request for remedy. Also on September 1, 2009, the Roche defendants withdrew their pending motions for a stay and to terminate the investigation. The Office of Unfair Import Investigations filed its response on September 17, 2009, supporting Amgen s motion for summary determination but deferring comment on remedy until a remedy phase of the investigation. No decision has been issued on Amgen s motion.

Human Genome Sciences (HGS) Litigations

On October 14, 2009, the Federal Circuit Court entered an order on HGS motion to dismiss HGS appeal from the U.S. District Court for the District of Delaware (the Delaware District Court). HGS had filed the action in Delaware District Court under 35 U.S.C. § 146 after it received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,240.

On October 21, 2009, the Delaware District Court entered an order on a stipulated motion dismissing with prejudice HGS action under 35 U.S.C. § 146 which had been filed by HGS after it had received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,380.

On October 21, 2009, the Delaware District Court entered an order on a stipulated motion dismissing with prejudice HGS action under 35 U.S.C. § 146 which had been filed by HGS after it had received an unfavorable final judgment from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 105,381.

Sensipar® Abbreviated New Drug Application (ANDA) Litigation

On May 21, 2009, Teva Pharmaceuticals USA, Inc. (Teva USA), Teva Pharmaceutical Industries Ltd. (Teva Ltd. , and together with Teva USA, Teva) and Barr Pharmaceuticals Inc. (Barr) filed a First Amended Answer, Defenses and Counterclaims with the Delaware District Court. On June 15, 2009, Amgen filed answers to Teva s and Barr s First Amended Counterclaim. On July 27, 2009,

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Teva and Barr filed a motion for an order that the parties proceed on representative claims. Amgen filed its answering brief in opposition to this motion on August 13, 2009 and Defendants filed their reply brief on August 26, 2009. The Delaware District Court set a status conference for September 23, 2009 and on September 24, 2009 and the Delaware District Court issued an order that the parties proceed on representative claims to be selected by Amgen on or before October 23, 2009.

Teva U.S. Patent No. 7,449,603 (603) Litigation

On August 10, 2009, Amgen filed an answer and counterclaims to Teva Ltd. s amended complaint with the U.S. District Court for the Eastern District of Pennsylvania. On August 24, 2009, Teva Ltd. filed an answer to Amgen s Counterclaims.

Federal Securities Litigation In re Amgen Inc. Securities Litigation

A class certification hearing before the U.S. District Court for the Central District of California (the California Central District Court), was held on July 17, 2009 and on August 12, 2009, the California Central District Court granted Plaintiffs motion for class certification. Amgen filed a petition for permission to appeal with the U.S. Court of Appeals for the 9th Circuit (the 9 Circuit) under Rule 23(f) on August 28, 2009. Defendants filed their opposition on September 25, 2009, Amgen filed its reply brief on September 30, 2009 and there is no time frame in which the 9th Circuit must respond. In the meantime, the parties are scheduled to appear before the California Central District Court for a joint status conference on November 16, 2009.

State Derivative Litigation

Birch v. Sharer, et al.

Oral argument on Amgen and the individual defendants motions to dismiss were heard on September 4, 2009 before the Los Angeles County Superior Court and the court granted the motions to dismiss but allowed the plaintiff an opportunity to amend her complaint by October 21, 2009. Plaintiff filed a request for dismissal without prejudice with the court on October 23, 2009. On October 29, 2009, Amgen received from plaintiff Birch a stockholder demand on the Board of Directors to take action to remedy breaches of fiduciary duties by the directors and certain executive officers of the Company. The stockholder alleges that the directors and certain executive officers violated their core fiduciary principles, causing Amgen to suffer damages. The stockholder demands that the Board of Directors take action against each of the officers and directors to recover damages and to correct deficiencies in the Company s internal controls that allowed the misconduct to occur.

ERISA Litigation

Harris v. Amgen Inc., et al. & Ramos v. Amgen Inc., et al.

On October 13, 2009, the California Central District Court granted plaintiffs Steve Harris and Dennis Ramos motion to be appointed interim co-lead counsel. Plaintiffs have until November 12, 2009 to file a consolidated and amended complaint and defendants have until December 14, 2009 to file their responsive pleading.

Qui Tam Actions

On September 1, 2009, the U.S. government filed a notice of non-intervention and 14 states and the District of Columbia filed notices of intervention. The Massachusetts District Court gave the states and the private relator 60 days from September 1 to file an amended complaint. Amgen filed a motion to unseal the record with regard to the Massachusetts Qui Tam Action on October 23, 2009. On October 30, 2009, 14 states and the District of Columbia filed an amended complaint in the Massachusetts District Court entitled *The United States of America, States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New Mexico, New York, Tennessee and Texas and the Commonwealths of Massachusetts and Virginia and the District of Columbia, ex rel Kassie Westmoreland v. Amgen Inc., Integrated Nephrology Network, AmerisourceBergen Specialty Group, ASD Healthcare and AmerisourceBergen Corporation.* The relator, Kassie Westmoreland, also filed a second amended complaint with the Massachusetts District Court on the same day. The complaints

allege violations of the federal Anti-Kickback Statute and violations of state false claims act statutes with regard to Amgen s marketing of overfill in vials of Aranesp® and with regard to Amgen s relationship with the Integrated Nephrology Network, a group purchasing organization. The relator s seconded amended complaint also alleges that Amgen retaliated against and wrongfully terminated Westmoreland.

Table of Contents

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Warren General Hospital v. Amgen

On September 25, 2009, Warren General Hospital of Warren, Pennsylvania (on its behalf and all others similarly situated) filed a class action in the U.S. District Court for the District of New Jersey against Amgen alleging Federal antitrust violations under Section 1 of the Sherman Act and Section 3 of the Clayton Act based on Amgen s contracting practices. The complaint seeks damages including treble damages, attorneys fees and costs. Amgen has until December 11, 2009 to respond to the allegations.

Kennedy Institute v. Amgen Inc. and Wyeth

On October 27, 2009, The Mathilda and Terence Kennedy Institute of Rheumatology Trust filed suit in the Delaware District Court alleging that Amgen and Wyeth have infringed U.S. Patent Number 6,270,766 by the distribution and sale of ENBREL for the treatment of arthritis by co-administration with methotrexate. The Complaint has not yet been served.

Other

On August 19, 2009, Amgen was served with a third supplemental subpoena from the U.S. Attorney s Office for the Western District of Washington related to the 219 clinical trial. Amgen intends to cooperate fully with the government s requests.

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.

14. Other charges

In the three and nine months ended September 30, 2009, we recorded loss accruals for settlements of certain commercial legal proceedings aggregating $8 million and $28 million, respectively. In the three and nine months ended September 30, 2008, we recorded loss accruals for settlements of certain commercial legal proceedings aggregating $4 million and $267 million, respectively, principally related to the settlement of the Ortho Biotech antitrust suit. Such expenses are included in Other charges in the Condensed Consolidated Statements of Income.

Table of Contents

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

Forward looking statements

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Words such as expect, anticipate, outlook, could, target, project, intend, plan, believe, seek, estimate, should, may, of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in *Item 1A. Risk Factors* in Part II herein. 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 Pfizer in the United States and Canada. Our international product sales consist principally of European sales of Aranesp®, Neulasta® and NEUPOGEN®. International product sales represented 22% of total product sales for both the three and nine months ended September 30, 2009. International product sales represented 23% and 22% of total product sales for the three and nine months ended September 30, 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 both the three and nine months ended September 30, 2009, our principal products represented 93% of worldwide product sales. For both the three and nine months ended September 30, 2008, our principal products represented 94% of worldwide product sales. For additional 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. 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,

Table of Contents

delays in receiving approvals or additional safety-related requirements or restrictions on the use of our products, including expanded safety labeling, required 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. For example as discussed in more detail below, in October 2009, the FDA issued complete response letters for our biologic license applications (BLAs) for Prolia (denosumab) in the treatment and prevention of postmenopausal osteoporosis (PMO) and in the treatment and prevention of bone loss due to Hormone Ablation Therapy (HALT) in breast and prostate cancer patients requesting additional information in connection with their review of our applications for product approval, which has extended the review time for our BLAs beyond their October 19, 2009 Prescription Drug User Fee Act (PDUFA) date. In addition, the FDA has determined that a REMS is necessary for Prolia and has requested a new clinical program to support approval of Prolia for the prevention of PMO. (The FDA has provisionally approved the trade name Prolia in the indications noted above, for which the drug is administered twice yearly subcutaneously at a 60 milligram (mg) dose. The trade name is only for these indications and may not apply for other indications of denosumab.)

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. Therefore, sales of our principal products have 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. Additionally, ongoing healthcare reform efforts 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 in the United States. Healthcare reform is a top priority for President Obama and Congress is now considering several different bills which would make wide-ranging changes to the United States healthcare system in order to expand and to fund coverage to millions of uninsured Americans, to substantially reduce the rate of increase in the costs of government-sponsored healthcare programs and to improve the quality and portability of healthcare. Bills on healthcare reform have been passed by key Congressional committees and are expected to be considered by the full Congress before the end of 2009. Further, a number of states, including California, Colorado, Connecticut, New York and Pennsylvania, are considering or have recently enacted legislative proposals that would significantly alter their healthcare systems. If healthcare reform legislation in the United States is passed, it may include reducing the coverage and reimbursement of our products by Medicare, Medicaid and other government programs and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, each of which could have a significant impact on our business.

Further, safety signals, trends, adverse events or results from clinical trials, including sub-analyses, 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 REMS, and/or additional or more extensive clinical trials as part of PMCs or a pharmacovigilance program, and may negatively impact sales or coverage or reimbursement of our products. For example, as discussed in more detail below, we announced on October 30, 2009, the publication of results from TREAT (the Trial to Reduce Cardiovascular Endpoints with Aranesp® Therapy), a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of patients with chronic kidney disease (CKD) not on dialysis, moderate anemia and type-2 diabetes. The study failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to end-stage renal disease (ESRD). We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete.

Certain regulatory and reimbursement developments have and may continue to negatively impact sales of certain of our products or require us to incur additional expenditures to obtain approval to market our products or to maintain approval once obtained, in particular in the United States where the impact of these developments on our business has thus far been more pronounced. As a result, we continue to focus on improving our cost structure and achieving greater efficiencies in how we conduct our business while continuing to support critical R&D and operational priorities, including preparing for the launch of Prolia .

Worldwide product sales for the three and nine months ended September 30, 2009 were $3,736 million and $10,608 million, respectively, representing decreases of 1% and 4%, respectively, compared to the corresponding periods in the prior year. U.S. product sales for the three months ended September 30, 2009 totaled $2,918 million, relatively unchanged compared to the prior year as the decline in U.S. Aranesp® sales of $125 million was largely offset by increased U.S. sales of our other principal products. U.S. product sales for the nine months ended September 30, 2009 were $8,253 million compared to $8,560 million for the nine months ended September 30, 2008, representing a decrease of 4%. For the nine months ended September 30, 2009, the decline in U.S. product sales was largely attributable to declines in Aranesp® sales of $327 million and ENBREL sales of $101 million, partially

26

Table of Contents

offset by increased sales of our other principal products. The decline in U.S. Aranesp® sales for the three and nine months ended September 30, 2009 principally reflects the negative impact, primarily in the supportive cancer care setting, of additional safety-related product label changes that occurred in August 2008. In addition, U.S. Aranesp® sales in the three and nine months ended September 30, 2008, benefited from a $54 million change in the accounting estimate related to product sales return reserves recorded in the three months ended September 30, 2008. The decline in ENBREL sales for the nine months ended September 30, 2009 primarily reflects a $120 million benefit to ENBREL s sales in 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, which resulted in this initial wholesaler stocking. International product sales were $818 million for the three months ended September 30, 2009 compared to $855 million for the three months ended September 30, 2008, representing a decrease of 4%. International product sales were $2,355 million for the nine months ended September 30, 2009 compared to $2,453 million for the nine months ended September 30, 2008, representing a decrease of 4%. The decrease in international product sales for the three and nine months ended September 30, 2009 reflects unfavorable foreign currency exchange rate changes of $76 million and $248 million, respectively. Excluding the impact of foreign currency exchange rate changes, worldwide product sales increased 1% for the three months ended September 30, 2009 and declined 1% for the nine months ended September 30, 2009. Excluding the impact of foreign currency exchange rate changes, international product sales for the three and nine months ended September 30, 2009 increased 5% and 6%, respectively.

For the three months ended September 30, 2009, net income was $1,386 million and diluted earnings per share were $1.36 compared to $1,121 million and $1.05, respectively, for the three months ended September 30, 2008, representing increases of 24% and 30%, respectively. For the nine months ended September 30, 2009, net income was $3,674 million and diluted earnings per share were $3.58 compared to $3,127 million and $2.90, respectively, for the nine months ended September 30, 2008, representing increases of 17% and 23%, respectively. Net income and diluted earnings per share for the three and nine months ended September 30, 2009 were favorably impacted by lower Cost of sales and R&D expenses and a lower effective tax rate. In addition, for the nine months ended September 30, 2008, operating expenses were negatively impacted by $267 million in loss accruals for settlements of certain commercial legal proceedings.

As of September 30, 2009, cash, cash equivalents and marketable securities aggregated $14.0 billion, of which approximately $11.1 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). Our total debt outstanding was $11.5 billion as of September 30, 2009 of which $1.0 billion is due on November 18, 2009, which we expect to repay without incurring additional indebtedness.

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

Denosumab Developments

Prolia for the Prevention and Treatment of PMO and the Prevention and Treatment of Bone Loss in Patients Undergoing HALT for either Prostate Cancer or Breast Cancer

On August 13, 2009, we announced the results of our meeting with the FDA s Advisory Committee for Reproductive Health Drugs (ACRHD) to review the potential use of Prolia for the prevention and treatment of PMO and the prevention and treatment of bone loss in patients undergoing HALT for either prostate cancer or breast cancer. The Committee recommended approval of Prolia for the treatment of PMO and for the treatment of bone loss in patients undergoing HALT for prostate cancer. The Committee recommended against approval of Prolia to treat or prevent bone loss in women with breast cancer undergoing HALT until additional data are available. The Committee also recommended against approval of Prolia to prevent bone loss in low-risk patients in all three populations. Finally, the panel recommended that Prolia have a REMS, which could include a medication guide and a healthcare provider communications plan. The ACRHD is an advisory committee of external experts who advise the FDA about the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology and related specialties. This committee is advisory only and FDA officials are not bound to or limited by their recommendations. However, the FDA commonly follows the recommendations of its advisory panels.

In October 2009, the FDA issued complete response letters for our BLAs for Prolia in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to HALT in breast and prostate cancer patients. The FDA issues complete response letters to request additional information needed to complete the review of applications for product approval.

The complete response letter related to the Prolia applications for the treatment and prevention of PMO requested several items, including further information on the design and background adverse event rates that will inform the methodology of our

27

Table of Contents

previously submitted post-marketing surveillance program although the letter did not require additional pre-marketing clinical trials to complete the review of the treatment indication. The FDA has also requested a new clinical program to support approval of Prolia for the prevention of PMO. In addition, the FDA has determined that a REMS is necessary for Prolia and must include a medication guide, a communication plan and a timetable for submission of assessments of the REMS. The FDA acknowledged receipt of our previously submitted proposed REMS materials. The FDA has also requested all updated safety data related to Prolia .

