AMGEN INC Form 10-Q November 09, 2004

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

OR

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

Commission file number 000-12477

AMGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	95-3540776		
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)		
One Amgen Center Drive, Thousand Oaks, California	91320-1799		
(Address of principal executive offices)	(Zip Code)		
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 [X] No

Indicate by check mark whether the registrant is an accelerated filer. [X]

As of October 15, 2004, the registrant had 1,270,136,214 shares of common stock, \$0.0001 par value, outstanding.

AMGEN INC.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

The information in this report for the three and nine months ended September 30, 2004 and 2003 is unaudited but includes all adjustments (consisting only of normal recurring accruals, unless otherwise indicated) which Amgen Inc., including its subsidiaries, (Amgen or the Company) 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 the Company s financial statements and the notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2003.

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

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AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In millions, except per share data) (Unaudited)

	Three Months Ended September 30,			nths Ended nber 30,
	2004	2003	2004	2003
Revenues:	42.5 60	42.05 0	Φ7.100	45.621
Product sales Other revenues	\$2,560 153	\$2,078 130	\$7,199 442	\$5,631 379
Total revenues	2,713	2,208	7,641	6,010
Operating expenses: Cost of sales (excludes amortization of acquired intangible				
assets presented below)	447	340	1,255	952
Research and development	502	408	1,411	1,153
Write-off of acquired in-process research and development	554		554	
Selling, general and administrative	632	519	1,740	1,341
Amortization of acquired intangible assets	84	84	252	252
Other items, net				(24)
Total operating expenses	2,219	1,351	5,212	3,674
Operating income	494	857	2,429	2,336
Interest and other income and expense, net	15	9	<u>46</u>	67
Income before income taxes	509	866	2,475	2,403
Provision for income taxes	<u>273</u>		801	<u>690</u>
Net income	\$ 236	\$ 612	\$1,674	\$1,713
Earnings per share: Basic Diluted	\$ 0.19 \$ 0.18	\$ 0.47 \$ 0.46	\$ 1.32 \$ 1.28	\$ 1.33 \$ 1.28
Shares used in calculation of earnings per share: Basic	1,272	1,289	1,273	1,289

Diluted 1,320 1,348 1,323 1,348

See accompanying notes.

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AMGEN INC.

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

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 986	\$ 837
Marketable securities	2,852	4,286
Trade receivables, net	1,413	1,008
Inventories	716	713
Other current assets	808	
Total current assets	6,775	7,402
Property, plant, and equipment, net	4,549	3,799
Intangible assets, net	4,278	4,456
Goodwill	10,437	9,716
Other assets	772	804
	\$26,811	\$26,177
LIABILITIES AND STOCKHOLDERS EQUITY Current liabilities: Accounts payable Accrued liabilities Convertible notes	\$ 337 1,950 2,904	\$ 327 1,877
Total current liabilities	5,191	2,204
Deferred tax liabilities	1,484	1,462
Other non-current liabilities	128	42
Long-term debt	200	3,080
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 - 1,270 shares in 2004 and 1,284 shares in 2003	21,812	19,995
Accumulated deficit	(2,041)	(667)
Accumulated other comprehensive income	37	61

See accompanying notes.

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AMGEN INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (In millions) (Unaudited)

Nine Months Ended September 30,

	September 30	
	2004	2003
Cash flows from operating activities:		
Net income	\$ 1,674	\$ 1,713
Write-off of acquired in-process research and development	554	
Depreciation and amortization	541	510
Tax benefits related to employee stock options	138	250
Other non-cash items	184	270
Cash provided by (used in) changes in operating assets and liabilities:		
Trade receivables, net	(405)	(249)
Inventories	(3)	(140)
Other current assets	(64)	(128)
Accounts payable and accrued liabilities	(32)	143
Net cash provided by operating activities	2,587	2,369
Cash flows from investing activities: Purchases of property, plant, and equipment Proceeds from maturities of marketable securities	(1,040) 167	(931) 331
Proceeds from sales of marketable securities	5,625	1,804
Purchases of marketable securities	(4,410)	(3,363)
Other	(28)	(147)
Net cash provided by (used in) investing activities	314	(2,306)
Cash flows from financing activities: Repurchases of common stock	(3.048)	(1.224)
Net proceeds from issuance of common stock upon the exercise of employee	(3,048)	(1,224)
1	302	469
stock options and in connection with an employee stock purchase plan	302	
Repayment of debt Repayment of commercial paper		(23)
Other	(6)	(100) 13
Ouici	(6)	
Net cash used in financing activities	(2,752)	(865)

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Increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of period	_	149 837	(802) 1,852
Cash and cash equivalents at end of period	\$	986	\$ 1,050

See accompanying notes.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2004

1. Summary of significant accounting policies

Business

Amgen Inc., including its subsidiaries, (Amgen or the Company) is a global biotechnology company that discovers, develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology.

Basis of presentation

The financial information for the three and nine months ended September 30, 2004 and 2003 is unaudited but includes all adjustments (consisting only of normal recurring accruals, unless otherwise indicated), which the Company considers 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 the Company as well as its wholly owned subsidiaries and majority-owned affiliates (affiliated companies in which the Company has a majority ownership interest and exercises control over their operations) that are not considered variable interest entities. As of September 30, 2004, the Company does 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 United States generally accepted accounting principles (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 year amounts have been reclassified to conform to the current year 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 are shown net of applicable reserves and allowances. Inventories consisted of the following (in millions):

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

	September 30, 2004	December 31, 2003
Raw materials	\$ 107	\$ 125
Work in process	488	452
Finished goods	121	136
	\$ 716	\$ 713

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 7 to 15 years on a straight-line basis (weighted average amortization period of 14.6 years at September 30, 2004). As of September 30, 2004 and December 31, 2003, accumulated amortization of intangible assets amounted to \$776 million and \$512 million, respectively. Intangible assets primarily consist of acquired product technology rights of \$4,060 million, net of accumulated amortization of \$741 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. The Company reviews its intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

In accordance with SFAS No. 142, Goodwill and Other Intangible Assets , goodwill, which primarily relates to the Immunex acquisition, is no longer amortized, but is subject to an annual impairment test.

Product sales

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

The Company has the exclusive right to sell Epoetin alfa for dialysis, certain diagnostics and all non-human, non-research uses in the United States. The Company sells Epoetin alfa under the brand name EPOGEN®. Amgen has 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, the Company 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, Amgen does not recognize product sales it makes into the exclusive market of Johnson & Johnson and does recognize the product sales made by Johnson & Johnson into Amgen s exclusive market. Sales in Amgen s exclusive market are derived from the Company s sales to

its customers, as adjusted for spillover. The Company is 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.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

Sales of the Company s 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), discounts, and other incentives (collectively sales incentives) and returns.

Research and development costs

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

Acquired in-process research and development

The fair value of acquired in-process research and development (IPR&D) projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred (see Note 7, Tularik Inc. acquisition). Acquired IPR&D is considered part of total R&D expense.

