AMGEN INC Form 10-Q August 08, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON D.C. 20549 FORM 10-O

(Mark One)

**DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the quarterly period ended June 30, 2005

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)

Registrant s telephone number, including area code

(805) 447-1000

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 b No o Indicate by check mark whether the registrant is an accelerated filer. b

As of July 15, 2005, the registrant had 1,233,806,783 shares of common stock, \$0.0001 par value, outstanding.

# AMGEN INC. INDEX

INDEA	
PART I FINANCIAL INFORMATION	Page No.
Item 1. Financial Statements	3
Condensed Consolidated Statements of Operations - Three and six months ended June 30, 2005 and 2004	4

Condensed Consolidated Balance Sheets - June 30, 2005 and December 31, 2004	5
Condensed Consolidated Statements of Cash Flows Six months ended June 30, 2005 and 2004	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	16
Item 4. Controls and Procedures	45
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	45
Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities	46
Item 4. Submissions of Matters to a Vote of Security Holders	47
Item 5. Other Items	47
Item 6. Exhibits	48
<u>Signatures</u>	49
Index to Exhibits Exhibit 3.3 Exhibit 10.49 Exhibit 10.61 Exhibit 31 Exhibit 32	50

#### **Table of Contents**

# PART I FINANCIAL INFORMATION

#### **Item 1. Financial Statements**

The information in this report for the three and six months ended June 30, 2005 and 2004 is unaudited but includes all adjustments (consisting only of normal recurring accruals, unless otherwise indicated) which Amgen Inc., including its subsidiaries ( Amgen ), 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, 2004.

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

3

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

		Months Ended (une 30,		onths Ended une 30,
	2005	2004	2005	2004
Revenues: Product sales	\$3,072	\$2,431	\$5,807	\$4,639
Other revenues	100	154	198	289
Total revenues	3,172	2,585	6,005	4,928
Operating expenses: Cost of sales (excludes amortization of acquire	.d			
intangible assets presented below)	530	435	1,019	809
Research and development	567	468	1,091	909
Selling, general and administrative	646	591	1,223	1,107
Amortization of acquired intangible assets Legal settlements	87 49	84	174 49	168
Total operating expenses	1,879	1,578	3,556	2,993
Operating income	1,293	1,007	2,449	1,935
Interest and other income and (expense), net	6	10	(4)	31
Income before income taxes	1,299	1,017	2,445	1,966
Provision for income taxes	270	269	562	528
Net income	\$1,029	\$ 748	\$1,883	\$1,438
Earnings per share: Basic Diluted	\$ 0.83 \$ 0.82	\$ 0.59 \$ 0.57	\$ 1.52 \$ 1.49	\$ 1.13 \$ 1.09
Shares used in calculation of earnings per share				
Basic	1,233	1,268	1,241	1,274
Diluted	1,250 See accompanying n 4	1,318 otes.	1,270	1,326

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

A CONTROL	June 30, 2005	December 31, 2004
ASSETS		
Current assets:	Φ 1 (21	ф. 1.50 <i>С</i>
Cash and cash equivalents  Marketable securities	\$ 1,621	\$ 1,526
Trade receivables, net	2,819 1,707	4,282 1,461
Inventories	984	888
Other current assets	894	1,013
Other current assets	0.74	1,013
Total current assets	8,025	9,170
Property, plant, and equipment, net	4,863	4,712
Intangible assets, net	3,872	4,033
Goodwill	10,519	10,525
Other assets	759	781
	\$28,038	\$ 29,221
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 503	\$ 507
Accrued liabilities	2,675	2,477
Convertible notes	1,749	1,173
Total current liabilities	4,927	4,157
Deferred tax liabilities	1,209	1,294
Convertible notes		1,739
Other long-term debt	2,198	2,198
Other non-current liabilities	123	128
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 - 1,231 shares in 2005 and 1,260 shares in 2004	22,468	22,078
Accumulated deficit	(2,918)	(2,376)
Accumulated other comprehensive income	31	3
Total stockholders equity	19,581	19,705
^ ·		•

\$28,038 \$29,221

See accompanying notes.

5

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

	Six Months Ended June 30,	
	2005	2004
Cash flows from operating activities: Net income Depreciation and amortization Tax benefits related to employee stock options Other items, net	\$ 1,883 419 124 (49)	\$ 1,438 355 92 72
Cash provided by (used in) changes in operating assets and liabilities: Trade receivables, net Inventories Other assets Accounts payable Accrued income taxes Other accrued liabilities	(246) (96) 39 (4) 78 192	(273) (13) 32 (15) (232) 58
Net cash provided by operating activities	2,340	1,514
Cash flows from investing activities: Purchases of property, plant, and equipment Proceeds from maturities of marketable securities Proceeds from sales of marketable securities Purchases of marketable securities Other  Net cash provided by investing activities	(403) 10,702 14,875 (24,114) 44 1,104	(742) 110 4,655 (3,087) (114) 822
Cash flows from financing activities: Repurchases of common stock Repayment of Convertible Notes Net proceeds from issuance of common stock upon the exercise of employee stock	(2,425) (1,175)	(1,650)
options and in connection with an employee stock purchase plan Other	270 (19)	195 (1)
Net cash used in financing activities	(3,349)	(1,456)
Increase in cash and cash equivalents	95	880
Cash and cash equivalents at beginning of period	1,526	837

Cash and cash equivalents at end of period

\$ 1,621

\$ 1,717

See accompanying notes.

6

# AMGEN INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS June 30, 2005

# 1. Summary of significant accounting policies

Business

Amgen Inc., including its subsidiaries, ( 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 six months ended June 30, 2005 and 2004 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 these periods. Interim results are not necessarily indicative of results for the full fiscal year.

Principles of consolidation

The Condensed Consolidated Financial Statements include the accounts of Amgen as well as its wholly owned subsidiaries. We do not have any significant interests in 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 Condensed Consolidated Financial Statements and accompanying notes. Actual results may differ from those estimates.

Reclassifications

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

Inventories

Inventories are stated at the lower of cost or market. Cost is determined in a manner, which approximates the first-in, first-out (FIFO) method. Inventories consisted of the following (in millions):

		December
	June 30,	31,
	2005	2004
Raw materials	\$148	\$ 117
Work in process	595	565
Finished goods	241	206
	\$984	\$ 888

#### AMGEN INC.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

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 14.4 years at June 30, 2005). As of June 30, 2005 and December 31, 2004, accumulated amortization of intangible assets amounted to \$1,021 million and \$834 million, respectively. Intangible assets primarily consist of acquired product technology rights of \$3,647 million, net of accumulated amortization of \$969 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. 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.

Goodwill principally relates to the acquisition of Immunex. The decrease in goodwill from the prior year is due to tax benefits realized upon exercise of Immunex related stock options during the six months ended June 30, 2005. We perform an impairment test annually and whenever events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable.

Product sales

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

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 have 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. The license agreement, which is perpetual, can be terminated upon mutual agreement of the parties, or default. Pursuant to this license, Amgen and Johnson & Johnson 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.

Sales of our other products are recognized when shipped and title and risk of loss have passed. Product sales are recorded net of accruals for estimated rebates (including Medicaid), wholesaler chargebacks, discounts, and other incentives (collectively sales incentives) and returns.

8

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

Research and development costs

Research and development ( R&D ) costs, which are expensed as incurred, are primarily comprised of the following types of costs incurred in performing R&D activities: salaries and benefits, overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. R&D expenses also include such costs related to activities performed on behalf of corporate partners.

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 include stock options under our employee stock option plans and potential issuances of stock under our equity incentive plans and under the assumed conversion of our Modified Convertible Notes utilizing the treasury stock method (collectively Dilutive Securities ). Potential common shares outstanding also include common shares to be issued under the assumed conversion of our Convertible Notes under the if-converted method. For further information regarding our convertible notes, see Note 4, Financing arrangements .

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Income (Numerator):				
Net income for basic EPS	\$1,029	\$ 748	\$1,883	\$1,438
Adjustment for interest expense on Convertible				
Notes, net of tax	1	5	6	11
Net income for diluted EPS, after assumed				
conversion	\$1,030	\$ 753	\$1,889	\$1,449
Shares (Denominator):				
Weighted-average shares for basic EPS	1,233	1,268	1,241	1,274
Effect of Dilutive Securities	9	15	10	17
Effect of Convertible Notes, after assumed				
conversion	8	35	19	35
Weighted-average shares for diluted EPS	1,250	1,318	1,270	1,326
Basic earnings per share	\$ 0.83	\$ 0.59	\$ 1.52	\$ 1.13
Diluted earnings per share	\$ 0.82 9	\$ 0.57	\$ 1.49	\$ 1.09

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

Employee stock options

We account for our employee stock options under the recognition and measurement principles of Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees, and related Interpretations, which generally results in no stock option expense. We grant our employee stock options at exercise prices equal to the market value of the underlying common stock on the date of grant and the related number of shares granted is fixed at that point in time resulting in no employee stock option expense reflected in net income.

The following table illustrates the effect on net income and EPS if we had applied the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, as amended (in millions, except per share information):

	<b>Three Months Ended</b>		Six Months Ended June 30,	
	Jun			
	2005	2004	2005	2004
Net income	\$1,029	\$ 748	\$1,883	\$1,438
Stock-based compensation, net of tax	(66)	(72)	(137)	(157)
Pro forma net income	\$ 963	\$ 676	\$1,746	\$1,281
Earnings per share:				
Basic	\$ 0.83	\$ 0.59	\$ 1.52	\$ 1.13
Impact of stock option expense	(0.05)	(0.06)	(0.11)	(0.12)
Basic pro forma	\$ 0.78	\$ 0.53	\$ 1.41	\$ 1.01
Diluted Impact of stock option expense	\$ 0.82 (0.05)	\$ 0.57 (0.05)	\$ 1.49 (0.11)	\$ 1.09 (0.11)
Diluted pro forma	\$ 0.77	\$ 0.52	\$ 1.38	\$ 0.98

The weighted-average fair value of common stock and stock options on the date of grant, and 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 three months ended June 30:

	2005	2004
Weighted average fair value of common stock	\$59.66	\$56.45
Weighted average fair value of stock options granted	\$16.07	\$21.97
Risk-free interest rate	3.7%	3.3%
Expected life (in years)	4.9	4.5
Expected volatility	22.0%	42.0%
Expected dividend yield	0%	0%

During the three months ended March 31, 2005, we revised our method of estimating expected volatility used in the Black-Scholes option valuation model to reflect the consideration of implied volatility in our publicly traded equity instruments.

Table of Contents 13

10

#### AMGEN INC.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123R, Share-Based Payment . SFAS No. 123R will require 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. Subsequently, the Securities and Exchange Commission (SEC) has provided for a phase-in implementation process for SFAS No. 123R, which requires us to adopt the new accounting standard no later than January 1, 2006. We plan to adopt SFAS No. 123R on January 1, 2006 and do not plan to restate our financial statements for periods ending prior to January 1, 2006. The adoption of SFAS No. 123R will have a material impact on our results of operations. The actual annual 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.

# 2. 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 six months ended June 30, 2005, our share of KA s profits were \$16 million and \$30 million, respectively. During the three and six months ended June 30, 2004 our share of KA s losses and profits were (\$1) million and \$5 million, respectively. 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. We currently market erythropoietin, G-CSF, darbepoetin alfa, and pegfilgrastim under the brand names EPOGEN®, NEUPOGEN®, Aranesp®, and Neulasta®, respectively. KA receives royalty income from us, as well as Kirin, Johnson & Johnson, F. Hoffmann-La Roche Ltd, and others under separate product license agreements for certain geographic areas outside of the United States. During the three and six months ended June 30, 2005 KA earned royalties from us of \$75 million and \$143 million, respectively. During the three and six months ended June 30, 2004, KA earned royalties from us of \$65 million and \$125 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 research and development activities conducted on its behalf by Amgen and Kirin. KA pays Amgen and Kirin for such services at negotiated rates. During the three and six months ended June 30, 2005, we earned revenues from KA of \$25 million and \$47 million, respectively, for certain research and development activities performed on KA s behalf. During the three and six months ended June 30, 2004, we earned revenues from KA of \$58 million and \$92 million, respectively. These amounts are included in Other revenues in the accompanying Condensed Consolidated Statements of Operations.