The complete response letter on the Prolia HALT applications requested additional information regarding the safety of Prolia in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving androgen deprivation therapy (ADT). Specifically, the FDA has requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia has no detrimental effects on either time-to-disease progression or overall survival.

Amgen is reviewing both complete response letters and will work with the FDA to determine the appropriate next steps regarding these applications.

We also have submitted Prolia for approval in PMO and bone loss in breast and prostate cancer patients due to HALT in the European Union (EU), Switzerland, Australia and Canada. We are working closely with regulatory agencies in each of these regions.

Denosumab Phase 3 Clinical Trials for the Prevention of Skeletal Related Events (SRE) Due to the Spread of Cancer to the Bone

Multiple Solid Tumors and Multiple Myeloma

On September 21, 2009, we announced detailed results from a phase 3 trial evaluating denosumab administered subcutaneously versus Zometa® (zoledronic acid) administered as an intravenous infusion in the treatment of bone metastases in 1,776 advanced cancer patients with solid tumors (not including breast and prostate cancer) or multiple myeloma. These detailed results were presented at the 2009 Congresses of the European CanCer Organization (ECCO) and European Society for Medical Oncology (ESMO) in Berlin, Germany. Top line results of this study were previously reported on August 3, 2009.

This was an international, phase 3, randomized, double-blind, active-comparator-controlled study comparing denosumab with Zometa® in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. Patients enrolled in this event-driven study were randomized in a one-to-one ratio to receive either 120 mg of denosumab subcutaneously every four weeks or Zometa® administered intravenously at a dose of 4 mg delivered as a single, 15-minute infusion every four weeks.

In clinical trials thus far to test new medications for bone metastases, treatment success has been measured by whether the bone complications, or SREs, caused by the tumor are reduced or delayed. The primary and secondary endpoints of the denosumab bone metastases studies use a composite endpoint of four SREs fracture, the need for radiation to bone, the need for bone surgery and spinal cord compression to measure the effectiveness of denosumab versus Zometa®.

The primary endpoint was to evaluate if denosumab is non-inferior to Zometa® with respect to the time to first on-study SRE in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma and bone metastases. Secondary endpoints were to evaluate if denosumab is superior to Zometa® with respect to the time to first on-study SRE, as well as time to first-and-subsequent on-study SREs, and to assess the safety and tolerability of denosumab compared with Zometa®.

For the primary endpoint of this study, the median time to first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) was 20.6 months for those patients receiving denosumab and 16.3 months for those patients receiving Zometa® (hazard ratio (HR) 0.84, [95% Confidence Interval (CI): 0.71-0.98]), which is statistically significant for non-inferiority (p=0.0007). Although numerically greater, the delay in the time to first SRE associated with denosumab was not statistically superior compared to Zometa® based upon the statistical testing strategy (adjusted p=0.06) (secondary endpoint). The time to first-and-subsequent SRE was also numerically greater but not statistically superior compared to Zometa® (HR 0.90, [95% CI: 0.77-1.04], p=0.14) (secondary endpoint). Denosumab also delayed the median time to first on-study SRE or hypercalcemia of malignancy (HCM) compared to Zometa® (HR 0.83, [95% CI: 0.71-0.97], p=0.02). The median time to first on-study SRE or HCM was 19.0 months for denosumab and 14.4 months for Zometa®.

In an exploratory analysis, patients on the denosumab arm reported worsening of pain later than those on the Zometa® arm (57 days versus 36 days, respectively). Adverse events rates (96% denosumab, 96% Zometa®) and serious adverse events (63% denosumab, 66% Zometa®) were similar between groups and were consistent with what has previously been reported for these two agents. Rates of osteonecrosis of the jaw (ONJ) were balanced and infrequent in both treatment groups (10 patients receiving

28

Table of Contents

denosumab as compared with 11 patients receiving Zometa®). Infectious adverse events were balanced between the two treatment arms, as was overall survival (HR 0.95, [95% CI: 0.83-1.08], p=0.43) and the time to cancer progression (HR 1.00, [95% CI: 0.89-1.12], p=1.0). In certain populations, such as non-small cell lung cancer (NSCLC), which represented 39% of the treated population, there was a difference in overall survival that favored denosumab, which was nominally statistically significant. For multiple myeloma, there was a difference in overall survival that favored Zometa®, which was nominally statistically significant.

Breast Cancer

On September 22, 2009, we announced detailed results from a phase 3, head-to-head trial evaluating denosumab versus Zometa® (zoledronic acid) in the treatment of bone metastases in 2,046 patients with advanced breast cancer that met its primary and secondary endpoints and demonstrated superior efficacy compared to Zometa®. These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. Top line results of this study were previously reported on July 7, 2009.

This was an international, phase 3, randomized, double-blind study comparing denosumab with Zometa® in the treatment of bone metastases in patients with advanced breast cancer. Patients enrolled in the study were randomized in a one-to-one ratio to receive either 120 mg of denosumab subcutaneously every four weeks or Zometa® administered intravenously at a dose of 4 mg in a 15-minute infusion every four weeks as per the label instructions.

In clinical trials testing new medications for bone metastases, treatment success has been measured by whether the bone complications, or SREs, caused by the tumor are reduced or delayed. The primary and secondary endpoints of the denosumab bone metastases studies use a composite endpoint of four SREs fracture, the need for radiation to bone, the need for bone surgery and spinal cord compression to measure the effectiveness of denosumab versus Zometa®.

The primary endpoint was to evaluate if denosumab is non-inferior to Zometa® with respect to the first, on-study SRE in patients with advanced breast cancer and bone metastases. Secondary endpoints were to evaluate if denosumab was superior to Zometa® with respect to the first, on-study SRE, as well as the first-and-subsequent on-study SREs, and to assess the safety and tolerability of denosumab compared with Zometa®.

Denosumab administered subcutaneously demonstrated superiority for both delaying the time to the first on-study SRE (fracture, radiation to bone, surgery to bone or spinal cord compression) (HR 0.82, [95% CI: 0.71-0.95]), and delaying the time to first-and-subsequent SREs (HR 0.77, [95% CI: 0.66-0.89]). Both results were statistically significant in this 34 month study. The median time to first on-study SRE was not reached for denosumab and therefore could not be estimated. The median time to first on-study SRE was 26.5 months for Zometa®, the current standard of care.

Denosumab also delayed the median time to first on-study SRE or HCM compared to Zometa® (HR 0.82, [95% CI: 0.70-0.95], p=0.007). The median time to first on-study SRE or HCM was not reached for denosumab and therefore could not be estimated. The median time to first on-study SRE or HCM was 25.2 months for Zometa®.

In a pre-specified exploratory analysis, patients on the denosumab arm reported worsening of pain later than those on the Zometa® arm (88 days versus 64 days, respectively; HR 0.87, [95% CI: 0.79-0.97], p=0.009). Overall, the incidence of adverse events (96% denosumab, 97% Zometa®) and serious adverse events (44% denosumab, 46% Zometa®) was consistent with what has previously been reported for these two agents. Adverse events potentially associated with renal toxicity occurred in 4.9% of patients treated with denosumab compared to 8.5% in patients treated with Zometa®. ONJ was seen infrequently in both treatment groups (20 patients receiving denosumab (2.0%) as compared with 14 patients (1.4%) receiving Zometa®). There was no statistically significant difference in the rate of ONJ between the two treatment arms. Overall survival (HR 0.95, [95% CI: 0.81-1.11], p=0.50) and time to cancer progression (HR 0.99, [95% CI: 0.89-1.11], p=0.90) was balanced between treatment arms.

ESA Developments

Our ESA products have and will continue to face future challenges. 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 ³ 10 grams per deciliter (g/dL) and that dose should be adjusted to maintain the lowest Hb level sufficient to avoid red blood cell transfusions and (iii) the removal of reference to the upper safety limit of 12 g/dL.

Additionally, in response to the FDA s request under authority prescribed by the Food and Drug Administration Amendments Act of 2007 (the FDAAA), we have submitted a proposed REMS and continue to work closely with the FDA to develop a REMS program for the class of ESA products. The

Table of Contents

components of the REMS approved by the FDA could be different for the use of ESAs in the oncology and nephrology indications. Further, we are working with the FDA to make Aranesp® product package insert changes associated with the Physician s Labeling Rule (PLR) conversion process. During the PLR conversion process from an old format to the new PLR format, the FDA may evaluate the package insert information to ensure that it accurately reflects current knowledge and may revise, add or remove information in the old format that could substantively impact the content of the product package insert for the new format.

TREAT study

On October 30, 2009, we announced the publication of results from TREAT, a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of 4,038 patients with CKD not on dialysis, moderate anemia and type-2 diabetes. Results of this study were previously reported on October 21, 2009 and top line results were released on August 25, 2009. The study, published on October 30, 2009 in the *New England Journal of Medicine* and presented at the 2009 annual meeting of the American Society of Nephrology, failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to ESRD.

The primary endpoints of the study were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or ESRD. Among the components of the primary cardiovascular composite endpoint, the risk of stroke increased by almost two-fold in patients in the Aranesp® arm (101 patients [5.0%] versus 53 patients [2.6%]; HR 1.92, [95% CI: 1.38-2.68], p<0.001). Although stroke is a recognized risk with ESA therapy, and has been identified in warnings in U.S. labeling since 2001, the risk observed in TREAT is of higher magnitude than that seen in previous clinical trials in CKD patients not on dialysis.

A post hoc analysis indicates that there were no significant differences between treatment arms in the number of patients with a reported diagnosis of cancer (139 in the Aranesp® group [6.9%] and 130 in the placebo group [6.4%] [p=0.53]) or of all-cause deaths in patients who developed cancer during the trial (53 in the Aranesp® group [2.6%] and 50 in the placebo group [2.5%]). Overall, 39 deaths were attributed to cancer in the 2012 patients in the Aranesp® group and 25 deaths were attributed to cancer in the 2026 patients in the placebo group (p=0.08 by the log-rank test). This analysis also showed an excess in overall mortality among patients in the Aranesp® arm with a history of cancer that requires further investigation. Specifically, among patients with a history of cancer at baseline, there were 60 deaths from any cause in the 188 patients assigned to Aranesp® and 37 deaths in the 160 patients assigned to placebo (p=0.13 by the log-rank test). In this subgroup, 14 of the 188 patients assigned to Aranesp® died from cancer, as compared with 1 of the 160 patients assigned to placebo (p=0.002 by the log-rank test).

TREAT was designed as a superiority study to demonstrate improved cardiovascular outcomes and is the largest study of ESA use in CKD patients to date. Patients enrolled in the study were randomized in a one-to-one ratio to receive either treatment with Aranesp® to a target Hb of 13 g/dL or placebo. Due to the increased risk of negative outcomes associated with low Hb levels, patients in the control arm whose Hb fell below 9 g/dL were given Aranesp® as a rescue medication until their Hb level reached 9 g/dL. Investigators were blinded to this intervention.

TREAT had two primary endpoints. The first evaluated the time to all-cause mortality or cardiovascular morbidity, including heart attack (myocardial infarction), congestive heart failure, hospitalization for angina (myocardial ischemia), or stroke (cerebrovascular accident). The second primary endpoint evaluated the time to all-cause mortality or chronic dialysis. TREAT was not designed to determine the appropriate Hb target in this patient population.

The TREAT results demonstrate that in many diabetic CKD patients not on dialysis with moderate anemia, the risk of treatment to a target Hb level of 13 g/dL will exceed the benefit of reducing the need for transfusions.

We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete.

Proposed bundled payment system

On September 15, 2009, the Centers for Medicare and Medicaid Services (CMS) released its proposed rule to implement the bundled prospective payment system for ESRD that, in accordance with the 2008 Medicare Improvements for Patients and Providers Act (MIPPA), requires the CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. Under the proposed rule, the bundled payment system will include dialysis services covered under the current composite rate, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including our ESAs products, intravenous iron, and intravenous vitamin D, as well as oral equivalent forms of these intravenous drugs. In addition, the proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, specifically Sensipar® and phosphate

binders. The bundled reimbursement rate will be phased in

Table of Contents

over a four year period in equal increments starting in 2011. Providers have the option to move to a full Medicare bundled payment system in 2011 or may elect to adopt certain components of the bundled payment system beginning in 2010.

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

In August 2009, the CMS announced it had scheduled a meeting on March 24, 2010 of the MEDCAC to review the available evidence on the use of ESAs to manage anemia in patients who have CKD. While a MEDCAC provides advice and recommendations to the CMS about the adequacy of scientific evidence and votes on certain questions proposed by the CMS, it functions as an independent advisory body and its advice and recommendations to the CMS are advisory only.

Preoperative Epirubicin Paclitaxel Aranesp® (PREPARE) study

Further, as we previously disclosed, in 2008 the FDA and European Medicines Agency (EMEA) reviewed interim results from the PREPARE study in neo-adjuvant breast cancer, a PMC study, which were ultimately incorporated into the ESA labeling in both the United States and the EU. We have since received the final results from the PREPARE study, which were substantially consistent with the interim results, and provided that data to the FDA and EMEA.

We believe that certain of the above-noted developments could have a material adverse impact on the future sales of Aranesp® and EPOGEN®. In addition, the proposed rule to implement the bundled Medicare payment system could have a material adverse impact on the future sales of Sensipar®.

Vectibix® (panitumumab) Developments

203 trial

On September 24, 2009, we announced detailed results from the phase 3 203 or PRIME (Panitumumab Randomized trial In combination with chemotherapy for Metastatic colorectal cancer to determine Efficacy) trial evaluating Vectibix® administered in combination with FOLFOX4 (an oxaliplatin-based chemotherapy) as the first-line treatment of metastatic colorectal cancer (mCRC). These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. On November 5, 2009, we announced that the 203 trial failed to meet a secondary endpoint of overall survival. Top line results of this study were previously reported on August 6, 2009.

Patients enrolled in the 203 trial were randomized to receive either 6.0 mg/kilogram (kg) of Vectibix® and FOLFOX4 once every two weeks or FOLFOX4 alone once every two weeks. The primary endpoint of the study is progression-free survival (PFS) by KRAS status and secondary endpoints include overall survival, objective response rate, time to progression, duration of response and safety.

Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in KRAS in the tumor itself. Tumor KRAS status was ascertained in more than 90% of the 1,183 patients enrolled in the trial.

We announced on September 24, 2009 that in this trial Vectibix® significantly improved median PFS by 1.6 months (9.6 versus 8.0 months for patients treated with FOLFOX4 alone, (HR 0.80, p=0.02)) in patients with *KRAS* wild-type mCRC (primary endpoint). Further, the addition of Vectibix® to chemotherapy also improved response rate in the *KRAS* wild-type patient population as measured by blinded central review (55% versus 48% in the FOLFOX4 only arm). Importantly, in patients with tumors harboring activating *KRAS* mutations, PFS was significantly inferior in the Vectibix® arm. For patients with mutant KRAS tumors, median PFS was 7.3 months with Vectibix® in combination with FOLFOX4 versus 8.8 months with FOLFOX4 alone (HR 1.29, p=0.02). These data confirm previous findings when oxaliplatin-based chemotherapy and an anti-epidermal growth factor receptor (EGFR) antibody are combined in patients bearing tumors with activating *KRAS* mutations. The median overall survival for patients with *KRAS* wild-type mCRC had not yet been reached.