Earnings per share

Basic earnings per share is based upon the weighted-average number of common shares outstanding. Diluted earnings per share is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Potential common shares outstanding include stock options under the Company s employee stock option plans, potential issuances of stock under the employee stock purchase plans, and restricted stock plans under the treasury stock method (collectively Dilutive Securities). Common shares to be issued under the assumed conversion of the outstanding 30-year, zero-coupon senior convertible notes (the Convertible Notes) (see Note 5, Convertible notes) are included under the if-converted method when dilutive.

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

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

	Three Months Ended September 30,		Nine Months Ende September 30,	
	2004	2003	2004	2003
Income (Numerator): Net income for basic EPS Adjustment for interest expense on Convertible Notes, net	\$ 236	\$ 612	\$1,674	\$1,713
of tax	5	5	16	16
Net income for diluted EPS, after assumed conversion of Convertible Notes	\$ 241	\$ 617	\$1,690	\$1,729
Shares (Denominator):				
Weighted-average shares for basic EPS	1,272	1,289	1,273	1,289
Effect of Dilutive Securities Effect of Convertible Notes, after assumed conversion of	13	24	15	24
Convertible Notes	35	35	35	35
Weighted-average shares for diluted EPS	1,320	1,348	1,323	1,348
Basic earnings per share Diluted earnings per share	\$ 0.19 \$ 0.18	\$ 0.47 \$ 0.46	\$ 1.32 \$ 1.28	\$ 1.33 \$ 1.28
Diluted earnings per share	\$ 0.18	\$ 0.46	\$ 1.28	\$ 1.28

Employee stock options

The Company accounts for its 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. Under APB No. 25, because the Company s employee stock options are granted with 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, no employee stock option expense is reflected in net income.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation, as amended:

	Three Months Ended September 30,			nths Ended nber 30,
	2004	2003	2004	2003
Net income Stock-based compensation, net of tax	\$ 236 (67)	\$ 612 (54)	\$1,674 (225)	\$1,713 (139)
Pro forma net income	\$ 169	\$ 558	\$1,449	\$1,574
Earnings per share:				
Basic	\$0.19	\$0.47	\$ 1.32	\$ 1.33
Basic-pro forma	\$0.13	\$0.43	\$ 1.14	\$ 1.22
Diluted	\$0.18	\$0.46	\$ 1.28	\$ 1.28
Diluted-pro forma	\$0.13	\$0.42	\$ 1.11	\$ 1.18

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 September 30:

	2004	2003
Weighted average fair value of common stock	\$56.32	\$66.06
Weighted average fair value of stock options granted	22.21	27.09
Risk-free interest rate	3.1%	2.4%
Expected life (in years)	4.8	4.1
Expected volatility	41.0%	50.0%
Expected dividend yield	0%	0%

Recent accounting developments

In March 2004, the Financial Accounting Standards Board (FASB) issued a Proposed SFAS, Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95 (Exposure Draft). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB No. 25, Accounting for Stock Issued to Employees , and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. The Company is closely monitoring developments related to the

Exposure Draft and will adopt the final standard upon issuance.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

2. Related party transactions

The Company owns a 50% interest in Kirin-Amgen (KA), a corporation formed in 1984 with Kirin Brewery Company, Limited (Kirin) for the development and commercialization of certain products based on advanced biotechnology. The Company accounts for its interest in KA under the equity method and includes its share of KA s profits or losses in Selling, general and administrative in the Condensed Consolidated Statements of Operations. KA s revenues consist of royalty income related to its licensed technology rights. All of Amgen s 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. The Company currently markets certain of these products under the brand names EPOGEN® (erythropoietin), NEUPOGEN® (G-CSF), Aranesp® (darbepoetin alfa), and Neulasta® (pegfilgrastim). KA receives royalty income from Amgen, 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 nine months ended September 30, 2004, KA earned royalties from Amgen of \$78 million and \$201 million, respectively. During the three and nine months ended September 30, 2003, KA earned royalties from Amgen of \$60 million and \$160 million, respectively. These amounts are included in Cost of sales, excludes amortization of acquired intangible assets presented below) in the accompanying 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 nine months ended September 30, 2004, Amgen earned revenues from KA of \$53 million and \$145 million, respectively, for certain research and development activities performed on KA s behalf. During the three and nine months ended September 30, 2003, Amgen earned revenues from KA of \$17 million and \$65 million, respectively. These amounts are included in Other revenues in the accompanying Condensed Consolidated Statements of Operations.

In August 2003, the Company paid a legal settlement to Genentech, Inc. (Genentech) in connection with settling a patent litigation relating to the Company s processes for producing NEUPOGEN® and Neulasta®. Pursuant to the terms of the license agreement with KA, KA indemnified the Company for the payment made to Genentech. During the three months ended September 30, 2003, the Company recorded \$47 million as its share of the loss incurred by KA, net of tax, in Selling, general and administrative in the accompanying Condensed Consolidated Statements of Operations.

In July 2004, KA received third-party reimbursement for a portion of the legal settlement paid to Genentech. During the three months ended September 30, 2004, the Company recorded \$11 million as its share of the reimbursement received by KA in Selling, general and administrative in the accompanying Condensed Consolidated Statements of Operations.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

3. Income taxes

The tax rates for the three and nine months ended September 30, 2004 are different from the statutory rate primarily as a result of the write-off of non-deductible IPR&D costs in connection with the acquisition of Tularik, Inc. (Tularik) and permanently reinvested earnings of the Company s foreign operations.

During 2002, the Company restructured its Puerto Rico manufacturing operations using a controlled foreign corporation. As permitted in APB 23, Accounting for Income Taxes Special Areas, the company does not provide U.S. income taxes on its controlled foreign corporations undistributed earnings that are intended to be permanently reinvested outside the U.S.

The Company s income tax returns are routinely audited by the Internal Revenue Service and various state tax authorities. While disputes may arise with these tax authorities, some of which may be significant, the Company believes that adequate tax liabilities have been established for all open audit years.

4. Stockholders equity

Stock repurchase program

A summary of the Company s repurchase activity for the nine months ended September 30, 2004 and 2003 is as follows (amounts in millions):

		2004	2003		
	Shares	Dollars	Shares	Dollars	
First quarter	10	\$ 650	8	\$ 451	
Second quarter	18	1,000	7	449	
Third quarter	24	1,398	5	324	
Total	52	\$3,048	20	\$1,224	

In December 2003, the Board of Directors authorized the Company to repurchase up to an additional \$5.0 billion of common stock. As of September 30, 2004, \$1,993 million was available for stock repurchases. The amount the Company spends and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which the Company is restricted from repurchasing shares.

AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

Other comprehensive income

SFAS No. 130, Reporting Comprehensive Income, requires unrealized gains and losses on the Company s available-for-sale securities and foreign currency forward contracts, which qualify and are designated as cash flow hedges, and foreign currency translation adjustments to be included in other comprehensive income. During the three and nine months ended September 30, 2004, total comprehensive income was \$233 million and \$1,650 million, respectively. During the three and nine months ended September 30, 2003, total comprehensive income was \$594 million and \$1,711 million, respectively.