11

#### AMGEN INC.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

#### 3. Income taxes

The tax rates for the three and six months ended June 30, 2005 are different from the statutory rate primarily as a result of favorable resolution of prior year foreign tax credit claims and research and development tax credits with the Internal Revenue Service (IRS) and indefinitely reinvested earnings of our foreign operations. The favorable impact of prior year tax matters amounted to approximately \$47 million, or \$0.04 per diluted share, for the three months ended June 30, 2005. We do not provide for U.S. income taxes on undistributed earnings of our controlled foreign corporations that are intended to be reinvested indefinitely outside the United States.

On October 22, 2004, the President of the United States signed the American Jobs Creation Act of 2004 (the Jobs Act ). The Jobs Act creates a temporary incentive for U.S. corporations to repatriate accumulated income earned abroad by providing an 85 percent dividends received deduction for certain dividends from controlled foreign corporations. The deduction is subject to a number of limitations. The IRS issued its first guidance on the repatriation provision of the Jobs Act on January 13, 2005. On May 10, 2005, the IRS issued additional guidance in this area. However, uncertainty still remains as to how to interpret certain provisions in the Jobs Act. We are still evaluating the repatriation provisions of the Jobs Act and our 2005 second quarter results of operations do not reflect any impact relating to such repatriation provisions. Based on our preliminary analysis to date, we are limited under the Jobs Act to repatriate up to \$500 million in foreign profits, and we estimate the tax liability to be approximately \$30 to \$40 million if we repatriate the full \$500 million. We expect to complete our evaluation within a reasonable period of time following the publication of additional guidance by the IRS.

Our income tax returns are routinely audited by the IRS 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. While it is not possible to accurately predict or determine the eventual outcome of these matters, we do not believe any such items will have a material adverse effect on our annual Consolidated Financial Statements, although an adverse resolution in any quarterly reporting period of one or more of these items could have a material impact on the results of operations for that period.

# 4. Financing arrangements

On March 2, 2005, as a result of certain holders of the outstanding 30-year, zero-coupon senior convertible notes (the Convertible Notes) exercising their March 1, 2005 put option, we repurchased \$1.59 billion aggregate principal amount of Convertible Notes for their then-accreted value of \$1,175 million in cash, representing approximately 40% of our then outstanding Convertible Notes. Upon the repurchase of such Convertible Notes, a pro rata portion, \$20 million, of the related debt issuance costs were immediately charged to interest expense in the three months ended March 31, 2005. Also on March 2, 2005, we made an aggregate cash payment of \$22 million to the holders of the Convertible Notes who did not exercise the put option and continued to hold Convertible Notes subsequent to March 1, 2005. This payment is approximately equal to 1.25% of each Convertible

12

#### AMGEN INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

Note s then-accreted value. Concurrently, we amended the terms of the Convertible Notes to add an additional put date in order to permit the remaining holders, at their option, to cause us to repurchase the Convertible Notes on March 1, 2006 at the then-accreted value.

On May 6, 2005, we exchanged new zero-coupon senior convertible notes (the Modified Convertible Notes ) and a cash payment of approximately \$6 million for approximately 95% of the remaining Convertible Notes then outstanding. The significant terms of the Modified Convertible Notes are the same as the Convertible Notes except as follows:

While the Convertible Notes are convertible into common stock at any time, the Modified Convertible Notes can only be converted if: 1) the closing price of common stock exceeds the conversion price per share during a defined period at the end of the previous calendar quarter, 2) we call the Modified Convertible Notes for redemption, or 3) we make certain significant distributions to common stockholders or enter into specified types of corporate transactions.

If converted, the Convertible Notes will be settled for a specified number of shares of common stock. The conversion of the Modified Convertible Notes will be settled for a conversion value equal to the product of the conversion rate (8.8601 shares of Amgen common stock per note as of June 30, 2005) multiplied by the average closing price of our common stock during a specified period following the conversion date. The conversion value is paid in: 1) cash equal to the lesser of the accreted value of the Modified Convertible Notes at the conversion date or the conversion value, and 2) shares of common stock, if any, to the extent the conversion value exceeds the accreted value.

The conversion rate of the Convertible Notes will be adjusted to the extent we pay cash dividends equal to, or in excess of, a specified amount in any 12-month period. The conversion rate of the Modified Convertible Notes will be adjusted for any cash dividend paid by an amount equal to the dividend divided by the average closing price of common stock during a specified period immediately prior to the ex-dividend date. If holders of the Convertible Notes exercise their option to require us to purchase all, or a portion of, their notes, we have the right to pay the accreted value in cash and/or shares of common stock. If holders of the Modified Convertible Notes exercise their option, we must pay the accreted value solely in cash. If certain conditions are met, we are required to pay contingent interest on the Convertible Notes equal to the greater of: 1) cash dividends per share paid multiplied by the conversion rate or 2) a specified percentage of the market price of the Convertible Notes, as defined. Contingent interest on the Modified Convertible Notes must be paid if these same conditions are met but in an amount equal to a specified percentage of the market price of the Modified Convertible Notes, as defined, without regard to the amount of cash dividends paid, if any.

The changes to the Convertible Notes outstanding as a result of the May 2005 exchange combined with those made in March 2005 are being accounted for as a debt modification.

13

#### AMGEN INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

Accordingly, all cash paid to the holders of the Modified Convertible Notes and Convertible Notes (collectively referred to as convertible notes) is being amortized to interest expense over the life of the convertible notes using the effective interest method, and the costs incurred to modify the terms of the convertible notes were expensed as incurred.

At June 30, 2005, we had convertible notes outstanding with the following accreted values:

Modified Convertible Notes	\$1,660
Convertible Notes	89
Total convertible notes	\$1.749

These convertible notes had an aggregate face amount of \$2.36 billion and yield to maturity of 1.125%. The original issue discount is being accreted to the balance of the convertible notes and recognized as interest expense over the life of the convertible notes using the effective interest method. The holders of the convertible notes may require us to purchase all or a portion of their notes on various dates, the earliest of which is March 1, 2006, at a price equal to the original issuance price plus the accrued original issue discount to the purchase dates. Accordingly, the convertible notes were classified as current in the accompanying Condensed Consolidated Balance Sheet as of June 30, 2005.

# 5. Stockholders equity

Stock repurchase program

A summary of our stock repurchase activity for the six months ended June 30, 2005 and 2004 is as follows:

	2005		2004	
	Shares	<b>Dollars</b>	Shares	<b>Dollars</b>
First quarter	27	\$1,675	10	\$ 650
Second quarter	12	750	17	1,000
Total	39	\$2,425	27	\$1,650

As of June 30, 2005, we had \$3,544 million available for stock repurchases under our stock repurchase program authorized by the Board of Directors in December 2004. The amount we spend and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which we are restricted from repurchasing shares.

14

## AMGEN INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

Other comprehensive income

Our other comprehensive income includes 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 six months ended June 30, 2005, total comprehensive income was \$1,060 million and \$1,911 million, respectively. During the three and six months ended June 30, 2004, total comprehensive income was \$712 million and \$1,417 million, respectively.

# 6. Contingencies

During the three months ended June 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.

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 annual Consolidated Financial Statements, although an adverse resolution in any quarterly reporting period of one or more of these items could have a material impact on the results of operations for that period.

15

# **Table of Contents**

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

Forward looking statements

This report and other documents we file with the 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, believ continue, variations of such words and similar expressions are intended to identify such forw should. assume. 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 Factors that may affect Amgen . 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, 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, 2004.

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 serious 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 nephrology, supportive cancer care, and inflammatory disease. For the three and six months ended June 30, 2005, total revenues were \$3,172 million and \$6,005 million, respectively, and net income was \$1,029 million and \$1,883 million, respectively, or \$0.82 per share and \$1.49 per share, respectively. As of June 30, 2005, cash, cash equivalents and marketable securities were \$4,440 million.

16

#### **Table of Contents**

Our principal products include Aranesp® (darbepoetin alfa), EPOGEN® (Epoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim), and ENBREL® (etanercept), which 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 our Annual Report on Form 10-K for the year ended December 31, 2004. For both the three and six months ended June 30, 2005 and 2004, product sales represented 97% and 94% of total revenues, respectively. Over the last several years, our product sales growth has been primarily driven by sales of Aranesp®, ENBREL®, and Neulasta®, which benefited from market share gains and/or market growth. We expect these products to continue to drive sales growth in the near term. However, we expect that continued market share gains on a sequential basis will be a challenge as we operate in a highly competitive environment. Going forward, we expect to continue to focus on market share gains, but we also expect to increase our focus on growing the market. Most patients receiving our principal products for approved indications, excluding ENBREL®, are covered by both government and private payer health care programs. Primary reimbursement for ENBREL® is obtained from private payers. Therefore, our product sales are and will be affected by government and private payer reimbursement below for further information.

International product sales for both the three and six months ended June 30, 2005 represented approximately 18% of total product sales as compared to approximately 17% and 18% for the three and six months ended June 30, 2004, respectively. Our international product sales consisted principally of European sales. Our international sales are impacted by foreign currency changes (see Results of Operations discussion below). International product sales growth for the three and six months ended June 30, 2005 benefited by approximately \$31 million and \$59 million, respectively, from foreign currency exchange rate changes. However, both positive and negative impacts from movements in foreign exchange rates have been mitigated by the natural, opposite impact to 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 six months ended June 30, 2005, operating income increased \$286 million and \$514 million, respectively, as compared to operating income for the three and six months ended June 30, 2004 primarily as a result of our product sales growth. Operating income as a percentage of product sales was 42% and 41% for the three months ended June 30, 2005 and 2004, respectively. For both the six months ended June 30, 2005 and 2004, operating income as a percentage of product sales was 42%. For the three and six months ended June 30, 2005, our operating income as a percentage of product sales was negatively impacted by a settlement expense of \$49 million, resulting from certain legal matters primarily related to a patent legal proceeding. For the remainder of 2005, we expect our operating expenses to increase as compared to the first half of 2005, in support of our anticipated product sales growth, and as a result of our continued investment in research and development ( R&D ) to advance our pipeline. Furthermore, operating expenses as a percentage of product sales for the second half of 2005 is expected to be higher than that of the first half of 2005.

We focus our R&D efforts on human therapeutics delivered in the form of proteins, monoclonal antibodies, and small molecules in the areas of oncology, inflammation, metabolic disorders, neuroscience, and general medicine. We focus on the development of novel therapeutics for the treatment of serious illness. We take a modality-independent approach to R&D that is, we

17

#### **Table of Contents**

identify targets, then choose the modality best suited to address a specific target. To enhance our internal R&D efforts, we have acquired and licensed certain product and technology rights and have established R&D collaborations. We expect to continue to invest significantly in R&D.

There are many economic and industry-wide factors that affect our business, including, among others, those relating to broad reimbursement changes, increased complexity and cost of R&D, increasingly intense competition for our currently marketed products and product candidates, complex and expanding regulatory requirements, and intellectual property protection. See Item 1. Business in our Annual Report on Form 10-K for the year ended December 31, 2004 and Factors That May Affect Amgen 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. Therefore, sales of Aranesp®, Neulasta®, and NEUPOGEN® are dependent, in part, on the availability and extent of reimbursement from third-party payers, including governments and private insurance plans. Primary reimbursement for ENBREL® is obtained from private payers. Generally, worldwide use of our products may be affected by cost containment pressures from governments and private insurers on health care providers in response to ongoing initiatives to reduce health care expenditures (see MD&A Factors That May Affect Amgen 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. )

The Medicare Prescription Drug Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003. For the first half of 2005, we believe that our product sales were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS is oncology demonstration project (the 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 Demonstration Project, which provides financial incentives to physicians for collecting and reporting oncology patient survey data, is currently scheduled to expire on December 31, 2005. However, we expect that during the remainder of 2005, reimbursement changes resulting from the MMA could negatively affect product sales of some of our marketed products.