The final overall survival results for the 203 study were announced on November 5, 2009 and showed that Vectibix®, when added to a FOLFOX4 chemotherapy regimen in patients with KRAS wild-type mCRC, resulted in a median overall survival of 23.9 months compared to 19.7 months for patients treated with FOLFOX4 alone. The median overall survival difference of 4.2 months in the Vectibix® arm did not reach statistical significance (HR 0.83, p=0.072). Consistent with an interim analysis, overall survival appeared to be reduced in patients with KRAS mutant tumors receiving Vectibix®. Although not statistically significant, this result emphasizes the importance, as described in product labeling, of ensuring that patients receiving Vectibix® do not bear tumors containing KRAS mutations.

31

Table of Contents

Adverse event rates were comparable across arms with the exception of known toxicities associated with anti-EGFR therapy such as rash, diarrhea and hypomagnesemia. Vectibix®-related grade 3 infusion reactions were reported for two patients (less than 1%).

181 Trial

On September 22, 2009, we announced detailed results from the phase 3 181 trial evaluating Vectibix® in combination with FOLFIRI (an irinotecan based chemotherapy), as a second-line treatment for mCRC. These detailed results were presented at the 2009 Congresses of the ECCO and ESMO in Berlin, Germany. Top line results of this study were previously reported on August 17, 2009.

The 181 trial is a global, multicenter, randomized phase 3 study. Patients enrolled in the study were randomized to receive either 6.0 mg/kg of Vectibix® and FOLFIRI once every two weeks or FOLFIRI alone once every two weeks. The independently tested co-primary endpoints were PFS and overall survival. Secondary endpoints included objective response rate, time to progression, duration of response and safety by *KRAS* status.

Originally designed to compare the treatment effect in the overall population, the study was amended to analyze outcomes with respect to the presence or absence of activating mutations in *KRAS* in the tumor itself. Tumor *KRAS* status was ascertained in 91% of the 1,186 patients enrolled in this trial, the highest number ever reported for a second-line trial.

In this trial, Vectibix® significantly improved PFS in patients with *KRAS* wild-type mCRC. The addition of Vectibix® to FOLFIRI significantly improved median PFS (co-primary endpoint) by two months (5.9 versus 3.9 months for patients treated with FOLFIRI alone, HR 0.73, p=0.004) in patients with *KRAS* wild-type mCRC. Although numerically greater (14.5 months versus 12.5 months, HR 0.85), the improvement in median overall survival (co-primary endpoint) in the Vectibix® arm did not achieve statistical significance (p=0.115) in the same patient population. Further, the addition of Vectibix® to FOLFIRI resulted in greater than a three-fold improvement (35% versus 10%) in response rate in the *KRAS* wild-type patient population as measured by a blinded central review.

In general, adverse events rates were comparable across arms with the exception of known toxicities associated with anti-EGFR therapy such as rash, diarrhea, and hypomagnesemia. Vectibix®-related grade $^{3}/4$ infusion reactions were reported in less than 1% of patients.

There were no differences in PFS, overall survival and response rates among patients with mutated *KRAS* who received Vectibix®.

Competition

On September 15, 2009, we announced that the Federal Circuit Court affirmed the Massachusetts District Court s October 2, 2008 judgment that the Roche Defendants peg-EPO product, Mircera®, infringes four Amgen patents, specifically the 933 Patent, the 422 Patent, the 698 Patent and the 868 Patent. Regarding the fifth patent-in-suit, the 349 Patent, the Federal Circuit Court reversed the holding of non-infringement by the District Court and remanded that issue for a new trial which would allow Amgen to prove that the Roche Defendants peg-EPO product infringes that patent as well. The Federal Circuit Court also affirmed the validity of Amgen s patents except for a single issue of obviousness-type double patenting which only impacts Amgen s later expiring patents (933, 422 and 349 Patents). The Federal Circuit Court remanded this validity issue to the Massachusetts District Court for further analysis. The Federal Circuit Court left undisturbed the permanent injunction that prohibits the Roche Defendants from selling its peg-EPO product, Mircera® in the United States until expiry of the infringed patents.

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®, NEUPOGEN® and Neulasta®, 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 NEUPOGEN® and Neulasta®. Further, in the United States, ENBREL will continue to face increased competition primarily due to the launch of new products, including competition from J&J s Stelara (ustekinumab) which was approved by the FDA in September 2009. Furthermore, as part of the broad healthcare reform initiatives in the United States, legislation has been proposed to create a regulatory pathway for the abbreviated approval of biosimilars, including limiting the period of time during which the data submitted in an innovator s regulatory application may not be relied upon or referenced by others in their application for approval to the FDA. This legislation may be passed into law as early as 2009.

Table of Contents

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, including biosimilars; 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

Worldwide product sales and total product sales by geographic region were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
Aranesp®	$ 685	$ 845	(19)%	$ 2,004	$ 2,431	(18)%
EPOGEN®	663	634	5%	1,866	1,810	3%
Neulasta®/NEUPOGEN®	1,210	1,192	2%	3,441	3,479	(1)%
ENBREL	924	893	3%	2,581	2,685	(4)%
Sensipar®	165	161	2%	480	444	8%
Other	89	59	51%	236	164	44%
Total product sales	$ 3,736	$ 3,784	(1)%	$ 10,608	$ 11,013	(4)%
Total U.S.	$ 2,918	$ 2,929	0%	$ 8,253	$ 8,560	(4)%
Total International	818	855	(4)%	2,355	2,453	(4)%
Total product sales	$ 3,736	$ 3,784	(1)%	$ 10,608	$ 11,013	(4)%

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, expansion into new countries, competitive products, product supply and acquisitions. In addition, general economic conditions may effect, or in some cases amplify, certain of these factors with a corresponding impact on our product sales.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
Aranesp® - U.S.	$ 333	$ 458	(27)%	$ 963	$ 1,290	(25)%
Aranesp® - International	352	387	(9)%	1,041	1,141	(9)%
Total Aranesp®	$ 685	$ 845	(19)%	$ 2,004	$ 2,431	(18)%

U.S. Aranesp® sales for the three and nine months ended September 30, 2009 decreased 27% and 25%, respectively. U.S. sales of Aranesp® in the three and nine months ended September 30, 2008 benefited from a $54 million change in the accounting estimate related to product sales return reserves. Excluding the positive impact of this prior year change in accounting estimate, U.S. sales of Aranesp® decreased 18% and 22% compared to the three and nine months ended September 30, 2008, respectively. These decreases were 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 a decrease in the average net sales price. In addition, the decreases in sales also reflect, to a lesser degree, a slight loss of segment share.

Table of Contents

International Aranesp® sales for both the three and nine months ended September 30, 2009 decreased 9%, due to the unfavorable impact of changes in foreign currency exchange rates and, to a lesser extent, segment decline. For the three months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately $29 million, international Aranesp® sales decreased 2%. For the nine months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately $100 million, international Aranesp® sales remained unchanged. Through September 30, 2009, biosimilars and other recently introduced marketed products in Europe have not had a significant impact on total Aranesp® segment share.

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

regulatory developments, including:

- 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;

- future product label changes, including those we are currently discussing with regulatory authorities;

reimbursement developments, including those resulting from:

- government s and/or third-party payer s reaction to regulatory developments, including the proposed REMS for the class of ESAs which we are discussing with the FDA, and future product label changes;

- CMS MEDCAC meeting on March 24, 2010 to review the available evidence on the use of ESAs to manage anemia in patients who have CKD;

- changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid, such as the proposed bundled payment system, which becomes effective in 2011, for dialysis services, drugs and biologicals furnished for treatment of ESRD that are currently billed separately;

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

proposed healthcare reform in the United States;

severity and duration of the current global economic downturn;

adverse events or results from clinical trials, including sub-analyses, studies, including our TREAT study, 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 therapies or 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 launched;

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®.

Table of Contents

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

EPOGEN®

Total EPOGEN® sales were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
EPOGEN® - U.S.	$ 663	$ 634	5%	$ 1,866	$ 1,810	3%

EPOGEN® sales for the three and nine months ended September 30, 2009 increased 5% and 3%, respectively, primarily due to an increase in demand. The increase in demand for both periods was principally due to patient population growth and, to a lesser extent, an increase in the average net sales price. In addition, demand was also favorably impacted, to a lesser extent, by an increase in dose/utilization for the three months ended September 30, 2009.

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:

- changes in reimbursement rates or changes in the basis for reimbursement by the federal and state governments, including Medicare and Medicaid, such as the proposed bundled payment system, which becomes effective in 2011, for dialysis services, drugs and biologicals furnished for treatment of ESRD that are currently billed separately;

- the federal government s reaction to regulatory developments, including the proposed REMS for the class of ESAs which we are discussing with the FDA, and future product label changes;

- CMS MEDCAC meeting on March 24, 2010 to review the available evidence on the use of ESAs to manage anemia in patients who have CKD;

- changes in healthcare providers prescribing behavior resulting in dose fluctuations due to the CMS revisions to its Erythropoietin Monitoring Policy (EMP), which became effective January 1, 2008;

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

regulatory developments, including those resulting from:

- 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;

- future product label changes;

proposed healthcare reform in the United States;

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, including sub-analyses, 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;

patient population growth;

changes in dose/utilization; and

Table of Contents

development of new modalities or therapies to treat anemia associated with CRF.

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

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

Neulasta®/NEUPOGEN®

Total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
Neulasta® - U.S.	$ 657	$ 633	4%	$ 1,876	$ 1,850	1%
NEUPOGEN® - U.S.	240	223	8%	672	667	1%
U.S. Neulasta®/NEUPOGEN® - Total	897	856	5%	2,548	2,517	1%
Neulasta® - International	214	219	(2)%	603	620	(3)%
NEUPOGEN® - International	99	117	(15)%	290	342	(15)%
International Neulasta®/NEUPOGEN® - Total	313	336	(7)%	893	962	(7)%
Total Neulasta®/NEUPOGEN®	$ 1,210	$ 1,192	2%	$ 3,441	$ 3,479	(1)%

U.S. sales of Neulasta®/NEUPOGEN® for the three months ended September 30, 2009 increased 5%, primarily due to an increase in demand. The increase in demand was driven by increases in units sold and the average net sales price. U.S. sales of Neulasta®/NEUPOGEN® for the nine months ended September 30, 2009 increased 1%, primarily due to an increase in demand as a result of an increase in the average net sales price.

International Neulasta®/NEUPOGEN® sales for both the three and nine months ended September 30, 2009 decreased 7%, due to the unfavorable impact of changes in foreign currency exchange rates, partially offset by an increase in demand driven by segment growth, including expansion into additional countries in central and eastern Europe, and by the continued conversion from NEUPOGEN® to Neulasta®. For the three and nine months ended September 30, 2009, excluding the impact of foreign currency exchange rate changes of approximately $33 million and $106 million, respectively, international Neulasta®/NEUPOGEN® sales increased 3% and 4%, respectively. Through September 30, 2009, biosimilars in Europe have not had a significant impact on total Neulasta®/NEUPOGEN® segment share.

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

proposed healthcare reform in the United States;

severity and duration of the current global economic downturn;

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

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

penetration of existing segments;

competitive products, including biosimilar products that have been or may be approved and launched in the EU;

adverse events or results from clinical trials, including sub-analyses, 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;

Table of Contents

our contracting and related pricing strategies; and

patient population growth.

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

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
ENBREL - U.S.	$ 872	$ 838	4%	$ 2,430	$ 2,531	(4)%
ENBREL - Canada	52	55	(5)%	151	154	(2)%
Total ENBREL	$ 924	$ 893	3%	$ 2,581	$ 2,685	(4)%

ENBREL sales for the three months ended September 30, 2009 increased 3%, primarily due to an increase in demand, partially offset by a favorable change in the accounting estimate recorded in the three months ended September 30, 2008 related to the accruals for sales incentives. The increase in demand was principally due to a high-single digit increase in the average net sales price partially offset by a decrease in units sold due to share declines as a result of competitive activity in the dermatology segment. ENBREL continues to maintain a leading position in both the rheumatology and dermatology segments.

ENBREL sales for the nine months ended September 30, 2009 declined 4%, which primarily reflects a $120 million benefit to ENBREL s sales in 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, which resulted in this initial wholesaler stocking. Excluding this positive impact to sales for the nine months ended September 30, 2008, ENBREL sales increased approximately 1%, primarily driven by an increase in demand, as a result of a mid-single digit increase in the average net sales price partially offset by a decline in units sold. The decline in units sold for the nine months ended September 30, 2009 reflects a slower rate of segment growth in the three months ended March 31, 2009 and share declines as a result of increased competitive activity.

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

the effects of competing products or therapies, including new competitive products coming to market, such as J&J s Simponi (golimumab) and Stelara (ustekinumab) and UCB/Nektar Therapeutics Cimzia® (PEGylated anti-TNF alpha) 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;

proposed healthcare reform in the United States;

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;

adverse events or results from clinical trials, including sub-analyses, 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; and

Table of Contents

patient population growth.

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 (dollar amounts in millions):

	Three months ended September 30,			Nine months ended September 30,		
	2009	2008	Change	2009	2008	Change
Operating expenses:						
Cost of sales (excludes amortization of certain acquired intangible assets)	$ 545	$ 677	(19)%	$ 1,553	$ 1,738	(11)%
% of product sales	15%	18%		15%	16%	
Research and development	$ 647	$ 729	(11)%	$ 1,973	$ 2,232	(12)%
% of product sales	17%	19%		19%	20%	
Selling, general and administrative	$ 932	$ 900	4%	$ 2,640	$ 2,678	(1)%
% of product sales	25%	24%		25%	24%	
Amortization of certain acquired intangible assets	$ 74	$ 74	0%	$ 221	$ 221	0%
Other charges	$ 9	$ 12	(25)%	$ 63	$ 306	(79)%

Cost of sales

Cost of sales, which excludes the amortization of certain acquired intangible assets, (Cost of sales) decreased 19% and 11% for the three and nine months ended September 30, 2009, respectively, primarily driven by lower royalty expenses and lower excess capacity charges, partially offset by higher fill and finish costs resulting from lower utilization at our manufacturing facility in Puerto Rico. The decrease in Cost of sales for the three and nine months ended September 30, 2009 was also driven by lower excess inventory write-offs, primarily due to the $84 million write-off of inventory resulting from a strategic decision to change manufacturing processes in the three months ended September 30, 2008. The decrease in Cost of sales for the nine months ended September 30, 2009 was also driven by lower sales volume.

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 R&D costs for R&D collaborations is recognized when the obligations are incurred or as we become entitled to the cost recovery.

R&D expenses decreased 11% for the three months ended September 30, 2009, which was primarily attributable to lower clinical trial costs of $34 million, including those associated with our marketed products, and lower staff-related expenses of $29 million, due in part to the optimization of our clinical supply network.

R&D expenses decreased 12% for the nine months ended September 30, 2009, which was primarily attributable to lower clinical trial costs of $114 million, including those associated with our denosumab and Vectibix® registrational studies, our marketed products and the delay of the phase 3 motesanib NSCLC trial. Additionally, we incurred lower licensing fees related to the $100 million expense in the nine months ended September 30, 2008 resulting from the upfront payment associated with the Kyowa Hakko collaboration, partially offset by the $50 million expense resulting from the payment to Cytokinetics in the nine months ended September 30, 2009. Also, staff-related costs were $49 million lower in the nine months ended September 30, 2009, due in part to the optimization of our clinical material supply network.

Table of Contents

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 certain 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.

