AMGEN INC
Form 10-Q
November 09, 2006

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, 2006

OR

o **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 o

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

Large accelerated filer x Accelerated filer o Non-accelerated filer o

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

As of October 20, 2006, the registrant had 1,166,518,456 shares of common stock, $0.0001 par value, outstanding.

AMGEN INC.

INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

The information in this report for the three and nine months ended September 30, 2006 and 2005 is unaudited but includes all adjustments (consisting only of normal recurring accruals, unless otherwise indicated) which Amgen Inc., including its subsidiaries (referred to as Amgen, we, our and us), considers necessary for a fair presentation of the results of operations for those periods.

The Condensed Consolidated Financial Statements should be read in conjunction with our Consolidated Financial Statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2005.

Interim results are not necessarily indicative of results for the full fiscal year.

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In millions, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues:				
Product sales	$ 3,503	$ 3,047	$ 10,121	$ 8,854
Other revenues	109	107	312	305
Total revenues	3,612	3,154	10,433	9,159
Operating expenses:				
Cost of sales (excludes amortization of acquired intangible assets presented below)	489	552	1,534	1,571
Research and development	872	562	2,315	1,653
Selling, general and administrative	807	656	2,336	1,879
Write-off of acquired in-process research and development			1,101	
Amortization of acquired intangible assets	122	86	296	260
Legal settlements				49
Total operating expenses	2,290	1,856	7,582	5,412
Operating income	1,322	1,298	2,851	3,747
Interest and other income and (expense), net	39	14	140	10
Income before income taxes	1,361	1,312	2,991	3,757
Provision for income taxes	259	345	874	907
Net income	$ 1,102	$ 967	$ 2,117	$ 2,850
Earnings per share:				
Basic	$ 0.94	$ 0.78	$ 1.79	$ 2.30
Diluted	$ 0.94	$ 0.77	$ 1.77	$ 2.26
Shares used in calculation of earnings per share:				
Basic	1,167	1,233	1,181	1,238
Diluted	1,178	1,249	1,194	1,263

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In millions, except per share data)

(Unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,291	$ 1,840
Marketable securities	4,490	3,415
Trade receivables, net	2,124	1,769
Inventories	1,711	1,258
Other current assets	1,040	953
Total current assets	10,656	9,235
Property, plant, and equipment, net	5,673	5,038
Intangible assets, net	3,819	3,742
Goodwill	11,206	10,495
Other assets	1,232	787
	$ 32,586	$ 29,297
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 569	$ 596
Accrued liabilities	3,946	2,999
Convertible notes	1,773	
Total current liabilities	6,288	3,595
Deferred tax liabilities	1,079	1,163
Convertible notes	5,000	1,759
Other long-term debt	2,233	2,198
Other non-current liabilities	265	131
Contingencies		
Stockholders equity:		
Preferred stock; $0.0001 par value; 5 shares authorized; none issued or outstanding		
Common stock and additional paid-in capital; $0.0001 par value; 2,750 shares authorized; outstanding - 1,166 shares in 2006 and 1,224 shares in 2005	23,500	23,561
Accumulated deficit	(5,789)	(3,132)
Accumulated other comprehensive income	10	22
Total stockholders equity	17,721	20,451
	$ 32,586	$ 29,297

See accompanying notes.

AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In millions)

(Unaudited)

	Nine Months Ended September 30,	
	2006	**2005**
Cash flows from operating activities:		
Net income	$ 2,117	$ 2,850
Write-off of acquired in-process research and development	1,101	
Depreciation and amortization	763	623
Stock-based compensation expense	330	76
Tax benefits related to employee stock-based compensation	52	247
Other items, net	(177)	(73)
Cash provided by (used in) changes in operating assets and liabilities:		
Trade receivables, net	(355)	(203)
Inventories	(378)	(171)
Other assets	(26)	2
Accounts payable	(11)	(10)
Accrued income taxes	326	194
Other accrued liabilities	405	247
Net cash provided by operating activities	4,147	3,782
Cash flows from investing activities:		
Cash paid for acquisition of Abgenix, Inc., net of cash acquired	(1,888)	
Purchases of property, plant, and equipment	(834)	(602)
Proceeds from maturities of marketable securities	858	519
Proceeds from sales of marketable securities	2,052	9,373
Purchases of marketable securities	(3,981)	(9,028)
Other	(136)	41
Net cash (used in) provided by investing activities	(3,929)	303
Cash flows from financing activities:		
Repurchases of common stock (see Notes 5 and 6)	(1,755)	(3,194)
Repayment of debt assumed in Abgenix, Inc. acquisition	(653)	
Repayment of convertible notes		(1,175)
Proceeds from issuance of convertible notes and related transactions, net (see Note 5)	440	
Proceeds from issuance of warrants (see Note 5)	774	
Net proceeds from issuance of common stock upon the exercise of employee stock options and in connection with an employee stock purchase plan	367	924
Other	60	(15)
Net cash used in financing activities	(767)	(3,460)
(Decrease) increase in cash and cash equivalents	(549)	625
Cash and cash equivalents at beginning of period	1,840	1,526
Cash and cash equivalents at end of period	$ 1,291	$ 2,151

See accompanying notes.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2006

(Unaudited)

1. Summary of significant accounting policies

Business

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

Basis of presentation

The financial information for the three and nine months ended September 30, 2006 and 2005 is unaudited but includes all adjustments (consisting only of normal recurring accruals, unless otherwise indicated), which we consider necessary for a fair presentation of the results of operations for those periods. Interim results are not necessarily indicative of results for the full fiscal year.

Principles of consolidation

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

Inventories

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

	September 30, 2006	December 31, 2005
Raw materials	$ 200	$ 145
Work in process	1,054	758
Finished goods	457	355
	$ 1,711	$ 1,258

Intangible assets and goodwill

Intangible assets are recorded at cost, less accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives ranging from 5 to 15 years on a straight-line basis (weighted-average amortization period of 14 years at September 30, 2006). Intangible assets primarily consist of acquired product technology rights of $3,177 million, net of accumulated amortization of $1,238 million, which relate to the identifiable intangible assets acquired in connection with the Immunex Corporation (Immunex) acquisition in July 2002. Amortization of acquired product technology rights is included in Amortization of acquired intangible assets in the accompanying Condensed Consolidated Statements of Operations. Intangible assets also include technology used in research and development with alternative future uses, specifically the XenoMouse® technology acquired in the Abgenix, Inc. (Abgenix) acquisition (see Note 8, Abgenix, Inc. acquisition). Amortization of the XenoMouse® technology is included in Research and development in the accompanying Condensed Consolidated Statements of Operations. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. During the three months ended September 30, 2006, we recognized a $49 million impairment charge related to a non-Enbrel® related intangible asset previously acquired in the Immunex acquisition, which is included in Amortization of acquired intangible assets in the accompanying Condensed Consolidated Statements of Operations.

Intangible assets subject to amortization	**Weighted-average amortization period**	**September 30, 2006**	**December 31, 2005**
Acquired product technology rights:			
Developed product technology	15 years	$ 2,877	$ 3,077
Core technology	15 years	1,348	1,348
Trade name	15 years	190	190
XenoMouse® technology	5 years	320	
Other intangible assets	11 years	454	335
		5,189	4,950
Less accumulated amortization		(1,370)	(1,208)
		$ 3,819	$ 3,742

Goodwill principally relates to the acquisition of Immunex. The increase over the balance at December 31, 2005 is due to the goodwill associated with the Abgenix acquisition on April 1, 2006 (see Note 8, Abgenix, Inc. acquisition) net of the decrease primarily due to tax benefits realized upon exercise of Immunex related stock options during the nine months ended September 30, 2006. We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

6

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.

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

Research and development costs

Research and development (R&D) costs, which are expensed as incurred, are primarily comprised of costs for: salaries and benefits associated with R&D personnel, overhead and occupancy, clinical trial and related clinical manufacturing, including contract services and other outside costs, process development, quality assurance, information systems and amortization of technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners.

Acquired in-process research and development

The fair value of acquired in-process R&D (IPR&D) projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are immediately expensed. In the second quarter of 2006 we expensed $1,101 million of acquired IPR&D related to the Abgenix acquisition (see Note 8, Abgenix, Inc. acquisition). Acquired IPR&D is considered part of total R&D expense.

Earnings per share

Basic earnings per share (EPS) is based upon the weighted-average number of common shares outstanding. Diluted EPS is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding principally include stock options under our employee stock option plans and potential issuances of stock under

7

our other equity incentive plans and under the assumed conversion of our 2032 Modified Convertible Notes, 2011 Convertible Notes, 2013 Convertible Notes and under the assumed exercise of our warrants using the treasury stock method (collectively Dilutive Securities). Potential common shares also include common stock to be issued upon conversion of our 2032 Convertible Notes under the if-converted method. For further information regarding our convertible notes and warrants (see Note 5, 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,	
	2006	2005	2006	2005
Income (Numerator):				
Net income for basic EPS	$ 1,102	$ 967	$ 2,117	$ 2,850
Adjustment for interest expense on 2032 Convertible Notes, net of tax				6
Net income for diluted EPS, after assumed conversion	$ 1,102	$ 967	$ 2,117	$ 2,856
Shares (Denominator):				
Weighted-average shares for basic EPS	1,167	1,233	1,181	1,238
Effect of Dilutive Securities	11	15	13	12
Effect of 2032 Convertible Notes, after assumed conversion		1		13
Weighted-average shares for diluted EPS	1,178	1,249	1,194	1,263
Basic earnings per share	$ 0.94	$ 0.78	$ 1.79	$ 2.30
Diluted earnings per share	$ 0.94	$ 0.77	$ 1.77	$ 2.26

Recent Accounting Pronouncements

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, using the modified-prospective-transition method. See Note 2, Employee stock-based payments for further discussion regarding this accounting pronouncement.

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. (FIN) 48, Accounting for Uncertainty in Income Taxes, effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of tax positions taken or expected to be taken in a tax return. We are currently evaluating the provisions in FIN 48, but have not yet determined its expected impact on us. We plan to adopt this new standard on January 1, 2007.

8

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation.

2. Employee stock-based payments

We have employee compensation plans under which various types of stock-based instruments are granted. These instruments, as more fully described below, principally include stock options, restricted stock (including restricted stock units) and performance units. As of September 30, 2006, these plans provide for future grants and/or issuances of up to approximately 43 million shares of common stock to our employees. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

Prior to January 1, 2006, we accounted for our employee stock-based compensation under the recognition and measurement principles of Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees, and related interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation. Under the recognition principles of APB No. 25, compensation expense related to restricted stock and performance units was recognized in our financial statements. However, APB No. 25 generally did not require the recognition of compensation expense for our stock options because the exercise price of these instruments was generally equal to the market value of the underlying common stock on the date of grant, and the related number of shares granted were fixed at that point in time.

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), Share-Based Payment. In addition to recognizing compensation expense related to restricted stock and performance units, SFAS No. 123(R) also requires us to recognize compensation expense related to the estimated fair value of stock options. We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under that transition method, compensation expense recognized subsequent to adoption includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the values estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair values estimated in accordance with the provisions of SFAS No. 123(R). Consistent with the modified-prospective-transition method, our results of operations for prior periods have not been adjusted to reflect the adoption of SFAS 123(R).

As a result of recognizing compensation expense for stock options pursuant to the provisions of SFAS No. 123(R), our income before income taxes for the three and nine months ended September 30, 2006, was $50 million and $179 million lower, respectively, and our net income was $36 million and $124 million lower, respectively, than if we had continued to account for stock options under APB No. 25. In addition, both basic and diluted earnings per share for the three and nine months ended September 30, 2006 were $0.03 and $0.11 lower, respectively, than if we had continued to account for stock options under APB No. 25.

9

The following table reflects the components of stock-based compensation expense recognized in our Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2006 and 2005 (amounts in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Stock options	$ 50	$	$ 179	$
Restricted stock	17	13	42	35
Performance units	34	13	109	41
Total stock-based compensation expense, pre-tax	101	26	330	76
Tax benefit from stock-based compensation expense	(29)	(8)	(103)	(23)
Total stock-based compensation expense, net of tax	$ 72	$ 18	$ 227	$ 53

The above table does not reflect any stock option compensation for the three and nine months ended September 30, 2005 as we generally did not record stock option expense under APB No. 25, as previously discussed. The following table illustrates the effect on net income and earnings per share for the three and nine months ended September 30, 2005 if we had applied the fair value recognition provisions to our stock options as provided under SFAS No. 123 (in millions, except per share information):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net income	$ 967	$ 2,850
Stock-based compensation, net of tax	(46)	(183)
Pro forma net income	$ 921	$ 2,667
Earnings per share:		
Basic	$ 0.78	$ 2.30
Impact of stock option expense	(0.03)	(0.15)
Basic - pro forma	$ 0.75	$ 2.15
Diluted	$ 0.77	$ 2.26
Impact of stock option expense	(0.03)	(0.14)
Diluted - pro forma	$ 0.74	$ 2.12

For purposes of this pro forma disclosure, the fair values of stock options were estimated using the Black-Scholes option valuation model and amortized to expense over the options vesting periods.