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. Effective January 1, 2005, in the physician clinic market segment, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a new Medicare Part B system that

\*

reimburses each product at 106% of

#### **Table of Contents**

its average sales price (ASP) (sometimes referred to as ASP+6%). ASP is calculated by the manufacturer based on a statutorily defined methodology 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 we submit for the fourth quarter of 2005 will be based on certain historical sales and sales incentive data for Aranesp® from July 1, 2004 through June 30, 2005. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The first second and third quarter 2005 reimbursement rates for Aranesp®, Neulasta®, and NEUPOGEN® (calculated at 106% of the ASPs), are lower than our 2004 reimbursement rates as the ASP methodology incorporates lagged sales incentives offered to healthcare providers. We expect that the ASPs for our products will trend downward throughout 2005, and we expect it will be towards the end of 2005 before our ASPs stabilize. Per the MMA, physicians in this market segment will have the choice between purchasing and billing for drugs under the ASP+6% system or obtaining drugs from vendors selected by CMS under the competitive acquisition program (CAP). Physicians who select to obtain drugs from CAP will no longer purchase or obtain reimbursement directly for such drugs. CMS issued an interim final rule related to CAP at the end of June of 2005. On August 3, 2005, CMS announced that it expects to publish a final rule in late 2005 and that drugs will first be delivered through the CAP by July 2006. Based on the interim final rule for CAP as proposed, we do not anticipate widespread adoption of this system initially. However, because we cannot fully predict how many physicians will select to obtain drugs from CAP, and because this is not a final rule, we cannot predict the full impact of the CAP on our business. While the rule does not provide the CAP vendors with the ability to utilize formularies, discounts to CAP vendors are included in the calculation of ASPs and therefore has the potential to impact the ASPs for certain of our products.

The Medicare hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, will continue to utilize 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 is based on the AWP of PROCRIT®. For 2005 the reimbursement rate for Aranesp® is 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 will change from an AWP based reimbursement system to a system based on average acquisition cost. This change will affect Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. In July 2005, CMS released its draft OPPS rule for 2006. This rule recommended removing the equitable adjustment for Aranesp®, as well as basing reimbursement for non-pass through products such as Aranesp® on an ASP plus 6% (based upon the ASP for the second quarter of 2005) and an additional 2% added for pharmacy handling costs. CMS is soliciting public comments on these recommendations, and we expect that the final rule will not be issued until October 2005.

Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 has been changed from the previous rate of \$10 per 1,000 Units to \$9.76 per 1,000 Units, a rate based upon an average

19

#### **Table of Contents**

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 has been added to the composite rate that dialysis providers receive for dialysis treatment. Again in 2006, the EPOGEN® rate may change, as the MMA provided for discretion in either continuing to pay for these separately reimbursed dialysis drugs at acquisition cost, or switching to an ASP based system. The payment rate for dialysis drugs not studied by the OIG, including Aranesp®, is ASP+6% in 2005, and could remain at this rate in 2006.

On August 1, 2005 CMS released the 2006 Medicare Physician Fee Schedule/ESRD Payment Proposed Rule. We are currently in the process of evaluating this proposed rule. As a result, as of the date of this filing, we cannot predict the potential full impact of this proposed rule on our business. This proposed rule recommends changing the payment mechanism for separately reimbursed dialysis drugs, including EPOGEN®, from the current acquisition cost approach to ASP+6. Based on our preliminary evaluation, the proposed rule appears to reduce reimbursement in a number of areas including certain drug administration fees. The comment period for this proposed rule ends September 30, 2005.

We believe that beginning on January 1, 2006, ENBREL®, Sensipar®, and Kineret® will be covered by the MMA-mandated Medicare outpatient prescription drug benefit (also known as Part D). With the exception of a Part D demonstration project that CMS is conducting in 2004-2005 that will, among other things, provide reimbursement for ENBREL® for certain Medicare beneficiary participants, Medicare currently does not cover prescriptions for ENBREL®, Sensipar®, and Kineret®.

With the exception of the Part D prescription drug benefit, we believe these changes driven by the MMA are lowering the 2005 reimbursement rate for all areas in which CMS provides reimbursement for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®. However, because we cannot predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, as of the date of this filing, we cannot predict the full impact of the MMA on our business; however, it could be negative.

In addition, on July 8, 2004, CMS released a proposed revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® utilization and appropriate hematocrit outcomes of dialysis patients. The proposed policy would not permit reimbursement for EPOGEN® in the following circumstances without medical justification: EPOGEN® doses greater than 40,000 Units per month in a patient with a hemoglobin greater than 13 grams per deciliter or doses greater than 20,000 Units per month in a patient with hemoglobin greater than 14 grams per deciliter. As of the date of this filing, the comment period for the proposed revision has expired and no final program memorandum has been issued. If the proposed revision, which has not yet been finalized, is adopted as the final form, it could result in a reduction in utilization of EPOGEN®. We and the nephrology community have provided public comment based on data analysis suggesting that the proposed revision to the HMA-PM is unwarranted. The nephrology community has worked closely with CMS in response to the draft policy to develop consensus recommendations for a new policy that is focused on appropriate EPOGEN® utilization rather than EPOGEN® dose or hemoglobin levels. It is possible that CMS may

20

#### **Table of Contents**

adopt all or some aspects of the consensus recommendations when issuing a final policy. Although the proposed revision was scheduled to go into effect as early as January 1, 2005, it is unclear as to when it may be implemented but we believe that implementation would be no earlier than January 2006. Given the importance of EPOGEN® utilization for maintaining the quality of care for dialysis patients, the precise impact of such a change on provider utilization remains unclear.

Our product sales 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 results of operations.

# **Results of Operations**

Product sales

For the three and six months ended June 30, 2005 and 2004, total product sales by geographic region were as follows (amounts in millions):

	Three mo	nths ended		Six mon	ths ended	
	June 30,			<b>June 30,</b>		
	2005	2004	Change	2005	2004	Change
Total U.S.	\$2,532	\$2,007	26%	\$4,763	\$3,825	25%
Total International	540	424	27%	1,044	814	28%
Total product sales	\$3,072	\$2,431	26%	\$5,807	\$4,639	25%

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, foreign exchange effects, new product launches and indications, competitive products, product supply, and acquisitions.

Sales growth was principally driven by demand for Aranesp®, ENBREL®, and Neulasta®. U.S. sales for Aranesp® and Neulasta® were impacted by higher sales incentives earned by customers under performance-based contracts. International product sales growth for the three and six months ended June 30, 2005 benefited by approximately \$31 million and \$59 million, respectively, from foreign currency exchange rate changes.

In the near term, we expect sales growth to continue to be driven primarily by Aranesp®, ENBREL®, and Neulasta®. For the first half of 2005, we believe that our product sales were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS s oncology demonstration project (the 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 Demonstration Project, which provides financial incentives to physicians for collecting and reporting oncology patient survey data, is currently scheduled to expire on December 31, 2005. However, we expect that during the remainder of 2005, reimbursement changes resulting from the MMA could negatively affect product sales of some of our marketed products. Further, reimbursement changes could impact sequential sales growth and historical sales trends (see Reimbursement above).

21

**Aranesp®** 

(Amounts in millions)

	Three months ended June 30,			Six months ended June 30,			
	2005	2004	Change	2005	2004	Change	
Aranesp® U.S.	\$536	\$380	41%	\$ 983	\$ 710	38%	
Aranesp® International	301	237	27%	577	450	28%	
Total Aranesp®	\$837	\$617	36%	\$1,560	\$1,160	34%	

The increase in U.S. Aranesp® sales for the three and six months ended June 30, 2005 was primarily driven by demand which benefited from market share gains in both oncology and nephrology and to a lesser extent market growth. Sales growth was impacted by higher incentives earned by customers attaining higher sales volumes and growth under performance-based contracts. The increase in international Aranesp® sales was principally driven by demand, and to a lesser extent, favorable changes in foreign currency exchange rates. International Aranesp® sales growth for the three and six months ended June 30, 2005, benefited by \$17 million and \$31 million, respectively, from foreign currency exchange rate changes.

We believe future worldwide Aranesp® sales growth will be dependent, in part, on such factors as: reimbursement by third-party payers (including governments and private insurance plans) (see Factors That May Affect Amgen 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. ); 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 such as the Demonstration Project; penetration of new and existing markets; patient population growth; the effects of pricing strategies; competitive products or therapies, including follow-on biologic products in Europe; the development of new treatments for cancer; and changes in foreign currency exchange rates. Also, we believe that U.S. sales for the remainder of 2005 could be negatively impacted as we expect that the ASPs for Aranesp® will trend downward throughout 2005. We expect it will be towards the end of 2005 before our ASPs for Aranesp® stabilize. *EPOGEN*®

(Amounts in millions)

		Three months ended			Six months ended			
		June 30,			Jun			
		2005	2004	Change	2005	2004	Change	
<b>EPOGEN®</b>	U.S.	\$647	\$633	2%	\$1,230	\$1,223	1%	

The growth in reported EPOGEN® sales for the three months ended June 30, 2005 was primarily due to changes in wholesaler inventory levels and to a lesser extent, a favorable revised estimate of dialysis demand for prior quarters. This revised estimate of demand is primarily spillover (See Note 1, Summary of significant accounting policies Product sales to the Condensed Consolidated Financial Statements). This increase was partially offset by a mid-single digit decline in

22

demand, impacted by higher sales incentives provided to customers and increased usage of Aranesp® in dialysis.

For the six months ended June 30, 2005, growth was primarily due to changes in wholesaler inventory levels.

Demand was comparable to the six months ended June 30, 2004, reflecting an increase in dialysis purchases offset by the impact of higher sales incentives provided to customers, both of which were in the mid-single digits. Demand was also impacted by increased usage of Aranesp® in 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. We believe EPOGEN® sales growth will primarily depend on dialysis patient population growth and changes in reimbursement rates or a change in the basis for reimbursement by the federal government (see Factors That May Affect Amgen 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 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. Further, EPOGEN® sales have been and may continue to be impacted by Aranesp® in the United States as some health care providers use Aranesp® to treat anemia associated with chronic renal failure instead of EPOGEN®. To the extent that future changes in reimbursement and/or our pricing strategies impact these products, we could experience further usage of Aranesp® for the treatment of anemia associated with chronic renal failure for patients who are on dialysis.

Neulasta®/NEUPOGEN® (Amounts in millions)

		nths ended e 30,	Six months ended June 30,					
	2005	2004	Change	2005	2004	Change		
Neulasta® U.S.	\$490	\$362	35%	\$ 906	\$ 698	30%		
Neulasta® International	97	64	52%	182	123	48%		
Neulasta® Total	587	426	38%	1,088	821	33%		
NEUPOGEN® U.S.	208	195	7%	390	367	6%		
NEUPOGEN® International	104	100	4%	216	197	10%		
NEUPOGEN® Total	312	295	6%	606	564	7%		
Total Neulasta®/NEUPOGEN®	\$899	\$721	25%	\$1,694	\$1,385	22%		

The increase in combined worldwide Neulasta®/NEUPOGEN® sales for the three and six months ended June 30, 2005 was driven primarily by demand for Neulasta® and to a lesser extent, changes in wholesaler inventory levels, primarily relating to Neulasta® sales in the United States. Sales growth was impacted by higher incentives earned by customers attaining higher sales volumes and growth under performance-based contracts for U.S. Neulasta® sales. Combined international Neulasta®/NEUPOGEN® sales growth for the three and six months ended June 30, 2005, benefited by \$11 million and \$23 million, respectively, from foreign currency exchange rate changes.