5. Financing arrangements

As of September 30, 2004, the Company had Convertible Notes (30-year, zero-coupon senior convertible notes) with an accreted value of \$2.9 billion outstanding and having an aggregate face amount of \$3.95 billion and yield to maturity of 1.125%. The original issue discount of \$1.13 billion 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 the Company to purchase all or a portion of their notes on various dates, the earliest of which is March 1, 2005, at a price equal to the original issuance price plus the accrued original issue discount to the purchase dates, and accordingly, the Convertible Notes were classified as current in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2004. In such event, under the terms of the Convertible Notes, the Company has the right to pay the purchase price in cash and/or shares of common stock, which would be issued at the then current market price.

Holders of the Convertible Notes may convert each of their notes into 8.8601 shares of common stock of the Company (the conversion rate) at any time on or before the maturity date, or approximately 35 million shares in the aggregate. The conversion price per share as of any day will equal the original issuance price plus the accrued original issue discount to that day, divided by the conversion rate, or \$82.98 per share as of September 30, 2004.

In July 2004, the Company established a \$1.0 billion five-year unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support. Additionally, the Company increased the size of its commercial paper authorization by \$1.0 billion to \$1.2 billion. No amounts were outstanding under the credit facility or commercial paper program as of September 30, 2004.

6. Contingencies

In the ordinary course of business, the Company is involved in various legal proceedings and other matters. While it is not possible to accurately predict or determine the eventual outcome of these items, the Company does not believe any such items currently pending will have a material adverse effect on its annual consolidated financial statements, although an adverse resolution in any reporting period of one or more of these items could have a material impact on the results of operations for that period.

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AMGEN INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS- (Continued)

7. Tularik Inc. acquisition

On August 13, 2004, the Company acquired all of the outstanding common stock of Tularik in a transaction accounted for as a business combination. Tularik was a company engaged in drug discovery related to cell signaling and the control of gene expression. Amgen issued 24 million shares in the acquisition. Additionally, Amgen issued 4 million stock options in exchange for Tularik stock options assumed in the acquisition. The purchase price of \$1.5 billion, which included the carrying value of Amgen s existing ownership interest in Tularik of approximately 21% or \$82 million, was preliminarily allocated to goodwill of \$748 million, IPR&D of \$554 million (see Note 1, Summary of significant accounting policies Acquired in-process research and development), and other net assets acquired of \$195 million. The amount preliminarily allocated to IPR&D was immediately expensed in the Condensed Consolidated Statement of Operations during the three months ended September 30, 2004. The estimated fair value of these R&D projects was determined through the assistance of an independent valuation firm and was based on discounted cash flows. The final determination of the purchase price allocation is expected to be completed as soon as practicable after the consummation of the acquisition. The results of Tularik s operations have been included in the Condensed Consolidated Financial Statements commencing August 14, 2004. The merger was structured to qualify as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

8. Other items, net

License Agreement arbitration

In September 1985, the Company granted Johnson & Johnson s affiliate, Ortho Pharmaceutical Corporation, a license relating to certain patented technology and know-how of the Company to sell Epoetin alfa throughout the United States for all human uses except dialysis and diagnostics. A number of disputes arose between Amgen and Johnson & Johnson as to their respective rights and obligations under the various agreements between them, including the agreement granting the license (the License Agreement). These disputes between Amgen and Johnson & Johnson have been resolved through binding arbitration. One of these disputes related to the alleged violation of the License Agreement by Johnson & Johnson. In October 2002, the Arbitrator issued a final order awarding the Company \$150 million for Johnson & Johnson s breach of the License Agreement. The legal award of \$151 million, which included interest, was recorded in the fourth quarter of 2002. In January 2003, the Company was awarded reimbursement of its costs and expenses, as the successful party in the arbitration. In May 2003, the Arbitrator issued a final order awarding the Company \$74 million in such costs and expenses, which were recorded during the three months ended June 30, 2003.

Amgen Foundation contribution

During the three months ended June 30, 2003, the Company made a \$50 million cash contribution to the Amgen Foundation. This contribution will allow the Amgen Foundation to continue its support of non-profit organizations that focus on issues in health and medicine, science education, and other activities that strengthen local communities.

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

Forward looking statements

This report and other documents we file with the Securities and Exchange Commission (SEC) contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management s assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, outlook. webcasts, phone calls, and conference calls. Words such as expect, anticipate, could, plan. believe. seek. estimate. should. assume. continue. variations of such words and similar expre intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict. We describe our respective risks, uncertainties, and assumptions that could affect the outcome or results of operations in 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, earnings per share, 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

Business

Amgen Inc. (including its subsidiaries, Amgen or the Company) is a global biotechnology company that discovers, develops, manufactures, and markets human therapeutics based on advances in cellular and molecular biology.

The Company focuses its research and development (R&D) efforts on human therapeutics delivered in the form of proteins, monoclonal antibodies, and small molecules in the areas of hematology, oncology, inflammation, metabolic and bone disorders, and neuroscience. In addition to internal R&D efforts, the Company has acquired certain product and technology rights and has established R&D collaborations.

The Company primarily earns revenues and income and generates cash from sales of human therapeutic products in the areas of hematology, oncology, and inflammation. In the near-term, the Company expects sales growth to be primarily driven by sales of Aranesp®, ENBREL®, and Neulasta®. For the three and nine months ended September 30, 2004, total revenues were \$2,713 million and \$7,641 million, respectively, and net income was \$236 million and \$1,674 million, respectively. As of September 30, 2004, cash and marketable securities were \$3,838 million.

Net income was \$236 million, or \$0.18 per share, for the three months ended September 30, 2004 compared with \$612 million, or \$0.46 per share, for the three months ended September 30, 2003.

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These decreases were primarily driven by the write-off of acquired in-process research and development (IPR&D) of \$554 million related to the Tularik Inc. (Tularik) acquisition (See Note 7, Tularik Inc. acquisition in the Condensed Consolidated Financial Statements), partially offset by a 23% increase in product sales from the same period of the prior year.

The Medicare Prescription Drug, Improvement and Modernization Act (or the Medicare Modernization Act (MMA)) was enacted into law in December 2003. We expect that, beginning in 2005, reimbursement changes resulting from the MMA are likely, to a degree, to 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:

- Currently, the Average Wholesale Price (AWP) mechanism is the basis of Medicare Part B payment for covered outpatient drugs and biologics; this is expected to change to an average sales price (ASP) methodology under the MMA. Effective January 1, 2005, in the physician clinic market segment, Aranesp®, Neulasta® and NEUPOGEN® will be reimbursed under a new Medicare Part B system that reimburses each product at 106% of its ASP (sometimes referred to as ASP + 6%). On November 3, 2004, The Centers for Medicare and Medicaid Services (CMS) released final rules for revisions to payment policies under the physician fee schedule for 2005. CMS is in the process of determining what each product s ASP will be based on submissions from the Company. CMS is expected to publish the ASPs to be in effect for the first quarter of 2005 in December 2004. These ASPs will remain in effect for one quarter and will be updated quarterly thereafter. We expect that 2005 reimbursement rates for Aranesp®, Neulasta®, and NEUPOGEN® (calculated at 106% of the ASPs and initially based on third quarter 2004 Company data), will be lower than our current 2004 reimbursement rates as the ASP methodology incorporates sales incentives offered to healthcare providers.
- 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. On November 3, 2004, CMS issued a final rule for the reimbursement of Aranesp® in 2005. Under this final rule, as in 2003 and 2004, CMS continued the application of an equitable adjustment such that the Aranesp® reimbursement rate for 2005 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. Although we do not know how CMS will define the OPPS acquisition cost, it is possible that CMS could link acquisition cost to ASP, which could lower the reimbursement rate.
- Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 will be changed from the current 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 prescription preparation. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed (including EPOGEN®) and the 2005 reimbursement rates for

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such drugs will be 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®, will be ASP+6%.