10

Employee stock option and restricted stock grants

Several of our equity-based compensation plans provide for grants of stock options to employees. The option exercise price is set at the closing price of our common stock on the date of grant, and the related number of shares granted is fixed at that point in time. These plans also provide for grants of restricted stock. Grants of these equity instruments generally vest/have restrictions which lapse over a three to five year period. In addition, stock option awards expire seven years from the date of grant. Eligible employees generally receive a grant of stock options and/or restricted stock annually with the number of shares and type of instrument generally determined by the employee s salary grade and performance level. In addition, certain management and professional level employees typically receive a stock option grant upon commencement of employment. These stock-based plans provide for accelerated vesting/lapse of restrictions if there is a change in control as defined in the plans.

We use the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. The expected volatility reflects the consideration of the implied volatility in our publicly traded instruments during the period the option is granted. We believe implied volatility in these instruments is more indicative of expected future volatility than the historical volatility in the price of our common stock. Upon the adoption of SFAS No. 123(R) the expected life of the option is estimated using the simplified method as provided in Securities and Exchange Commission Staff Accounting Bulletin No. 107. Under this method, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. Prior to adoption of SFAS No. 123(R), we used historical data to estimate the expected life of the options. The risk-free interest rates for periods within the expected life of the option are based on the U.S. Treasury yield curve in effect during the period the options were granted. Upon adoption of SFAS No. 123(R), we began using historical data to estimate forfeiture rates applied to the gross amount of expense determined using the option valuation model. Prior to adoption of SFAS No. 123(R), we recognized forfeitures as they occurred. There was no material impact upon adoption of SFAS No. 123(R) between these methods of accounting for forfeitures. The weighted-average assumptions used to estimate the fair value of the stock options using the Black-Scholes option valuation model were as follows for the nine months ended September 30:

	2006	2005
Fair value of common stock	$ 71.05	$ 61.40
Fair value of stock options granted	$ 21.84	$ 17.93
Risk-free interest rate	4.8%	4.0%
Expected life (in years)	4.8	5.1
Expected volatility	24.3%	23.6%
Expected dividend yield	0%	0%

11

Stock option information with respect to our stock-based compensation plans during the nine months ended September 30, 2006 is as follows (options and dollars in millions, except per share amounts):

	Options	Weighted-average exercise price	Weighted-average remaining contractual life (Yrs)	Aggregate intrinsic value
Balance unexercised at December 31, 2005	67.6	$ 56.03		
Granted	10.3	$ 71.04		
Assumed from Abgenix (including 1.4 vested)	1.9	$ 33.79		
Exercised	(8.0)	$ 36.80		
Forfeited/expired	(2.2)	$ 56.66		
Balance unexercised at September 30, 2006	69.6	$ 59.86	3.9	$ 837
Vested or expected to vest at September 30, 2006	66.0	$ 59.55	3.9	$ 812
Exercisable at September 30, 2006	41.8	$ 56.83	3.0	$ 619

The total intrinsic value of options exercised during the three and nine months ended September 30, 2006 was $43 million and $260 million, respectively.

The fair values of shares of restricted stock are determined based on the closing price of Amgen common stock on the grant dates. Information regarding our restricted stock during the nine months ended September 30, 2006 is as follows (shares in millions):

Nonvested shares	Shares	Weighted-average grant date fair value
Nonvested at December 31, 2005	2.8	$ 58.90
Granted	2.3	$ 71.56
Vested	(0.8)	$ 59.23
Forfeited	(0.2)	$ 62.25
Nonvested at September 30, 2006	4.1	$ 65.68

The total fair value of shares of restricted stock that vested during the three and nine months ended September 30, 2006 was $4 million and $55 million, respectively.

As of September 30, 2006, there was $563 million of total unrecognized compensation cost related to nonvested awards of both stock options and shares of restricted stock. That cost is expected to be recognized over a weighted-average period of 1.5 years. For stock option and restricted stock awards subject to graded vesting that were issued after January 1, 2006, we recognize compensation cost on a straight-line basis over the service period for the entire award.

12

Performance award program

Beginning in 2004, certain management-level employees receive annual grants of performance units. A performance unit gives the recipient the right to receive common stock that is contingent upon achievement of specified pre-established performance goals over a three-year performance period. The performance goals are based upon both Amgen s standalone performance and its performance compared to other benchmark companies, in each case with respect to compound annual growth rates for revenue and earnings per share, as defined in the program. Performance units are assigned a unit value based on the fair market value of Amgen common stock on the grant date. The ultimate level of attainment of performance goals is determined at the end of the performance period and expressed as a percentage (within a range of 0% to 225%). This percentage is multiplied by the number of performance units initially granted and by the initial value per unit to determine the aggregate dollar value of the award. The aggregate dollar value is then divided by the average closing price of Amgen common stock during a specified period following the performance period to determine the number of shares of common stock payable to the recipient.

Because the first performance period for these instruments ends on December 31, 2006, no performance units have yet vested and no common stock has been issued to any recipient. As of September 30, 2006, there was $165 million of total estimated unrecognized compensation cost related to performance units that is expected to be recognized over a weighted-average period of 1.0 year.

Under APB No. 25, the estimated amounts owed for grants of performance units were classified in stockholders equity, but upon adoption of SFAS 123(R), these amounts are classified as liabilities. Accordingly, on January 1, 2006, a reclassification was made from stockholders equity to liabilities (current and non-current) totaling $104 million.

3. Related party transactions

We own a 50% interest in Kirin-Amgen, Inc. (KA), a corporation formed in 1984 with Kirin Brewery Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. We account for our interest in KA under the equity method and include our share of KA s profits or losses in Selling, general and administrative in the Condensed Consolidated Statements of Operations. During the three and nine months ended September 30, 2006, our share of KA s profits were $15 million and $43 million, respectively. During the three and nine months ended September 30, 2005, our share of KA s profits were $13 million and $43 million, respectively. At September 30, 2006 and December 31, 2005, the carrying value of our equity method investment in KA was $223 million and $180 million, respectively, and is included in non-current other assets in the accompanying 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 erythropoietin, granulocyte colony-stimulating factor (G-CSF), darbepoetin alfa and pegfilgrastim are pursuant to exclusive licenses from KA, which we currently

13

market certain of these products under the brand names EPOGEN®, NEUPOGEN®, Aranesp® and Neulasta®, respectively. KA receives royalty income from us, as well as Kirin, Johnson & Johnson and F. Hoffmann-La Roche Ltd under separate product license agreements for certain geographic areas outside of the United States. During the three and nine months ended September 30, 2006, KA earned royalties from us of $82 million and $238 million, respectively. During the three and nine months ended September 30, 2005, KA earned royalties from us of $72 million and $215 million, respectively. These amounts are included in Cost of sales (excludes amortization of acquired intangible assets) in the Condensed Consolidated Statements of Operations.

KA s expenses primarily consist of costs related to R&D activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and nine months ended September 30, 2006, we earned revenues from KA of $35 million and $98 million, respectively, for certain R&D activities performed on KA s behalf. During the three and nine months ended September 30, 2005, we earned revenues from KA of $34 million and $81 million, respectively. These amounts are included in Other revenues in the accompanying Condensed Consolidated Statements of Operations.

4. Income taxes

The tax rates for the three and nine months ended September 30, 2006 are different from the statutory rate primarily as a result of the favorable resolution of prior year federal and state audits and indefinitely invested earnings of our foreign operations. In addition, the tax rate for the nine months ended September 30, 2006 was impacted by the write-off of non-deductible acquired IPR&D in connection with the acquisition of Abgenix. The favorable impact of prior year tax matters recognized in the three months ended September 30, 2006 amounted to approximately $60 million, or $0.05 per diluted share. 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.

Our income tax returns are routinely audited by the Internal Revenue Service and various state and foreign tax authorities. Significant disputes can arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions because of differing interpretations of tax laws and regulations. We periodically evaluate our exposures associated with tax filing positions. While we believe our positions comply with applicable laws, we record liabilities based upon estimates of the ultimate outcomes of these matters.

14

5. Financing arrangements

The following table reflects the carrying value of our long-term borrowings under our various financing arrangements as of September 30, 2006 and December 31, 2005 (in millions):

	September 30, 2006	December 31, 2005
0.125% convertible notes due 2011 (2011 Convertible Notes)	$ 2,500	$
0.375% convertible notes due 2013 (2013 Convertible Notes)	2,500	
Zero coupon 30 year modified convertible notes due in 2032 (2032 Modified Convertible Notes)	1,753	1,739
4.85% notes due 2014 (2014 Notes)	1,000	1,000
4.00% notes due 2009 (2009 Notes)	999	998
6.5% debt securities due 2007 (2007 Notes)	100	100
8.1% notes due 2097 (Century Notes)	100	100
Non-interest bearing note due 2013 (acquired Abgenix note)	34	
Zero coupon 30 year convertible notes due in 2032 (2032 Convertible Notes)	20	20
Total borrowings	9,006	3,957
Less current portion	1,773	
Total non-current debt	$ 7,233	$ 3,957

2011 and 2013 Convertible Notes

In February 2006, we issued $2.5 billion principal amount of convertible notes due in 2011 (the 2011 Convertible Notes) and $2.5 billion principal amount of convertible notes due in 2013 (the 2013 Convertible Notes) in a private placement. 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 2011 Convertible Notes and the 2013 Convertible Notes may be convertible based on an initial conversion rate of 12.5247 shares and 12.5814 shares, respectively, per $1,000 principal amount of notes (which represents an initial conversion price of approximately $79.84 and $79.48 per share, respectively). These conversion rates will be adjusted if we make specified types of distributions or enter into certain other transactions in respect to our common stock. The 2011 Convertible Notes and the 2013 Convertible Notes may only be converted: 1) during any calendar quarter beginning after June 30, 2006 if the closing price of our common stock exceeds 130% of the respective conversion price per share during a defined period at the end of the previous quarter, 2) if we make specified distributions to holders of our common stock or specified corporate transactions occur, or 3) one month prior to the respective maturity date. Upon conversion, a holder would receive the conversion value equal to the conversion rate multiplied by the volume weighted average price of our common stock during a specified period following the conversion date. The conversion value will be paid in: 1) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and 2) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock, cash or a combination of common stock and cash, at our option (the excess conversion value). In addition, upon a change in control, as defined, the holders may require us to purchase for cash all or a portion of their notes for 100% of the principal amount of the notes plus accrued and unpaid interest, if any. Debt issuance costs totaled approximately $88 million and are being amortized over the life of the notes.

15

In connection with issuance of these convertible notes, a total of $3.0 billion of our common stock was repurchased under our stock repurchase program. Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we purchased convertible note hedges in private transactions. The convertible note hedges allow us to receive shares of our common stock and/or cash from the counterparties to the transactions equal to the amounts of common stock and/or cash related to the excess conversion value that we would issue and/or pay to the holders of the 2011 Convertible Notes and the 2013 Convertible Notes upon conversion. These transactions will terminate at the earlier of the maturity dates of the related notes or the first day none of the related notes remain outstanding due to conversion or otherwise. The cost of the convertible note hedges aggregated approximately $1.5 billion. The net proceeds received from the issuance of the 2011 and 2013 Convertible Notes, the repurchase of our common stock and the purchase of the convertible note hedges was $440 million.

Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we sold warrants to acquire shares of our common stock at an exercise price of $107.90 per share in a private placement. Pursuant to these transactions, warrants for approximately 31.3 million shares of our common stock may be settled in May 2011 and warrants for approximately 31.5 million shares of our common stock may be settled in May 2013 (the settlement dates). If the average price of our common stock during a defined period ending on or about the respective settlement dates exceeds the exercise price of the warrants, the warrants will be settled, at our option, in cash or shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately $774 million.

Because we have the choice of settling the convertible note hedges and warrants in cash or shares of our stock, and these contracts meet all of the applicable criteria for equity classification as outlined in EITF No. 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock, the cost of the convertible note hedges and net proceeds from the sale of the warrants are classified in stockholders equity. In addition, because both of these contracts are classified in stockholders equity and are indexed to our own common stock, they are not accounted for as derivatives under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities.

2032 Convertible Notes and 2032 Modified Convertible Notes

In 2002, we issued zero coupon, 30 year convertible notes (2032 Convertible Notes). In March 2005, certain of these notes were repurchased at their then accreted value, for cash, in accordance with their terms. Subsequently, in March and August, of 2005, we modified the terms of substantially all of the remaining 2032 Convertible Notes (2032 Modified Convertible Notes). Pursuant to the terms of the 2032 Convertible Notes and 2032 Modified Convertible Notes, as amended, holders of such notes may require us to purchase on specific dates all or some of their notes generally for cash. The next specified date when holders can require us to repurchase some or all of their notes at their then accreted value is on March 1, 2007. Accordingly, the notes are classified as current liabilities in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2006.

16

6. Stockholders equity

Stock repurchase program

A summary of activity under our stock repurchase program for the nine months ended September 30, 2006 and 2005 is as follows (in millions):

	2006		2005	
	Shares	Dollars	Shares	Dollars
First quarter	46.7	$ 3,374	26.8	$ 1,675
Second quarter	13.0	876	12.1	750
Third quarter	7.3	505	9.5	769
Total	67.0	$ 4,755	48.4	$ 3,194

As of September 30, 2006, $1,784 million was available for stock repurchases under our stock repurchase program authorized by the Board of Directors in December 2005. The manner of purchases, the amount we spend, and the number of shares repurchased will vary based on a variety of factors including the stock price and blackout periods in which we are restricted from repurchasing shares, and may include private block purchases as well as market transactions.