#### **Table of Contents**

We believe 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) (see Factors That May Affect Amgen 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. ); 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 such as the Demonstration Project; penetration of existing markets; patient population growth; the effects of pricing strategies; competitive products or therapies, including follow-on biologic products in Europe; the development of new treatments for cancer; and changes in foreign currency exchange rates. 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. NEUPOGEN® sales have been adversely impacted by conversion to Neulasta®. However, we believe that most of the conversion in the United States has occurred. We believe that we are experiencing conversion of NEUPOGEN® patients to Neulasta® in Europe, but we believe that this conversion will occur to a lesser extent than that experienced in the United States. However, we cannot accurately predict the rate or timing of future conversion of NEUPOGEN® patients to Neulasta® in Europe. Also, we believe that U.S. Neulasta®/NEUPOGEN® sales for the remainder of 2005 could be negatively impacted as we expect their ASPs will trend downward throughout 2005. We expect it will be towards the end of 2005 before our ASPs for U.S. Neulasta®/NEUPOGEN® stabilize. **ENBREL®** 

(Amounts in millions)

		Three months ended June 30,					
		2005	2004	Change	2005	2004	Change
<b>ENBREL®</b>	U.S.	\$614	\$423	45%	\$1,184	\$805	47%
<b>ENBREL®</b>	International	25	17	47%	47	32	47%
Total ENBR	EL®	\$639	\$440	45%	\$1,231	\$837	47%

ENBREL® sales growth for the three and six months ended June 30, 2005 was driven by demand, benefiting from ENBREL® s competitive profile and significant growth of biologics in the rheumatology and dermatology markets. In the dermatology market, ENBREL® sales have grown significantly since its approval for moderate to severe psoriasis in April of 2004.

We believe that future ENBREL® sales growth will be dependent, in part, on such factors as: the effects of competing products or therapies; penetration of existing and new markets, including potential new indications; the availability and extent of reimbursement by government and third-party payers; governmental or private organization regulations or guidelines relating to the use of our products (see Factors That May Affect Amgen Our sales depend on payment and reimbursement from third-party payers, and, to the extent that reimbursement for our products is reduced, this could negatively impact the utilization of our products ); and limits on the current supply of and sources of ENBREL® (see Factors That May Affect Amgen Limits on supply for ENBREL® may constrain ENBREL® sales ).

24

#### **Table of Contents**

Selected operating expenses

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

	Three months ende June 30,		ıded			ths ended te 30,	
		2005		2004	2005	2	2004
Product sales	\$3	3,072	\$2	2,431	\$5,807	\$4	1,639
Operating expenses:							
Cost of sales (excludes amortization of acquired							
intangible assets)	\$	530	\$	435	\$1,019	\$	809
% of product sales		17%		18%	18%		17%
Research and development	\$	567	\$	468	\$1,091	\$	909
% of product sales		18%		19%	19%		20%
Selling, general and administrative	\$	646	\$	591	\$1,223	\$1	,107
% of product sales		21%		24%	21%		24%

Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see Condensed Consolidated Statements of Operations ), increased 22% and 26% for the three and six months ended June 30, 2005, respectively, primarily due to higher sales volumes. Costs of sales as a percentage of product sales was comparable to the three and six months ended June 30, 2004.

Research and development

R&D expenses are primarily comprised of salaries and benefits associated with R&D personnel, overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. R&D expenses increased 21% and 20% for the three and six months ended June 30, 2005, respectively, primarily driven by higher staff-related costs including the addition of R&D personnel from Tularik, and to a lesser extent, higher costs relating to key clinical trials and clinical manufacturing, including the ramp up of large-scale phase 3 trials for AMG 162, Amgen s investigational therapy for bone loss. During the three months ended June 30, 2005, staff-related costs and clinical trial and clinical manufacturing costs increased approximately \$54 million and \$49 million, respectively. During the six months ended June 30, 2005, staff-related costs and clinical trial and clinical manufacturing costs increased approximately \$96 million and \$76 million, respectively. In 2005, we expect our R&D expenses to increase primarily due to higher clinical manufacturing, clinical trial, and staff-related costs, including the addition of R&D personnel from Tularik, to support our development efforts for AMG 162 and other product candidates as compared to 2004.

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 9% and 10% for the three and six months ended June 30, 2005, respectively, primarily due to higher staff-related expenses and higher outside marketing expenses in support of

25

# **Table of Contents**

our key products. Outside marketing expenses include the Wyeth profit share related to ENBREL®, which has increased due to ENBREL® sales growth. During the three months ended June 30, 2005, outside marketing expenses and staff-related costs increased approximately \$43 million and \$41 million, respectively. During the six months ended June 30, 2005, outside marketing expenses and staff-related costs increased approximately \$99 million and \$36 million, respectively. The three and six month increases in outside marketing and staff-related expenses were partially offset by higher earnings from our affiliates, primarily Kirin-Amgen, Inc. (see Note 2, Related party transactions , to the Condensed Consolidated Financial Statements for further information.) For the remainder of 2005, we expect our SG&A expenses to increase, compared to the first half of 2005, primarily due to continued support of our marketed products including higher Wyeth profit share expense due to expected ENBREL® sales growth. Furthermore, SG&A expense as a percentage of product sales is expected to be higher in the second half of 2005, than that of the first half of 2005. However we have seen and expect to continue to see some leveraging of our 2004 SG&A spending during 2005.

Legal settlements

During the three months ended June 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.

Income taxes

Our effective tax rates for the three and six months ended June 30, 2005 were 20.8% and 23.0%, respectively, compared with 26.4% and 26.8%, respectively, for the same periods last year. Our effective tax rates for the three and six months ended June 30, 2005 have decreased primarily due to favorable resolution of prior year foreign tax credit claims and research and development tax credits with the Internal Revenue Service (IRS) and an increase in indefinitely reinvested earnings of our foreign operations. The favorable impact of prior year tax matters amounted to approximately \$47 million, or \$0.04 per diluted share, for the three months ended June 30, 2005. For the remainder of 2005, the effective tax rate is expected to be slightly lower than our first quarter 2005 rate of 25.5%.

We do not provide for U.S. income taxes on undistributed earnings of our controlled foreign corporations that are intended to be reinvested indefinitely outside the United States.

On October 22, 2004, the President of the United States signed the American Jobs Creation Act of 2004 (the Jobs Act ), which provides a temporary incentive to repatriate undistributed foreign earnings. There are uncertainties that remain as to how to interpret certain provisions in the Jobs Act. As such, we are still evaluating the repatriation provisions of the Jobs Act and our 2005 second quarter results of operations do not reflect any impact relating to such repatriation provisions. We expect to complete our evaluation within a reasonable period of time following the publication of additional guidance by the IRS.

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

26

### Financial Condition, Liquidity and Capital Resources

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

		December
	<b>June 30,</b>	31,
	2005	2004
Cash, cash equivalents, and marketable securities	\$ 4,440	\$ 5,808
Total assets	28,038	29,221
Current debt	1,749	1,173
Non-current debt	2,198	3,937
Stockholders equity	19,581	19,705

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. However, in order to provide for greater financial flexibility and liquidity, we may raise additional capital from time to time.

Cash, cash equivalents, and marketable securities

Of the total cash, cash equivalents, and marketable securities at June 30, 2005, approximately \$2.6 billion represents cash 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, additional taxes on certain of these amounts would be required to be paid. Based on our preliminary analysis to date, we are limited under the Jobs Act to repatriate up to \$500 million in foreign profits. See Results of Operations Income taxes for further discussion.

Financing arrangements

As of June 30, 2005 we had convertible notes (30-year, zero-coupon senior convertible notes) with an accreted value of \$1.7 billion outstanding and having an aggregate face amount of \$2.36 billion and yield to maturity of 1.125%. The holders of the convertible notes may require us to purchase all or a portion of their notes on various dates (the Put Option ), the earliest of which is March 1, 2006, at a price equal to the original issuance price plus the accrued original issue discount to the purchase dates. Accordingly, the convertible notes were classified as current in the accompanying Condensed Consolidated Balance Sheet as of June 30, 2005. Holders of the convertible notes may convert each of their notes according to the terms as outlined in Note 4, Financing arrangements. In the event the holders of the convertible notes exercise their Put Option or elect to convert their convertible notes, we are required to pay substantially all the accreted value in cash. Moody s and Standard & Poor s rate our outstanding convertible notes A2 and A+, respectively.

As of June 30, 2005 we had \$2 billion of long-term senior notes outstanding. These long-term senior notes consisted of: 1) \$1 billion of senior notes that bear interest at a fixed rate of 4.0% and mature in 2009, and 2) \$1 billion of senior 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.

27

# **Table of Contents**

As of June 30, 2005, we had \$200 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 (the \$500 Million Shelf), and 2) \$100 million of debt securities that bear interest at a fixed rate of 8.1% and mature in 2097. 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 five-year unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support. 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 June 30, 2005.

We have a \$1.0 billion shelf registration (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 June 30, 2005, no securities had been issued under the \$1 Billion Shelf.

Certain of our financing arrangements contain non-financial covenants and as of June 30, 2005, we are in compliance with all applicable covenants.

Cash flows

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

	Six months ended June 3		
	2005	2004	
Net cash provided by operating activities	\$ 2,340	\$ 1,514	
Net cash provided by investing activities	1,104	822	
Net cash used in financing activities	(3,349)	(1,456)	

**Operating** 

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. The increase in cash provided by operating activities during the six months ended June 30, 2005 resulted primarily from higher cash receipts from customers driven by the growth in product sales and timing differences of cash payments relating to our tax and other accrued liabilities. (See Condensed Consolidated Statements of Cash Flows).

Investing

Capital expenditures totaled \$403 million during the six months ended June 30, 2005, compared with \$742 million during the same period last year. The decrease in capital expenditures

28

# **Table of Contents**

during the six months ended June 30, 2005 is primarily due to lower expenditures relating to the new ENBREL® manufacturing plant in Rhode Island, which has been completed and is awaiting final FDA approval. These capital expenditures were more than offset by net proceeds from maturities and sales of marketable securities of \$1,463 million during the six months ended June 30, 2005.

We currently estimate 2005 spending on capital projects and equipment to be \$1.1 billion, an amount slightly less than our 2004 expenditures. The most significant of these expenditures are expected to relate to the Puerto Rico manufacturing and the Thousand Oaks site expansions.

**Financing** 

During the six months ended June 30, 2005 and 2004, we repurchased 39 million and 27 million shares of our common stock, respectively, at a total cost of \$2,425 million and \$1,650 million, respectively. As of June 30, 2005, we had \$3,544 million available for stock repurchases under our stock repurchase program authorized by the Board of Directors. The amount we spend and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which we are restricted from repurchasing shares. Repurchases under our stock repurchase programs have reflected, in part, our confidence in the long-term value of Amgen common stock.

See Part II Other Information, Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities for additional information regarding our stock repurchase program.

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

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 \$270 million and \$195 million of cash during the six months ended June 30, 2005 and 2004, 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.

29

# **Table of Contents**

### Factors that may affect Amgen

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

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 both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payers such as state and federal governments, under programs such as Medicare and Medicaid in the United States, and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the United States, there have been, there are, and we expect there will continue to be, a number of state and federal laws and/or regulations, or in some cases draft legislation or regulations that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. For example, the Medicare Prescription Drug, Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions in response to legislation or regulations, including, without limitation, the MMA. For the first half of 2005, we believe that our product sales were not significantly impacted by the reimbursement changes resulting from the MMA. We believe this was, in part, due to the effects of CMS s oncology demonstration project (the 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 Demonstration Project, which provides financial incentives to physicians for collecting and reporting oncology patient survey data, is currently scheduled to expire on December 31, 2005. However, we expect that during the remainder of 2005, reimbursement changes resulting from the MMA could negatively affect product sales of some of our marketed products.