For the three months ended September 30, 2009, the 4% increase in SG&A was primarily due to higher product promotional expenses of $53 million, including increased spending for activities in anticipation of the approval and launch of Prolia , and higher expenses associated with the Pfizer profit share expense of $8 million, partially offset by lower litigation expenses of $13 million, lower staff-related costs of $8 million and $12 million of expense recoveries associated with our GlaxoSmithKline collaboration agreement for Prolia in PMO in Europe, Australia, New Zealand and Mexico. For the three months ended September 30, 2009 and 2008, the Pfizer profit share expense was $306 million and $298 million, respectively. Excluding Pfizer profit share expense, SG&A expenses increased 4% compared to the three months ended September 30, 2008.

For the nine months ended September 30, 2009, the 1% decrease in SG&A was primarily due to the lower staff-related costs of $57 million, lower litigation expenses of $42 million, lower global ERP system related expenses of $28 million, lower expenses associated with the Pfizer profit share expense of $31 million and $12 million of expense recoveries associated with our GlaxoSmithKline collaboration agreement for Prolia , partially offset by higher product promotional expenses of $138 million, including increased spending for activities in anticipation of the approval and launch of Prolia , and higher restructuring and related costs of $24 million. For the nine months ended September 30, 2009 and 2008, the Pfizer profit share expense was $855 million and $886 million, respectively. Excluding Pfizer profit share expense, SG&A expenses remained relatively unchanged compared to the nine months ended September 30, 2008.

Other charges

For the three and nine months ended September 30, 2009, the Company recorded loss accruals for settlements of certain commercial legal proceedings aggregating $8 million and $28 million, respectively. For the three and nine months ended September 30, 2008, the Company recorded loss accruals for settlements of certain commercial legal proceedings aggregating $4 million and $267 million, respectively, principally related to the settlement of the Ortho Biotech antitrust suit.

For the three and nine months ended September 30, 2009, we incurred $1 million and $35 million, respectively, in connection with certain cost saving initiatives. For the three and nine months ended September 30, 2008, we incurred $8 million and $39 million, respectively, in connection with our restructuring plan announced in 2007 and in connection with certain additional cost saving initiatives.

Interest and other income, net

For the three months ended September 30, 2009 and 2008, interest and other income, net was $74 million and $62 million, respectively. This increase is primarily due to higher net gains on sales of investments of $15 million, higher foreign currency exchange gains of $15 million and the loss accrued in the three months ended September 30, 2008 on the sale of certain less significant marketed products and related assets of $9 million, partially offset by lower interest income of $19 million, principally due to lower portfolio investment returns.

For the nine months ended September 30, 2009 and 2008, interest and other income, net was $182 million and $264 million, respectively. This decrease is primarily due to lower interest income of $43 million, principally due to lower portfolio investment returns, losses on certain leases that will no longer be used in our operations of $31 million and lower net gains on sales of investments of $19 million partially offset by higher foreign currency exchange gains of $12 million and the loss accrued in the three months ended September 30, 2008 on the sale of certain less significant marketed products and related assets of $9 million.

Income taxes

Our effective tax rates for the three and nine months ended September 30, 2009 were 10.0% and 11.0%, respectively, compared to 20.6% and 20.3%, respectively, for the same periods last year. The decrease in our effective tax rate was primarily due to: (i) favorable resolution of certain prior years matters with tax authorities during the three and nine months ended September 30, 2009, (ii) increased manufacturing and profit in Puerto Rico, (iii) the inclusion of the benefit of the federal research and experimentation (R&E) tax credit in the three and nine months ended September 30, 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 (iv) a benefit in the nine

39

Table of Contents

months ended September 30, 2009 relating to adjustments to previously established deferred taxes due to changes in California tax law effective for future periods. The resolution of prior years tax matters recognized in the three months ended September 30, 2009 reduced the effective tax rates for the three and nine months ended September 30, 2009 by 6.4% and 5.2%, respectively.

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

Recent accounting pronouncements

In June 2009, the FASB issued a new accounting standard which amends guidance regarding consolidation of variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of the variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, this standard requires any enterprise that holds a variable interest in a variable interest entity to make ongoing assessments of whether it has a controlling financial interest in the variable interest entity and to provide enhanced disclosures that will provide users of financial statements with more transparent information about an enterprise s involvement in the variable interest entity. This standard is effective for us for interim and annual reporting periods beginning on or after January 1, 2010. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In August 2009, the FASB issued a new accounting standard which clarifies guidance for determining the fair value of a liability when a quoted price in an active market for an identical liability is not available. This standard provides for the use of one or more valuation techniques including use of quoted prices of identical or similar liabilities when traded as assets, quoted prices of similar liabilities and other techniques consistent with the fair value measurement framework, such as the amount an entity would pay to transfer the identical liability or would receive to enter into the identical liability. This standard is effective for us for interim and annual periods beginning on or after October 1, 2009. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

In October 2009, the FASB issued a new accounting standard which amends guidance on accounting for revenue arrangements involving the delivery of more than one element of goods and/or services. This standard addresses the unit of accounting for arrangements involving multiple deliverables and removes the previous separation criteria that objective and reliable evidence of fair value of any undelivered item must exist for the delivered item to be considered a separate unit of accounting. This standard also addresses how the arrangement consideration should be allocated to each deliverable. Finally, this standard expands disclosures related to multiple element revenue arrangements. This standard is effective for us for annual periods beginning on or after January 1, 2011. The adoption of this standard is not expected to have a material impact on our condensed consolidated results of operations, financial position or cash flows.

Financial Condition, Liquidity and Capital Resources

The following table summarizes selected financial data. The amounts reflect the adoption of a new accounting standard which changed the method of accounting for our convertible debt (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 this new accounting standard, effective January 1, 2009)(in millions):

	September 30, 2009	December 31, 2008
Cash, cash equivalents and marketable securities	$ 14,013	$ 9,552
Total assets	40,940	36,427
Current debt	1,000	1,000
Non-current debt	10,536	8,352
Stockholders equity	22,858	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 expect that we will repay the $1.0 billion of our 4.00% notes due on November 18, 2009 without incurring additional indebtedness.

40

Table of Contents

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at September 30, 2009, approximately $11.1 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).

Financing arrangements

The following table identifies our long-term borrowings under our various financing arrangements and the amounts reflect, where applicable, the adoption of the new accounting standard that changed the method of accounting for our convertible debt (dollar amounts in millions):

	September 30, 2009	December 31, 2008
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,307	$ 2,206
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,058	1,970
5.85% notes due 2017 (2017 Notes)	1,099	1,099
4.00% notes due 2009 (2009 Notes)	1,000	1,000
4.85% notes due 2014 (2014 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)	499	498
Zero-coupon modified convertible notes due in 2032 (2032 Modified Convertible Notes)	82	81
Other	100	100
Total borrowings	11,536	9,352
Less current portion	1,000	1,000
Total non-current debt	$ 10,536	$ 8,352

Certain of our financing arrangements contain non-financial covenants and we were in compliance with all applicable covenants as of September 30, 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 9, *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 the new accounting standard that changed the method of accounting for our convertible debt.

Cash flows

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

	Nine months ended September 30, 2009	2008
Net cash provided by operating activities	$ 4,513	$ 4,591
Net cash used in investing activities	(2,863)	(2,618)
Net cash provided by (used in) financing activities	153	(1,475)

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities during the nine months ended September 30, 2009 decreased $78 million primarily due to the prior year receipt of $300 million for an upfront milestone payment related to our licensing agreement with Takeda Pharmaceutical Company Limited; the negative impact of the timing and amounts of receipts from customers and payments to vendors and others;

Table of Contents

partially offset by higher net income of $547 million. The prior year receipt of the $300 million upfront milestone payment is included in Changes in deferred revenue in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2008.

Investing

Cash used in investing activities during the nine months ended September 30, 2009 increased primarily due to the net purchases of marketable securities. Net purchases of marketable securities were $2.5 billion for the nine months ended September 30, 2009 compared to net purchases of $2.2 billion for the nine months ended September 30, 2008. Capital expenditures totaled $386 million during the nine months ended September 30, 2009, compared to $494 million during the corresponding period of the prior year. The capital expenditures during the nine months ended September 30, 2009 were primarily associated with manufacturing capacity expansions in Puerto Rico and other site development. The capital expenditures during the nine months ended September 30, 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 less than $600 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 nine months ended September 30, 2009, we repurchased 37.5 million shares of our common stock at a total cost of $2.0 billion. During the nine months ended September 30, 2008, we repurchased 32.7 million shares of our common stock at a total cost of $1.6 billion. As of September 30, 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 $146 million and $114 million of cash during the nine months ended September 30, 2009 and 2008, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of our stock relative to the exercise price of such options.

Item 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures, as such term is defined under Exchange Act Rule 13a-15(e), that are designed to ensure that information required to be disclosed in Amgen s Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to Amgen s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and, in reaching a reasonable level of assurance, Amgen s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2009.

Management determined that, as of September 30, 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.

42

Table of Contents

PART II - OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

See Note 13, *Commitments and 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, Note 11, *Contingencies* to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and Note 13, *Commitments and Contingencies* to our Condensed Consolidated Financial Statements in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.

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, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.

We and certain of our licensees and partners conduct research, preclinical testing and clinical trials for our product candidates and marketed products for both their existing indications as well as for new and/or expanded indications. In addition, we manufacture and contract manufacture, and certain of our licensees and partners manufacture our products and product candidates, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, such as the EMEA in European countries and similar regulatory bodies in Canada and Australia. Currently, we are required in the United States and in foreign countries to obtain approval from those countries regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to 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 to assure safe use of the drug, as the FDA deems are necessary, 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 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. For example, we recently announced that we had received complete response letters from the FDA for the BLA for our late-stage product candidate Prolia™ in the treatment and prevention of PMO and in the treatment and prevention of bone loss due to HALT in breast and prostate cancer patients. The complete response letter related to the PMO indication requested several items,

including further information on the design and background adverse event rates that will inform the methodology of our previously submitted post-marketing surveillance program although the letter did not

Table of Contents

require additional pre-marketing clinical trials to complete the review of the treatment indication. The FDA also requested a new clinical program to support approval of Prolia™ for the prevention of PMO, updated safety data and stated that a REMS is necessary for Prolia™ and must include a medication guide, a communication plan, and a timetable for submission of assessments of the REMS. The FDA acknowledged receipt of our previously submitted proposed REMS materials. The complete response letter related to the HALT indications requested additional information regarding the safety of Prolia™ in patients with breast cancer receiving aromatase inhibitor therapy and patients with prostate cancer receiving ADT and specifically requested results from additional adequate and well-controlled clinical trials demonstrating that Prolia ™ has no detrimental effects on either time-to-disease progression or overall survival. Although we are working with the FDA to determine the appropriate next steps regarding our applications, a significant delay in regulatory approval to market and sell Prolia™ for the treatment of PMO could have a material adverse affect on our business and results of operations.

In addition, certain companion diagnostics or devices required to be approved as part of the BLA or other regulatory approval application for certain of our products or product candidates may be provided by single-source unaffiliated third-party companies. Our product candidates or expanded indications of our products may not be approved if the companion diagnostic or device does not gain or maintain regulatory approval. We are dependent on the sustained cooperation and effort of these third-party companies in conducting the studies required for such approval by the applicable regulatory agencies. Delays in the studies, including the third-party company s failure to obtain the necessary rights to all of the elements of the companion diagnostic or device, or failure of the third party company to obtain regulatory approval of the companion diagnostic or device, could negatively impact our product candidate or the expanded indication or our product through increased development costs, delays in regulatory approval and associated delays in a product candidate reaching the market or the expansion of existing product labels for new indications.

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 through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would 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, including sub-analyses, 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 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. During the PLR conversion process from an old format to the new PLR format, the FDA may evaluate the package insert information to ensure that it accurately reflects current knowledge and may revise, add or remove information in the old format that could substantively impact the content of the product package insert for the new format. 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

44

Table of Contents

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 August 4, 2009, the FDA issued an announcement regarding the results of the safety review of TNF-blockers and as a result of this review the FDA has required strengthened warnings about the occurrence of lymphoma and other cancers in children, adolescents and young adults using these medicines. In addition, the FDA conducted analyses related to the occurrence of leukemia and new-onset psoriasis in patients treated with TNF-blockers. We are working with the FDA to update the U.S. prescribing information (PI) and medication guide for ENBREL with this information as well as to communicate the revised product labeling to both healthcare providers and patients. The FDA has determined that we are required to conduct additional post-marketing clinical studies to assess the known serious risk of malignancies in pediatric patients and we will work with FDA to define what the studies would consist of. Further, on June 18, 2008, we participated in a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) to review data supporting the supplemental 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 and recommended we conduct additional clinical trials. In August 2009, we informed the FDA that after careful consideration of the FDA s recommendations, we concluded that it was not feasible to implement the suggested FDA approaches because the limited number of eligible pediatric patients with moderate to severe plaque psoriasis was too small to conduct clinical trials of sufficient magnitude to adequately inform the FDA s concerns and that, as a result, we were withdrawing the supplemental BLA for this expanded use of ENBREL in pediatric patients. 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 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, strongly discourage or affirmatively limit patient access to our products, place administrative burdens on healthcare providers in prescribing 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, we have submitted a proposed REMS for our ESAs in response to the FDA s requests and continue to work closely with the FDA to finalize the REMS program for our ESA products under authority prescribed by the FDAAA. Although we cannot predict what the final REMS for ESAs will include, the components of the REMS may include a medication guide, communication plan and elements to assure safe use in the oncology indication and may include a medication guide and communication plan in the nephrology indication. 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, 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 which could adversely affect the sales of Nplate®. Additionally, following the FDA web-alert on September 4, 2008 regarding their review of histoplasmosis and other

45

Table of Contents

opportunistic fungal infections in patients treated with TNF-blockers, the FDA requested that the boxed warning and WARNINGS sections of the U.S. PI and the medication guide for ENBREL (and other TNF-blockers) be strengthened to include the risk of unrecognized histoplasmosis and other invasive fungal infections with the goal of increasing timely diagnosis and treatment. The FDA also requested that the approved REMS for ENBREL be modified with a communication plan to healthcare providers regarding the risk of unrecognized fungal infections. 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 ENBREL and our other products as well which could have a material adverse effect on product sales, our business and results of operations.

Additionally, some products are approved by regulators on a conditional basis. For example, 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 voluntary recalled two manufacturing lots of EPOGEN® and our licensee, Ortho Biotech, voluntarily recalled one manufacturing lot of PROCRIT® (Epoetin alfa) that was manufactured in our manufacturing facilities after having identified cracks in the necks of a small number of vials upon post-manufacturing inspection. In September 2009, we initiated a voluntary wholesaler recall of a limited number of ENBREL SureClick® lots due to a defect in the glass syringe barrel which resulted in a small number of broken syringes following assembly of the autoinjector device. Although there have been no observable adverse event trends associated with these recalls, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends which may adversely affect the sales of our products. Additionally, if other parties (including our licensees, such as J&J and Pfizer, 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 which could adversely affect the sales of our products and our business and results of operations.