Stockholder Rights Agreement

On July 11, 2006, Amgen s board of directors voted unanimously to terminate our preferred stock rights plan. The plan was originally scheduled to expire on December 12, 2010, but was amended to accelerate the expiration date to July 31, 2006.

Comprehensive income

Our comprehensive income includes net income, unrealized gains and losses on our available-for-sale securities and foreign currency forward and option contracts, which qualify and are designated as cash flow hedges, and foreign currency translation adjustments. During the three and nine months ended September 30, 2006, total comprehensive income was $1,128 million and $2,105 million, respectively. During the three and nine months ended September 30, 2005, total comprehensive income was $953 million and $2,864 million, respectively.

7. Contingencies

In the ordinary course of business, we are involved in various legal proceedings and other matters, including those that are tax-related. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

17

8. Abgenix, Inc. acquisition

On April 1, 2006, we acquired all of the outstanding common stock of Abgenix, a company that specialized in the discovery, development and manufacture of human therapeutic antibodies. We paid cash consideration of $22.50 per share in this transaction that was accounted for as a business combination. Additionally, we issued 1.9 million stock options in exchange for Abgenix stock options assumed in the acquisition, 1.4 million of which were vested at the date of acquisition. The purchase price was as follows (in millions):

Cash paid for shares	$	2,103
Other, principally fair value of vested options assumed	92	
Total	$	2,195

The purchase price was preliminarily allocated to all of the tangible and intangible assets acquired, including acquired IPR&D, and liabilities assumed based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair values of assets and liabilities acquired was assigned to goodwill. The following table summarizes the estimated fair values at the acquisition date (in millions):

In-process research and development	$ 1,101
Identifiable intangible asset	320
Cash	252
Deferred tax assets, net	258
Property, plant and equipment	220
Other assets	76
Liabilities, principally convertible debt	(762)
Goodwill	730
Net assets acquired	$ 2,195

The preliminary estimated fair values of IPR&D, the identifiable intangible asset and property, plant and equipment were determined with the assistance of an independent valuation firm. The estimated fair values of the intangible assets were determined based upon discounted after-tax cash flows adjusted for the probabilities of successful development and commercialization. The final determination of the purchase price allocation is expected to be completed as soon as practicable. The identifiable intangible asset consists of Abgenix s XenoMouse® technology that has alternative future uses in our R&D activities and will be amortized over its 5-year estimated useful life. The amount preliminarily allocated to IPR&D was immediately expensed in the Condensed

18

Consolidated Statement of Operations during the three months ended June 30, 2006 (see Note 1, Summary of significant accounting policies Acquired in process-research and development). The results of Abgenix s operations have been included in the Condensed Consolidated Financial Statements commencing April 1, 2006. Pro forma results of operations for the three and nine months ended September 30, 2006 assuming the acquisition of Abgenix had taken place at the beginning of 2006 would not differ significantly from actual reported results.

9. Subsequent events

On October 24, 2006, we completed the acquisition of Avidia, Inc. (Avidia). Avidia was a privately held biopharmaceutical company focused on the discovery and development of a new class of human therapeutic known as Avimer proteins. Pursuant to the merger agreement, we paid in cash approximately $290 million, net of cash acquired and our existing equity stake in Avidia, and may be subject to pay additional amounts upon the achievement of certain future events. Avidia s operations will be included in our Condensed Consolidated Financial Statements commencing October 24, 2006. In connection with the acquisition, which will be accounted for as a business combination, we will expense the estimated fair value of Avidia s acquired IPR&D during the three months ended December 31, 2006. The purchase price allocation has not been finalized at this time.

19

Item 2. **Management s Discussion and Analysis of Financial Condition and Results of Operations**

Forward looking statements

This report and other documents we file with the Securities and Exchange Commission (SEC) contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, 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, sh continue, variations of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Item 1A. Risk Factors. We have based our forward looking statements on our management s beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward looking statements. Reference is made in particular to forward looking statements regarding product sales, reimbursement, expenses, earnings per share (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 (MD&A) is intended to assist the reader in understanding Amgen s business. MD&A is provided as a supplement to, and should be read in conjunction with, our Condensed Consolidated Financial Statements and accompanying notes included in this Quarterly Report on Form 10-Q and our Consolidated Financial Statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2005.

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 inflammation, nephrology and supportive cancer care. Also, in the third quarter 2006 we received U.S. Food and Drug Administration (FDA) approval and launched Vectibix (panitumumab), our first cancer therapeutic, however we do not expect product sales of Vectibix to be significant for the remainder of 2006. For the three and nine months ended September 30, 2006, total revenues were $3.6 billion and $10.4 billion, respectively. For the three and nine months ended September 30, 2006, net income was $1.1 billion and $2.1 billion, respectively, or

20

$0.94 per share and $1.77 per share, respectively. The results of our operations for the nine months ended September 30, 2006 reflect the $1.1 billion write-off of acquired in-process research and development (IPR&D) costs associated with the Abgenix, Inc. (Abgenix) acquisition recorded in the three months ended June 30, 2006. As of September 30, 2006, cash, cash equivalents and marketable securities were $5.8 billion, of which approximately $4.7 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. The total debt outstanding was $9.0 billion as of September 30, 2006.

Our principal products include Aranesp® (darbepoetin alfa), EPOGEN® (Epoetin alfa), Neulasta® (pegfilgrastim)/NEUPOGEN® (Filgrastim) and Enbrel® (etanercept). ENBREL is marketed under a co-promotion agreement with Wyeth in the United States and Canada. For additional information about our principal products, their approved indications and where they are marketed, see Item 1. Business Principal products in Part I of our Annual Report on Form 10-K for the year ended December 31, 2005. For the three and nine months ended September 30, 2006 and 2005, product sales represented 97% of total revenues. Over the last several years, our product sales growth has been primarily driven by sales of Aranesp®, ENBREL and Neulasta®, which have benefited primarily from share gains and/or segment growth. We expect these products to continue to drive year over year sales growth for the remainder of 2006. However, we expect that maintaining or increasing share will be more of a challenge than in previous years as we operate in an increasingly competitive environment and we have experienced share loss with ENBREL. Going forward, we will focus on growing our segments, including increasing our penetration in the therapeutic areas in which our products are used, while also continuing to focus on segment share. Our principal products have attained significant sales levels, and for certain of our products, in a relatively short period of time. As a result, although we have experienced significant year over year sales growth, in the near term we expect our product sales growth to be lower than that achieved in the past several years. Furthermore, various factors can influence sales growth on a sequential quarterly basis, such as wholesaler and end-user inventory management practices and fluctuations in foreign exchange rates. For example, wholesaler buying patterns in advance of holidays may result in higher sequential quarterly sales growth for the quarters ending June 30 and December 31.

Most patients receiving our principal products for approved indications are covered by either government or private payer health care programs. Beginning in the first quarter of 2006, ENBREL and Sensipar® (cinacalcet HCl) also became eligible for coverage from the U.S. Government under Medicare Program Part D. Therefore, our principal product sales and sales growth are and will be affected by government and private payer reimbursement policies. While we believe that our product sales for 2005 and the nine months ended September 30, 2006 have not been nor, for the remainder of 2006, are expected to be significantly impacted by the reimbursement changes resulting from the Medicare Prescription Drug Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) enacted in 2005, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. See Reimbursement below for further information.

International product sales represented approximately 18% of total product sales for each of the three and nine month periods ended September 30, 2006 and 2005. Our international product sales consist principally of European sales of Aranesp® and Neulasta®/NEUPOGEN® and were favorably impacted by approximately $16 million for the three months ended September 30, 2006 from foreign currency changes but were unfavorably impacted by approximately $39 million (see Results of Operations discussion below) for the nine months ended September 30, 2006. However, both the positive and negative impacts that movements in foreign exchange rates have on our

21

international product sales are mitigated, in part, by the natural, opposite impact these exchange rate movements have on our international operating expenses and as a result of our foreign currency hedging activities. Our hedging activities seek to offset the impact, both positive and negative, that foreign exchange rate changes may have on our net income. As such, the impact to our net results of operations from changes in foreign currency exchange rates has been largely mitigated.

For the three and nine months ended September 30, 2006 and 2005, operating income was as follows:

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Operating Income	$ 1,322	$ 1,298	2%	$ 2,851	$ 3,747	(24)%

Operating income as a percentage of product sales was 38% and 43% for the three months ended September 30, 2006 and 2005, respectively. The decline in operating income as a percentage of product sales for the three months ended September 30, 2006 compared to the three months ended September 30, 2005 primarily reflects the increase in research and development (R&D) expenses. For the nine months ended September 30, 2006 and 2005, operating income as a percentage of product sales was 28% and 42%, respectively. The decline in operating income for the nine month period ended September 30, 2006 largely reflects the write-off of acquired IPR&D of $1.1 billion in connection with the Abgenix acquisition.

We focus our R&D on novel human therapeutics for the treatment of grievous illness. We have expanded and will need to continue to significantly expand our clinical development resources, including human capital, to manage and execute increasingly larger and more complex clinical trials. Throughout 2006, we have experienced a significant increase in the number, size, duration and complexity of our clinical trials, in particular with respect to denosumab, our late-stage investigational product for osteoporosis and metastatic bone cancer. For example, testing denosumab in the osteoporosis setting requires large clinical trials, substantial time and resources to recruit patients and significant expense to execute. We have begun nine mega-site trials (involving 200 or more sites) in 2006 to support denosumab and our other late-stage programs. (Two additional mega-site trials associated with our late-stage program for AMG 706, specifically the Phase 3 studies in first line breast cancer and first line non-small cell lung cancer, previously expected to begin in the fourth quarter of 2006 have been delayed subject to additional Phase 1 and 2 data and protocol modifications as a result of observing an increased frequency of cholecystitis, inflammation of the gall bladder, in patients treated with this late stage product candidate. See Item 1A. Risk Factors in Part II herein Before we commercialize and sell any of our product candidates, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.) To execute our clinical trial programs, we need to continue to accelerate the growth of our development organization and associated R&D support organizations, implement new management structures and approaches and increase dependence on third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we have and will continue to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some Central and South American countries utilizing third-party contract clinical trial providers.

22

On April 1, 2006, we paid shareholders of Abgenix $22.50 in cash per common share for a total value of approximately $2.1 billion to acquire all of the shares and assumed Abgenix s outstanding debt with a fair value of approximately $686 million. Abgenix specialized in the discovery, development and manufacture of human therapeutic antibodies and was our co-development partner for Vectibix (panitumumab). The results of Abgenix s operations have been included in our Condensed Consolidated Financial Statements commencing April 1, 2006.

On October 24, 2006, we completed our acquisition of Avidia, Inc (Avidia). Pursuant to the merger agreement, we paid in cash approximately $290 million, net of cash acquired and our existing equity stake in Avidia, and may be subject to pay additional amounts upon the achievement of certain future events. Avidia focused on the discovery and development of a new class of human therapeutic known as Avimer proteins. The transaction provides Amgen with Avidia s lead product candidate, an inhibitor of interleukin 6 (IL-6) for the treatment of inflammation and autoimmune diseases, which is in Phase 1 clinical trials.

There are many economic and industry-wide factors that affect our business generally and uniquely, including, among others, those relating to broad reimbursement changes, increased complexity and cost of R&D, an increasingly competitive environment for our currently marketed products and product candidates including the expected introduction of biosimilar products in Europe, 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, 2005 and Item 1A. Risk Factors in Part II herein for further information on these economic and industry-wide factors and their impact on our business.

Reimbursement

In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the End Stage Renal Disease Program (ESRD Program) of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement rate is established by federal law and is monitored and implemented by the Centers for Medicare & Medicaid Services (CMS). Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer health care programs. Since January 1, 2006, ENBREL and Sensipar® are eligible for coverage from the U.S. government under Medicare Part D. Although both ENBREL and Sensipar® have received broad formulary placement in 2006 and 2007, Part D formulary placements are made by individual Part D plan sponsors with oversight by CMS and are subject to revision in the future. Generally, in Europe and other countries outside the U.S., 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. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to health care providers in response to ongoing initiatives to reduce health care expenditures. Therefore, 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.

23

The MMA was enacted into law in December 2003 and implemented January 1, 2005. Changes resulting from the MMA, which lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. We believe that our product sales for 2005 and the nine months ended September 30, 2006, have not been nor, for the remainder of 2006, are expected to be significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS oncology demonstration project (the 2005 Demonstration Project) on sales of our products used in supportive cancer care, especially Aranesp®. Furthermore, we believe this was also, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2005 Demonstration Project, which provided financial incentives to physicians for collecting and reporting oncology patient survey data, expired on December 31, 2005. In November 2005, CMS announced a new demonstration project (the 2006 Demonstration Project) that uses different criteria for how patients with cancer are evaluated and treated and that is targeted at approximately half of the funding originally targeted for the 2005 Demonstration Project. The final rule for the 2006 Medicare Physician Fee Schedule Payment Final Rule issued in November 2005 reduced payments for physician services in 2006 by approximately 4.4% on average, although legislation eliminated this reduction for 2006. The Medicare Physician Fee Schedule Payment Final Rule for 2007 issued in November 2006 and effective January 1, 2007, reduces payments for physician services in 2007 by approximately 5.0% on average. It is uncertain whether legislation will eliminate this reduction in 2007 or if payments for physician services will again be reduced after 2007. Because we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, we cannot estimate the full impact of the MMA on our business. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future.