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. Effective January 1, 2005, in the physician clinic market segment, Aranesp®, Neulasta® and NEUPOGEN® are being reimbursed under a new Medicare Part B system 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 methodology 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 we submit for the fourth quarter of 2005 will be based on certain historical sales and sales incentive data for Aranesp® from July 1, 2004 through June 30, 2005. CMS publishes the ASPs for products in advance of the quarter in which they go into effect. The first second and third quarter 2005 reimbursement rates for Aranesp®, Neulasta®, and NEUPOGEN® (calculated at 106% of the ASPs), are lower than our 2004 reimbursement rates as the ASP methodology incorporates lagged sales incentives offered to healthcare providers. We expect that the

#### **Table of Contents**

ASPs for our products will trend downward throughout 2005, and we expect it will be towards the end of 2005 before our ASPs stabilize.

Per the MMA, physicians in this market segment will have the choice between purchasing and billing for drugs under the ASP+6% system or obtaining drugs from vendors selected by CMS under the competitive acquisition program (CAP). Physicians who select to obtain drugs from CAP will no longer purchase or obtain reimbursement directly for such drugs. CMS issued an interim final rule related to CAP at the end of June of 2005. On August 3, 2005, CMS announced that it expects to publish a final rule in late 2005 and that drugs will first be delivered through the CAP by July 2006. Based on the interim final rule for CAP as proposed, we do not anticipate widespread adoption of this system initially. However, because we cannot fully predict how many physicians will select to obtain drugs from CAP, and because this is not a final rule, we cannot predict the full impact of the CAP on our business. While the rule does not provide the CAP vendors with the ability to utilize formularies, discounts to CAP vendors are included in the calculation of ASPs and therefore has the potential to impact the ASPs for certain of our products.

The Medicare hospital outpatient prospective payment system (OPPS), which determines payment rates for specified covered outpatient drugs and biologics in the hospital outpatient setting, will continue to utilize 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 is based on the AWP of PROCRIT®. For 2005 the reimbursement rate for Aranesp® is 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 will change from an AWP based reimbursement system to a system based on average acquisition cost. This change will affect Aranesp®, Neulasta® and NEUPOGEN® when administered in the hospital outpatient setting. In July 2005, CMS released its draft OPPS rule for 2006. This rule recommended removing the equitable adjustment for Aranesp®, as well as basing reimbursement for non-pass through products such as Aranesp® on an ASP plus 6% (based upon the ASP for the second quarter of 2005) and an additional 2% added for pharmacy handling costs. CMS is soliciting public comments on these recommendations, and we expect that the final rule will not be issued until October 2005.

Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 has been changed from the previous rate of \$10 per 1,000 Units to \$9.76 per 1,000 Units, 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 has been added to the composite rate that dialysis providers receive for dialysis treatment. Again in 2006, the EPOGEN® rate may change, as the MMA provided for discretion in either continuing to pay for these separately reimbursed dialysis drugs at acquisition cost, or switching to an ASP based system. The payment rate for dialysis drugs not studied by the OIG, including Aranesp®, is ASP+6% in 2005, and could remain at this rate in 2006.

31

#### **Table of Contents**

On August 1, 2005 CMS released the 2006 Medicare Physician Fee Schedule/ESRD Payment Proposed Rule. We are currently in the process of evaluating this proposed rule. As a result, as of the date of this filing, we cannot predict the potential full impact of this proposed rule on our business. This proposed rule recommends changing the payment mechanism for separately reimbursed dialysis drugs, including EPOGEN®, from the current acquisition cost approach to ASP+6. Based on our preliminary evaluation, the proposed rule appears to reduce reimbursement in a number of areas including certain drug administration fees. The comment period for this proposed rule ends September 30, 2005.

We believe these changes driven by the MMA are lowering the 2005 reimbursement rate for all areas in which CMS provides reimbursement for EPOGEN®, Aranesp®, Neulasta® and NEUPOGEN®. However, because we cannot predict the impact of any such changes on how, or under what circumstances, healthcare providers will prescribe or administer our products, as of the date of this filing, we cannot predict the full impact of the MMA on our business; however, it could be negative.

In addition, on July 8, 2004, CMS released a proposed revision to the Hematocrit Measurement Audit Program Memorandum (HMA-PM), a Medicare payment review mechanism used by CMS to audit EPOGEN® utilization and appropriate hematocrit outcomes of dialysis patients. The proposed policy would not permit reimbursement for EPOGEN® in the following circumstances without medical justification: EPOGEN® doses greater than 40,000 Units per month in a patient with a hemoglobin greater than 13 grams per deciliter or doses greater than 20,000 Units per month in a patient with hemoglobin greater than 14 grams per deciliter. As of the date of this filing, the comment period for the proposed revision has expired and no final program memorandum has been issued. If the proposed revision, which has not yet been finalized, is adopted as the final form, it could result in a reduction in utilization of EPOGEN®. We and the nephrology community have provided public comment based on data analysis suggesting that the proposed revision to the HMA-PM is unwarranted. The nephrology community has worked closely with CMS in response to the draft policy to develop consensus recommendations for a new policy that is focused on appropriate EPOGEN® utilization rather than EPOGEN® dose or hemoglobin levels. It is possible that CMS may adopt all or some aspects of the consensus recommendations when issuing a final policy. Although the proposed revision was scheduled to go into effect as early as January 1, 2005, it is unclear as to when it may be implemented but we believe that implementation would be no earlier than January 2006. Given the importance of EPOGEN® utilization for maintaining the quality of care for dialysis patients, the precise impact of such a change on provider utilization remains unclear.

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 or revenues, which could have a material adverse effect on us and our results of operations. For example, in the United States the use of EPOGEN® 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 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

32

#### **Table of Contents**

product is approved, the governmental and/or private coverage and reimbursement for that product is uncertain. 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 results of operations.

Our current products and products in development cannot be sold if we do not maintain regulatory approval. 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 Europe. 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 product), market and sell our products in those countries. In our experience, obtaining regulatory approval is costly and takes many years, and after it is obtained, it remains costly to maintain. 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, require changes in labeling of our products, and mandate product withdrawals. 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-affects, we may voluntarily withdraw, or regulatory authorities may mandate the withdrawal of such product from the market for some period or permanently. We currently manufacture and market all our approved principal products, and we plan to manufacture and market many of our potential products. See 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. Even though we have obtained regulatory approval for our marketed products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. In addition, ENBREL® is manufactured both by us at our Rhode Island manufacturing facility and by third-party contract manufacturers, including Boehringer Ingelheim Pharma KG ( BI Pharma ). Fill and finish of bulk product produced at our Rhode Island manufacturing facility is done by us and third-party service providers. The third-party contract manufacturers and third-party service providers are also subject to FDA regulatory authority. (See Limits on supply for ENBREL® may constrain ENBREL® sales. ) In addition, later discovery of unknown problems with our products or manufacturing processes or those of our contract manufacturers or third-party service providers could result in restrictions on the sale, manufacture, or use of such products, including potential withdrawal of the products from the market. If regulatory authorities determine that we or our 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 contract manufacturers or third-party service providers comply, or indefinitely. In addition, if regulatory authorities determine that we or our licenser or partner conducting research and development activities on our behalf have not complied with regulations in the research and

#### **Table of Contents**

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.

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 example, Roche is developing a pegylated erythropoietin molecule that, according to Roche s public statements, they expect to bring to the US market despite their acknowledgement of our U.S. erythropoietin 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, 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 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®, NEUPOGEN®, Aranesp®, Neulasta®, and ENBREL®, respectively.

	General Subject Matter	
U.S.		
	Process of making erythropoietin (issued in 1995 and 1997)	8/15/2012
	Product claims to erythropoietin (issued in 1996 and 1997)	8/20/2013
	Pharmaceutical compositions of erythropoietin (issued in 1999)	8/20/2013
	Cells that make certain levels of erythropoietin (issued in 1998)	5/26/2015
Europe(1)	Glycosylation analogs of erythropoietin proteins (issued in 1999)	10/12/2010
	Glycosylation analogs of erythropoietin proteins (issued in 1997) 34	8/16/2014
		U.S.  Process of making erythropoietin (issued in 1995 and 1997)  Product claims to erythropoietin (issued in 1996 and 1997)  Pharmaceutical compositions of erythropoietin (issued in 1999)  Cells that make certain levels of erythropoietin (issued in 1998)  Europe(1)  Glycosylation analogs of erythropoietin proteins (issued in 1999)  Glycosylation analogs of erythropoietin proteins (issued in 1997)

#### **Table of Contents**

Product		General Subject Matter	Expiration	
Filgrastim	U.S.	Methods for recombinant production of G-CSF (issued in 1998)	8/23/2005	
		Analogs of G-CSF (issued in 1999)	8/23/2005	
		Pharmaceutical Compositions Comprising G-CSF	8/23/2005	
		(issued in 2002)		
		DNA, vectors, cells and processes relating to recombinant G-CSF	3/7/2006	
		(issued in 1989 and 1991)		
		G-CSF polypeptides (issued in 1996)		
		Methods of treatment using G-CSF polypeptides (issued in 1996)		
	Europe(1)	G-CSF DNA Vectors, cells, polypeptides, methods of use and		
		production (issued in 1991)		
pegfilgrastim	U.S.	Pegylated G-CSF (issued in 1998)		
	Europe(1)	Pegylated G-CSF (issued in 1999)	2/8/2015	
Etanercept	U.S.	Methods of treating TNF dependent disease (issued in 2003)	9/5/2009	
		TNFR proteins and pharmaceutical compositions (issued in 1999 and	9/5/2009	
		2001)		
		TNFR DNA vectors, cells and processes for making proteins (issued	10/23/2012	
		in 1995 and 2000)		

(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 European patent relating to erythropoietin expired on December 12, 2004 and our European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, other companies could receive approval for and market follow-on or biosimilar products to each of these products in Europe; 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 erythropoietin in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson s and others erythropoietin products. We believe that the EU is currently in the process of developing regulatory guidelines related to the development and approval of biosimilar products. Until such guidelines are finalized, we cannot predict when follow-on or biosimilar products could appear on the market in the EU or to what extent such additional competition would impact future Aranesp® and NEUPOGEN®/Neulasta® sales in the EU. However, based on the process and timing outlined by the European Agency for the Evaluation of Medical Products (EMEA), we believe product specific guidelines are not likely to be finalized before 2006. In July 2005, the EMEA issued clinical trial guidance for certain biosimilar products including

erythropoeitins and granulocyte-colony stimulating factors, which guidance recommends that applicants seeking approval of such biosimilar products conduct pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program.

35

#### **Table of Contents**

Limits on supply for ENBREL® may constrain ENBREL® sales.

U.S. and Canadian supply of ENBREL® is impacted by many manufacturing variables, such as the timing and actual number of production runs, production success rate, bulk drug yield, and the timing and outcome of product quality testing. For example, in the second quarter of 2002, the prior co-marketer 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. If we are at any time unable to provide an uninterrupted supply of ENBREL® to patients, we may lose patients, physicians may elect to prescribe competing therapeutics instead of ENBREL®, and ENBREL® sales will be adversely affected, which could materially and adversely affect our results of operations. See We are dependent on third parties for a significant portion of our supply and the fill and finish of ENBREL®; and our sources of supply are limited.

We are dependent on third parties for a significant portion of our supply and the fill and finish of ENBREL®; and our sources of supply are limited.

We currently produce a substantial portion of annual ENBREL® supply at our Rhode Island manufacturing facility. However, we also depend on third parties for a significant portion of our ENBREL® supply as well as for the fill and finish of ENBREL® that we manufacture. BI Pharma is our primary third-party 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 manufacturers used for the 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, due to regulatory requirements or action, or due to contamination of product lots or product recalls. This in turn could materially reduce our ability to satisfy demand for ENBREL®, which could materially and adversely affect our operating results. Factors that will affect our actual supply of ENBREL® at any time include, without limitation, the following:

BI Pharma does not produce ENBREL® continuously; rather, it produces the bulk drug substance through a series of periodic campaigns throughout the year. Our Rhode Island manufacturing facility is currently dedicated to ENBREL® production. The amount of commercial inventory available to us at any time depends on a variety of factors, including the timing and actual number of BI Pharma s production runs, the actual number of runs at our Rhode Island manufacturing facility, and, for either the Rhode Island or BI Pharma facilities, the level of production yields and success rates, the timing and outcome of product quality testing, and the amount of filling and packaging capacity.