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 through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.*)

Table of Contents

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

As a result of adverse safety results involving ESA products that were observed beginning in 2006 in various studies exploring the use of ESAs in settings different from those outlined in the FDA-approved label, our ESA products have been the subject of ongoing review and scrutiny from regulatory authorities over the past several years. In the United States, we have engaged and continue to engage in discussions with the FDA regarding the benefit/risk profile of ESAs, which have resulted and could result in future changes to ESA labeling and usage. For example, on July 30, 2008, we received a complete response letter from the FDA to the revisions to the ESA labeling we proposed earlier in the year. The letter proposed, among other things, (i) the addition to the boxed warning of a statement that ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome of such therapy is cure, (ii) the addition of a statement in the DOSAGE and ADMINISTRATION section of the label that ESA therapy should not be initiated at Hb levels ³ 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 or other changes required by the FDA, 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, companion diagnostics or devices, as applicable, 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 also have ongoing PMC studies for our ESAs. 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 initiated Study 782 as part of our Aranesp® pharmacovigilance program, a randomized double-blind, placebo controlled, phase 3 non-inferiority study evaluating overall survival when comparing NSCLC patients on Aranesp® to patients receiving placebo. We are currently identifying clinical sites for Study 782 and have begun enrolling patients in the study. (See *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*) Further, as we previously disclosed, in 2008 the FDA and EMEA reviewed interim results from the PREPARE study in neo-adjuvant breast cancer, a PMC study, which were ultimately incorporated into the ESA labeling in both the United States and the EU. We have since received the final results from the PREPARE study, which were substantially consistent with the interim results, and provided that data to the FDA and EMEA. Although we cannot predict the results or the outcomes of ongoing clinical trials, or the extent to which regulatory authorities may require additional labeling changes as a result of these or other trials, we cannot exclude the possibility that adverse results from clinical trials could have a material adverse impact on the reimbursement, use and sales of our ESAs, which would have a material adverse effect on our business and results of operations.

In addition, regulatory authorities outside the United States have also reviewed and scrutinized the use of our ESA products. On March 5, 2008, we announced that the European Commission reached its decision to amend the product labeling for the class of ESAs, including Aranesp®, which set uniform target Hb range for all ESAs of 10 g/dL to 12 g/dL with guidance to avoid sustained Hb levels above 12 g/dL. Subsequently, on June 26, 2008, the EMEA recommended updating the product information for ESAs with a new warning for their use in cancer patients, which was approved by the European Commission in October 2008. The product information for all ESAs was updated to advise that in some clinical situations blood transfusions should be the preferred treatment for the management of anemia in patients with cancer and that the decision to administer ESAs should be based on a benefit-risk assessment with the participation of the individual patient, which should take into account the specific clinical context and that factors that should be considered in the assessment should include the type of tumor and its stage, the degree of anemia, life-expectancy, the environment in which the patient is being treated and patient preference. Since the October 2008 revision, we have experienced a reduction of Aranesp® sales in the supportive cancer care setting in the EU and, although we cannot predict what further impact the revised EU ESA product information could have on our business, the reimbursement, use and sales of Aranesp® in Europe could further be materially adversely affected, which would have a material adverse effect on our business and results of operations.

Moreover, we continue to receive results from meta-analyses or previously initiated clinical trials using ESAs. For example, on September 30, 2008, we announced that we had received a summary of preliminary results from the Cochrane Collaboration s independent meta-analysis of patient-level data from previously conducted, randomized, controlled, clinical studies evaluating ESAs in cancer patients which we submitted to the FDA and the EMEA. These results were also presented by the Cochrane Haematological Malignancies Group in December at the 2008 American Society of Hematology Congress, and a final manuscript was published in

47

Table of Contents

May 2009. This Cochrane meta-analysis of patient level data from previous studies corroborates prior analyses indicating that the use of ESAs may increase the risk of death in cancer patients. The studies in the analysis all predate the current label, which advises using the least amount of ESA necessary to avoid transfusion. The analyses on all cancer patients were based on 53 previously conducted studies involving 13,933 patients. None of these studies utilized ESAs according to current label guidance. The overall survival results corroborate an earlier review by the Cochrane Collaboration, published in 2006, which is included in the WARNINGS section of the current U.S. PI (HR: 1.08 [95% CI 0.99-1.18]). The ESA treatment arm had increased on-study deaths (HR: 1.17 [95% CI 1.06-1.30]) and decreased overall survival (HR: 1.06 [95% CI 1.00-1.12]) compared to controls. The analyses on patients undergoing chemotherapy, the cancer indication for which ESAs are approved, were based on 38 studies with 10,441 patients. None of these studies utilized ESAs according to current label guidance. The ESA treatment arm had increased on-study deaths (HR: 1.10 [95% CI 0.98-1.24]) and decreased overall survival (HR: 1.04 [95% CI 0.97-1.11]) compared to controls. While neither of these results is statistically significant, they do not exclude the potential for adverse outcomes when ESAs are prescribed according to the current label.

Further, on October 30, 2009, we announced the publication of results from TREAT, a large, randomized, double-blind, placebo-controlled, phase 3 pivotal study of 4,038 patients with CKD not on dialysis, moderate anemia and type-2 diabetes. Results of this study were previously reported on October 21, 2009 and top line results were released on August 25, 2009. The study, published on October 30, 2009 in the *New England Journal of Medicine* and presented at the 2009 annual meeting of the American Society of Nephrology, failed to meet its primary objectives of demonstrating a reduction in all-cause mortality, cardiovascular morbidity, including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia, or time to ESRD.

The primary endpoints of the study were a composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or ESRD. Among the components of the primary cardiovascular composite endpoint, the risk of stroke increased by almost two-fold in patients in the Aranesp® arm (101 patients [5.0%] versus 53 patients [2.6%]; HR 1.92, [95% CI: 1.38-2.68], p<0.001). Although stroke is a recognized risk with ESA therapy, and has been identified in warnings in U.S. labeling since 2001, the risk observed in TREAT is of higher magnitude than that seen in previous clinical trials in CKD patients not on dialysis. A post hoc analysis indicates that there were no significant differences between treatment arms in the number of patients with a reported diagnosis of cancer (139 in the Aranesp® group [6.9%] and 130 in the placebo group [6.4%] [p=0.53]) or of all-cause deaths in patients who developed cancer during the trial (53 in the Aranesp® group [2.6%] and 50 in the placebo group [2.5%]). Overall, 39 deaths were attributed to cancer in the 2012 patients in the Aranesp® group and 25 deaths were attributed to cancer in the 2026 patients in the placebo group (p=0.08 by the log-rank test). This analysis also showed an excess in overall mortality among patients in the Aranesp® arm with a history of cancer that requires further investigation. Specifically, among patients with a history of cancer at baseline, there were 60 deaths from any cause in the 188 patients assigned to Aranesp® and 37 deaths in the 160 patients assigned to placebo (p=0.13 by the log-rank test). In this subgroup, 14 of the 188 patients assigned to Aranesp® died from cancer, as compared with 1 of the 160 patients assigned to placebo (p=0.002 by the log-rank test).

TREAT was designed as a superiority study to demonstrate improved cardiovascular outcomes and is the largest study of ESA use in CKD patients to date. Patients enrolled in the study were randomized in a one-to-one ratio to receive either treatment with Aranesp® to a target Hb of 13 g/dL or placebo. Due to the increased risk of negative outcomes associated with low Hb levels, patients in the control arm whose Hb fell below 9 g/dL were given Aranesp® as a rescue medication until their Hb level reached 9 g/dL. Investigators were blinded to this intervention. TREAT was not designed to determine the appropriate Hb target in this patient population.

The TREAT results demonstrate that in many diabetic CKD patients not on dialysis with moderate anemia, the risk of treatment to a target Hb level of 13 g/dL will exceed the benefit of reducing the need for transfusions. We have shared this information with global regulatory authorities and anticipate that the TREAT results will be included in the labeling of our ESAs once analyses and discussions are complete. The FDA may also require that we update the proposed REMS for ESAs or possibly call an advisory committee meeting to discuss the results from the study. In addition, CMS may consider the results from the TREAT study at the upcoming March 2010 MEDCAC meeting and based on MEDCAC s recommendations, CMS could enact a national coverage determination (NCD) for ESAs used in CKD. All of these activities could have a material adverse impact on the coverage, reimbursement, and sales of our ESAs, which would have a material adverse effect on our business and results of operations.

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

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought or our existing products are safe and effective for use in humans in new indications sought. Additionally, we may be required to conduct additional trials as a condition of the approval of our label or as a

48

Table of Contents

result of perceived or existing safety concerns. The results of these clinical trials are used as the basis to obtain regulatory approval from regulatory authorities such as the FDA. Clinical trials are experiments conducted using our products or product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking or to support our existing label. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate or the extent of the safety concerns, post-marketing issues and/or exposure to patients and therefore, we may spend several years and incur substantial expense in completing certain trials. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, the rate of occurrence of the clinical trial events being studied, regulatory and institutional review board approval, availability of clinical study material and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals, associated delays in product candidates reaching the market and revisions to existing product labels. In addition, in order to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, India, East Asia and some Central and South American countries either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to identify and understand the unique regulatory environments of individual countries. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and regulatory diverse clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially adversely affected. Additional information on our clinical trials can be found on our website at www.amgen.com. (This website address is not intended to function as a hyperlink, and the information contained on our website is not intended to be a part of this filing.)

Patients may also suffer adverse medical events or side effects in the course of our, our licensees, partners or independent investigator s clinical trials of our products or product candidates that may delay the clinical program, require additional or longer trials to gain approval, prohibit regulatory approval of our product candidates or additional indications for our currently approved products, may render the product candidate commercially unfeasible or limit our ability to market existing products in certain therapeutic areas or at all. Delays may sometimes be substantial. For example, as a result of observing an increased frequency of cholecystitis (inflammation of the gall bladder) in patients treated with our late-stage product candidate motesanib, we delayed our phase 3 trial in first-line NSCLC, which was previously expected to begin in the fourth quarter of 2006, until the second half of 2007. Following initiation of the trial, in November 2008, we and our development partners announced that enrollment in this phase 3 trial had been temporarily suspended following a planned safety data review of 600 patients by the study s independent Data Monitoring Committee (DMC). The study s DMC also recommended that patients with squamous NSCLC immediately discontinue motesanib therapy but did not recommend discontinuation of motesanib therapy for patients with non-squamous NSCLC. In February 2009, the DMC recommended the trial resume enrollment of patients with non-squamous NSCLC, and, in June 2009, we reinitiated enrollment in this patient population following an FDA-approved revision to the study protocol. Clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on an out of date standard of medical care, limiting the utility and application of such trials. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval for new product candidates, product label extensions or maintenance of our current labels on this basis. Further, clinical trials conducted by others, including our licensees, partners or independent investigators, may result in unfavorable clinical trials results that may call into question the safety of our products in off-label or on label uses that may result in label restrictions and/or additional trials.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a pharmacovigilance program of our product or for approval of a new indication. For example, we are moving forward with Study 782 as part of our Aranesp® pharmacovigilance program. (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.*). The addition of this or other clinical trials to our pharmacovigilance program and any additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense and their outcomes could result in additional label restrictions or the loss of regulatory approval for an approved indication, each of which may have a material adverse effect on our business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our ESA products.

Table of Contents

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

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 through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.

Sales of all of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Our products are predominantly sold in the United States and we rely in large part on the reimbursement of our principal products through government programs such as Medicare and Medicaid. Further, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of healthcare costs of patients. Governments may regulate access to, prices or reimbursement levels of our products to control costs or to affect levels of use of our products. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to healthcare providers or patients in response to ongoing initiatives to reduce or reallocate healthcare expenditures. The 2008 U.S. general elections resulted in a renewed focus on healthcare issues in the United States. Healthcare reform is a top priority for President Obama and Congress is now considering several different bills which would make wide-ranging changes to the United States healthcare system in order to expand and to fund coverage to millions of uninsured Americans, to substantially reduce the rate of increase in the costs of government-sponsored healthcare programs and to improve the quality and portability of healthcare. Bills on healthcare reform have been passed by key Congressional committees and are expected to be considered by the full Congress before the end of 2009. If healthcare reform legislation in the United States is passed, it may include reducing the coverage and reimbursement of our products by Medicare, Medicaid and other government programs and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, each of which could have a significant impact on our business. Additionally, it is possible that applicable statutes, such as the Medicare Prescription Drug Improvement and Modernization Act, could be modified or new regulation introduced in 2009 or later that could also include a focus on reducing drug costs and change coverage and reimbursement methodologies for government healthcare programs. Further, a number of states, including California, Colorado, Connecticut, New York and Pennsylvania, are considering or have recently enacted legislative proposals that would significantly alter their healthcare systems. Although we cannot predict what final legislation on healthcare reform affecting coverage and reimbursement from third-party payers will include, any such legislation which changes and/or reduces the coverage and reimbursement of our products or the way our products are used or prescribed would cause our sales to decrease and our revenues to decline.

Adverse events or results from clinical trials or studies performed by us or by others or from the marketed use of our drugs may expand the safety information in the labeling for our approved products which could negatively impact worldwide reimbursement for our products. For example, on January 14, 2008, CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice. A more detailed discussion of the Decision Memorandum follows below. (See also *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Guidelines and recommendations published by various organizations can reduce the use of our products.*)

An increasing focus on cost containment by public and private insurers has resulted, and could result in the future, in lower reimbursement rates for our products. Most patients receiving our principal products for approved indications are covered by government and/or private payer healthcare programs. Medicare and Medicaid government healthcare programs payment policies for drugs and biologics are subject to various laws and regulations. Effective January 1, 2009 in the hospital outpatient setting, most of our products are reimbursed under a Medicare Part B payment methodology that reimburses each product at 104% of its average sales price (ASP) (sometimes referred to as ASP+4%). The rate of reimbursement in the hospital outpatient setting has been reduced twice since the inception of ASP-based payment in this setting, with reimbursement rates set at ASP+5% for 2008 and ASP+6% from 2006 to 2007. CMS has the regulatory authority to alter or maintain the Medicare payment rates for Part B drugs and biologicals in the future for the hospital outpatient setting. Effective January 1, 2005, in the physician office setting, Aranesp®, Neulasta® and NEUPOGEN® are reimbursed under a Medicare Part B payment methodology that reimburses each product at ASP+6%. A product s ASP is calculated and reported to CMS on a quarterly basis and may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP-based payment rate for Aranesp® that will be in effect for the third quarter of 2009 is based in part on certain historical sales and sales incentive data for Aranesp® from July 1, 2008 through June 30, 2009. ASP-based

50

Table of Contents

reimbursements of products under Medicare may, in some circumstances, be below the cost that medical providers paid for such products, which could adversely affect sales of our products.

We face certain risks relating to the calculation of ASP. ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. CMS further defines the statutory formula through regulations and other CMS guidance. However, the statute, regulations, and CMS guidance do not define specific methodologies for all aspects of the calculation of ASP. For example, in the Medicare Physician Fee Schedule Proposed Rule for 2010, CMS did not address a proposed methodology for treatment of bundled price concessions. Consequently, the current CMS guidance that manufacturers may make reasonable assumptions in their calculation of ASP, consistent with the general requirements and the intent of the Medicare statute, federal regulations and their customary business practices, finalized in the Medicare Physician Fee Schedule Final Rule for 2009 remains in effect. While we believe that any assumptions it employs in its ASP calculation methodology satisfy this reasonable assumption standard, such assumptions require us to apply judgment and are subject to CMS review, and CMS or other third parties may not agree with our assessment as to the reasonableness of our assumptions. If our reasonable assumptions are subsequently advised to have been incorrect, it could subject us to substantial fines and penalties which could have a material adverse effect on our results of operations. CMS stated that it will continue to monitor this issue and may provide more specific guidance in the future. Any such specific guidance could result in a change in our ASP calculation methodology, which, if significant, could have a material adverse effect on our results of operations.