The main components of the MMA that affect our currently marketed products are as follows:

- Through 2004, the Average Wholesale Price (AWP) mechanism was the basis of Medicare Part B payment for covered outpatient drugs and biologics. Since January 1, 2005, in the physician clinic setting, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its average sales price (ASP) (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product s ASP is calculated on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP for Aranesp® that will be in effect for the first quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp® from October 1, 2005 through September 30, 2006. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The ASPs for Aranesp® and Neulasta® trended downward during the first three quarters of 2005, began to stabilize during the fourth quarter of 2005 and have remained relatively stable in 2006.

- Since August 1, 2006, physicians in the physician clinic setting have had the choice between purchasing and billing for specific drugs under the ASP+6% system or obtaining those drugs from vendors selected by CMS under the competitive acquisition program (CAP). We believe CAP is unlikely to have a significant impact on our business.

- Medicare s hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized AWP as the basis for reimbursement in 2005. CMS 2005 reimbursement rate, as in 2003 and 2004, continued the application of an equitable adjustment such that the 2005 Aranesp® reimbursement rate was based on the AWP of PROCRIT®. For 2005, the reimbursement rate for Aranesp® was 83% of the AWP for PROCRIT®, down from 88% of the AWP for PROCRIT® in 2004, with a dose conversion ratio of 330 U PROCRIT® to 1 mcg Aranesp®, the same ratio as 2004. Effective January 1, 2006, the OPPS system changed from an AWP based reimbursement system to a system based on ASP. This change affects Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. The OPPS rule for 2006 based reimbursement for non-pass through products such as Aranesp®, Neulasta® and NEUPOGEN® on ASP+6% using the same payment amounts as used in the physician clinic setting and did not apply an equitable adjustment to tie the reimbursement rate for Aranesp® to PROCRIT® using a dose conversion ratio. In the OPPS final rule for 2007, CMS states that it will not apply an equitable adjustment to the payment rate for Aranesp® in 2007, and will, as in 2006, reimburse hospitals for the costs associated with administering specific Medicare-covered outpatient drugs and biologicals (such as Aranesp®, Neulasta® and NEUPOGEN®) at ASP+6%. CMS noted in the 2005 final rule and has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp® in future years.

- Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 changed from the previous rate in 2004 of $10 per 1,000 Units to $9.76 per 1,000 Units, in 2005, a rate based upon an average acquisition cost for 2003 determined by the Office of the Inspector General (OIG) and adjusted for price inflation based on the Producer Price Index for pharmaceutical products. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed outside the dialysis composite rate (including EPOGEN®) and the 2005 reimbursement rates for such drugs was added to the composite rate that dialysis providers receive for dialysis treatment. Pursuant to the Medicare Physician Fee Schedule Payment Final Rule for 2006, effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both freestanding and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting and calculated quarterly in the same manner as described above for our products under the Medicare Part B payment methodology. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Based upon the 2006 final rule, the reimbursement rate for EPOGEN® for 2006 decreased from the reimbursement rate in 2005. In the Medical Physician Fee Schedule Payment Final Rule for 2007, CMS continues the 2006 payment mechanism of ASP+6% for EPOGEN® and other separately reimbursed dialysis drugs in both freestanding and hospital-based dialysis centers. Because we cannot accurately predict the extent to which this reimbursement will impact how, or under what circumstances, healthcare providers will prescribe or administer EPOGEN®, we cannot estimate the full impact of the ASP+6% reimbursement rate on our EPOGEN® product sales. However, we believe that it has not been and is unlikely to be significant in 2006 and 2007.

25

The Medicare Physician Fee Schedule Proposed Rule for 2007 addressed several new topics regarding the ASP payment methodology. In the proposed rule, CMS invited comment on the need for future guidance concerning the methodology for calculating the ASP of drugs sold under market-based pricing arrangements, including bundled arrangements, described by CMS as, for example, when a purchaser s price for one or more drugs is contingent upon the purchase of other drugs or items. In the Medicare Physician Fee Schedule Final Rule for 2007, CMS chose not to establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. However, CMS stated that it may provide more specific guidance in the future through rulemaking, program instruction or other guidance. Any changes to the ASP calculation could adversely affect the Medicare reimbursement for our products administered in the physician office and the hospital outpatient setting.

In addition, on November 9, 2005, CMS released a revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. The new policy, Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (Claims Monitoring Policy), became effective April 1, 2006 and was further revised effective October 1, 2006. The revised Claims Monitoring Policy provides that if a patient s hemoglobin is greater than 13 grams per deciliter, providers are instructed to reduce the patient s EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient s EPOGEN® and Aranesp® dose and there is no medical documentation to support the higher dosage, reimbursement will be reduced to the level it would have been had the provider reduced dosage by twenty-five percent. Based on our preliminary evaluation, we do not expect the Claims Monitoring Policy to have a negative impact on EPOGEN® and Aranesp® sales and given the importance of EPOGEN® and Aranesp® for maintaining the quality of care for dialysis patients, we do not expect that the policy will substantially impact the utilization of EPOGEN® and Aranesp®. However, given the recent revisions, we are currently in the process of further evaluating the Claims Monitoring Policy. As a result, we cannot predict the potential full impact of this final guidance on our business.

Further, the Deficit Reduction Act of 2005 (DRA) included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that become effective in 2007 will increase the level of Medicaid rebates paid by us. We are currently in the process of further evaluating the impact of the DRA, and as a result we cannot predict the potential full impact on our business.

Results of Operations

Product sales

For the three and nine months ended September 30, 2006 and 2005, worldwide product sales and total product sales by geographic region were as follows:

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Aranesp®	$ 1,067	$ 840	27%	$ 3,015	$ 2,400	26%
EPOGEN®	633	599	6%	1,850	1,829	1%
Neulasta®/NEUPOGEN®	998	882	13%	2,899	2,576	13%
Enbrel®	705	668	6%	2,087	1,899	10%
Sensipar®	83	43	93%	223	106	110%
Other	17	15	13%	47	44	7%
Total product sales	$ 3,503	$ 3,047	15%	$ 10,121	$ 8,854	14%
Total U.S.	$ 2,864	$ 2,504	14%	$ 8,296	$ 7,267	14%
Total International	639	543	18%	1,825	1,587	15%
Total product sales	$ 3,503	$ 3,047	15%	$ 10,121	$ 8,854	14%

Product sales are influenced by a number of factors, including demand, third-party reimbursement availability and policies, pricing strategies, wholesaler and end-user inventory management practices, fluctuations in foreign exchange rates, new product launches and indications, competitive products, product supply and acquisitions.

Sales growth for the three and nine months ended September 30, 2006 was principally driven by demand for Aranesp®, Neulasta® and ENBREL. International product sales growth for the three months were favorably impacted by approximately $16 million from foreign currency exchange rate changes but were unfavorably impacted by approximately $39 million for the nine months ended September 30, 2006.

We expect Aranesp®, Neulasta® and ENBREL to continue to drive year over year sales growth for the remainder of 2006. However, we expect that maintaining or increasing share will be more of a challenge than in previous years as we operate in an increasingly competitive environment and we have experienced share loss with ENBREL. Going forward, we will focus on growing our segments, including increasing our penetration in the therapeutic areas in which our products are used, while also continuing to focus on segment share.

While we believe that our product sales for 2005 and the nine months ended September 30, 2006 have not been nor, for the remainder of 2006, are expected to be significantly impacted by the reimbursement changes resulting from the MMA implemented in 2005, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future. For additional information on reimbursement and its impact on our business, see Reimbursement above.

Aranesp®

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Aranesp® - U.S.	$ 720	$ 542	33%	$ 2,029	$ 1,525	33%
Aranesp® - International	347	298	16%	986	875	13%
Total Aranesp®	$ 1,067	$ 840	27%	$ 3,015	$ 2,400	26%

The increase in U.S. Aranesp® sales for the three and nine months ended September 30, 2006 was primarily driven by demand reflecting both segment growth and share gains. The increase in international Aranesp® sales for the three and nine months ended September 30, 2006 was also principally driven by demand. International sales for the nine months ended September 30, 2006 were unfavorably impacted by $27 million due to changes in foreign currency exchange rates.

For the remainder of 2006, we believe that Aranesp® sales growth will be driven primarily by increased demand due to both segment growth and continued share gains. Further, sales of Aranesp® have been and may continue to be benefited by its use in U.S. hospital dialysis clinics to treat anemia associated with chronic renal failure instead of EPOGEN®, however, we believe this conversion stabilized as of June 30, 2006. In addition, we believe future worldwide Aranesp® sales growth will also be dependent, in part, on such factors as: reimbursement by third-party payers (including governments and private insurance plans); cost containment pressures from governments and private insurers on health care providers; governmental or private organization regulations or guidelines relating to the use of our products; government programs; penetration of existing and new segments, including potential new indications; patient population growth; the effects of pricing strategies; an increasingly competitive environment of competitive products or therapies, including biosimilar products in Europe; the development of new treatments for cancer; and changes in foreign currency exchange rates (see Item 1A. Risk Factors in Part II herein Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.).

EPOGEN®

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
EPOGEN® - U.S.	$ 633	$ 599	6%	$ 1,850	$ 1,829	1%

Reported EPOGEN® sales for the three months ended September 30, 2006 increased primarily due to favorable year over year wholesaler inventory changes and underlying demand in the freestanding dialysis clinics. These increases were partially offset by year over year increased use of Aranesp® in the hospital setting. Reported EPOGEN® sales for the nine months ended September 30, 2006 increased modestly primarily due to the increased demand in the freestanding dialysis centers largely offset by the increased use of Aranesp® in the hospital setting. We believe that conversion to Aranesp® in the hospital setting stabilized as of June 30, 2006.

We believe EPOGEN® should experience sales growth for the remainder of 2006 primarily as a result of patient population growth and the stabilization of conversion to Aranesp® in the U.S. hospital dialysis clinics. On an annual basis, we believe demand for EPOGEN® in the freestanding dialysis clinics, which account for a majority of EPOGEN® sales, remains consistent with an estimated annual patient population growth of 3-4 percent. Dialysis patients receiving treatment for anemia associated with end stage renal disease with EPOGEN® are covered primarily under medical programs provided by the federal government. Therefore, going forward, we believe EPOGEN® sales growth will further depend on changes in reimbursement rates or a change in the basis for reimbursement by the federal government. We believe EPOGEN® sales growth will also be dependent, in part, on future governmental or private organization regulations or guidelines relating to the use of our products, cost containment pressures from the federal government on health care providers and the effects of pricing strategies (see Item 1A. Risk Factors in Part II herein Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.). We recently entered into a five-year sole sourcing and supply agreement with an affiliate of Fresenius Medical Care North America, Inc. (Fresenius), on its behalf and on behalf of certain of its affiliates, to purchase, and we have agreed to supply, all of Fresenius commercial requirements for erythropoietic stimulating proteins for use in managing the anemia of its hemodialysis patients in the United States and Puerto Rico, based on forecasts provided by Fresenius and subject to the terms and conditions of the agreement.

Neulasta®/NEUPOGEN®

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Neulasta® - U.S.	$ 560	$ 475	18%	$ 1,636	$ 1,381	18%
NEUPOGEN® - U.S.	212	205	3%	609	595	2%
U.S. Neulasta®/NEUPOGEN® - Total	772	680	14%	2,245	1,976	14%
Neulasta® - International	130	102	27%	363	284	28%
NEUPOGEN® - International	96	100	(4)%	291	316	(8)%
International Neulasta®/NEUPOGEN® - Total	226	202	12%	654	600	9%
Total Worldwide Neulasta®/NEUPOGEN®	$ 998	$ 882	13%	$ 2,899	$ 2,576	13%

The increase in U.S. Neulasta®/NEUPOGEN® sales for the three and nine months ended September 30, 2006 was driven primarily by demand for Neulasta®. In addition, the increase in demand for Neulasta® for the three and nine months ended September 30, 2006 also includes the impact of a 2 percent U.S. price increase in April 2006. U.S. demand for Neulasta® continued to benefit from a product label extension based on clinical data demonstrating the value of first cycle

utilization in moderate-high risk chemotherapy regimens. The increase in international Neulasta®/NEUPOGEN® sales for the three and nine months ended September 30, 2006 was driven primarily by demand for Neulasta®. International sales for the nine months ended September 30, 2006 were unfavorably impacted by $16 million in foreign currency exchange rate changes.