BI Pharma schedules the vialing production runs for ENBREL® in advance, based on the expected timing and yield of bulk drug production runs. Therefore, if BI Pharma realizes production yields beyond expected levels, or provides additional manufacturing capacity for ENBREL®, it may not have sufficient vialing capacity for all of the ENBREL® bulk drug that it produces. As a result, even if we are able to increase our supply of ENBREL® bulk drug, BI Pharma may not be able to fill and finish the extra bulk drug in time to prevent any supply interruptions.

We are dependent on third parties for some fill and finish and packaging of ENBREL® bulk drug substance manufactured at our Rhode Island facility. If third-party fill and finish and packaging

36

#### **Table of Contents**

manufacturers are unable to provide sufficient capacity or are otherwise unable to provide services to us, then supply of ENBREL® could be adversely affected.

Our current plan to increase U.S. and Canadian supply of ENBREL® includes requiring regulatory approval of an additional large-scale cell culture commercial manufacturing facility adjacent to the current Rhode Island manufacturing facility. We submitted this facility for FDA approval in April 2005. In addition, Wyeth has constructed a new manufacturing facility in Ireland and has filed for licensure by the EMEA. These facilities are expected to increase the U.S. and Canadian supply of ENBREL®. If the additional ENBREL® manufacturing capacity at the Rhode Island site, or in Ireland do not receive FDA or the EMEA approval before we encounter supply constraints, our ENBREL® sales would be restricted, which could have a material adverse effect on our results of operations. (See

Limits on supply for ENBREL® may constrain ENBREL® sales. ) If these manufacturing facilities are completed and approved by the various regulatory authorities, our costs of acquiring bulk drug may fluctuate.

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®, NEUPOGEN® and Neulasta® and some formulation, fill and finish operations for ENBREL® at our manufacturing facility in Juncos, Puerto Rico. Our global supply of these products is dependent on the uninterrupted and efficient operation of this facility. Power failures, the breakdown, failure or substandard performance of equipment, the improper installation or operation of equipment, natural or other disasters, including hurricanes, or failures to comply with regulatory requirements, including those of the FDA, among others, could adversely affect our formulation, fill and finish operations. As a result, we may be unable to supply these products, which could adversely and materially affect our product sales. 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 materially and adversely affecting our operating results.

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

We operate in a highly competitive environment. Our products compete with other products or treatments for diseases for which our products may be indicated. For example, ENBREL® competes in certain circumstances with products marketed by Biogen IDEC Inc., Centocor, Inc., Johnson & Johnson, Abbott, Genentech, Pfizer, Novartis, and Sanofi-Aventis, as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. Additionally, Aranesp® competes with products marketed by Johnson & Johnson in the United States and the EU. Further, if our currently marketed products are approved for new uses, or if we sell new products, we may face new, additional competition that we do not face today. Additionally, some of our competitors, including biotechnology and pharmaceutical companies, market products or are actively engaged in research and development in areas where we have products or where we are developing product candidates or new indications for existing products. In the future, we expect that our products will compete with new drugs currently in development, drugs approved for other indications that may be approved for the same indications as those of our products, and off-label use of drugs approved for other indications. Our European patent relating to erythropoietin expired on

37

#### **Table of Contents**

December 12, 2004 and our European patent relating to G-CSF expires on August 22, 2006. We believe that after the expiration of each of these patents, other companies could receive approval for and market follow-on or biosimilar products to each of these products in Europe; presenting additional competition to our products. While we do not market erythropoietin in Europe as this right belongs to Johnson & Johnson (through KA), we do market Aranesp® in the EU, which competes with Johnson & Johnson s and others erythropoietin products. We believe that the EU is currently in the process of developing regulatory guidelines related to the development and approval of follow-on or biosimilar products. Until such guidelines are finalized, we cannot predict when follow-on or biosimilar products could appear on the market in the EU or to what extent such additional competition would impact future Aranesp® and NEUPOGEN®/Neulasta® sales in the EU. However, based on the process and timing outlined by the EMEA, we believe product specific guidelines are not likely to be finalized before 2006. In July 2005, the EMEA issued 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 pharmacodynamic, toxicological, clinical safety studies and a pharmacovigilance program. Our products may compete against products that have lower prices, superior performance, are easier to administer, or that are otherwise competitive with our products. Our inability to compete effectively could adversely affect product sales.

Large pharmaceutical corporations may have greater clinical, research, regulatory, manufacturing, marketing, financial experience and human resources than we do. In addition, some of our competitors may have technical or competitive advantages over us for the development of technologies and processes. These resources may make it difficult for us to compete with them to successfully discover, develop, and market new products and for our current products to compete with new products or new product indications that these competitors may bring to market. Business combinations among our competitors may also increase competition and the resources available to our competitors.

Certain of our raw materials, medical devices and components are single-sourced from third parties; third-party supply failures could adversely affect our ability 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 fill, finish, and packaging 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 due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our operating results.

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

38

#### **Table of Contents**

biological sources. 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 too, in turn, could adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our operating results.

Our product development efforts may not result in 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 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

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 six months of the double-blind treatment phase of the study even though a small phase

39

#### **Table of Contents**

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 commercially successful products. Further, clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians, and others, which may delay, limit, or prevent further clinical development or regulatory approvals of a product candidate. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval.)

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.

If we or others identify side effects 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.

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. 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. 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 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. The revision of product labeling or the regulatory actions described above could have a material adverse effect on sales of the affected products and on our business and results of operations. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval. )

Our business may be impacted by government investigations or litigation.

We and certain of our subsidiaries are involved in legal proceedings relating to various patent matters, government investigations, and other legal proceedings that arise from time to time in the

40

#### **Table of Contents**

ordinary course of our business. Matters required to be disclosed by us are set forth in Item 3. Legal Proceedings in our Form 10-K for the year ended December 31, 2004 and are updated as required in subsequently filed Form 10-Qs. Litigation is inherently unpredictable, and excessive verdicts can occur. Consequently, it is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages that could have a material adverse effect on our results of operations in the period in which such amounts are incurred.

The Federal government, state governments and private payers are investigating, and many have filed actions against, numerous pharmaceutical and biotechnology companies, including Amgen and Immunex, alleging that the reporting of prices for pharmaceutical products has resulted in false and overstated Average Wholesale Price (AWP), which in turn is alleged to have improperly inflated the reimbursement paid by Medicare beneficiaries, insurers, state Medicaid programs, medical plans and other payers to health care providers who prescribed and administered those products. As of the date of this filing, a number of these actions have been brought against us and/or Immunex, now a wholly owned subsidiary of ours. Additionally, a number of states have pending investigations regarding our Medicaid drug pricing practices and the U.S. Departments of Justice and Health and Human Services have requested that Immunex produce documents relating to pricing issues. Further, certain state government entity plaintiffs in some of these AWP cases are also alleging that companies, including ours, are not reporting their best price to the states under the Medicaid program. These cases and investigations are described in Item 3. Legal Proceedings Average Wholesale Price Litigation in our Form 10-K for the year ended December 31, 2004, and are updated as required in subsequent Form 10-Qs. Other states and agencies could initiate investigations of our pricing practices. A decision adverse to our interests on these actions and/or investigations could result in substantial economic damages and could have a material adverse effect on our results of operations in the period in which such amounts are incurred.

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

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

Our operating results may fluctuate, and this fluctuation could cause financial results to be below expectations. Our operating results may fluctuate from period to period for a number of reasons. In budgeting our operating expenses for the foreseeable future, we assume that revenues will continue to grow; however, some of our operating expenses are fixed in the short term. Because of this, even a relatively small revenue shortfall may cause a period s results to be below our expectations or projections. A revenue shortfall could arise from any number of factors, some of which we cannot control. For example, we may face:

changes in the government s or private payers reimbursement policies for our products

inability to maintain regulatory approval of marketed products or manufacturing facilities

41

#### **Table of Contents**

changes in our product pricing strategies

lower than expected demand for our products

inability to provide adequate supply of our products

changes in wholesaler buying patterns

increased competition from new or existing products

fluctuations in foreign currency exchange rates

Of course, there may be other factors that affect our revenues in any given period. Similarly if investors or the investment community are uncertain about our financial performance for a given period, our stock price could also be adversely impacted.

We have grown rapidly, and if we fail to adequately manage that growth our business could be adversely impacted. We have had an aggressive growth plan that has included substantial and increasing investments in research and development, sales and marketing, and facilities. We plan to continue to grow and our plan has a number of risks, some of which we cannot control. For example:

we need to generate higher revenues to cover a higher level of operating expenses, and our ability to do so may depend on factors that we do not control

we will need to assimilate new staff members

we will need to manage complexities associated with a larger and faster growing organization

we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity, and our ability to do so may depend on factors that we do not control

we will need to start up and operate a number of new manufacturing facilities, which may result in temporary inefficiencies and higher cost of goods

Of course, there may be other risks and we cannot guarantee that we will be able to successfully manage these or other risks.

Our stock price is volatile, which could adversely affect your investment.

Our stock price, like that of other biotechnology companies, is highly volatile. For example, in the fifty-two weeks prior to July 22, 2005, the trading price of our common stock has ranged from a high of \$83.10 per share to a low of \$52.00 per share. Our stock price may be affected by a number of factors, such as:

42

#### **Table of Contents**

changes in reimbursement policies or medical practices

adverse developments regarding the safety or efficacy of our products

clinical trial results

actual or anticipated product supply constraints

product development announcements by us or our competitors

regulatory matters

announcements in the scientific and research community

intellectual property and legal matters

broader economic, industry and market trends unrelated to our performance.

In addition, if our revenues, earnings or other financial results in any period fail to meet the investment community s expectations, there could be an immediate adverse impact on our stock price.

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

The development, manufacturing, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, is subject to extensive federal and state regulation. (See Our current products and products in development cannot be sold if we do not maintain regulatory approval. 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. ) While we have developed and instituted a corporate compliance program based on current best practices, we cannot assure you that we or our employees are or will be in compliance with all potentially applicable federal and state regulations and/or laws. If we fail to comply with any of these regulations and/or laws a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

Our marketing of ENBREL® will be dependent in part upon Wyeth.

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

43

#### **Table of Contents**

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our products.

However, professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration, and use of related therapies. Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and health care providers could result in decreased use of our products. In addition, the perception by the investment community or stockholders that recommendations or guidelines will result in decreased use of our products could adversely affect prevailing market prices for our common stock.

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

In connection with our ongoing process improvement activities associated with products we manufacture, we continually invest in our various manufacturing practices and related processes with the objective of increasing production yields and success rates to gain increased cost efficiencies and capacity utilization. Depending on the timing and outcomes of these efforts and our other estimates and assumptions regarding future product sales, the carrying value of certain manufacturing facilities or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The potential recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations.

We may not realize all of the anticipated benefits of our merger with Tularik.

On August 13, 2004, we merged with Tularik Inc. The success of our merger with Tularik will depend, in part, on our ability to retain Tularik staff and to realize the anticipated synergies, cost savings, and growth opportunities from integrating the businesses of Tularik with the businesses of Amgen. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations and personnel of Tularik. The integration of two independent companies is a complex, costly, and time-consuming process. The difficulties of combining the operations of the companies include, among others:

retaining key staff members

consolidating research and development operations

consolidating corporate and administrative infrastructures

preserving ours and Tularik s research and development, and other important relationships

\_ 11

#### **Table of Contents**

minimizing the diversion of management s attention from ongoing business concerns

coordinating geographically separate organizations

In addition, even if we are able to integrate Tularik s operations successfully, this integration may not result in the realization of the full benefits of the synergies, cost savings, or sales and growth opportunities that we expect or that these benefits will be achieved within the anticipated time frame. For example, as of the date of this filing, we have discontinued a number of Tularik clinical development programs and may discontinue other or all such programs. Further, the elimination of significant duplicative costs may not be possible or may take longer than anticipated and the benefits from the merger may be offset by costs incurred in integrating the companies. We cannot assure you that the integration of Tularik with us will result in the realization of the full benefits anticipated by us to result from the merger. Our failure to achieve these benefits could have a material adverse effect on our results of operations.