In the dialysis setting, our products may also be subject to downward pressure on reimbursement rates. In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the ESRD Program of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement methodology is established by federal law and is monitored and implemented by CMS. Currently, the ESRD reimbursement rate for separately reimbursed dialysis drugs in both free-standing and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is set at ASP+6%. Although we cannot predict the payment levels of EPOGEN® in future quarters or the extent to which Medicare payments for dialysis drugs may be modified by future federal regulation or legislation, a decrease in the reimbursement rate for EPOGEN® may have a material adverse effect on our business and results of operations. Any changes to the ASP calculations directly affect the Medicare reimbursement for our products administered in the physician office setting, dialysis facility setting and hospital outpatient setting. These calculations are regularly reviewed for completeness and based on such review, we have revised our reported ASPs to reflect calculation changes both prospectively and retroactively. For example, partially as a result of our methodology changes, our ASP reimbursement rate for EPOGEN® was reduced for the third quarter of 2007. Since April 1, 2006, the Medicare reimbursement for ESAs administered to dialysis patients has been subject to an EMP, the Medicare payment review mechanism used by CMS to monitor EPOGEN® and Aranesp® utilization and hematocrit outcomes of dialysis patients. The EMP was revised, effective January 1, 2008, requiring a 50% reduction in Medicare reimbursement if a patient s Hb is above 13 g/dL for three or more consecutive months. In addition, the revised EMP reduced the monthly dosing limits to 400,000 international units (IUs) of EPOGEN®, from 500,000 IUs, and to 1,200 micrograms (mcgs) of Aranesp®, from 1,500 mcgs. The implementation of the revised EMP and ESA labeling changes led to a decline in EPOGEN® sales for the first quarter of 2008 compared to the first quarter of 2007 primarily due to a decline in both overall utilization and as well as average dosing per patient. While this dose decline subsequently stabilized in 2008, it may further fluctuate in the future, which could have a material adverse effect on sales of EPOGEN® and our business and results of operations.

On July 15, 2008, the 2008 MIPPA became law with a number of Medicare and Medicaid reforms including a broader payment bundle for dialysis services and drugs which will require CMS, beginning in 2011, to establish a bundled Medicare payment rate that includes dialysis services and drug/labs that are currently separately billed. On September 15, 2009, CMS released its proposed rule to implement the bundled prospective payment system for ESRD. Under the proposed rule, the bundled payment system will include dialysis services covered under the current composite rate, as well as drugs and biologicals furnished for treatment of ESRD that are currently billed separately, including ESAs, intravenous iron, and intravenous vitamin D, as well as oral equivalent forms of these intravenous drugs. In addition, the proposed rule also includes in the bundled payment oral drugs that are not equivalent to separately billable Part B drugs, specifically Sensipar® and phosphate binders. The public comment period ends on November 16, 2009. The bundled reimbursement rate will be phased in over a four year period in equal increments starting in 2011. Providers have the option to move to a full Medicare bundled payment system in 2011 or may elect to adopt certain components of the bundled payment system beginning in 2010. CMS will also be required to establish a quality incentive program that begins concurrently with bundling in 2011. Beginning in 2012, facilities would be subject to up to a 2% annual reduction in Medicare reimbursement for failure to meet or exceed CMS quality performance standards, including performance standards related to anemia management and dialysis adequacy. Bundling initiatives that have been implemented in other healthcare settings have occasionally resulted in lower utilization of services that had not previously been a part of the bundled payment. Although we cannot predict what the final rule on the bundled payment system for ESRD services will include, implementation of the rule as proposed could have a material adverse impact on the reimbursement, use and sales of EPOGEN®, Aranesp® or Sensipar®.

51

Table of Contents

Other initiatives reviewing the coverage or reimbursement of our products, including those related to safety, could result in less extensive coverage or lower reimbursement and could negatively affect sales of some of our marketed products. For example, on March 14, 2007, shortly after the March 9, 2007 FDA labeling changes for all ESAs, CMS announced that the agency had begun reviewing all Medicare policies related to the administration of ESAs in non-renal disease applications as part of a national coverage analysis (NCA) which is generally CMS first step toward developing a NCD. Generally, an NCD is a national policy statement granting, limiting or excluding Medicare coverage for a specific medical item or service. On May 14, 2007, CMS issued a proposed NCD that was open for public comment through June 13, 2007. On July 30, 2007, CMS issued its Decision Memorandum which was substantially altered from the proposed NCD. On January 14, 2008, CMS issued changes to its Medicare NCD Manual, adding the ESA Decision Memorandum, effective for claims with dates of service on and after July 30, 2007 with an implementation date of April 7, 2008. In the Decision Memorandum, CMS determined that ESA treatment was not reasonable and necessary for certain clinical conditions, and established Medicare coverage parameters for FDA-approved ESA use in oncology. We believe this restriction on reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations. Additionally, to our knowledge, although no private payers have fully implemented the Decision Memorandum to date, many private payers have implemented the portions of the restrictions included in the Decision Memorandum, most commonly the provisions that reflect the prescriber package insert. Further, we believe many healthcare providers have reduced ESA utilization for all of their patients regardless of insurance coverage. While we cannot fully predict the further impact of the Decision Memorandum on how, or under what circumstances, healthcare providers will prescribe or administer our ESAs, it had a significant impact to our business and we believe that it may continue to impact us in the future.

In addition, the FDA held a joint meeting of the Cardiovascular-Renal Drug Advisory Committee and the Drug Safety and Risk Management Advisory Committee on September 11, 2007 to evaluate safety data on ESA use in renal disease. On July 30, 2008, CMS issued a listing of potential topics for future NCDs as a step to increase transparency in the NCD process, which included as potential topics the use of ESAs in ESRD and CKD. Also included in the initial potential future NCD topic list is the category of thrombopoiesis stimulating agents (platelet growth factors), the category of drugs that includes Nplate®. Medicare currently does not have a NCD for the use of ESAs for anemia in patients who have CKD. CMS has not announced whether it will proceed to a NCD for ESAs in ESRD or CKD, or for thrombopoiesis stimulating agents and we cannot predict whether either ESAs in the renal setting or thrombopoiesis stimulating agents will be the subject of a future NCD; however, any final NCD for ESAs in the renal setting, which may include non-coverage and/or new dosing and treatment restrictions similar to those proposed in Decision Memorandum for treatment of anemia in oncology with ESAs, could negatively affect use, reduce reimbursement and coverage, negatively affect product sales of our ESA products and may have a material adverse effect on our business and results of operations. More recently, in August 2009, CMS announced it had scheduled a meeting for March 24, 2010 of the MEDCAC to review the available evidence on the use of ESAs to manage anemia in patients who have CKD. While a MEDCAC provides advice and recommendations to CMS about the adequacy of scientific evidence and votes on certain questions proposed by CMS, it functions as an independent advisory body and its advice and recommendations to CMS are advisory only.

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

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies patents. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or

52

Table of Contents

technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We are currently, and in the future may be, involved in patent litigation. However, a patent dispute or litigation may not discourage a potential violator from bringing the product that is alleged to infringe to market and we may be subject to competition during certain periods of litigation. Further, under the Hatch-Waxman Act, products approved by the FDA under a new drug application (NDA) may be the subject of patent litigation with generic competitors before the five year period of data exclusivity provided for under the Hatch-Waxman Act has expired and prior to the expiration of the patents listed for the product. For example, on July 25, 2008, we, NPS Pharmaceuticals and Brigham and Women s Hospital filed a lawsuit against Teva and Barr Barr for infringement of four Sensipar® patents. The lawsuit is based on ANDAs filed by Teva and Barr which seek approval to market generic versions of Sensipar® before expiration of the patents. This lawsuit is described in Note 10, *Contingencies* to the Consolidated Financial Statements in our 2008 Form 10-K and in Note 13, *Commitments and contingencies* to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities; be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab, romiplostim and our product candidate denosumab. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim, etanercept, cinacalcet, panitumumab and romiplostim products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), Enbrel® (etanercept), Sensipar®/Mimpara® (cinacalcet), Vectibix® (panitumumab) and Nplate® (romiplostim), respectively. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States.

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

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

We may not be able to develop commercial products.

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

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results
- the product candidate was not effective or more effective than currently available therapies in treating a specified condition or illness

the product candidate had harmful side effects in humans or animals

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

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

Table of Contents

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

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

we and certain of our licensees, partners or independent investigators may fail to effectively conduct clinical development or clinical manufacturing activities

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

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

Further, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF) and Glial Cell Lined-Derived Neurotrophic Factor (GDNF). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig s Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson s disease did not meet the primary study endpoint upon completion of nine months of the double-blind treatment phase of the study even though a small phase 1 pilot investigator-initiated open-label study over a three-year period appeared to result in improvements for advanced Parkinson s disease patients. Subsequently, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson s disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data in rhesus monkeys showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials of GDNF and, as a part of that decision and based on thorough scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.* ; *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, and we may be required to perform additional clinical trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market.* and *Before we commercialize and sell any of our product candidates or existing products for new indications, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.*)

Our business may be affected by government investigations or litigation.

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, our business operations, government requests for information and other legal proceedings that arise from time to time in the ordinary course of our business. Matters required to be disclosed by us are set forth in Note 10, *Contingencies* to the Consolidated Financial Statements in our 2008 Form 10-K and are updated as required in subsequently filed Form 10-Qs. Civil and criminal litigation is inherently unpredictable, and the outcome can result in excessive verdicts, fines, penalties and/or injunctive relief that affects how we operate our business. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our results of operations, financial position or cash flows.

We have received subpoenas from a number of government entities, including the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington, as well as the Attorneys General of New York and New Jersey. The federal subpoenas have been issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. 3486), while the Attorneys General subpoenas have been issued pursuant to state specific statutes relating to consumer fraud laws and state false claims acts. In general, the subpoenas request documents relating to the sales and marketing of our products, and our collection

54

Table of Contents

and dissemination of information reflecting clinical research as to the safety and efficacy of our ESAs. Based on representations in a U.S. government filing that became public on or about May 7, 2009 relating to the Massachusetts Qui Tam Action, we now believe the subpoenas we received from the U.S. Attorney s Offices for the Eastern District of New York and the Western District of Washington also relate to nine additional Qui Tam Actions which are purportedly pending against Amgen, including eight pending in the U.S. District Court for the Eastern District of New York and one pending in the U.S. District Court for the Western District of Washington. The U.S. government filing further alleges that a large number of states (17) are involved in the Qui Tam investigations, led by the State of New York. These investigations are represented to be joint criminal and civil investigations. On October 30, 2009 fourteen states and the District of Columbia s state attorneys general filed an amended complaint in intervention against Amgen alleging violations of the federal Anti-Kickback Statute and various state false claims acts. Additionally, the U.S. government may seek to intervene in the lawsuit filed by the states at any time. (See Note 10, *Contingencies* to the Consolidated Financial Statements in our 2008 Form 10-K, and Note 13, *Commitments and contingencies* to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.)

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

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

Our revenues and operating results may fluctuate from period to period for a number of reasons, some of which we cannot control. Even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections as some of our operating expenses are fixed in the short term and cannot be reduced within a short period of time to offset reductions in revenue. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Changes in credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities. Additionally, our stock price, like that of other biotechnology companies, is volatile. For example, in the fifty-two weeks prior to September 30, 2009, the trading price of our common stock has ranged from a high of $64.76 per share to a low of $44.96 per share.

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

- actual or anticipated clinical trial results of ours or our licensees, partners or independent investigators, including our clinical trials for denosumab and Aranesp®, in particular TREAT
- significant delay in approval of a product candidate, in particular Prolia™
- regulatory matters or actions, label changes or risk management activities, including a REMS
- adverse developments regarding the safety or efficacy of our products
- changes in the government s or private payers reimbursement policies, particularly for supportive cancer care products, or prescribing guidelines for our products
- proposed healthcare reform in the United States

current volatility and disruption of the financial markets

severity and duration of the current global economic downturn

development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy

inability to maintain regulatory approval of marketed products or manufacturing facilities

Table of Contents

- business development or licensing activities
- product development or other business announcements by us or our competitors
- lower than expected demand for our products or a change in product mix, either or both of which may result in less than optimal utilization of our manufacturing facilities and the potential to incur excess capacity or impairment charges
- changes in our product contracting and related pricing strategies
- changes in wholesaler buying patterns
- increased competition from new or existing products
- fluctuations in foreign currency exchange rates
- announcements in the scientific and research community
- intellectual property and legal matters
- actual or anticipated product supply constraints
- broader economic, industry and market trends unrelated to our performance

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

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

The capital and credit markets have recently experienced extreme volatility and disruption which, particularly during the latter part of 2008 and continuing into the first half 2009, has led to uncertainty and liquidity issues for both borrowers and investors. Historically, we have occasionally and opportunistically accessed the capital markets to support certain business activities including acquisitions, in-licensing activities, share repurchases and to refinance existing debt. In the event of adverse capital and credit market conditions, we may not be able to obtain capital market financing on similar favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Based on our current liquidity, we currently expect that we will repay the $1.0 billion of our 4.00% notes due on November 18, 2009 without incurring additional indebtedness.

We have some exposure to financial institutions which came under significant pressure during the recent credit crisis. For example, we have previously had 16 financial institutions participate in our revolving credit facility including a subsidiary of Lehman, which had a $178 million commitment. Lehman declared bankruptcy on September 15, 2008, and the subsidiary participant in our credit facility subsequently declared bankruptcy on October 5, 2008, and we thereafter removed them from our facility and correspondingly reduced the amount available for

borrowing under the facility. Additionally, the conversion feature of our 0.125% Convertible Notes due 2011 and our 0.375% Convertible Notes due 2013 are hedged pursuant to transactions entered into with two financial institutions. We have also entered into interest rate swap agreements for certain of our outstanding debt and routinely enter into foreign currency exchange contracts with financial institutions as counterparties. Deterioration in the financial condition of these counterparties could adversely impact the accounting for these transactions. Further, additional bankruptcies in the financial sector could limit our ability to replace these transactions on favorable terms, or at all, or to manage the risks inherent in our business which could have a material adverse effect on our business and results of operations.

Additionally, we maintain a significant portfolio of investments disclosed as cash equivalents and marketable securities on our Condensed Consolidated Balance Sheet. The value of our investments may be adversely affected by interest rate fluctuations, downgrades in credit ratings, illiquidity in the capital markets and other factors which may result in other than temporary declines in the value of our investments. Any of these events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on the sale of investments. We seek to mitigate these risks with the help of our investment advisors by generally investing in high quality securities and continuously monitoring the overall risk of our portfolio. To date in 2009, we have not realized any material impairments within our investment portfolio.

Table of Contents

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

Our operations and performance have been, and may continue to be, affected by economic conditions. Sales of our principal products are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. (See *Our sales depend on coverage and reimbursement from third-party payers, and to the extent that access to and reimbursement for our products is reduced through healthcare reform legislation, or reduced or eliminated through governmental actions or otherwise, it would negatively impact the utilization of our products.*) As a result of the current global economic downturn, our third-party payers may delay or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement from government programs, including Medicare and Medicaid, and/or private payer healthcare programs could have a material adverse affect on the sales of our products, our business and results of operations.