For the remainder of 2006, we believe sales growth for Neulasta®/NEUPOGEN® will continue to benefit from a Neulasta® label extension based on clinical data demonstrating the value of first cycle utilization in moderate-high risk chemotherapy regimes. In addition, future worldwide Neulasta®/NEUPOGEN® sales growth will be dependent, in part, on such factors as: reimbursement by third-party payers (including governments and private insurance plans); cost containment pressures from governments and private insurers on health care providers; governmental or private organization regulations or guidelines relating to the use of our products; government programs (see Item 1A. Risk Factors in Part II herein Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.); penetration of existing segments; patient population growth; the effects of pricing strategies; competitive products or therapies, including biosimilar products in Europe; changes in foreign currency exchange rates and the development of new treatments for cancer. Future chemotherapy treatments that are less myelosuppressive may require less Neulasta®/NEUPOGEN®, however, other future chemotherapy treatments that are more myelosuppressive, such as dose dense chemotherapy, could require more Neulasta®/NEUPOGEN®. NEUPOGEN® competes with Neulasta® in the United States and Europe. U.S. and International NEUPOGEN® sales have been adversely impacted by conversion to Neulasta®. However, we believe that most of the conversion in the United States has occurred. In Europe, we have been actively converting NEUPOGEN® patients to Neulasta®, emphasizing its less frequent dosing requirements as compared to NEUPOGEN®. While conversion of NEUPOGEN® patients to Neulasta® in Europe is still occurring, we believe that this conversion has mainly stabilized.

ENBREL

(Amounts in millions)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
ENBREL - U.S.	$ 669	$ 641	4%	$ 1,983	$ 1,825	9%
ENBREL - International	36	27	33%	104	74	41%
Total ENBREL	$ 705	$ 668	6%	$ 2,087	$ 1,899	10%

ENBREL sales growth for the three and nine months ended September 30, 2006 was driven by demand. For the three months ended September 30, 2006, growth was primarily driven by demand in the Rheumatology segment. In addition, the increase in demand for the three and nine months ended September 30, 2006 also includes the impact of a 4.9 percent U.S. price increase that went into effect May 1, 2006. While ENBREL continued to maintain a leading position in both rheumatology and dermatology, we have experienced share loss in both segments year over year. ENBREL sales growth has been affected in 2006 by slowing segment growth in dermatology and by increased competitive activities in both segments.

We believe sales growth for the remainder of 2006 will be principally driven by growth of the rheumatology segment. Going forward, future ENBREL sales growth will be dependent, in part, on such factors as: the effects of competing products or therapies; segment growth; the availability and extent of reimbursement by government and third-party payers; cost containment pressures from governments and private insurers on health care providers; governmental or private organization regulations or guidelines relating to the use of our products; and the effects of pricing strategies (see Item 1A. Risk Factors in Part II herein Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products.).

Selected operating expenses

The following table summarizes selected operating expenses (amounts in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2006	2005	Change	2006	2005	Change
Product sales	$ 3,503	$ 3,047	15%	$ 10,121	$ 8,854	14%
Operating expenses:						
Cost of sales (excludes amortization of acquired intangible assets)	$ 489	$ 552	(11)%	$ 1,534	$ 1,571	(2)%
% of product sales	14%	18%		15%	18%	
Research and development	$ 872	$ 562	55%	$ 2,315	$ 1,653	40%
% of product sales	25%	18%		23%	19%	
Selling, general and administrative	$ 807	$ 656	23%	$ 2,336	$ 1,879	24%
% of product sales	23%	22%		23%	21%	
Write-off of acquired in-process research and development	$	$		$ 1,101	$	
Amortization of acquired intangible assets	$ 122	$ 86		$ 296	$ 260	

Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see Condensed Consolidated Statements of Operations), decreased 11% for the three months and 2% for the nine months ended September 30, 2006, respectively. The decrease in the three months ended September 30, 2006 was primarily driven by lower royalty expenses, a favorable product mix and, to a lesser extent, production efficiencies. Royalty expenses were lower in the three months ended September 30, 2006 due to the expiration of certain contractual royalty obligations on Neulasta® and NEUPOGEN® sales and the acquisition of certain royalty rights on sales of ENBREL and European Union Neulasta® and NEUPOGEN® sales. The moderate decrease in costs of sales for the nine months ended September 30, 2006 was primarily due to cost savings from lower royalty expenses, a favorable product mix and production efficiencies largely offset by higher manufacturing costs during the three months ended March 31, 2006.

Research and development

R&D expenses are primarily comprised of costs and expenses for: salaries and benefits associated with R&D personnel, overhead and occupancy, clinical trial and related clinical manufacturing, including contract services and other outside costs, process development, quality assurance, information systems and amortization of technology used in R&D with alternative future uses. R&D expenses also include such costs related to activities performed on behalf of corporate partners. R&D expenses increased 55% and 40%, respectively, for the three and nine months ended September 30, 2006 primarily driven by higher staff-related costs and increased funding to support clinical trials for our late stage programs, including higher clinical material and manufacturing costs. In addition, R&D costs for the three and nine months ended September 30, 2006, include approximately $21 million and $78 million, respectively, in stock option expense, which was not reflected in our Consolidated Results of Operations prior to January 1, 2006 (see Recent accounting pronouncements below) and approximately $16 million and $32 million, respectively, in non-cash amortization expense of the intangible asset, XenoMouse® technology, acquired in the Abgenix acquisition. During the three months ended September 30, 2006, staff-related costs, including stock option compensation, and clinical trial and clinical manufacturing costs increased approximately $139 million and $121 million, respectively. During the nine months ended September 30, 2006, staff-related costs, including stock option compensation, and clinical trial and clinical manufacturing costs increased approximately $347 million and $246 million, respectively.

Selling, general and administrative

Selling, general and administrative (SG&A) expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel; outside marketing expenses; overhead and occupancy costs; and other general and administrative costs. SG&A increased 23% and 24% for the three and nine months ended September 30, 2006, reflecting higher staff levels and additional infrastructure costs, primarily associated with our Global Enterprise Resource Planning (ERP) system, to support our growing organization. In addition, SG&A costs for the three and nine months ended September 30, 2006 include approximately $25 million and $96 million, respectively, in stock option expense, which was not reflected in our Consolidated Results of Operations prior to January 1, 2006 (see Recent accounting pronouncements below). During the three months ended September 30, 2006, staff-related costs, including stock option compensation, and additional infrastructure costs increased over the three months ended September 30, 2005 by approximately $109 million and $12 million, respectively. In addition, we incurred $6 million in higher legal costs associated with ongoing litigation and $46 million in increased outside marketing expenses in support of our principal products, including the Wyeth profit share related to ENBREL. During the nine months ended September 30, 2006, staff-related costs, including stock option compensation, and additional infrastructure costs increased over the nine months ended September 30, 2005 by $312 million and $35 million, respectively. In addition, we incurred $41 million in higher legal costs associated with ongoing litigation and $111 million in increased outside marketing expenses in support of our principal products, including the Wyeth profit share related to ENBREL for the nine month period.

Write-off of acquired in-process research and development

The fair value of acquired IPR&D projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are immediately expensed. In the second quarter of 2006 we expensed $1,101 million of acquired IPR&D related to the Abgenix acquisition. Acquired IPR&D is considered part of total R&D expense.

Amortization of acquired intangible assets

Amortization of acquired intangible assets relates to the acquired products technology rights acquired in connection with the Immunex Corporation (Immunex) acquisition. This amortization also included $49 million for the three and nine months ended September 30, 2006 related to the impairment of a non-Enbrel® related intangible asset previously acquired in the Immunex acquisition.

Legal settlements

During the nine months ended September 30, 2005, we settled certain legal matters, primarily related to a patent legal proceeding, and recorded an expense of $49 million, net of amounts previously accrued.

Interest and other income and (expense), net

Interest and other income (expense), net for the three months ended September 30, 2006 was $39 million of income compared to $14 million of income for the three months ended September 30, 2005. Interest and other income (expense), net for the nine months ended September 30, 2006 was $140 million of income compared to $10 million of income for the nine months ended September 30, 2005. These increases were principally attributable to an increase in interest income.

Income taxes

Our effective tax rates for the three and nine months ended September 30, 2006 were 19.0% and 29.2%, respectively, compared with 26.3% and 24.2%, respectively, for the same periods last year. The decrease in our effective tax rate for the three months ended September 30, 2006 as compared to the three months ended September 30, 2005 was primarily due to the favorable resolution of prior year federal and state audits and an increase in the amount of earnings intended to be invested indefinitely outside of the United States, partially offset by the expiration of the federal research and experimentation (R&E) credit in 2005. Our effective tax rate for the nine months ended September 30, 2006 as compared to the nine months ended September 30, 2005 has increased primarily due to the write-off of acquired IPR&D costs in connection with the acquisition of Abgenix, and to a lesser degree, the expiration of the federal R&E credit in 2005. The increase in the rates for the nine months ended September 30, 2006 was partially offset by an increase in the amount of foreign earnings intended to be invested indefinitely outside of the United States. As permitted in Accounting Principles Board Opinion (APB) No. 23, Accounting for Income Taxes Special Areas, 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.

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

Recent accounting pronouncements

On January 1, 2006 we adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment. SFAS No. 123(R) requires us to account for our stock options using a fair-value-based method as described in such statement and recognize the resulting compensation expense in our financial statements. Prior to January 1, 2006, we accounted for our employee stock options using the intrinsic value method under APB No. 25, Accounting for Stock Issued to

Employees and related interpretations, as permitted by SFAS No. 123, Accounting for Stock-Based Compensation, which generally did not result in any employee stock option expense. We adopted SFAS No. 123(R) using the modified-prospective-transition method. Under this transition method, compensation expense recognized subsequent to adoption includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the values estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair values estimated in accordance with the provisions of SFAS No. 123(R). The modified-prospective-transition method did not require recognition of related compensation expense in our financial statements for prior periods. Comparability, therefore, of the current period financial statements to prior periods has been and will be impacted.

The adoption of SFAS No. 123(R) will have a material impact on our results of operations for 2006. The actual annual stock option expense in 2006 is dependent on a number of factors including the number of stock options granted, our common stock price and related expected volatility and other inputs utilized in estimating the fair value of the stock options at the time of grant. As a result of recognizing compensation expense for stock options pursuant to the provisions of SFAS No. 123(R), our income before income taxes for the three and nine months ended September 30, 2006, was $50 million and $179 million lower, respectively, and our net income was $36 million and $124 million lower, respectively, than if we had continued to account for stock options under APB No. 25. In addition, both basic and diluted earnings per share for the three and nine months ended September 30, 2006 were $0.03 and $0.11 lower, respectively, than if we had continued to account for stock options under APB No. 25. We expect the impact of stock option expense to be in the range of $0.12 to $0.14 per share in 2006 compared to $0.19 for 2005 (see Note 2, Employee stock-based payments in the Condensed Consolidated Financial Statements). The estimated annual impact of stock option expense for 2006 is less than the corresponding pro forma expense amount for 2005 principally due to a reduction in the number of stock options granted in recent years in favor of a combination of other equity awards. Other equity awards are comprised principally of restricted stock and performance units. Pre-tax stock-based compensation expense relating to these other equity awards for the three months ended September 30, 2006 and September 30, 2005 were $51 million and $26 million, respectively. As of September 30, 2006, there was $563 million of total unrecognized compensation cost related to unvested stock options and shares of restricted stock that is expected to be recognized over the weighted-average period of 1.5 years and $165 million of total unrecognized compensation cost related to performance units that is expected to be recognized over the weighted-average period of 1.0 year.

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. (FIN) 48, Accounting for Uncertainty in Income Taxes, effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing rules for recognition, measurement, classification and disclosure in our financial statements of tax positions taken or expected to be taken in a tax return. We are currently evaluating the provisions in FIN 48, but have not yet determined its expected impact on us. We plan to adopt this new standard on January 1, 2007.

Financial Condition, Liquidity and Capital Resources

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

	September 30, 2006	December 31, 2005
Cash, cash equivalents, restricted cash, and marketable securities	$ 5,781	$ 5,255
Total assets	32,586	29,297
Current debt	1,773	
Non-current debt	7,233	3,957
Stockholders equity	17,721	20,451

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditure and debt service requirements for the foreseeable future, as well as to support our stock repurchase program and other business initiatives, including acquisitions and licensing activities. However, in order to provide for greater financial flexibility and liquidity, we may raise additional capital from time to time by accessing both public and private markets.

Cash, cash equivalents and marketable securities

Of the total cash, cash equivalents and marketable securities at September 30, 2006, approximately $4.7 billion was generated from operations in foreign tax jurisdictions and is intended for use outside the United States. If these funds are repatriated for use in our U.S. operations, substantial additional taxes on certain of these amounts will be required to be paid.

Financing arrangements

In February 2006, we issued $2.5 billion principal amount of convertible notes due in 2011 (the 2011 Convertible Notes) and $2.5 billion principal amount of convertible notes due in 2013 (the 2013 Convertible Notes) in a private placement. 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 2011 Convertible Notes and the 2013 Convertible Notes may be convertible based on an initial conversion rate of 12.5247 shares and 12.5814 shares, respectively, per $1,000 principal amount of notes (which represents an initial conversion price of approximately $79.84 and $79.48 per share, respectively). The 2011 Convertible Notes and the 2013 Convertible Notes may only be converted: 1) during any calendar quarter beginning after June 30, 2006 if the closing price of our common stock exceeds 130% of the respective conversion price per share during a defined period at the end of the previous quarter, 2) if we make specified distributions to holders of our common stock or specified corporate transactions occur, or 3) one month prior to the respective maturity date. Upon conversion, a holder would receive: 1) cash equal to the lesser of the principal amount of the note or the conversion value, as defined, and 2) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock, cash or a combination of common stock and cash, at our option (the excess conversion value). In addition, upon a change in control, as defined, the holders may require us to purchase for cash all or a portion of their notes for 100% of the principal amount of the notes plus accrued and unpaid interest, if any. Debt issuance costs totaled approximately $88 million and are being amortized over the life of the notes. Moody s and Standard & Poor s rate our outstanding convertible notes A2 and A+, respectively.