#### **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 June 30, 2005.

Further, management determined that, as of June 30, 2005, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### 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, 2004, with material developments since that report described in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2005 and below. While it is impossible to predict accurately or to determine the eventual outcome of these matters, we do not believe any

45

#### **Table of Contents**

such proceedings currently pending will have a material adverse effect on our annual Consolidated Financial Statements, although an adverse resolution in any reporting period of one or more of the proceedings could have a material impact on the results of operations for that period.

Israel Bio-Engineering Project Litigation

The U.S. District Court for the Central District of California set a trial date for January 31, 2006.

Average Wholesale Price Litigation

City of New York v. Abbott, et. al. Amgen and Immunex were named in a Consolidated Complaint filed on June 15, 2005 in U.S. District Court for the District of Massachusetts. The consolidated complaint includes complaints filed by 31 New York counties in the Northern, Southern, Eastern and Western Districts of New York. These lawsuits broadly allege that Amgen and Immunex, together with many other pharmaceutical manufacturers, reported prices for certain products in a manner that allegedly inflated reimbursement under the Medicaid program. The complaints generally assert varying claims or fraud, and other causes of action under federal and state laws. The complaints seek an undetermined amount of damages, as well as other relief, including declaratory and injunctive relief. All of these cases are a part of the federal Multi-District proceeding captioned In Re: Pharmaceutical Industry Average Wholesale Price Litigation MDL. No. 1456 pending in the U.S. District Court for the District Court of Massachusetts.

Columbia Litigation

On July 13, 2005, Amgen and Columbia filed a Stipulation to Dismiss With Prejudice the actions filed by Amgen and by its affiliates.

#### Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

During the three months ended June 30, 2005, we had one outstanding stock repurchase program. The amount we spend and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which we are restricted from repurchasing shares. Repurchases under our stock repurchase program reflect, in part, our confidence in the long-term value of Amgen common stock. A summary of our repurchase activity for the three months ended June 30, 2005 is as follows:

			Total Number of Shares Purchased as	Maximum \$ Value
	<b>Total Number</b>	Average Price	Part	that May Yet Be Purchased Under
	of Shares	Paid	of Publicly Announced	the
	Purchased	per Share	<b>Programs</b>	<b>Programs</b>
April 1- April 30	14,477	\$57.42	_	\$4,293,991,590
May 1 - May 31	12,125,267	61.91	12,113,400	3,543,924,735
June 1 - June 30	4,427	37.21		3,543,924,735
Total	12,144,171	\$61.90	12,113,400	
	2	46		

#### **Table of Contents**

(1) The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to repurchases of common stock from certain employees in connection with their exercise of stock options issued prior to June 23, 1998 as well as shares of common stock withheld by us for the payment of taxes upon vesting of certain employees restricted stock.

#### Item 4. Submission of Matters to a Vote of Security Holders

- (a) The Company held its Annual Meeting of Stockholders on May 11, 2005.
- (b) Omitted pursuant to Instruction 3 to Item 4 of Form 10-Q.
- (c) The three items voted upon at the meeting were: (i) to elect three directors to a three year term of office expiring at the 2008 Annual Meeting of Stockholders ( Item One ); (ii) to ratify the selection of Ernst & Young LLP as the independent registered public accounting firm for the Company for the year ending December 31, 2005 ( Item Two ); and (iii) the Stockholder Proposals ( Item Three ): (A) Stockholder Proposal #1 relating to in vitro testing, (B) Stockholder Proposal #2 relating to executive compensation and (C) Stockholder Proposal # 3 relating to stock retention by senior executives.

**Against** 

The voting was as follows:

	In Favor	("Withheld" for purposes of Item One)	Abstain	Broker Non-Votes
Item One	III Favoi	One)	Austain	Non-votes
Dr. David Baltimore	1,001,399,763	93,386,532	0	0
Ms. Judith C. Pelham	1,050,447,669	44,338,626	0	0
Mr. Kevin W. Sharer	1,042,130,141	52,656,154	0	0
Item Two	1,065,592,524	19,991,085	9,104,584	0
Item Three				
Stockholder Proposal #1	19,621,198	733,707,612	103,620,890	237,836,595
Stockholder Proposal #2	68,119,703	773,527,507	15,139,006	238,000,079
Stockholder Proposal #3	306,449,418	522,443,387	28,514,203	237,379,287

All nominees to the Board of Directors were declared to have been elected as directors to hold office until the 2008 Annual Meeting of Stockholders. Item Two was declared to have been approved. Stockholder Proposals #s 1, 2 and 3 were declared to have not been approved.

(d) Not applicable.

#### **Item 5. Other Items**

The Company s 2006 Annual Meeting of Stockholders will be held May 10, 2006.

47

#### **Table of Contents**

### Item 6. Exhibits

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

48

#### **Table of Contents**

#### **SIGNATURES**

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

Amgen Inc. (Registrant)

Date: August 5, 2005 By: /s/ Richard D. Nanula

Richard D. Nanula Executive Vice President and Chief Financial Officer

49

#### **Table of Contents**

# AMGEN INC. INDEX TO EXHIBITS

Exhibit No. 3.1	Description Restated Certificate of Incorporation as amended. (9)
3.2	Certificate of Amendment of Restated Certificate of Incorporation. (19)
3.3*	Amended and Restated Bylaws of Amgen Inc. (as amended and restated May 11, 2005).
3.4	Certificate of Designations of Series A Junior Participating Preferred Stock. (22)
4.1	Indenture dated January 1, 1992 between the Company and Citibank N.A., as trustee. (3)
4.2	6.50% Notes Due December 1, 2007. (11)
4.3	First Supplemental Indenture, dated February 26, 1997, to Indenture, dated January 1, 1992, between the Company and Citibank N.A., as trustee. (6)
4.4	Officer s Certificate pursuant to Sections 2.1 and 2.3 of the Indenture, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between Amgen Inc. and Citibank, N.A., as Trustee, establishing a series of securities entitled 6.50% Notes Due December 1, 2007 (11)
4.5	8-1/8% Debentures due April 1, 2097. (8)
4.6	Officer s Certificate pursuant to Sections 2.1 and 2.3 of the Indenture, dated as of January 1, 1992, as supplemented by the First Supplemental Indenture, dated as of February 26, 1997, each between the Company and Citibank, N.A., as Trustee, establishing a series of securities entitled 8 1/8% Debentures due April 1, 2097. (8)
4.7	Form of Liquid Yield Option Note due 2032. (29)
4.8	Indenture, dated as of March 1, 2002, between Amgen Inc. and LaSalle Bank National Association. (29)
4.9	Supplemental Indenture, dated as of March 2, 2005, between Amgen Inc. and LaSalle Bank National Association. (48)
4.10	Registration Rights Agreement, dated as of March 1, 2002, between Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (29)
4.11	Indenture, dated as of August 4, 2003, between the Company and JP Morgan Chase Bank, N.A., as trustee. (39)
4.12	Form of 4.00% Senior Note due 2009. (45)
4.13	Form of 4.85% Senior Notes due 2014. (45)

4.14	Officers Certificate of Amgen Inc. dated November 18, 2004, including forms of the Company s 4.00% Senior Notes due 2009 and 4.85% Senior Notes due 2014. (45)
4.15	Registration Rights Agreement, dated as of November 18, 2004, among Amgen Inc. and Morgan Stanley & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated as representatives of the several initial purchasers. (45)
4.16	Form of Zero Coupon Convertible Note due 2032 (54)
4.17	Indenture, dated as of May 6, 2005, between Amgen Inc. and LaSalle Bank National Association. (54)
10.1+	Corporate Commercial Paper Master Note between and among Amgen Inc., as Issuer, Cede & Co., as nominee of The Depository Trust Company and Citibank, N.A. as Paying Agent. (12)
10.2+	Form of stock certificate for the common stock, par value \$.0001 of the Company. (9)
10.3+	Amended and Restated 1991 Equity Incentive Plan (as of March 7, 2005). (49)
10.4+	Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements for the Amended and Restated 1991 Equity Incentive Plan (Amended and Restated effective March 7, 2005). (49) 50

#### **Table of Contents**

Exhibit No. 10.5+	Description Amgen Inc. Director Equity Incentive Program (Amended and Restated effective December 6, 2004).  (46)
10.6+	Form of Restricted Stock Unit Agreement pursuant to the Director Equity Incentive Plan. (40)
10.7+	Amgen Inc. Amended and Restated 1997 Equity Incentive Plan (as of March 7, 2005). (49)
10.8+	Forms of Stock Option Grant Agreements and Restricted Stock Unit Agreements for the 1997 Equity Incentive Plan (Amended and Restated effective March 7, 2005). (49)
10.9+	Amended and Restated 1999 Equity Incentive Plan (as of March 7, 2005). (49)
10.10+	Forms of Stock Option Grant Agreements for 1999 Equity Incentive Plan (Amended and Restated March 7, 2005). (49)
10.12+	Amended and Restated Employee Stock Purchase Plan of Amgen Inc. (19)
10.13+	First Amendment, effective July 12, 2005, to the Amended and Restated Employee Stock Purchase Plan of Amgen Inc. (55)
10.14+	Retirement and Savings Plan of Amgen Inc. (As amended and restated effective January 1, 2003). (40)
10.15+	First Amendment, effective January 1, 2004, and Second Amendment, effective June 1, 2004, to the Amgen Retirement and Savings Plan. (50)
10.16+	Third Amendment, effective January 1, 2005, to the Amgen Retirement and Savings Plan (As Amended and Restated effective as of January 1, 2003). (44)
10.17+	Fourth Amendment, effective January 1, 2004, to the Amgen Retirement and Savings Plan (As Amended and Restated effective as of January 1, 2003). (46)
10.18+	Amgen Inc. Supplemental Retirement Plan (As Amended and Restated effective as of January 1, 2005). (44)
10.19+	Amgen Inc. Change of Control Severance Plan effective as of October 20, 1998. (14)
10.20+	First Amendment to Amgen Inc. Change of Control Severance Plan. (19)
10.21+	Second Amendment to the Amgen Inc. Change of Control Severance Plan. (25)
10.22+	Third Amendment to the Amgen Inc. Change of Control Severance Plan. (50)
10.23+	Fourth Amendment to the Amgen Inc. Change of Control Severance Plan. (50)
10.24+	Fifth Amendment to the Amgen Inc. Change of Control Severance Plan. (46)
10.25+	Amgen Inc. Executive Incentive Plan. (30)

10.26+	First Amendment to the Amgen Inc. Executive Incentive Plan. (46)
10.27+	Amgen Inc. Executive Nonqualified Retirement Plan, effective January 1, 2001. (28)
10.28+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated effective January 1, 2005). (44)
10.29+	Amended and Restated Amgen Inc. Performance Award Program (Amended and Restated effective March 7, 2005). (49)
10.30+	Form of Performance Unit Agreement (Amended and Restated effective March 7, 2005). (49)
10.31+	Amended and Restated 1987 Directors Stock Option Plan of Amgen Inc. (7)
10.32+	2002 Special Severance Pay Plan for Amgen Employees. (35)
10.33+	Agreement between Amgen Inc. and Mr. George J. Morrow, dated March 3, 2001. (23)
10.34+	Promissory Note of Mr. George J. Morrow, dated March 11, 2001. (23)
10.35+	Agreement between Amgen Inc. and Dr. Roger M. Perlmutter, M.D., Ph.D., dated March 5, 2001. (23)
10.36+	Promissory Note of Dr. Roger M. Perlmutter, dated June 29, 2001. (24)
10.37+	Agreement between Amgen Inc. and Mr. Brian McNamee, dated May 5, 2001. (24)
10.38+	Promissory Note of Mr. Brian McNamee, dated May 30, 2001. (25)
10.39+	Restricted Stock Purchase Agreement between Amgen Inc. and Brian M. McNamee, dated March 3, 2003. (38)