- 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 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 is likely to be, to a degree, 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. As of the date of this filing, the comment period for the proposed revision has expired and no final program memoranda has been issued. The proposed policy would not permit reimbursement for EPOGEN® in the following circumstances without medical justification: where EPOGEN® dose is greater than 40,000 units in a patient with a hemoglobin greater than 13 grams per deciliter or where dose is greater than 20,000 units in a patient with hemoglobin greater than 14 grams per deciliter. If the proposed revision is adopted as the final form, we expect it to go into effect on or after January 1, 2005 and it could result in a reduction in utilization of EPOGEN®. Amgen and the dialysis community have provided public comment based on data analysis suggesting that revision to the proposed policy is warranted. Given the importance of EPOGEN® utilization for maintaining the quality of care for patients, the precise impact of such a change on provider utilization remains unclear.

Sales of all our products are and will be affected by government and private payor reimbursement policies. Reduction in reimbursement for our products could have a material adverse effect on our results of operations.

Key products

The Company markets human therapeutic products in the areas of hematology, oncology, and inflammation. The Company s key products include EPOGEN® (Epoetin alfa), Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim), NEUPOGEN® (Filgrastim), and ENBREL® (etanercept), which is marketed under a co-promotion agreement with Wyeth.

EPOGEN® and Aranesp® stimulate the production of red blood cells. EPOGEN® is marketed in the United States for the treatment of anemia associated with chronic renal failure in patients on dialysis. Aranesp® is marketed in the United States, most countries in Europe, Canada,

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Australia, and New Zealand for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. Aranesp® is also marketed in the United States for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies. Aranesp® is also marketed in Europe for the treatment of anemia in adult cancer patients with solid tumors receiving chemotherapy and for the treatment of chemotherapy-induced anemia in adult patients with non-myeloid malignancies.

Neulasta® and NEUPOGEN® selectively stimulate the production of neutrophils, one type of white blood cell. Neulasta® is marketed in the United States to decrease the incidence of infection, as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta® is marketed in most countries in Europe and Canada for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients with cytotoxic chemotherapy for malignancy. NEUPOGEN® is marketed in the United States, certain countries in Europe, Canada, and Australia for use in decreasing the incidence of infection in patients undergoing myelosuppressive chemotherapy. In addition, NEUPOGEN® is marketed in most of these countries for use in increasing neutrophil counts in various other treatment modalities.

ENBREL® blocks the biologic activity of tumor necrosis factor (TNF) by competitively inhibiting TNF, a substance induced in response to inflammatory and immunological responses. In April 2004, the FDA approved ENBREL® for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and immediately launched ENBREL® for this indication. ENBREL® is marketed in the United States for reducing the signs and symptoms, improving physical function, and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis; and for reducing the signs and symptoms and inhibiting the progression of structural damage in patients with psoriatic arthritis. In addition, ENBREL® is approved for reducing the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying medicines; to treat the signs and symptoms in patients with active ankylosing spondylitis; and for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

For additional information about these and the Company s other products and their approved indications see Item 1. Business Products in the Company s Annual Report on Form 10-K for the year ended December 31, 2003.

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Results of Operations

Product sales

For the three and nine months ended September 30, 2004 and 2003, total product sales by geographic region were as follows (amounts in millions):

		Three months ended September 30,				Nine moi Septer		
	2004	2003	Change	2004	2003	Change		
Total U.S Total International	\$2,141 419	\$1,778 300	20% 40%	\$5,966 1,233	\$4,864 767	23% 61%		
Total product sales	\$2,560	\$2,078	23%	\$7,199	\$5,631	28%		

See Overview Key products for a discussion of these products and their approved indications. Product sales are influenced by a number of factors, including demand, third-party reimbursement availability and policies, pricing strategies, wholesaler 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. Excluding the beneficial impact of foreign currency exchange rates of \$28 million and \$125 million, respectively, international product sales increased 31% and 44%, respectively, for the three and nine months ended September 30, 2004.

In the near-term, the Company expects sales growth to be driven primarily by Aranesp®, ENBREL®, and Neulasta®. The Company believes that changes in reimbursement for its products are likely to, to a degree, adversely affect the prescription and administration of the Company s products by healthcare providers impacting sequential sales growth and historical sales trends.

EPOGEN®/Aranesp®

(Amounts in millions)

		Three months ended September 30,			Nine months ended September 30,	
	2004	2003	Change	2004	2003	Change
EPOGEN® - U.S	\$ 681	\$ 626	9%	\$1,904	\$1,784	7%

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Aranesp® - U.S.	374	284	32%	1,084	659	64%
Aranesp® - International	234	154	52%	684	382	79%
		·				
Aranesp® - Total	608	438	39%	1,768	1,041	70%
Total EPOGEN® and Aranesp®	\$1,289	\$1,064	21%	\$3,672	\$2,825	30%

The increase in combined EPOGEN® and worldwide Aranesp® sales was primarily driven by worldwide demand for Aranesp®.

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The growth in reported EPOGEN® sales for the three months ended September 30, 2004 was primarily due to increases in wholesaler inventory levels, and to a lesser extent, demand. For the nine months ended September 30, 2004, the growth in reported EPOGEN® sales was primarily due to demand, and to a lesser extent, changes in wholesaler inventory levels.

The Company believes EPOGEN® sales growth will primarily depend on dialysis patient population growth. Patients receiving treatment for end stage renal disease are covered primarily under medical programs provided by the federal government. The Company believes future EPOGEN® sales growth will be dependent in part on future changes in reimbursement rates or a change in the basis for reimbursement by the federal government and governmental or private organization regulations (see Factors that may affect Amgen Our sales depend on payment and reimbursement from third-party payors, and, to the extent that reimbursement falls below provider acquisition costs, this could negatively impact the utilization of our products.) or guidelines relating to the use of our products. EPOGEN® competes to a slight degree with Aranesp® in the United States as some health care providers use Aranesp® to treat anemia associated with chronic renal failure instead of EPOGEN®. Additionally, from a trend perspective, reported sales in the first quarter for EPOGEN® have tended to be comparable or slightly less than reported sales in the fourth quarter of the previous year.