In addition, as a result of the economic downturn, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees. Job losses or other economic hardships may also result in reduced levels of coverage for some individuals, potentially resulting in lower levels of healthcare coverage for themselves or their families. These economic conditions may affect patients ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to changes in patient behavior and spending patterns that negatively affect usage of certain of our products, including delaying treatment, rationing prescription medications, leaving prescriptions unfilled, reducing the frequency of visits to healthcare facilities, utilizing alternative therapies and/or foregoing healthcare insurance coverage. In addition to its effects on consumers, the economic downturn may have also increased cost sensitivities among medical providers in the United States, such as oncology clinics, particularly in circumstances where providers may experience challenges in the collection of patient co-pays or be forced to absorb treatment costs as a result of coverage decisions or reimbursement terms. Collectively, we believe that these changes have resulted and may continue to result in reduced demand for our products, which could continue to adversely affect our business and results of operations. Any resulting decrease in demand for our products could also cause us to experience excess inventory write-offs and/or excess capacity or impairment charges at certain of our manufacturing facilities.

Additionally, we rely upon third-parties for certain parts of our business, including licensees and partners, wholesale distributors of our products, contract clinical trial providers, contract manufacturers and single third-party suppliers. Because of the recent volatility in the financial markets, there may be a disruption or delay in the performance or satisfaction of commitments to us by these third-parties which could have a material adverse affect on our business and results of operations. Current economic conditions may adversely affect the ability of our distributors, customers and suppliers to obtain liquidity required to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations. Further, economic conditions appear to have affected, and may continue to affect, the business practices of our wholesale distributors in a manner that has and may continue to contribute to lower sales of our products. For example, in the first quarter of 2009, certain of our wholesale distributors lowered their levels of inventory on hand, which we believe was done to reduce their carrying costs and improve their results of operations, and inventory levels remained relatively unchanged in the second quarter of 2009. In addition, although we monitor our distributors , customers and suppliers financial condition and their liquidity, in order to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could negatively impact our business and results of operations.

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

Certain raw materials necessary for commercial and clinical manufacturing and formulation of our products are provided by single-source unaffiliated third-party suppliers. Also, certain medical devices and components necessary for formulation, fill and finish of our products are provided by single-source unaffiliated third-party suppliers. Certain of these raw materials, medical devices and components are the proprietary products of these unaffiliated third-party suppliers and, in some cases, such proprietary products are specifically cited in our drug application with regulatory agencies so that they must be obtained from that specific sole source and could not be obtained from another supplier unless and until the regulatory agency approved such supplier.

We would be unable to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including:

- regulatory requirements or action by regulatory agencies or others

adverse financial developments at or affecting the supplier

Table of Contents

- unexpected demand for or shortage of raw materials, medical devices or components
- labor disputes or shortages, including the effects of a pandemic flu outbreak or otherwise
- failure to comply with our quality standards which results in quality and product failures, product contamination and/or recall

These events could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. For example, we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility without impact on our ability to supply these products. However, we may experience these or other shortages in the future resulting in delayed shipments, supply constraints and/or stock-outs of our products. Also, certain of the raw materials required in the commercial and clinical manufacturing and the formulation of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. Some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. We are investigating alternatives to certain biological sources and alternative manufacturing processes that do not require the use of certain biologically derived substances as such raw materials may be subject to contamination and/or recall.

A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances or other raw materials, which may be sourced from other countries, used in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially. Further, any disruptions or delays by us or by third-party suppliers or partners in converting to alternatives to certain biologically derived substances and alternative manufacturing processes or our ability to gain regulatory approval for the alternative materials and manufacturing processes could increase our associated costs or result in the recognition of an impairment in the carrying value of certain related assets, which could have a material and adverse affect on our results of operations.

Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.

We currently manufacture all of our principal products, and we plan to manufacture many of our product candidates. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. We currently manufacture our products and product candidates at our manufacturing facilities located in Thousand Oaks and Fremont, California; Boulder and Longmont, Colorado; West Greenwich, Rhode Island and Juncos, Puerto Rico. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, 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.*)

Additionally, we currently use third-party contract manufacturers to produce or assist in the production of ENBREL, Sensipar®/Mimpara® and Nplate® as well as our late-stage product candidate denosumab and plan to use contract manufacturers to produce a number of our other late-stage product candidates. Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers, which is impacted by many manufacturing variables including:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier
- capacity of our facilities and those of our contract manufacturers
- facility contamination by microorganisms or viruses

labor disputes or shortages, including the effects of a pandemic flu outbreak

compliance with regulatory requirements

changes in forecasts of future demand

Table of Contents

timing and actual number of production runs

updating of manufacturing specifications

production success rates and bulk drug yields

timing and outcome of product quality testing

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

We manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Although we have obtained regulatory approval for our marketed products, these products and our manufacturing processes and those of our third-party contract manufacturers must undergo a potentially lengthy FDA or other regulatory approval process and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build and license a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. In order to maintain supply, mitigate risks associated with the majority of our formulation, fill and finish operations being performed in a single facility and to adequately prepare to launch a number of our late-stage product candidates, in particular denosumab, we must successfully implement a number of manufacturing projects on schedule, including construction and the related qualification and licensure of a new formulation and filling facility at our Puerto Rico site, expansion and the related qualification and licensure of our existing bulk protein facilities at our Puerto Rico site, operate our facilities at appropriate production capacity over the next few years, optimize manufacturing asset utilization, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance.

If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us for any reason, we may experience delayed shipments, supply constraints, stock-outs and/or recalls of our products. If we are unable to manufacture, market and sell our products, our business and results of operations would be materially and adversely affected. Additionally, we distribute a substantial volume of our commercial products through a single distribution center in Louisville, Kentucky for the United States and another in Breda, the Netherlands for Europe and the rest of the world. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers and our third-party logistics providers.

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

We currently perform all of the formulation, fill and finish for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®, some formulation, fill and finish operations for ENBREL, and all of the bulk manufacturing for Aranesp®, Neulasta® and NEUPOGEN® at our manufacturing facility in Juncos, Puerto Rico. In addition, the Puerto Rico facility will be the primary facility producing Prolia™ drug product, upon FDA approval. Our global supply of these products is significantly dependent on the uninterrupted and efficient operation of this facility. A number of factors could adversely affect our operations, including:

power failures and/or other utility failures

breakdown, failure or substandard performance of equipment

improper installation or operation of equipment

Table of Contents

labor disputes or shortages, including the effects of a pandemic flu outbreak

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

natural or other disasters, including hurricanes

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

For example, this facility in Puerto Rico has experienced manufacturing component shortages and there was evidence of adverse trends in the microbial bioburden of the production environment that reduced the production output in the past. Although these experiences in Puerto Rico have not impacted our ability to supply product in the past, the same or other problems may result in our being unable to supply these products, which could adversely affect our product sales and operating results materially. Although we have obtained limited insurance to protect against certain business interruption losses, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all. The extent of the coverage of our insurance could limit our ability to mitigate for lost sales and such losses could adversely affect our product sales and operating results materially. In addition to the factors associated with the Puerto Rico facility, it is also subject to the same difficulties, disruptions or delays in manufacturing seen among our other manufacturing facilities. For example, the limited number of lots of ENBREL voluntarily recalled in September 2009 were manufactured at our Puerto Rico facility and we have made commitments to the FDA to address the causes behind the recall. Our failure to adequately address the FDA s expectations could lead to new inspections of the facility or regulatory actions. (See *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.*)

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

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

In addition to competition from the above-noted marketed products, a number of companies are developing products that could potentially compete with Aranesp® and/or EPOGEN® in the future. Affymax Inc. and Takeda are co-developing Hematide , an ESA for the treatment of anemia in renal patients. FibroGen is developing FG-2216 and FG-4592, orally active ESAs, for the treatment of anemia and for the treatment in anemia in CKD. Ratiopharm is developing a biosimilar ESA, EpoTheta, expected to launch in the EU in 2009. Additionally in December 2008, Merck & Company, Inc. (Merck) announced the formation of a new biotech division, Merck Bioventures, which is developing a pegylated ESA (MK-2578), which they have announced they expect to launch in 2012. Further, if our currently marketed products are approved for new uses, or if we sell new products, or our competitors get new or expanded indications, we may face new, additional competition that we do not face today. Further, adverse clinical developments for our current products could limit our ability to compete. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion diagnostics or devices, as applicable, 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.*)

ENBREL competes in certain circumstances with products marketed by J&J, Abbott Laboratories (Abbott), Biogen IDEC Inc., Barr, Genentech, Inc., Bristol-Myers Squibb Corporation, Novartis AG and Sanofi-Aventis and others, as well as the generic drug methotrexate. ENBREL now faces competition from J&J s Simponi™ (golimumab), which was approved by the FDA in April 2009 for the treatment of moderate-to-severe rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis, UCB/Nektar Therapeutic s Cimzia® (PEGylated anti-TNF alpha), which was approved by the FDA in May 2009 for the treatment of adult patients with moderately to severely active rheumatoid arthritis, and J&J s Stelara™ (ustekinumab), which was approved in September 2009 for the treatment of moderate or severe psoriasis. ENBREL may also face competition from other potential therapies being developed, including Roche s Actemra (tocilizumab), Abbott s ABT-874 and Pfizer s JAK-3 inhibitor CP-690,550. Additionally, in the first quarter of 2008 Abbott received approval from the FDA to market HUMIRA® as a treatment for

adult

Table of Contents

patients with moderate to severe chronic plaque psoriasis and HUMIRA® now competes with ENBREL in both the rheumatology and dermatology segments and ENBREL has experienced and continues to experience share loss to competitors.

Certain of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in R&D in areas where we have products or where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. As with Merck s recent announcement of its intention to expand into biotechnology and with Pfizer s merger with Wyeth, pharmaceutical companies and generic manufacturers that have traditionally developed and marketed small molecule pharmaceutical products are expanding into the biotechnology field with increasing frequency, and some of these companies are seeking to develop biosimilar products that may compete with our products. Large biopharmaceutical companies may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we do, and our products may compete against products that have lower prices, equivalent or superior performance, are easier to administer or that are otherwise competitive with our products. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. Business combinations among our competitors may also increase competition and the resources available to our competitors.

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

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

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In 2006, the EMEA developed and issued final regulatory guidelines related to the development and approval of biosimilar products. The final guidelines included clinical trial guidance for certain biosimilar products, including erythropoietins and G-CSFs, recommending that applicants seeking approval of such biosimilar products conduct pharmacodynamic, toxicological and clinical safety studies as well as a pharmacovigilance program. Some companies have received and other companies are seeking approval to market erythropoietin and G-CSF biosimilars in the EU, presenting additional competition for our products. (See *Our marketed products face substantial competition and other companies may discover, develop, acquire or commercialize products before or more successfully than we do.*) For example, following the expiration of the principal European patent relating to recombinant G-CSF on August 22, 2006, the European Commission issued marketing authorizations for the first G-CSF biosimilar products to Ratiopharm s Ratiograstim®/Filgrastim Ratiopharm®, CT Arzneimittel s Biograstim® and Teva s Tevagrastim® in September 2008. These companies launched their G-CSF biosimilar product in certain EU countries in 2008 and 2009 and are expected to launch in other European markets in 2009. In February 2009, the European Commission issued marketing authorizations for an additional G-CSF biosimilar product to Sandoz s Zarzio® and Hexal s Filgrastim Hexal®. Sandoz and Hexal launched their G-CSF biosimilar product in certain EU countries in 2009 and are expected to launch in other countries. There are currently two G-CSF biosimilars available in the EU marketed by different companies and these G-CSF biosimilar products compete with NEUPOGEN® and Neulasta®. We cannot predict to what extent the entry of biosimilar products or other competing products will impact future NEUPOGEN® or Neulasta® sales in the EU. Our inability to compete effectively could reduce sales, which could have a material adverse effect on our results of operations.

In the United States, there currently is no regulatory pathway for the abbreviated approval of BLAs for biosimilars, but legislation on biosimilars may be enacted in the coming months or years. Such biosimilars would reference biotechnology products already approved under the U.S. Public Health Service Act. Under current law, potential competitors may introduce biotechnology products in the United States only by filing a complete BLA. Before biosimilar products could enter the U.S. market through an abbreviated approval process, Congress would need to pass legislation to create a new approval pathway and the FDA may also then promulgate associated regulations or guidance. The Obama Administration has expressed support for the creation of such an approval pathway for biosimilars, including as a part of its broader healthcare reform effort, which the Administration has identified as one of its top priorities. In each of 2007, 2008 and 2009, a number of bills that would create a legal framework for approving biosimilars have been introduced by members of Congress. In July 2009, the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce passed, out of committee, bills that would provide twelve years of

61

Table of Contents

data exclusivity for innovative biological products. Data exclusivity protects the data in the innovator s regulatory application by, for a limited period of time, prohibiting others from gaining FDA approval based in part by relying on or referencing the innovator s data in their application to the FDA. The debate on biosimilars continues, however, with a number of members of Congress supporting a shorter period of data exclusivity. We cannot predict what the specific provisions of any final legislation might be or the timing of implementation of the pathway by the FDA. To the extent that an abbreviated biosimilar pathway is created through legislation in the United States, we would likely face greater competition and downward pressure on our product prices, sales and revenues, subject to our ability to enforce our patents. Further, biosimilar manufacturers with approved products in Europe may seek to quickly obtain U.S. approval if an abbreviated regulatory pathway for biosimilars is adopted.

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

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

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

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

Our marketing of ENBREL is dependent in part upon Pfizer (formerly Wyeth).

On October 15, 2009, Pfizer and Wyeth completed their merger and our relationship with Pfizer may be different than our prior relationship with Wyeth, including changes in management, strategy or otherwise. Under a co-promotion agreement, we and Pfizer market and sell ENBREL in the United States and Canada. A management committee comprised of an equal number of representatives from us and Pfizer is responsible for overseeing the marketing and sales of ENBREL including strategic planning, the approval of an annual marketing plan and the establishment of a brand team. The brand team, with equal representation from us and Pfizer, prepares and implements the annual marketing plan, which includes a minimum level of financial and sales personnel commitment from each party, and is responsible for all sales activities. If Pfizer fails to effectively deliver on its marketing commitments to us or if we and Pfizer fail to coordinate our efforts effectively, our sales of ENBREL may be materially adversely affected.

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

As a result of various regulatory and reimbursement developments that began in 2007 and, in particular those affecting our marketed ESA products, we recently completed a restructuring of our worldwide operations in order to improve our cost structure while continuing to make significant R&D investments and build the framework for our future growth. As part of these actions, we reduced staff, made changes to certain capital projects, closed certain production operations and abandoned leases primarily for certain R&D facilities that will not be used in our operations. We may not realize, in full or in part, all of the anticipated benefits and savings from these efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve or maintain all of the resulting savings or benefits to our business or other unforeseen events occur, our business and results of operations may be adversely affected.

Our business continues to face a variety of challenges. As a result, we may be forced to undertake further cost saving and/or restructuring initiatives in the future to achieve increased operating efficiencies, improve our competitive standing or results of operations and/or to address unfavorable economic conditions. The current economic climate has forced many U.S. companies to cut

62

Table of Contents

costs in order to maintain their competitive standing, including through restructurings and reorganizations. As a result of the global economic downturn, we have worked, and we continue to work, to increase cost efficiencies and to reduce discretionary expenditures, and in the event of further deterioration of the economy, we may also be required to consider further steps to improve our cost structure. Additionally, the anticipated benefits of our cost reduction initiatives are based on forecasts which could vary substantially from actual results, and we cannot provide assurance that any such cost saving initiatives will not have a material adverse effect on our business.