In connection with the issuance of these convertible notes, a total of $3.0 billion of our common stock was repurchased under our stock repurchase program. Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we purchased convertible note hedges in private transactions. The convertible note hedges allow us to receive shares of our common stock and/or cash from the counterparties to the transactions equal to the amounts of common stock and/or cash related to the excess conversion value that we would pay to the holders of the 2011 Convertible Notes and the 2013 Convertible Notes upon conversion. These transactions will terminate the earlier of the maturity dates of the related notes or the first day none of the related notes remain outstanding due to conversion or otherwise. The cost of the convertible note hedges, which aggregated approximately $1.5 billion, was recorded as a reduction of equity. The net proceeds from the issuance of the 2011 and 2013 Convertible Notes, the repurchase of common stock and the purchase of the convertible note hedges was $440 million.

Also concurrent with the issuance of the 2011 Convertible Notes and the 2013 Convertible Notes, we sold warrants to acquire shares of our common stock at an exercise price of $107.90 per share in a private placement. Pursuant to these transactions, warrants for approximately 31.3 million shares of our common stock may be settled in May 2011 and warrants for approximately 31.5 million shares of our common stock may be settled in May 2013 (the settlement dates). If the average price of our common stock during a defined period ending on or about the respective settlement dates exceeds the exercise price of the warrants, the warrants will be settled, at our option, in cash or shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately $774 million.

As of September 30, 2006 we had zero coupon convertible notes due in 2032 with an accreted value of $1.8 billion outstanding and having an aggregate face amount of $2.36 billion and yield to maturity of 1.125%. The holders of these convertible notes may require us to purchase, generally for cash, all or a portion of their convertible notes on specified dates (the Put Option), at a price equal to the original issuance price plus the accrued original issue discount through the purchase date. The next available Put Option date is on March 1, 2007. Accordingly, the convertible notes were classified as current liabilities in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2006. Moody s and Standard & Poor s rate our outstanding convertible notes A2 and A+, respectively.

As of September 30, 2006 we had $2.0 billion of long-term notes outstanding. These long-term notes consisted of: 1) $1.0 billion of notes that bear interest at a fixed rate of 4.0% and mature in 2009, and 2) $1.0 billion of notes that bear interest at a fixed rate of 4.85% and mature in 2014. Moody s and Standard & Poor s rate our outstanding long-term senior notes A2 and A+, respectively.

As of September 30, 2006, we had $234 million of additional long-term debt securities outstanding. These long-term debt securities consisted of: 1) $100 million of debt securities that bear interest at a fixed rate of 6.5% and mature in 2007 under a $500 million debt shelf registration statement (the $500 Million Shelf), 2) $100 million of debt securities that bear interest at a fixed rate of 8.1% and mature in 2097, and 3) $34 million in notes due in 2013 with an effective rate of 5.35% assumed in the Abgenix acquisition. Our outstanding long-term debt is rated A2 by Moody s and A+ by Standard & Poor s. Under the $500 Million Shelf, all of the remaining $400 million of debt securities available for issuance may be offered from time to time under our medium-term note program with terms to be determined at the time of issuance.

We have a $1.0 billion unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support, which matures in November 2010. Additionally, we have a commercial paper program, which provides for unsecured, short-term borrowings of up to an aggregate of $1.2 billion. No amounts were outstanding under the credit facility or commercial paper program as of September 30, 2006.

We have a $1.0 billion shelf registration statement (the $1 Billion Shelf) which allows us to issue debt securities, common stock and associated preferred share purchase rights, preferred stock, warrants to purchase debt securities, common stock or preferred stock, securities purchase contracts, securities purchase units and depositary shares. The $1 Billion Shelf was established to provide for further financial flexibility and the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. As of September 30, 2006, no securities had been issued under the $1 Billion Shelf.

Certain of our financing arrangements contain non-financial covenants and as of September 30, 2006, we were in compliance with all applicable covenants.

Cash flows

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

	Nine months ended September 30,	
	2006	**2005**
Net cash provided by operating activities	$ 4,147	$ 3,782
Net cash (used in) provided by investing activities	(3,929)	303
Net cash used in financing activities	(767)	(3,460)

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, 2006 increased from the prior year nine month period due to higher cash receipts from customers driven by the growth in product sales and the timing of payments in the ordinary course of business. (See Condensed Consolidated Statements of Cash Flows).

Investing

On April, 1, 2006, we completed our acquisition of Abgenix and paid $2.1 billion in cash to the shareholders of Abgenix to acquire all outstanding shares. In addition, we acquired $252 million in cash, and subsequent to the completion of the acquisition, we paid off $653 million of convertible debt assumed in this transaction.

Capital expenditures totaled $834 million during the nine months ended September 30, 2006, compared with $602 million during the same period last year. The capital expenditures during the nine months ended September 30, 2006 were primarily associated with ongoing manufacturing capacity and site expansions in Ireland, Puerto Rico and other locations and costs associated with

implementing our ERP system. The capital expenditures during the nine months ended September 30, 2005 were primarily associated with manufacturing and site expansion in Puerto Rico and Colorado and site development in Thousand Oaks and other locations.

We currently estimate 2006 spending on capital projects and equipment to be in excess of $1 billion as we continue to increase our manufacturing and R&D operations globally and implementation of our ERP system. The most significant of these expenditures are expected to be incurred with the further expansion of the Puerto Rico bulk manufacturing, formulation, fill and finish facilities, the start of engineering and construction of a new process development, bulk manufacturing, formulation, fill and finish facility in Ireland, the expansion of R&D operations at existing sites in the United States and the United Kingdom and construction of a new development center in Uxbridge, United Kingdom.

On October 24, 2006, we completed our acquisition of Avidia and paid $290 million in cash, net of cash acquired and our existing equity stake in Avidia. In addition, we may be subject to pay additional amounts upon the achievement of certain future events.

Financing

In February 2006, we issued $5.0 billion convertible notes, of which $2.5 billion pay interest at 0.125% and are due in 2011 and $2.5 billion pay interest at 0.375% and are due in 2013. In connection with the issuance of these convertible notes, a total of $3.0 billion of our common stock was repurchased under our stock repurchase program. Also concurrent with the issuance of these convertible notes, we purchased convertible note hedges at a cost of approximately $1.5 billion. The net proceeds received from the issuance of the 2011 and 2013 Convertible Notes, the repurchase of common stock and the purchase of the convertible note hedges was $440 million. Also concurrent with the issuance of the convertible notes, we sold 62.8 million warrants to acquire shares of our common stock for proceeds of $774 million, 31.3 million of which may be settled in May 2011 and 31.5 million of which may be settled in May 2013. For further information on these transactions, see Financing arrangements above.

During the nine months ended September 30, 2006 and 2005, we repurchased 67.0 million and 48.4 million shares of our common stock, respectively, at a total cost of $4,755 million and $3,194 million, respectively. As of September 30, 2006, we had $1,784 million available for stock repurchases under our stock repurchase program authorized by the Board of Directors. The manner of purchases, amount we spend and the number of shares repurchased will vary based on a variety of factors including the stock price and blackout periods in which we are restricted from repurchasing shares, and may include private block purchases as well as market transactions. Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of Amgen common stock. Additionally, we believe that it is an effective way of returning cash to our stockholders.

For additional information regarding our stock repurchase program see Part II Other Information, Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

On March 2, 2005, as a result of certain holders of the zero coupon convertible notes due in 2032 exercising their March 1, 2005 Put Option, we repurchased $1.59 billion aggregate principal amount or approximately 40% of the then outstanding convertible notes at their then-accreted value for $1,175 million in cash.

We receive cash from the exercise of employee stock options and proceeds from the sale of stock pursuant to the employee stock purchase plan. Employee stock option exercises and proceeds from the sale of stock by us pursuant to the employee stock purchase plans provided $367 million and $924 million of cash during the nine months ended September 30, 2006 and 2005, 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, 2006.

Further, management determined that, as of September 30, 2006, 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.

39

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Certain of our legal proceedings are reported in our Annual Report on Form 10-K for the year ended December 31, 2005, with material developments since that report described in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006, and below. While it is not possible to accurately predict or determine the eventual outcome of these items, we do not believe any such items currently pending will have a material adverse effect on our consolidated financial position or liquidity, although an adverse resolution in any quarterly or annual reporting period of one or more of these items could have a material impact on the consolidated results of our operations for that period.

Transkaryotic Therapies (TKT) and Aventis Litigation

On August 17, 2006, Amgen filed a combined petition for panel rehearing and rehearing en banc with the United States Court of Appeals for the Federal Circuit regarding the claim construction with respect to claim 1 of the U.S. Patent No. 5,955,422 (the 422 Patent).

Israel Bio-Engineering Project Litigation (IBEP)

The United States Court of Appeals for the Federal Circuit held oral argument on October 4, 2006.

Average Wholesale Price Litigation

In the Multi-District Litigation (the MDL) Proceeding, on September 12, 2006, a hearing before the United States District Court in Boston, Massachusetts was held on plaintiffs motion for class certification as to the Phase II defendants, which include Amgen and Immunex Corporation (Immunex).

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

The case remains stayed and another status conference is scheduled for April 2, 2007.

Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc. et. al.

On October 11, 2006, the case was removed to the United States District Court for the Eastern District of Pennsylvania.

State of Wisconsin v. Amgen Inc., et. al.

On October 11, 2006, the case was removed to the United States District Court for the Western District of Wisconsin.

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

On October 11, 2006, the case was removed to the United States District Court for the Middle District of Alabama. On November 3, 2006, the case was remanded to the Circuit Court of Montgomery County, Alabama.

People of State of Illinois v. Abbott Laboratories, Inc., et. al

On October 11, 2006, the case was removed to United States District Court for the Northern District of Illinois.

County of Erie v. Abbott Laboratories, Inc., et al.

On September 7, 2006, the court granted in part, and denied in part defendants motions to dismiss. Immunex s motion to dismiss was granted. Amgen s motion to dismiss was denied. On October 11, 2006, the case was removed to United States District Court for the Western District of New York.

State of Mississippi v. Abbott Laboratories, Inc., et al.

On October 11, 2006, the case was removed to United States District Court for the Northern District of Mississippi.

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

On October 10, 2006, the case removed to the United States District Court for the District of Massachusetts and will be transferred into the MDL proceeding.

State of Alaska v. Abbott Laboratories, Inc., et. al.:

On October 6, 2006, the Attorney General of the state of Alaska filed a complaint naming Amgen and Immunex, along with several other pharmaceutical manufacturers, as defendants in the litigation. The complaint was filed with the Alaska Superior Court in Anchorage, Alaska. Amgen was served with the complaint filed on October 19, 2006. Immunex has yet to be served.

County of Schenectady v. Abbott Laboratories, Inc., et al.

On August 21, 2006, Immunex was served with the complaint and on August 24, 2006, Amgen was served with the complaint filed in the Supreme Court of New York, Schenectady County. On October 11, 2006, the case was removed to United States District Court for the Northern District of New York.

County of Oswego v. Abbott Laboratories, Inc., et al.

On August 21, 2006, Immunex was served with the complaint and on August 24, 2006, Amgen was served with the complaint filed in the Supreme Court of New York, Oswego County. On October 11, 2006, the case was removed to United States District Court for the Northern District of New York.

Johnson & Johnson Matters

Arbitration/Demand for Separate BLA

From September 11-15, 2006, a final arbitration hearing was held before the arbitration panel in Chicago, Illinois. Closing arguments have been scheduled for November 29, 2006.

Ortho Biotech Litigation

On September 27, 2006, closing arguments were held on Ortho Biotech s motion for preliminary injunction in Trenton, New Jersey before the United States District Court for the District of New Jersey.

Roche Matters

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

On October 20, 2006, the U.S. District Court for the District of Massachusetts denied F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH and Hoffman-La Roche, Inc. s (collectively, Roche) motion to dismiss based upon lack of subject matter jurisdiction and denied Ortho Biotech s motion to intervene in the lawsuit. On October 23, 2006, a scheduling conference was held in which the judge set September 2007 as the target date for the trial to commence. On November 6, 2006, Roche filed an answer to the complaint in which Roche denies that they infringe the patents-in-suit, assert legal and equitable defenses and counterclaims including non-infringement, patent invalidity, patent unenforceability, patent misuse, as well as accusing Amgen of violating state and federal antitrust and unfair competition law.

U.S. International Trade Commission

On August 31, 2006, the U.S. International Trade Commission (the Commission) adopted the Administrative Law Judge s summary determination terminating the investigation based on the clinical trial exemption to patent infringement liability under 35 U.S.C. 271(e)(1). On October 11, 2006, Amgen filed a petition for review of the Commission s decision with the United States Court of Appeals for the Federal Circuit.

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

On September 11, 2006, the U.S. District Court for the District of Delaware denied Ariad Pharmaceuticals, Inc. s (Ariad) motion to dismiss for lack of subject matter jurisdiction and denied without prejudice Ariad s motion to dismiss for failure to name indispensable parties. On September 25, 2006, Ariad filed a motion seeking certification for interlocutory appeal of the Court s denial of Ariad s Motion to Dismiss for lack of subject matter jurisdiction. On October 5, 2006, Ariad filed a renewed motion to dismiss for failure to name indispensable parties. The Court heard oral argument on these motions on November 3, 2006 and granted Ariad s motion seeking certification for an interlocutory appeal. The Court denied without prejudice Ariad s renewed motion to dismiss and motion to transfer.