#### **Table of Contents**

Exhibit No. 10.40+	Description Agreement between Amgen Inc. and Mr. Richard Nanula, dated May 15, 2001. (24)
10.41+	Promissory Note of Mr. Richard Nanula, dated June 27, 2001. (24)
10.42+	Restricted Stock Purchase Agreement between Amgen Inc. and Mr. Richard Nanula, dated May 16, 2001. (25)
10.43+	Promissory Note of Dr. Hassan Dayem, dated July 10, 2002. (35)
10.44+	Amended and Restated Agreement between Amgen Inc. and David J. Scott, dated February 16, 2004. (40)
10.45	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 30, 1985 between Amgen Inc. and Ortho Pharmaceutical Corporation. (19)
10.46	Shareholder s Agreement of Kirin-Amgen, Inc., dated May 11, 1984, between the Company and Kirin Brewery Company, Limited. (22)
10.47	Amendment Nos. 1, 2, and 3, dated March 19, 1985, July 29, 1985 and December 19, 1985, respectively, to the Shareholder s Agreement of Kirin-Amgen, Inc., dated May 11, 1984. (19)
10.48	Amendment Nos. 4, 5, 6, 7, 8, 9, 10 and 11 dated October 16, 1986 (effective July 1, 1986), December 6, 1986 (effective July 1, 1986), May 11, 1984, July 17, 1987 (effective April 1, 1987), May 28, 1993 (effective November 13, 1990), December 9, 1994 (effective June 14, 1994), March 1, 1996 and March 20, 2000 respectively, to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (22)
10.49*	Amendment No. 12 dated January 31, 2001 to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984.
10.50	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985 between Kirin-Amgen, Inc. and Ortho Pharmaceutical Corporation. (19)
10.51	Research, Development Technology Disclosure and License Agreement PPO, dated January 20, 1986, by and between Amgen Inc. and Kirin Brewery Co., Ltd. (1)
10.52	Amendment, dated June 30, 1988, to Research, Development, Technology Disclosure and License Agreement: GM-CSF dated March 31, 1987, between Kirin Brewery Company, Limited and Amgen Inc. (2)
10.53	Assignment and License Agreement, dated October 16, 1986, between Amgen Inc. and Kirin-Amgen, Inc. (22)
10.54	G-CSF United States License Agreement dated June 1, 1987 (effective July 1, 1986), Amendment No. 1 dated October 20, 1988 and Amendment No. 2 dated October 17, 1991 (effective November 13, 1990) between Kirin-Amgen, Inc. and Amgen Inc. (22)

- 10.55 G-CSF European License Agreement, dated December 30, 1986, Amendment No. 1 dated June 1, 1987, Amendment No. 2 dated March 15, 1998, Amendment No. 3 dated October 20, 1988, and Amendment No. 4 dated December 29, 1989 between Kirin-Amgen, Inc. and Amgen Inc. (22)
- 10.56 Partnership Purchase Agreement, dated March 12, 1993, between Amgen Inc., Amgen Clinical Partners, L.P., Amgen Development Corporation, the Class A limited partners and the Class B limited partner. (4)
- 10.57 ENBREL(R) Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated as of November 5, 1998 (with certain confidential information deleted therefrom). (15)
- 10.58 Amendment No. 1 to the ENBREL(R) Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated June 27, 2000 (with certain confidential information deleted therefrom). (33)

52

#### **Table of Contents**

Exhibit No. 10.59	Description  Amendment No. 2 to the ENBREL(R) Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated June 3, 2002 (with certain confidential information deleted therefrom). (35)
10.60	Amendment No. 3 to the ENBREL(R) Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated December 18, 2002 (with certain confidential information deleted therefrom). (37)
10.61*	Amendment No. 4 to the ENBREL(R) Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated May 21, 2004.
10.62	Agreement Regarding Governance and Commercial Matters by and among Wyeth (formerly American Home Products Corporation), American Cyanamid Company and Amgen Inc. dated December 16, 2001 (with certain confidential information deleted therefrom). (30)
10.63	Asset Purchase Agreement, dated May 2, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft (with certain confidential information deleted therefrom). (35)
10.64	Amendment No. 1 dated as of September 25, 2002 and Amendment No. 2 dated as of July 17, 2002to the Asset Purchase Agreement dated as of September 25, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft. (35)
10.65	Amended and Restated Promotion Agreement By and Among Wyeth, Amgen Inc. and Immunex Corporation entered into as of December 16, 2001 (with certain confidential information deleted therefrom). (30)
10.66 W	Description of Amendment No. 1 to Amended and Restated Promotion Agreement By and Among yeth, Amgen Inc. and Immunex Corporation, effective as of July 8, 2003 (with certain confidential information deleted therefrom). (40)
10.67	Description of Amendment No. 2 to Amended and Restated Promotion Agreement By and Among Wyeth, Amgen Inc. and Immunex Corporation, effective as of April 20, 2004. (42)
10.68	Description of Amendment No. 3 To Amended and Restated Promotion Agreement By and Among Wyeth, Amgen Inc. and Immunex Corporation, effective as of January 1, 2005, (with certain confidential information deleted therefrom). (53)
10.69	Amgen Inc. Credit Agreement, dated as of July 16, 2004, among Amgen Inc. the Banks therein named, Citibank N.A., as Issuing Bank, Citicorp USA, Inc., as Administrative Agent and Barclays Bank PLC, as Syndication Agent. (43)
10.70	Purchase Agreement, dated as of November 15, 2004, among Amgen Inc. and Morgan Stanley & Co. and Merrill Lynch, Pierce, Fenner & Smith Incorporated as representatives of the several initial purchasers. (45)
31*	Rule 13a-14(a) Certifications.

#### 32\*\* Section 1350 Certifications.

(\* = filed herewith)

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

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

(1) Filed as an exhibit to Amendment No. 1 to Form S-1 Registration Statement (Registration No. 33-3069) on March 11, 1986 and incorporated herein by reference.

53

#### **Table of Contents**

- (2) Filed as an exhibit to Form 8 amending the Quarterly Report on Form 10-Q for the quarter ended June 30, 1988 on August 25, 1988 and incorporated herein by reference.
- (3) Filed as an exhibit to Form S-3 Registration Statement dated December 19, 1991 and incorporated herein by reference.
- (4) Filed as an exhibit to the Form 8-A dated March 31, 1993 and incorporated herein by reference.
- (5) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 1996 on November 5, 1996 and incorporated herein by reference.
- (6) Filed as an exhibit to the Form 8-K Current Report dated March 14, 1997 on March 14, 1997 and incorporated herein by reference.
- (7) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1996 on March 24, 1997 and incorporated herein by reference.
- (8) Filed as an exhibit to the Form 8-K Current Report dated April 8, 1997 on April 8, 1997 and incorporated herein by reference.
- (9) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 1997 on May 13, 1997 and incorporated herein by reference.
- (10) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 1997 on August 12, 1997 and incorporated herein by reference.
- (11) Filed as an exhibit to the Form 8-K Current Report dated and filed on December 5, 1997 and incorporated herein by reference.
- (12) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.
- (13) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 1998 on August 14, 1998 and incorporated herein by reference.
- (14) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1998 on March 16, 1999 and incorporated herein by reference.
- (15) Filed as an exhibit to the Annual Report on Form 10-K of Immunex Corporation for the year ended December 31, 1998.
- (16) Filed as an exhibit to the Form S-8 dated March 17, 1999 and incorporated herein by reference.
- (17) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 1999 on August 3, 1999 and incorporated herein by reference.
- (18) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 1999 on March 7, 2000 and incorporated herein by reference.
- (19) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 2000 on August 1, 2000 and incorporated herein by reference.
- (20) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 2000 on November 14, 2000 and incorporated herein by reference.
- (21) Filed as an exhibit to the Form 8-K Current Report dated December 13, 2000 on December 18, 2000 and incorporated herein by reference.
- (22) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2000 on March 7, 2001 and incorporated herein by reference.
- (23) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 2001 on May 14, 2001 and incorporated herein by reference.
- (24) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 2001 on July 27, 2001 and incorporated herein by reference.
- (25) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 2001 on October 26, 2001 and incorporated herein by reference.
- (26) Filed as an exhibit to the Form 8-K Current Report dated December 16, 2001 on December 17, 2001 and incorporated herein by reference.

(27)

Filed as an exhibit to the Form S-4 Registration Statement dated January 31, 2002 and incorporated herein by reference.

54

#### **Table of Contents**

- (28) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2001 on February 26, 2002 and incorporated herein by reference.
- (29) Filed as an exhibit to the Form 8-K Current Report dated February 21, 2002 on March 1, 2002 and incorporated herein by reference.
- (30) Filed as an exhibit to Amendment No. 1 to the Form S-4 Registration Statement dated March 22, 2002 and incorporated herein by reference.
- (31) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 2002 on April 29, 2002 and incorporated herein by reference.
- (32) Filed as an exhibit to the Post-effective Amendment No. 1 to the Form S-4 Registration Statement dated July 15, 2002 and incorporated herein by reference.
- (33) Filed as an exhibit to Form 8-K Current Report of Immunex Corporation dated April 12, 2002 on May 7, 2002 and incorporated herein by reference.
- (34) Filed as an exhibit to the Form 10-Q of Immunex Corporation for the quarter ended June 30, 2000.
- (35) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 2002 on August 13, 2002 and incorporated herein by reference.
- (36) Filed as an exhibit to the Form 10-Q for the quarter ended September 30, 2002 on November 5, 2002 and incorporated herein by reference.
- (37) Filed as an exhibit to the Form 10-K for the year ended December 31, 2002 on March 10, 2003 and incorporated herein by reference.
- (38) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 2003 on July 30, 2003 and incorporated herein by reference.
- (39) Filed as an exhibit to Form S-3 Registration Statement dated August 4, 2003 and incorporated herein by reference.
- (40) Filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2003 on March 11, 2004 and incorporated herein by reference.
- (41) Filed as an exhibit to the Form S-4 dated April 26, 2004 and incorporated herein by reference.
- (42) Filed as an exhibit to the Form S-4/A dated June 29, 2004 and incorporated herein by reference.
- (43) Filed as an exhibit to the Form 10-Q for the quarter ended June 30, 2004 on August 6, 2004 and incorporated herein by reference.
- (44) Filed as an exhibit to the Form 8-K Current Report dated October 5, 2004 on October 12, 2004 and incorporated herein by reference.
- (45) Filed as an exhibit to Form 8-K dated November 15, 2004 and incorporated herein by reference.
- (46) Filed as an exhibit to Form 8-K dated December 6, 2004 and incorporated herein by reference.
- (47) Filed as an exhibit to Form S-8 dated August 16, 2004 and incorporated herein by reference.
- (48) Filed as an exhibit to Form 8-K dated March 2, 2005 and incorporated herein by reference.
- (49) Filed as an exhibit to Form 8-K dated March 7, 2005 and incorporated herein by reference.
- (50) Filed as an exhibit to Form 10-K for the year ended December 31, 2004 on March 9, 2005 and incorporated herein by reference.
- (51) Filed as an exhibit to Form S-4 dated March 14, 2005 and incorporated by reference.
- (52) Filed as an exhibit to Form S-4 dated April 5, 2005 and incorporated by reference.
- (53) Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2005 on May 4, 2005 and incorporated herein by reference.
- (54) Filed as an exhibit to Form 8-K dated May 5, 2005 and incorporated herein by reference.
- (55) Filed as an exhibit to Form 8-K dated July 11, 2005 and incorporated herein by reference.

Table of Contents 64

55