The increases in U.S. Aranesp® sales for the three and nine months ended September 30, 2004 were driven by demand and market share gains. Sales growth was impacted by higher sales incentives earned by customers attaining higher sales volumes and growth under performance-based contracts. The Company expects similar levels of sales incentives in the fourth quarter. Adjusting for the impact of a change in the estimate related to the performance-based contracts and excluding the revision to the estimate for product sales returns, sequential sales growth for U.S. Aranesp® sales for the three months ended September 30, 2004 would have been approximately 10%. 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 nine months ended September 30, 2004, benefited by \$16 million and \$70 million, respectively, from foreign currency exchange rate changes.

The Company believes future worldwide Aranesp® sales growth will be dependent, in part, on such factors as: reimbursement by third party payors (including governments and private insurance plans) (see Factors that may affect Amgen Our sales depend on payment and reimbursement from third-party payors, and, to the extent that reimbursement falls below provider acquisition costs, this could negatively impact the utilization of our products.); governmental or private organization regulations or guidelines relating to the use of our products; the effects of pricing strategies; competitive products or therapies; penetration of existing and new market opportunities; and changes in foreign currency exchange rates. In addition, future worldwide sales growth may be affected by cost containment pressures from governments and private insurers on health care providers.

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Neulasta®/NEUPOGEN®

(Amounts in millions)

	Three months ended September 30,			Nine months ended September 30,		
	2004	2003	Change	2004	2003	Change
Neulasta® - U.S Neulasta® - International	\$ 384 66	\$ 304 23	26% 187%	\$1,082 189	\$ 848 41	28% 361%
Neulasta® - Total	450	327	38%	1,271	889	43%
NEUPOGEN® - U.S. NEUPOGEN® - International	207 95	228 102	(9%) (7%)	574 292	655 290	(12%) 1%
NEUPOGEN® - Total	302	330	(8%)	866	945	(8%)
Total Neulasta® and NEUPOGEN®	\$ 752	\$ 657	14%	\$2,137	\$1,834	17%

The increase in combined worldwide Neulasta® and NEUPOGEN® sales was driven by worldwide demand for Neulasta®.

The increases in U.S. Neulasta® sales for the three and nine months ended September 30, 2004 were driven by demand. Sales growth was impacted by higher sales incentives earned by customers attaining higher sales volumes and growth under performance-based contracts. The Company expects similar levels of sales incentives in the fourth quarter. The increase in international Neulasta® sales was primarily due to demand, which reflects the January 2003 launch of Neulasta® in Europe.

The decrease in NEUPOGEN® sales in the United States for the three and nine months ended September 30, 2004, was principally due to a decline in demand.

The Company believes future worldwide Neulasta® and NEUPOGEN® sales growth will be dependent, in part, on such factors as: reimbursement by third-party payors (including governments and private insurance plans) (see Factors that may affect Amgen Our sales depend on payment and reimbursement from third-party payors, and, to the extent that reimbursement falls below provider acquisition costs, this could negatively impact the utilization of our products.); penetration of existing markets; patient population growth; price increases; the effects of pricing strategies; competitive products or therapies; the development of new treatments for cancer; governmental or private organization regulations or guidelines relating to the use of our products; and changes in foreign currency exchange

rates. In addition, future worldwide sales growth may be affected by cost containment pressures from governments and private insurers on health care providers. 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. The Company believes that U.S. NEUPOGEN® sales have and will continue to be adversely impacted by Neulasta®. However, the Company believes that most of the conversion in the U.S. has occurred due to the rapid adoption of Neulasta®. The Company believes that it is experiencing conversion of NEUPOGEN® patients to Neulasta® in Europe, but believes this conversion will occur to a lesser extent than that experienced in the United States. The Company cannot accurately predict the rate or timing of future conversion of NEUPOGEN® patients to Neulasta® worldwide. Additionally, from a trend perspective, reported

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sales in the first quarter for combined Neulasta®/NEUPOGEN® have tended to be comparable or slightly less than respective reported sales in the fourth quarter of the previous year.

ENBREL®

(Amounts in millions)

	Three months ended September 30,			Nine months ended September 30,		
	2004	2003	Change	2004	2003	Change
ENBREL® - U.S	\$ 477	\$ 329	45%	\$1,282	\$887	45%
ENBREL® - International		13	46%	51	32	<u>59</u> %
Total ENBREL®	\$ 496	\$ 342	45%	\$1,333	\$919	45%

ENBREL® sales growth for the three and nine months ended September 30, 2004 was driven by increased demand in the rheumatology and dermatology segments due to greater use of biologics. Dermatology growth was driven by the April 2004 approval of ENBREL® for use in psoriasis.

The Company believes that future sales growth of ENBREL® will be dependent, in part, on such factors as: limits on the current supply of and sources of ENBREL®; the effects of competing products or therapies; penetration of existing and new market opportunities, including potential new indications; governmental or private organization regulations or guidelines relating to the use of our products; and the availability and extent of reimbursement by third-party payors (see Factors that may affect Amgen Our sales depend on payment and reimbursement from third-party payors, and, to the extent that reimbursement falls below provider acquisition costs, this could negatively impact the utilization of our products.).

Selected operating expenses

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

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Product sales Operating expenses:	\$2,560	\$2,078	\$7,199	\$5,631
Cost of sales (excludes amortization of acquired intangible assets)	\$ 447	\$ 340	\$1,255	\$ 952

% of product sales		17%	16%	17%	17%
Research and development	\$	502	\$ 408	\$1,411	\$1,153
% of product sales		20%	20%	20%	20%
Write-off of acquired in-process research and					
development	\$	554	\$	\$ 554	\$
% of product sales		22%	%	8%	%
Selling, general and administrative	\$	632	\$ 519	\$1,740	\$1,341
% of productsales		25%	25%	24%	24%
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Cost of sales

Cost of sales, which excludes the amortization of acquired intangible assets (see Condensed Consolidated Statements of Operations), increased 31% and 32% for the three and nine months ended September 30, 2004, respectively, primarily due to higher sales volumes and product mix changes.

Research and development

R&D expenses increased 23% and 22% for the three and nine months ended September 30, 2004, respectively primarily due to: 1) higher staff-related costs including the addition of R&D personnel from Tularik, 2) higher outside R&D costs, driven by a higher level of clinical development activity, and 3) higher clinical manufacturing costs. During the three months ended September 30, 2004, staff-related costs, outside R&D costs, and clinical manufacturing costs increased approximately \$53 million, \$21 million, and \$20 million, respectively. During the nine months ended September 30, 2004, staff-related costs, outside R&D costs, and clinical manufacturing costs increased approximately \$145 million, \$73 million, and \$42 million, respectively.

Acquired in-process research and development

During the three and nine months ended September 30, 2004, the Company incurred a charge of \$554 million associated with writing off the fair value of IPR&D acquired in the Tularik acquisition. This amount represents an estimate of the fair value of the various R&D projects and technologies in Tularik s pipeline that, as of the acquisition date, had not reached technological feasibility and had no alternative future use (See Note 7, Tularik Inc. acquisition in the Condensed Consolidated Financial Statements).