Item 1A. Risk Factors

The following items are representative of the risks, uncertainties and assumptions that could affect the outcome of the forward looking statements and actual results could be materially different.

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

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. To date, there has emerged no consistent policy regarding breadth of claims allowed in such companies patents. Third parties may challenge, invalidate or circumvent our patents and patent applications relating to our products, product candidates and technologies. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our product candidates, there are third parties who have patents or pending patents that they may claim prevent us from commercializing these product candidates in certain territories. Patent disputes are frequent, costly and can preclude or delay commercialization of products. We are currently, and in the future may be, involved in patent litigation. For example, F. Hoffmann-La Roche Ltd (Roche) is developing a pegylated erythropoietin molecule that, according to Roche s public statements, they expect to bring to the U.S. market despite their acknowledgement of our U.S. erythropoietin patents. On November 8, 2005, we filed a lawsuit against Roche for patent infringement of six of our U.S. patents. This lawsuit is described in Item 3. Legal Proceedings Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al. in our Form 10-K for the year ended December 31, 2005, and updated in Item 1. Legal Proceedings Roche Matters above. In addition, on April 11, 2006, we filed a complaint with the U.S. International Trade Commission (ITC) requesting that the ITC institute an investigation of Roche s importation of pegylated recombinant human erythropoietin. This matter is described in Item 1. Legal Proceedings Roche Matters. Further, we are currently involved in an ongoing patent infringement lawsuit against Transkaryotic Therapies, Inc. (TKT) and Aventis with respect to our erythropoietin patents. If we lose or settle current or future litigations at certain stages or entirely, we could be: subject to competition and/or significant liabilities; required to enter into third-party licenses for the infringed product or technology; or required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. We have filed applications for a number of patents and have been granted patents or obtained rights relating to erythropoietin, natural and recombinant granulocyte-colony stimulating factors or G-CSF, darbepoetin alfa, pegfilgrastim, etanercept and our other products and potential products. We market our erythropoietin, recombinant G-CSF, darbepoetin alfa, pegfilgrastim and etanercept products as EPOGEN® (Epoetin alfa), NEUPOGEN® (Filgrastim), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim) and Enbrel® (etanercept), respectively. Our material patents are set forth below. With respect to our material patents, we have had a number of G-CSF patent expiries in the United States and one expiry in the European Union (the EU) and one erythropoietin patent expiry in the EU.

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

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

We also have been granted or obtained rights to patents in Europe relating to: erythropoietin; G-CSF; pegfilgrastim (pegylated G-CSF); etanercept; two relating to darbepoetin alfa; and hyperglycosylated erythropoietic proteins. Our principal European patent relating to erythropoietin expired on December 12, 2004 and our principal European patent relating to G-CSF expired on August 22, 2006. We believe that as these patents have expired, other companies could receive approval for and market follow-on or biosimilar 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.) While we do not market EPOGEN® in Europe as this right belongs to Johnson & Johnson (through Kirin Amgen, Inc. (KA)), we do market Aranesp® in the EU, which competes with Johnson & Johnson s EPREX® product, Roche s Neorecormon® product and others erythropoietin products. Although we cannot predict with certainty when the first biosimilar products could appear on the market in the EU, we expect that biosimilar erythropoietin products may be approved in the EU in 2007 and could be available in the EU shortly after approval. In addition, based on an announcement by Shire Pharmaceuticals Group plc (Shire), we expect that a competing erythropoietin product, manufactured by Shire, may appear on the market in the EU in 2007. We also expect that the first biosimilar G-CSF product may be approved in the EU as early as third quarter of 2007 and that it would compete with Neulasta® and NEUPOGEN®. In 2006, the European Medicines Agency (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 granulocyte-colony stimulating factors, which guidance recommends that applicants seeking approval of such biosimilar products conduct fairly extensive pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. Although, we cannot predict whether or to what extent the entry of biosimilar products would impact future Aranesp®, Neulasta® or NEUPOGEN® sales in the EU, biosimilar or other products that effectively compete with our products could reduce sales which could have a material adverse affect on our results of operations.

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

Before we can sell any products, we must conduct clinical trials which demonstrate that our product candidates are safe and effective for use in humans for the indications sought. The results of these clinical trials are used as the basis to obtain regulatory approval from government authorities such as the U.S. Food and Drug Administration (FDA). Clinical trials are experiments conducted using our product candidates in human patients having the diseases or medical conditions we are trying to address. Conducting clinical trials is a complex, time-consuming and expensive process. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims we are seeking. The length of time, number of trial sites and patients required for clinical trials vary substantially according to the type, complexity, novelty and intended use of the product candidate, and therefore, we may spend as much as several years completing certain trials. Our ability to timely complete our clinical trials depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval and the rate of patient enrollment in clinical trials. Patient enrollment is a function of several factors, including the size and location of the patient population, enrollment criteria and competition with other clinical trials for eligible patients. As such, there may be limited availability of patients who meet the criteria for certain clinical trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals and associated delays in product candidates reaching the market. Patients may also suffer adverse medical events or side effects in the course of our clinical trials that may delay or prohibit regulatory approval of our product candidates or may render the product candidate commercially infeasible. 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 AMG 706, we recently announced that two of our mega-site trials (involving 200 or more sites) associated with the AMG 706 program, specifically the Phase 3 study in first line breast cancer and first line non-small cell lung cancer, previously expected to begin in the fourth quarter of 2006, have been delayed subject to additional Phase 1 and 2 data and protocol modifications. Additionally, clinical trials must be designed based on the current standard of medical care. However in certain diseases, such as cancer, the standard of care is evolving rapidly. In these diseases, the duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on an out of date standard of medical care, limiting the utility and application of such trials. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval on this basis.

The number, size, duration and complexity of our clinical trials has increased and we expect will continue to increase significantly for 2006, in particular with respect to denosumab, our late-stage investigational product for osteoporosis and metastatic bone cancer. Due to the number of large-scale clinical trials initiated this year, we expect to see further accelerated growth in research and development expense in 2006 as compared to 2005. For example, testing denosumab in the osteoporosis setting requires large clinical trials, substantial time and resources to recruit patients and significant expense to execute. We have begun nine mega-site trials in 2006 to support denosumab and our other late-stage programs. To execute our clinical trial programs, we need to accelerate the growth of our development organization, implement new management structures and approaches and increase dependence on third-party contract clinical trial providers. Further, to increase the number of patients available for enrollment for our clinical trials, we are planning, with the assistance of third-party contract clinical trial providers, to open clinical sites and enroll patients in a number of new geographic locations where our experience conducting clinical trials is more limited, including Russia, China, India and some Central and South American countries.

If we fail to adequately manage the increasing number, size and complexity of our clinical trials, our clinical trials and corresponding regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether. If we are unable to market and sell our product candidates or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be adversely affected materially.

We may not be able to develop commercial products.

We intend to continue an aggressive research and development program. Successful product development in the biotechnology industry is highly uncertain, and very few research and development projects produce a commercial product. Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive preclinical trial results

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

- the product candidate had harmful side effects in humans or animals

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

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

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

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

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

Several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to, Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF) and Glial Cell Lined-Derived Neurotrophic Factor (GDNF). For example, in 1997, we announced the failure of BDNF for the treatment of amyotrophic lateral sclerosis, or Lou Gehrig s Disease, because the product candidate, when administered by injection, did not produce acceptable clinical results for a specific use after a phase 3 trial, even though BDNF had progressed successfully through preclinical and earlier clinical trials. In addition, in 1998, we discontinued development of MGDF, a novel platelet growth factor, at the phase 3 trial stage after several people in platelet donation trials developed low platelet counts and neutralizing antibodies. Also, in June 2004, we announced that the phase 2 study of GDNF for the treatment of advanced Parkinson s disease did not meet the primary study endpoint upon

completion of nine months of the double-blind treatment phase of the study even though a small phase 1 pilot investigator initiated open label study over a three year period appeared to result in improvements for advanced Parkinson s disease patients. Subsequently, in the fall of 2004 we discontinued clinical development of GDNF in patients with advanced Parkinson s disease after several patients in the phase 2 study developed neutralizing antibodies and new preclinical data showed that GDNF caused irreversible damage to the area of the brain critical to movement control and coordination. On February 11, 2005, we confirmed our previous decision to halt clinical trials and, as a part of that decision and based on thorough scientific review, we also concluded that we will not provide GDNF to the 48 patients who participated in clinical trials that were terminated in the fall of 2004. Of course, there may be other factors that prevent us from marketing a product. We cannot guarantee we will be able to produce or manufacture commercially successful products. (See Difficulties, disruptions or delays in manufacturing or failure to comply with manufacturing regulations may limit supply of our products and limit our product sales. ; Our current products and products in development cannot be sold if we do not maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market. ; and Before we commercialize and sell any of our product candidates, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.)

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

In the United States, dialysis providers are primarily reimbursed for EPOGEN® by the federal government through the End Stage Renal Disease Program (ESRD Program) of Medicare. The ESRD Program reimburses approved providers for 80% of allowed dialysis costs; the remainder is paid by other sources, including patients, state Medicaid programs, private insurance, and to a lesser extent, state kidney patient programs. The ESRD Program reimbursement rate is established by federal law and is monitored and implemented by the Centers for Medicare & Medicaid Services (CMS). Most patients receiving Aranesp®, Neulasta® and NEUPOGEN® for approved indications are covered by both government and private payer health care programs. Since January 1, 2006, ENBREL and Sensipar® are eligible for coverage from the U.S. government under Medicare Part D. Although both ENBREL and Sensipar® have received broad formulary placement in 2006 and 2007, Part D formulary placements are made by individual Part D plan sponsors with oversight by CMS and are subject to revision in the future. Generally, in Europe and other countries outside the U.S., 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. Worldwide use of our products may be affected by these cost containment pressures and cost shifting from governments and private insurers to health care providers in response to ongoing initiatives to reduce health care expenditures. Therefore, 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.

The Medicare Prescription Drug Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003 and implemented January 1, 2005. Changes resulting from the MMA, which lowered reimbursement for our products, could negatively affect product sales of some of our marketed products. We believe that our product sales for 2005 and the nine months ended September 30, 2006, have not been nor, for the remainder of 2006,

are expected to be significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS oncology demonstration project (the 2005 Demonstration Project) on sales of our products used in supportive cancer care, especially Aranesp®. Furthermore, we believe this was also, in part, due to increased reimbursement rates to physicians from CMS for services associated with drug administration. The 2005 Demonstration Project, which provided financial incentives to physicians for collecting and reporting oncology patient survey data, expired on December 31, 2005. In November 2005, CMS announced a new demonstration project (the 2006 Demonstration Project) that uses different criteria for how patients with cancer are evaluated and treated and that is targeted at approximately half of the funding originally targeted for the 2005 Demonstration Project. The final rule for the 2006 Medicare Physician Fee Schedule Payment Final Rule issued in November 2005 reduced payments for physician services in 2006 by approximately 4.4% on average, although legislation eliminated this reduction for 2006. The Medicare Physician Fee Schedule Payment Final Rule for 2007 issued in November 2006 and effective January 1, 2007, reduces payments for physician services in 2007 by approximately 5.0% on average. It is uncertain whether legislation will eliminate this reduction in 2007 or if payments for physician services will again be reduced after 2007. Because we cannot accurately predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, we cannot estimate the full impact of the MMA on our business. However, additional provisions of the MMA and other regulations affecting reimbursement that have gone or may go into effect could affect our product sales and related sales growth in the future.

The main components of the MMA that affect our currently marketed products are as follows:

- Through 2004, the Average Wholesale Price (AWP) mechanism was the basis of Medicare Part B payment for covered outpatient drugs and biologics. Since January 1, 2005, in the physician clinic setting, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a Medicare Part B payment methodology that reimburses each product at 106% of its average sales price (ASP) (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined formula and submitted to CMS. A product s ASP is calculated on a quarterly basis and therefore may change each quarter. The ASP in effect for a given quarter (the Current Period) is based upon certain historical sales and sales incentive data covering a statutorily defined period of time preceding the Current Period. For example, the ASP for Aranesp® that will be in effect for the first quarter of 2007 will be based in part on certain historical sales and sales incentive data for Aranesp® from October 1, 2005 through September 30, 2006. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The ASPs for Aranesp® and Neulasta® trended downward during the first three quarters of 2005, began to stabilize during the fourth quarter of 2005 and have remained relatively stable in 2006.

- Since August 1, 2006, physicians in the physician clinic setting have had the choice between purchasing and billing for specific drugs under the ASP+6% system or obtaining those drugs from vendors selected by CMS under the competitive acquisition program (CAP). We believe CAP is unlikely to have a significant impact on our business.