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

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

On July 31, 2009, the Kidney Disease: Improving Global Outcomes group (KDIGO) released its Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). The guideline includes detailed recommendations for the diagnosis and evaluation of the three components of CKD-MBD: abnormalities of serum markers (calcium, phosphorus, parathyroid hormone and vitamin D), vascular calcification and disorders of the bone, followed by recommendations for treatment. These recommendations could affect how healthcare providers prescribe Sensipar® for ESRD patients. KDIGO is a global non-profit foundation managed by the National Kidney Foundation (the NKF) that is dedicated to improving the care and outcomes of kidney disease patients worldwide through promoting coordination, collaboration, and integration of initiatives to develop and implement clinical practices guidelines. While it is uncertain just how the KDIGO guidelines will be viewed in the context of existing regional guidelines for managing mineral and bone disorders among those with kidney disease such as the NKF-KDOQI Guidelines in the United States and others in Europe, Canada, Australia and the United Kingdom, the impact of the new recommendations on clinical practice or the use of Sensipar® is not yet known.

On August 30, 2007, the NKF distributed to the nephrology community final updated Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines and clinical practice recommendations for anemia in CKD. The NKF s Anemia Work Group conducted an extensive review of results from 26 new and existing randomized controlled trials, comparing the risks and benefits of a range of Hb therapeutic targets in CKD patients. Based on this review, the NKF-KDOQI Anemia Work Group recommended in their 2007 Update to the NKF-KDOQI Anemia Management Guidelines that physicians target Hb in the range of 11 g/dL to 12 g/dL, and also stipulated that the target not be above 13 g/dL.

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

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

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

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our products, together with our general operations, are subject to extensive federal and state regulation in the United States and to extensive regulation in foreign countries. (See *Our current products and products in development cannot be sold if we do not gain or maintain regulatory approval of our products and, companion*

diagnostics or devices, as applicable, and we may be required to perform additional clinical

Table of Contents

trials or change the labeling of our products or conduct other potentially limiting or costly risk management activities if we or others identify side effects or safety concerns after our products are on the market. and *Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales; timing and availability of supply may also be affected by operation of our distribution and logistics centers and providers.*) While we have developed and instituted a corporate compliance program, we cannot guarantee you that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable foreign regulations and/or laws. If we or our agents fail to comply with any of these regulations and/or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Additionally, while we have implemented numerous risk mitigation measures, we cannot guarantee that we will be able to effectively mitigate all operational risks. If we fail to effectively mitigate all operational risks, our product supply may be materially adversely affected, which could have a material adverse effect on our product sales and results of operations.

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

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

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

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

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

Our operations are subject to the tax laws, regulations and administrative practices of the United States, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on the results of operations. For example, our effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. taxes have been provided because such earnings are intended to be invested indefinitely outside the United States. Substantial reform of U.S. tax law regarding tax on certain foreign profits could result in an increase in our effective tax rate, which could have a material adverse effect on our financial results. (See also *Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Financial Condition, Liquidity and Capital Resources Cash, cash equivalents and marketable securities* in Part I herein and Note 3, *Income taxes* to the Condensed Consolidated Financial Statements.)

Table of Contents

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

Repurchases under our stock repurchase programs reflect, in part, our confidence in the long-term value of our common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders. The manner of purchases, the amount we spend and the number of shares repurchased will vary based on a number of factors including the stock price, blackout periods in which we are restricted from repurchasing shares, and our credit rating and may include private block purchases as well as market transactions.

During the three months ended September 30, 2009, we had one outstanding stock repurchase program. A summary of our repurchase activity for the three months ended September 30, 2009 is as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced programs	Maximum $ value that may yet be purchased under the programs [1]
July 1 - July 31	-	$ -	-	$ 2,174,252,048
August 1 - August 31	7,133	62.16	-	2,174,252,048
September 1 - September 30	-	-	-	2,174,252,048
	7,133[2]	62.16	- [2]	

[1] In July 2007, the Board of Directors authorized us to repurchase up to an additional $5.0 billion of our common stock. As of September 30, 2009, $2.2 billion was available for stock repurchase under our stock repurchase program.

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

Item 6. EXHIBITS

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

Table of Contents

SIGNATURES

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

Amgen Inc.
(Registrant)

Date: November 6, 2009

By: /s/ Robert A. Bradway
Robert A. Bradway
Executive Vice President

and Chief Financial Officer

Table of Contents

AMGEN INC.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Restated Certificate of Incorporation (As Restated December 6, 2005). (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
3.2	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.3	Certificate of Correction of the Restated Certificate of Incorporation (As Corrected May 24, 2007). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
3.4	Certificate of Elimination of the Certificate of Designations of the Series A Junior Participating Preferred Stock (As Eliminated December 10, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
3.5	Certificate of Amendment of the Restated Certificate of Incorporation (As Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.6	Certificate of Correction of the Restated Certificate of Incorporation (As Amended May 11, 2009). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
3.7	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated October 6, 2009). (Filed as an exhibit to Form 8-K filed on October 7, 2009 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	Two Agreements of Resignation, Appointment and Acceptance in the same form as the previously filed Exhibit 4.3 hereto are omitted pursuant to instruction 2 to Item 601 of Regulation S-K. Each of these agreements, which are dated December 15, 2008, replaces the current trustee under the agreements listed as Exhibits 4.9 and 4.16, respectively, with Bank of New York Mellon. Amgen Inc. hereby agrees to furnish copies of these agreements to the Securities and Exchange Commission upon request.
4.5	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.6	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.7	Officer s Certificate, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, establishing a series of securities entitled 8 1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K filed on April 8, 1997 and incorporated herein by reference.)
4.8	Form of Liquid Yield Option Note due 2032. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.9	Indenture, dated as of March 1, 2002. (Filed as an exhibit to Form 8-K on March 1, 2002 and incorporated herein by reference.)
4.10	First Supplemental Indenture, dated March 2, 2005. (Filed as an exhibit to Form 8-K filed on March 4, 2005 and incorporated herein by reference.)
4.11	Indenture, dated as of August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)

Table of Contents

Exhibit No.	Description
4.12	Form of 4.00% Senior Note due 2009. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.13	Form of 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.14	Officers Certificate, dated November 18, 2004, including forms of the 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (Filed as an exhibit to Form 8-K on November 19, 2004 and incorporated herein by reference.)
4.15	Form of Zero Coupon Convertible Note due 2032. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.16	Indenture, dated as of May 6, 2005. (Filed as an exhibit to Form 8-K on May 6, 2005 and incorporated herein by reference.)
4.17	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.125% Convertible Senior Note due 2011). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.18	Indenture, dated as of February 17, 2006 and First Supplemental Indenture, dated as of June 8, 2006 (including form of 0.375% Convertible Senior Note due 2013). (Filed as exhibit to Form 10-Q for the quarter ended June 30, 2006 on August 9, 2006 and incorporated herein by reference.)
4.19	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.20	Officers Certificate of Amgen Inc. dated as of May 30, 2007, including forms of the Company s Senior Floating Rate Notes due 2008, 5.85% Senior Notes due 2017 and 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.21	Registration Rights Agreement, dated as of May 30, 2007, among Amgen Inc. and Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Barclays Capital Inc., Credit Suisse Securities (USA) LLC, Goldman, Sachs & Co., Citigroup Global Markets Inc., J.P. Morgan Securities Inc. and Lehman Brothers Inc. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
10.1+	Amgen Inc. 2009 Equity Incentive Plan. (Filed as Appendix A to Amgen Inc. s Proxy Statement on March 26, 2009 and incorporated herein by reference.)
10.2+*	Form of Stock Option Agreement and Restricted Stock Unit Agreement for the Amgen Inc. 2009 Equity Incentive Plan.
10.3+*	Amgen Inc. 2009 Performance Award Program (As Amended and Restated on October 5, 2009).
10.4+*	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program.
10.5+	Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.6+	Form of Grant of Non-Qualified Stock Option Agreement and Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (Filed as an exhibit to Form 8-K on May 8, 2009 and incorporated herein by reference.)
10.7+	Amgen Supplemental Retirement Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.8+	Amendment and Restatement of the Amgen Change of Control Severance Plan (As Amended December 9, 2008). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.9+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.10+	Amgen Inc. Executive Nonqualified Retirement Plan. (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)
10.11+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2009.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2008 on November 7, 2008 and incorporated herein by reference.)

Table of Contents

Exhibit No.	Description
10.12+	2002 Special Severance Pay Plan for Amgen Employees. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.)
10.13	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between Amgen and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.14	Shareholders Agreement, dated May 11, 1984, among Amgen, Kirin Brewery Company, Limited and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.15	Amendment No. 1 dated March 19, 1985, Amendment No. 2 dated July 29, 1985 (effective July 1, 1985), and Amendment No. 3, dated December 19, 1985, to the Shareholders Agreement dated May 11, 1984. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.16	Amendment No. 4 dated October 16, 1986 (effective July 1, 1986), Amendment No. 5 dated December 6, 1986 (effective July 1, 1986), Amendment No. 6 dated June 1, 1987, Amendment No. 7 dated July 17, 1987 (effective April 1, 1987), Amendment No. 8 dated May 28, 1993 (effective November 13, 1990), Amendment No. 9 dated December 9, 1994 (effective June 14, 1994), Amendment No. 10 effective March 1, 1996, and Amendment No. 11 effective March 20, 2000 to the Shareholders Agreement, dated May 11, 1984. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.17	Amendment No. 12 to the Shareholders Agreement, dated January 31, 2001. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2005 on August 8, 2005 and incorporated herein by reference.)
10.18	Amendment No. 13 to the Shareholders Agreement, dated June 28, 2007 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.19	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985, between Kirin-Amgen, Inc. and Ortho Pharmaceutical Corporation. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.)
10.20	Research, Development Technology Disclosure and License Agreement: PPO, dated January 20, 1986, by and between Kirin Brewery Co., Ltd. and Amgen Inc. (Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement on March 11, 1986 and incorporated herein by reference.)
10.21	Amendment Agreement, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.)
10.22	Assignment and License Agreement, dated October 16, 1986 (effective July 1, 1986, between Amgen and Kirin-Amgen, Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.23	G-CSF United States License Agreement, dated June 1, 1987 (effective July 1, 1986), Amendment No. 1, dated October 20, 1988, and Amendment No. 2, dated October 17, 1991 (effective November 13, 1990), between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)
10.24	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen and Amgen, Amendment No. 1 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated June 1, 1987, Amendment No. 2 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated March 15, 1998, Amendment No. 3 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated October 20, 1988, and Amendment No. 4 to Kirin-Amgen, Inc. / Amgen G-CSF European License Agreement, dated December 29, 1989, between Kirin-Amgen, Inc. and Amgen Inc. (Filed as exhibits to Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.)

Table of Contents

Exhibit No.	Description
10.25	Agreement Regarding Governance and Commercial Matters, dated December 16, 2001, by and among American Home Products Corporation, American Cyanamid Company and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.26	Amended and Restated Promotion Agreement, dated as of December 16, 2001, by and among Immunex Corporation, American Home Products Corporation and Amgen Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Amendment No. 1 to Form S-4 Registration Statement on March 22, 2002 and incorporated herein by reference.)
10.27	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as of July 8, 2003, among Wyeth, Amgen Inc. and Immunex Corporation, (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.)
10.28	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective as of April 20, 2004, by and among Wyeth, Amgen Inc. and Immunex Corporation. (Filed as an exhibit to Form S-4/A on June 29, 2004 and incorporated herein by reference.)
10.29	Amendment No. 3 to Amended and Restated Promotion Agreement, effective as of January 1, 2005, by and among Wyeth, Amgen Inc. and Immunex Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.)
10.30	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International related to the 0.125% Convertible Senior Notes Due 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.31	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International related to 0.375% Convertible Senior Notes Due 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.32	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co. International Limited related to the 0.125% Convertible Senior Notes Due 2011 Notes. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.33	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.34	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Merrill Lynch International for warrants expiring in 2013. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.35	Confirmation of OTC Warrant Transaction, dated February 14, 2006, to Amgen Inc. from Morgan Stanley & Co. International Limited for warrants maturing in 2011. (Filed as an exhibit to Form 10-K for the year ended December 31, 2005 on March 10, 2006 and incorporated herein by reference.)
10.36	Purchase Agreement, dated May 24, 2007, among Amgen Inc., Morgan Stanley & Co. Incorporated, Merrill Lynch, Pierce, Fenner & Smith Incorporated and the Initial Purchasers Names in Schedule A thereof. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.37	Purchase Agreement, dated May 29, 2007, between Amgen Inc. and Merrill Lynch International. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2007 on August 9, 2007 and incorporated herein by reference.)
10.38	Collaboration Agreement, dated July 11, 2007, between Amgen Inc. and Daiichi Sankyo Company (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2007 on November 9, 2007 and incorporated herein by reference.)
10.39	Credit Agreement, dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 8-K filed on November 2, 2007 and incorporated herein by reference.)

Table of Contents

Exhibit

No.	Description
10.40	Amendment No. 1, dated May 18, 2009, to the Credit Agreement dated November 2, 2007, among Amgen Inc., with Citicorp USA, Inc., as administrative agent, Barclays Bank PLC, as syndication agent, Citigroup Global Markets, Inc. and Barclays Capital, as joint lead arrangers and joint book runners, and the other banks party thereto. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 10, 2009 and incorporated herein by reference.)
10.41	Multi-product License Agreement with Respect to Japan between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.42	License Agreement for motesanib diphosphate between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.43	Supply Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.44	Sale and Purchase Agreement between Amgen Inc. and Takeda Pharmaceutical Company Limited dated February 1, 2008 (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2008 on May 12, 2008 and incorporated herein by reference.)
10.45	Variable Term Accelerated Share Repurchase Transaction dated May 28, 2008, between Amgen Inc. and Lehman Brothers, Inc. acting as Agent Lehman Brothers OTC Derivatives Inc., acting as Principal. (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2009 on August 8, 2008 and incorporated herein by reference.)
10.46	Underwriting Agreement, dated May 20, 2008, among Amgen Inc. with Goldman, Sachs & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representatives of the underwriters. (Filed as an exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
10.47	Underwriting Agreement, dated January 13, 2009, by and among the Company and Goldman, Sachs & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters named therein. (Filed as an exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
10.48	Master Services Agreement, dated October 22, 2008, between Amgen Inc. and International Business Machines Corporation (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.49	Integrated Facilities Management Services Agreement, dated February 4, 2009 between Amgen Inc. and Jones Lang LaSalle Americas, Inc. (with certain confidential information deleted therefrom). (Filed as an exhibit to Form 10-K for the year ended December 31, 2008 on February 27, 2009 and incorporated herein by reference.)
10.50*	Collaboration Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly-owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom).
10.51*	Expansion Agreement dated July 27, 2009 between Amgen Inc. and Glaxo Group Limited, a wholly-owned subsidiary of GlaxoSmithKline plc (with certain confidential information deleted therefrom).
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
101.INS**	XBLR Instance Document.
101.SCH**	XBLR Taxonomy Extension Schema Document.
101.CAL**	XBLR Taxonomy Calculation Linkbase Document.
101.LAB**	XBLR Taxonomy Label Linkbase Document.
101.PRE**	XBLR Taxonomy Presentation Linkbase Document.

Table of Contents

(* = filed herewith)

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

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