Selling, general and administrative

Selling, general and administrative (SG&A) expenses increased 22% for the three months ended September 30, 2004, primarily due to higher outside marketing expenses to support products in competitive markets and sales growth and higher staff-related costs including incentive compensation. Outside marketing expenses include the Wyeth profit share related to ENBREL®. These increases were partially offset by an increase in earnings from affiliates primarily resulting from the Genentech legal settlement which occurred in the third quarter of 2003 (See Note 2, Related party transactions in the Condensed Consolidated Financial Statements). During the three months ended September 30, 2004, outside marketing expenses and staff-related costs increased approximately \$58 million and \$57 million, respectively, partially offset by an increase in earnings from affiliates of approximately \$51 million. SG&A expenses increased 30% for the nine months ended September 30, 2004, primarily due to higher staff-related costs and higher outside marketing expenses. During the nine months ended September 30, 2004, staff-related costs and outside marketing expenses increased approximately \$181 million and \$165 million, respectively.

SG&A expenses in the fourth quarter are expected to increase over the first three quarters of the year in a trend similar to that seen in previous years.

Other items, net

During the nine months ended September 30, 2003, other items, net consisted of a benefit for the recovery of costs and expenses associated with a legal award related to an arbitration proceeding

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with Johnson & Johnson of \$74 million, partially offset by a charitable contribution to the Amgen Foundation of \$50 million (See Note 8, Other items, net in the Condensed Consolidated Financial Statements).

Income taxes

The Company s effective tax rates for the three and nine months ended September 30, 2004 were 53.7% and 32.4% respectively, compared with 29.3% and 28.7% respectively, for the same periods last year.

The Company's effective tax rates for the three and nine months ended September 30, 2004 have increased primarily due to the write-off of non-deductible IPR&D costs in connection with the acquisition of Tularik. Excluding the effect of the IPR&D write-off, the effective tax rates for the three and nine months ended September 30, 2004 would have been 25.7% and 26.4%, respectively. The Company's effective tax rates for the three and nine months ended September 30, 2004, excluding the effect of the IPR&D write-off, as compared to the three and nine months ended September 30, 2003, have decreased primarily due to an increase in the amount of permanently reinvested foreign earnings.

During 2002, the Company restructured its Puerto Rico manufacturing operations using a controlled foreign corporation. As permitted in APB 23, Accounting for Income Taxes Special Areas, the company does not provide U.S. income taxes on its controlled foreign corporations undistributed earnings that are intended to be permanently reinvested outside the U.S.

The American Jobs Creation Act of 2004 (the Jobs Creation Act) was enacted on October 22, 2004 and will permit the Company to repatriate approximately \$500 million of foreign earnings at a reduced effective Federal income tax rate of 5.25%. The Company is evaluating the implications of this new legislation.

Financial Condition, Liquidity and Capital Resources

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

	September 30, 2004	December 31, 2003
Cash, cash equivalents, and marketable		
securities	\$ 3,838	\$ 5,123
Total assets	26,811	26,177
Total current and non-current debt	3,104	3,080
Stockholders equity	19,808	19,389

The Company believes that existing funds, cash generated from operations, and existing sources of and access to financing are adequate to satisfy its working capital, capital expenditure and debt service requirements for the foreseeable future, as well as to support its stock repurchase program. However, the Company is currently reviewing additional borrowing opportunities in an amount in excess of the combined amounts currently available under the Shelves (as defined below). The Company would expect to use any proceeds raised by such borrowing primarily for open market

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purchases of shares under the Company s stock repurchase program and for general corporate purposes, including capital expenditures and working capital.

Cash, cash equivalents, and marketable securities

Of the total cash, cash equivalents, and marketable securities at September 30, 2004, approximately \$2.2 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 the Company s U.S. operations, additional taxes on certain of these amounts would be required to be paid. In addition, the Company is currently evaluating the implications of the Jobs Creation Act (see Results of Operations Selected operating expenses Income taxes).

Financing activities

As of September 30, 2004, the Company had Convertible Notes (30-year, zero-coupon senior convertible notes) with an accreted value of \$2.9 billion outstanding and having an aggregate face amount of \$3.95 billion and yield to maturity of 1.125%. The original issue discount of \$1.13 billion 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 the Company to purchase all or a portion of their notes on various dates, the earliest of which is March 1, 2005, at a price equal to the original issuance price plus the accrued original issue discount to the purchase dates, and accordingly, the Convertible Notes are classified as current in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2004. In such event, under the terms of the Convertible Notes, the Company has the right to pay the purchase price in cash and/or shares of common stock, which would be issued at the then current market price.

Holders of the Convertible Notes may convert each of their notes into 8.8601 shares of common stock of the Company (the conversion rate) at any time on or before the maturity date, or approximately 35 million shares in the aggregate. The conversion price per share as of any day will equal the original issuance price plus the accrued original issue discount to that day, divided by the conversion rate, or \$82.98 per share as of September 30, 2004. The Company s Convertible Notes are rated A2 by Moody s and A+ by Standard & Poor s.

In July 2004, the Company established a \$1.0 billion five-year unsecured revolving credit facility to be used for general corporate purposes, including commercial paper support. Additionally, the Company increased the size of its commercial paper authorization by \$1.0 billion to \$1.2 billion. No amounts were outstanding under the credit facility or commercial paper program as of September 30, 2004.

The Company has a \$1.0 billion shelf registration (the \$1 Billion Shelf) and a \$500 million debt shelf registration (the \$500 Million Shelf) collectively the Shelves. The \$1 Billion Shelf allows the Company 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 of the Company. The \$1 Billion Shelf was established to provide for further financial flexibility and the securities available for issuance may be offered from time to time with terms to be determined at the time of issuance. As of September 30, 2004, no securities had been issued under the \$1 Billion Shelf.

The Company has \$100 million of debt securities outstanding bearing interest at a fixed rate of 6.5% and maturing in 2007 (the Notes) under the \$500 Million Shelf. Under the \$500 Million Shelf,

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all of the remaining \$400 million of debt securities available for issuance may be offered from time to time under the Company s medium-term note program with terms to be determined at the time of issuance.

Cash flows

The following table summarizes the Company s cash flow activity (amounts in millions):

		nded September 80,
	2004	2003
Net cash provided by operating activities	\$ 2,587	\$ 2,369
Net cash provided by (used in) investing activities	314	(2,306)
Net cash used in financing activities	(2,752)	(865)

Operating

Cash provided by operating activities has been and is expected to continue to be the Company s primary recurring source of funds. The increase in cash provided by operating activities during the nine months ended September 30, 2004 resulted primarily from higher earnings, excluding the non-cash write-off of acquired IPR&D (See Condensed Consolidated Statements of Cash Flows).

Investing

Capital expenditures totaled \$1,040 million during the nine months ended September 30, 2004, compared with \$931 million during the same period last year. The increase in capital expenditures during the nine months ended September 30, 2004 primarily related to the new ENBREL® manufacturing plant in Rhode Island, the Thousand Oaks site expansion, and the Puerto Rico manufacturing expansion. These capital expenditures were offset by net sales and maturities of marketable securities of \$1,382 million during the nine months ended September 30, 2004.

The Company currently estimates spending on capital projects and equipment to be approximately \$1.3 billion to \$1.5 billion in 2004, the most significant of which relate to the new ENBREL® manufacturing plant in Rhode Island, the Puerto Rico manufacturing expansion, and the Thousand Oaks site expansion.