- Medicare s hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, utilized AWP as the basis for reimbursement in 2005. CMS

2005 reimbursement rate, as in 2003 and 2004, continued the application of an equitable adjustment such that the 2005 Aranesp® reimbursement rate was based on the AWP of PROCRIT®. For 2005, the reimbursement rate for Aranesp® was 83% of the AWP for PROCRIT®, down from 88% of the AWP for PROCRIT® in 2004, with a dose conversion ratio of 330 U PROCRIT® to 1 mcg Aranesp®, the same ratio as 2004. Effective January 1, 2006, the OPPS system changed from an AWP based reimbursement system to a system based on ASP. This change affects Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. The OPPS rule for 2006 based reimbursement for non-pass through products such as Aranesp®, Neulasta® and NEUPOGEN® on ASP+6% using the same payment amounts as used in the physician clinic setting and did not apply an equitable adjustment to tie the reimbursement rate for Aranesp® to PROCRIT® using a dose conversion ratio. In the OPPS final rule for 2007, CMS states that it will not apply an equitable adjustment to the payment rate for Aranesp® in 2007, and will, as in 2006, reimburse hospitals for the costs associated with administering specific Medicare-covered outpatient drugs and biologicals (such as Aranesp®, Neulasta® and NEUPOGEN®) at ASP+6%. CMS noted in the 2005 final rule and has maintained that it reserves the right to apply an equitable adjustment to the payment rate for Aranesp® in future years.

- Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 changed from the previous rate in 2004 of $10 per 1,000 Units to $9.76 per 1,000 Units, in 2005, a rate based upon an average acquisition cost for 2003 determined by the Office of the Inspector General (OIG) and adjusted for price inflation based on the Producer Price Index for pharmaceutical products. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed outside the dialysis composite rate (including EPOGEN®) and the 2005 reimbursement rates for such drugs was added to the composite rate that dialysis providers receive for dialysis treatment. Pursuant to the Medicare Physician Fee Schedule Payment Final Rule for 2006, effective January 1, 2006, the payment mechanism for separately reimbursed dialysis drugs in both freestanding and hospital-based dialysis centers, including EPOGEN® and Aranesp®, is reimbursed by Medicare at ASP+6% using the same payment amounts used in the physician clinic setting and calculated quarterly in the same manner as described above for our products under the Medicare Part B payment methodology. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. Based upon the 2006 final rule, the reimbursement rate for EPOGEN® for 2006 decreased from the reimbursement rate in 2005. In the Medical Physician Fee Schedule Payment Final Rule for 2007, CMS continues the 2006 payment mechanism of ASP+6% for EPOGEN® and other separately reimbursed dialysis drugs in both freestanding and hospital-based dialysis centers. Because we cannot accurately predict the extent to which this reimbursement will impact how, or under what circumstances, healthcare providers will prescribe or administer EPOGEN®, we cannot estimate the full impact of the ASP+6% reimbursement rate on our EPOGEN® product sales. However, we believe that it has not been and is unlikely to be significant in 2006 and 2007.

The Medicare Physician Fee Schedule Proposed Rule for 2007 addressed several new topics regarding the ASP payment methodology. In the proposed rule, CMS invited comment on the need for future guidance concerning the methodology for calculating the ASP of drugs sold under market-based pricing arrangements, including bundled arrangements, described by CMS as, for example, when a purchaser s price for one or more drugs is contingent upon the purchase of other drugs or items. In the Medicare Physician Fee Schedule Final Rule for 2007, CMS chose not to establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. However, CMS stated that it may provide more specific guidance in the future through rulemaking, program instruction or other guidance. Any changes to the ASP calculation could adversely affect the Medicare reimbursement for our products administered in the physician office and the hospital outpatient setting.

In addition, on November 9, 2005, CMS released a revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® and Aranesp® (when used in dialysis) utilization and appropriate hematocrit outcomes of dialysis patients. The new policy, Claims Monitoring Policy: Erythropoietin/darbepoetin alfa usage for beneficiaries with end stage renal disease (Claims Monitoring Policy), became effective April 1, 2006 and was further revised effective October 1, 2006. The revised Claims Monitoring Policy provides that if a patient s hemoglobin is greater than 13 grams per deciliter, providers are instructed to reduce the patient s EPOGEN® and Aranesp® dose and report this reduction on claims using a coding modifier. If the provider does not reduce the patient s EPOGEN® and Aranesp® dose and there is no medical documentation to support the higher dosage, reimbursement will be reduced to the level it would have been had the provider reduced dosage by twenty-five percent. Based on our preliminary evaluation, we do not expect the Claims Monitoring Policy to have a negative impact on EPOGEN® and Aranesp® sales and given the importance of EPOGEN® and Aranesp® for maintaining the quality of care for dialysis patients, we do not expect that the policy will substantially impact the utilization of EPOGEN® and Aranesp®. However, given the recent revisions, we are currently in the process of further evaluating the Claims Monitoring Policy. As a result, we cannot predict the potential full impact of this final guidance on our business.

Further, the Deficit Reduction Act of 2005 (DRA) included provisions, which are phased in over time, regarding state collection and submission of data for the purpose of collecting Medicaid drug rebates from manufacturers for physician-administered drugs. We expect that state compliance with elements of these provisions that become effective in 2007 will increase the level of Medicaid rebates paid by us. We are currently in the process of further evaluating the impact of the DRA, and as a result we cannot predict the potential full impact on our business.

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, health care 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 end stage renal disease is funded primarily by the U.S. federal government. In early 1997, CMS, formerly known as Healthcare Financing Administration (HCFA), instituted a reimbursement change for EPOGEN®, which materially and adversely affected our EPOGEN® sales until the policies were revised. Also, we believe the increasing emphasis on cost-containment initiatives in the United States, Europe and other countries has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain and a failure to demonstrate clear economic value associated with the use of

a new therapeutic product as compared to existing therapeutic products or practices may result in inadequate or no reimbursement. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a late stage of development, and current reimbursement policies for marketed products may change at any time. Sales of all our products are and will be affected by government and private payer reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our product sales and results of operations.

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

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

- regulatory requirements or action by the FDA or others
- adverse financial developments at or affecting the supplier
- unexpected demand for or shortage of raw materials, medical devices or components
- labor disputes or shortages, including the effects of a pandemic flu outbreak, or otherwise
- failure to comply with our quality standards which results in quality failures, product contamination and/or recall

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

Also, certain of the raw materials required in the commercial manufacturing and the formulation of our products are derived from biological sources, including mammalian tissues, bovine serum and human serum albumin, or HSA. We are investigating alternatives to certain biological sources as such raw materials may be subject to contamination and/or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. A material shortage, contamination, recall and/or restriction of the use of certain biologically derived substances in the manufacture of our products could

adversely impact or disrupt our commercial manufacturing of our products or could result in a mandated withdrawal of our products from the market. This could adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially.

Our current products and products in development cannot be sold if we do not maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.

We and certain of our licensors and partners conduct research, preclinical testing and clinical trials for our product candidates. In addition, we manufacture and contract manufacture and certain of our licensors and partners manufacture our product candidates. We also manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Currently, we are required in the United States and in foreign countries to obtain approval from those countries regulatory authorities before we can manufacture (or have our third-party manufacturers produce), market and sell our products in those countries. The FDA and other U.S. and foreign regulatory agencies have substantial authority to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, mandate product withdrawals and require changes in labeling of our products.

In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, remains costly to maintain. With the occurrence of a number of high profile safety events with certain pharmaceutical products such as Vioxx and Bextra, regulatory authorities, members of Congress, the Government Accountability Office (GAO), 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. As a result, clinical trials may receive greater scrutiny with respect to safety. Any safety concerns may result in the FDA or other regulatory authorities requiring longer or additional clinical trials that may result in substantial additional expense. (See Before we commercialize and sell any of our product candidates, we must conduct clinical trials in humans; if we fail to adequately manage these trials we may not be able to sell future products and our sales could be adversely affected.) In addition, if regulatory authorities determine that we or our licensor or partner conducting research and development activities on our behalf have not complied with regulations in the research and development of a product candidate, then they may not approve the product candidate and we will not be able to market and sell it. If we were unable to market and sell our products or product candidates, our business and results of operations would be materially and adversely affected.

Substantially all of our marketed products are currently approved in the United States and most are approved in Europe and in other foreign countries for specific uses. However, later discovery of unknown problems with our products could result in restrictions on the sale or use of such products, including potential withdrawal of the product from the market. If new medical data suggests an unacceptable safety risk or previously unidentified side-effects, we may voluntarily withdraw, or regulatory authorities may mandate the withdrawal of, such product from the market for some period or permanently. For example, we initiated a voluntary recall of the Neulasta® SureClick™ pre-filled pen in Europe because of the potential risk to patients of receiving an incomplete dose and we have previously conducted a voluntary wholesaler recall of a limited

number of lots of ENBREL as a result of a small number of reports of missing, detached or loose rubber caps on the needle-less syringe filled with diluent liquid by a third-party contract manufacturer and packaged with the vials of ENBREL. Although there have been no observable adverse event trends associated with the Neulasta ® SureClick™ pen or with the reports of missing detached or loose rubber caps, we may experience the same or other problems in the future resulting in broader product recalls or adverse event trends. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

If we or others identify side effects before or after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and changes to or re-approvals of our manufacturing facilities may be required, any of which could have a material adverse effect on sales of the affected products and on our business and results of operations. Certain labels or label changes may be necessary for a number of reasons, including: the identification of actual or theoretical safety or efficacy concerns by regulatory agencies; the discovery of significant problems with a similar product that implicates an entire class of products or subsequent concerns about the sufficiency of the data or studies underlying the label. Before any of our products are approved for commercial use, regulatory bodies could decide that the product label include certain warning language as part of an evolving label change to a particular class of products. For example, the VectibixTM (panitumumab) prescribing information includes warning language from the FDA on dermatologic toxicities and severe infusion reactions as part of an evolving FDA labeling to the anti-epidermal growth factor receptor (EGFr) class. In addition, after any of our products are approved for commercial use, we or regulatory bodies could decide, and have in the past decided, that changes to our product labeling are required. For example, the FDA also instituted a class label change for the three recombinant erythropoiesis stimulating proteins (ESPs) marketed in the U.S. The label change to the class, which included EPOGEN® and Aranesp®, added information about pure red cell aplasia (PRCA) to the adverse event profile section to the three ESP product labels in the U.S. Any significant concerns raised about the safety or efficacy of our products could also result in the need to reformulate those products, to conduct additional clinical trials, to make changes to our manufacturing processes or to seek re-approval of our manufacturing facilities. Significant concerns about the safety and effectiveness of a product could ultimately lead to the revocation of its marketing approval. The labeling of a new product, a revision of product labeling or the regulatory actions described above could be required even if there is no clearly established connection between the product and the safety or efficacy concerns that have been raised. If the labeling of a new product, a revision of product labeling or the regulatory actions described above resulted in decreased use of our products, it could have a material adverse effect on sales of the affected products and on our business and results of operations.

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

We currently manufacture and market all our principal products, and we plan to manufacture and market many of our potential products. Manufacturing biologic human therapeutic products is difficult, complex and highly regulated. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval of our products and we may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market.) We currently manufacture our products at our

manufacturing facilities located in Thousand Oaks, California, Boulder and Longmont, Colorado, West Greenwich, Rhode Island and Juncos, Puerto Rico (See We formulate, fill and finish substantially all our products at our Puerto Rico manufacturing facility; if significant natural disasters or production failures occur at this facility, we may not be able to supply these products.). Additionally, we currently use third-party contract manufacturers to produce ENBREL and plan to use contract manufacturers to produce a number of our late stage product candidates. (See We are dependent on third parties for a significant portion of our bulk supply and the formulation, fill and finish of ENBREL.) Our ability to adequately and timely manufacture and supply our products is dependent on the uninterrupted and efficient operation of our facilities which is impacted by many manufacturing variables, including:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier
- facility capacity
- facility contamination by microorganisms or viruses
- compliance with regulatory requirements
- changes in forecasts of future demand
- timing and actual number of production runs
- production success rates and bulk drug yields
- timing and outcome of product quality testing

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

We manufacture and contract manufacture, price, sell, distribute and market or co-market our products for their approved indications. These activities are subject to extensive regulation by numerous state and federal governmental authorities in the United States, such as the FDA and CMS, as well as in foreign countries, including European countries, Canada, Australia and Japan. Although we have obtained regulatory approval for our marketed products, these products and our manufacturing processes and those of our third-party contract manufacturers must undergo a potentially lengthy FDA or other regulatory approval process are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build and license a new manufacturing plant and it can take longer than three years to qualify a new contract manufacturer. In order to maintain adequate supply to keep up with growing demand for our products, mitigate risks associated with the vast majority of our formulation, fill and finish operations located in Puerto

Rico, and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at nearly full production capacity over the next few years and maintain a state of regulatory compliance. Key manufacturing projects include: 1) construction, qualification and licensure of our new plant in Ireland; 2) construction, qualification and licensure of new formulation, fill and finish facilities at our Puerto Rico site; and 3) expansion of existing bulk protein facilities at our Puerto Rico site including the licensure of our Puerto Rico plant for production of Aranesp® and EPOGEN® bulk drug substance.

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

We 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® and some formulation, fill and finish operations for ENBREL at our manufacturing facility in Juncos, Puerto Rico. Our global supply of these products is significantly dependent on the uninterrupted and efficient operation of this facility. Additionally, to keep up with the growing demand for our products, we are operating this facility at nearly full production capacity. A number of factors could adversely affect our formulation, fill and finish operations, including:

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

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

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

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

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

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