Financing

The Company receives cash from the exercise of employee stock options and proceeds from the sale of stock by Amgen pursuant to the employee stock purchase plan. Employee stock option exercises and proceeds from the sale of stock by Amgen pursuant to the employee stock purchase plans provided \$302 million and \$469 million of cash during the nine months ended September 30, 2004 and 2003, 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 the Company s stock relative to the exercise price of such options.

In December 2003, the Board of Directors authorized the Company to repurchase up to an additional \$5.0 billion of common stock. As of September 30, 2004, \$1,993 million was available for stock repurchases. The amount the Company spends and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which the Company is

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restricted from repurchasing shares. Repurchases under the Company s stock repurchase program reflect, in part, the Company s confidence in the long-term value of Amgen common stock. A summary of the Company s repurchase activity for the nine months ended September 30, 2004 and 2003 is as follows (amounts in millions):

	2004		2003	
	Shares	Dollars	Shares	Dollars
First quarter	10	\$ 650	8	\$ 451
Second quarter	18	\$1,000	7	\$ 449
Third quarter	24	\$1,398	5	\$ 324
•	_		_	
Total	52	\$3,048	20	\$1,224

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

Summary of Critical Accounting Policies

The preparation of the Company s consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

EPOGEN® revenue recognition

The Company has the exclusive right to sell Epoetin alfa for dialysis, certain diagnostics, and all non-human, non-research uses in the United States. Amgen has granted to Johnson & Johnson a license relating to Epoetin alfa for sales in the United States for all human uses except dialysis and diagnostics. Pursuant to this license, the Company 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, Amgen does not recognize product sales it makes into the exclusive market of Johnson & Johnson and does recognize the product sales made by Johnson & Johnson into Amgen s exclusive market. Sales in Amgen s exclusive market are derived from the Company s sales to its customers, as adjusted for spillover. The Company is employing an arbitrated audit methodology to measure each party s spillover based on independent third-party data on shipments to end users and their estimated usage. Data on end user usage is derived in part using market sampling techniques, and accordingly, the results of such sampling can produce variability in the amount of recognized spillover. The Company initially recognizes spillover based on estimates of shipments to end users and their usage, utilizing historical third-party data and subsequently adjusts such amounts based on revised third-party data could produce materially different amounts for recognized EPOGEN® sales. However, such differences to date have not been material.

Deferred income taxes

The Company s effective tax rate reflects the impact of undistributed foreign earnings for which no U.S. taxes have been provided because such earnings are intended to be permanently

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reinvested internationally based on the Company s projected cash flow, working capital, and long-term investment requirements of its U.S. and foreign operations. If future events, including material changes in estimates of cash, working capital, and long-term investment requirements necessitate that certain assets associated with these earnings be repatriated to the United States, an additional tax provision and related liability would be required which could materially impact the Company s effective future tax rate.

Sales incentives and returns

Product sales are recorded net of accruals for estimated rebates (including Medicaid), discounts, and other incentives (collectively—sales incentives—) and returns. These accruals are established in the same period the related sales are recognized and are included in accrued liabilities. The accruals are based on reasonable estimates of the amounts earned or to be claimed during the related periods. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, historical data (both internal and external) and forecasted activity of the number of customers that ultimately earn or claim such amounts. Sales incentives and returns are product-specific and, therefore, for any given year, can be impacted by the mix of products sold.

The most significant and difficult to estimate of these sales incentives relate to rebates earned by healthcare providers such as clinics, hospitals and pharmacies which are performance-based incentive offers, primarily based on sales volumes and growth. As a result, the calculation of the accrual for these rebates is complicated by the need to estimate customer buying patterns and the resulting applicable contractual rebate rate(s) to be earned over a contractual period. The Company believes that the accruals we have established for rebates are reasonable and appropriate given current facts and circumstances. However, actual results may differ. For example, a 5 percent change in the revenue reduction attributable to rebates recognized in 2003 would have had an approximate \$35 million effect on the Company s reported product sales in 2003.

Amounts accrued for sales incentives and returns are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. However, such adjustments to date have not been material to results of operations or financial position.

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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 payors, and, to the extent that reimbursement falls below provider acquisition costs, 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 payors 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, or in some cases draft regulations or legislative proposals 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. We expect that, beginning in 2005, reimbursement changes resulting from the MMA are likely, to a degree, to 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:

- Currently, the Average Wholesale Price (AWP) mechanism is the basis of Medicare Part B payment for covered outpatient drugs and biologics; this is expected to change to an average sales price (ASP) methodology under the MMA. Effective January 1, 2005, in the physician clinic market segment, Aranesp®, Neulasta® and NEUPOGEN® will be reimbursed under a new Medicare Part B system that reimburses each product at 106% of its ASP (sometimes referred to as ASP + 6%). On November 3, 2004, The Centers for Medicare and Medicaid Services (CMS) released final rules for revisions to payment policies under the physician fee schedule for 2005. CMS is in the process of determining what each product s ASP will be based on submissions from the Company. CMS is expected to publish the ASPs to be in effect for the first quarter of 2005 in December 2004. These ASPs will remain in effect for one quarter and will be updated quarterly thereafter. We expect that 2005 reimbursement rates for Aranesp®, Neulasta®, and NEUPOGEN® (calculated at 106% of the ASPs and initially based on third quarter 2004 Company data), will be lower than our current 2004 reimbursement rates as the ASP methodology incorporates sales incentives offered to healthcare providers.
- 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. On November 3, 2004, CMS issued a final rule for the reimbursement of Aranesp® in 2005. Under this final rule, as in 2003 and 2004, CMS continued the application of an equitable adjustment such that the Aranesp® reimbursement rate for 2005 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. Although we do not

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know how CMS will define the OPPS acquisition cost, it is possible that CMS could link acquisition cost to ASP, which could lower the reimbursement rate.

- Pursuant to final rules issued by CMS on November 3, 2004, Medicare reimbursement for EPOGEN® used in the dialysis setting for calendar year 2005 will be changed from the current 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 prescription preparation. Pursuant to the CMS final rules, the difference between the 2004 reimbursement rates for all drugs separately billed (including EPOGEN®) and the 2005 reimbursement rates for such drugs will be 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®, will be ASP+6%.

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 is likely to be, to a degree, 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. As of the date of this filing, the comment period for the proposed revision has expired and no final program memoranda has been issued. The proposed policy would not permit reimbursement for EPOGEN® in the following circumstances without medical justification: where EPOGEN® dose is greater than 40,000 units in a patient with a hemoglobin greater than 13 grams per deciliter or where dose is greater than 20,000 units in a patient with hemoglobin greater than 14 grams per deciliter. If the proposed revision is adopted as the final form, we expect it to go into effect on or after January 1, 2005 and it could result in a reduction in utilization of EPOGEN®. Amgen and the dialysis community have provided public comment based on data analysis suggesting that revision to the proposed policy is warranted. Given the importance of EPOGEN® utilization for maintaining the quality of care for 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 HCFA, instituted a reimbursement change for EPOGEN®, which materially and adversely affected our EPOGEN® sales until the policies were revised. 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,

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without limitation, the MMA. 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 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 payor 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 obtain and maintain regulatory approval.

We and certain of our licensors and partners conduct research, preclinical testing, and clinical trials and 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 discretion 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. We currently manufacture and market all our approved key 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, Boehringer Ingelheim Pharma KG (BI Pharma) and, as of October 2004, Genentech, Inc. (Genentech). Fill and finish of bulk product produced both at our Rhode Island manufacturing facility and at Genentech is done by us and third-party service providers. BI Pharma and these third-party service providers are subject to FDA regulatory Limits on supply for ENBREL® may constrain ENBREL® sales. In addition, later discovery of authority. See unknown problems with our products or manufacturing processes or those of our contract manufacturers or third-party service providers could result in restrictions on such products or manufacturing processes, 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 licensor or partner conducting research and development activities on our behalf have not complied with regulations in the research and development of a product candidate, then they may not approve the product candidate and we will not be able to market and sell it. If we were unable to market and sell

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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 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 commercialization of products. We are currently, and in the future may be, involved in patent litigation. For example, we are 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 these or other 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, 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. Our material patents are listed in the table below:

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PRODUCT		GENERAL SUBJECT MATTER	EXPIRATION
Epoetin alfa	U.S.	- DNA and host cells (issued in 1987) - Process of making erythropoietin (issued in 1995)	10/27/2004 8/15/2012
		and 1997) - 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⁾	- Erythropoietin DNA cells, polypeptides and processes (issued in 1990)	12/12/2004
darbepoetin alfa	Europe ⁽¹⁾	- Glycosylation analogs of erythropoietin proteins (issued in 1999)	10/12/2010
ana		- Glycosylation analogs of erythropoietin proteins (issued in 1997)	8/16/2014
Filgrastim	U.S.	- Methods for recombinant production of G- CSF (issued in 1998)	8/23/2005
		Analogs of G-CSF (issued in 1999)Pharmaceutical Compositions Comprising G-CSF	8/23/2005 8/23/2005
		(issued in 2002)- DNA, vectors, cells and processes relating to recombinant G-CSF (issued in 1989 and 1991)	3/7/2006
		- G-CSF polypeptides (issued in 1996)	12/3/2013
		- Methods of treatment using G-CSF polypeptides (issued in 1996)	12/10/2013
	Europe ⁽¹⁾	- G-CSF DNA Vectors, cells, polypeptides, methods of use and production (issued in 1991)	8/22/2006
pegfilgrastim	U.S.	- Pegylated G-CSF (issued in 1998)	10/20/2015
	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 2001)	9/5/2009
		- TNFR DNA vectors, cells and processes for making proteins (issued in 1995 and 2000)	3/7/2012

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

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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 patents relating to erythropoietin and G-CSF expire on December 12, 2004 and August 22, 2006, respectively, and we believe that after the expiration of these patents, other companies could develop and market follow-on or biosimilar products to our 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 requirements that would affect the development and approval of new competitive products. Until such requirements 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.

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 manufacture 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

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- our Rhode Island manufacturing facility, and, for either 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 fill and finish and packaging of ENBREL® bulk drug substance manufactured at our Rhode Island facility. If third-party fill and finish and packaging manufacturers are unable to provide sufficient capacity or 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 construction of an additional large-scale cell culture commercial manufacturing facility adjacent to the current Rhode Island manufacturing facility, which, once completed, will be subject to FDA approval. Additionally, we have entered into a manufacturing agreement with Genentech to produce ENBREL® at Genentech s manufacturing facility in South San Francisco. California and the FDA approved this facility for ENBREL® production in October 2004. Under the terms of the agreement, Genentech is expected to produce ENBREL® through 2005, with an extension through 2006 by mutual agreement. ENBREL® bulk drug substance produced at the Genentech facility will be produced in campaigns similar to those conducted at BI Pharma. Consequently, supply from the Genentech facility is expected to also be dependent on the timing and number of production runs in addition to the other manufacturing risk discussed above. In addition, Wyeth is constructing a new manufacturing facility in Ireland, which is 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 are not completed on time, or if these manufacturing facilities do not receive FDA or The European Agency for the Evaluation of Medicinal Products (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 third-party manufacturing facilities are completed and approved by the various regulatory authorities, our costs of acquiring bulk drug may fluctuate.

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.

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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 rheumatoid arthritis products marketed by Abbott Laboratories/Knoll, Centocor Inc./Johnson & Johnson, Aventis Pharmaceuticals, Inc., and Pfizer Inc., as well as the generic drug methotrexate, and may face competition from other potential therapies being developed. Additionally, Aranesp® competes with 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 patents relating to erythropoietin and G-CSF expire on December 12, 2004 and August 22, 2006, respectively, and we believe that after the expiration of these patents, other companies could develop and market follow-on or biosimilar products to our 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 requirements that would affect the development and approval of follow-on or biosimilar products. Until such requirements 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. 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 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

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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 plasma. We are investigating alternatives to certain biological sources. Raw materials may be subject to contamination 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, 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
- 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 Brain Derived Neurotrophic Factor (BDNF), Megakaryocyte Growth and Development Factor (MGDF), and Glial Cell Lined-Derived

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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 1 pilot investigator initiated open label study over a three year period appeared to result in improvements for advanced Parkinson s disease patients. Subsequently, 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. 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 products and products in development cannot be sold if we do not obtain and 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 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 or the discovery of significant problems with a similar product that implicates an entire class of products. 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 one of our products 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 obtain and maintain regulatory approval.

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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 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, 2003 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 payors 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 payors to health care providers who prescribed and administered those products. As of the date of this filing, seventeen of these actions have been brought against us and/or Immunex, now a wholly owned subsidiary of ours. Eleven states and Puerto Rico have pending investigations regarding our 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, 2003, and are updated as required in subsequent Form 10-Qs (See Part II Other Information, Item 1. Legal Proceedings). 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 statention, and adversely affect our reputation and the demand for our products.

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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, 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 payors reimbursement policies for our products
- 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 these, we would only have control over changes in our product pricing strategies and, 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 will 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 a large number of new employees
- 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

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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 September 30, 2004, the trading price of our common stock has ranged from a high of \$67.50 per share to a low of \$52.15 per share. Our stock price may be affected by a number of factors, such as:

- clinical trial results
- changes in reimbursement policies or medical practices
- adverse developments regarding the safety or efficacy of our products
- 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 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, 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 obtain and 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. If we fail to comply with any of these regulations 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, or other sanctions or litigation.

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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.

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.

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 employees
- consolidating research and development operations
- consolidating corporate and administrative infrastructures
- preserving ours and Tularik s research and development, and other important relationships
- minimizing the diversion of management s attention from ongoing business concerns
- coordinating geographically separate organizations

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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 several 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.

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Item 4. Controls and Procedures

The Company maintains 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 the Company 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 the Company 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, the Company 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 the Company s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has carried out an evaluation under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective in ensuring that material information relating to the Company, is made known to the Chief Executive Officer and Chief Financial Officer by others within the Company during the period in which this report was being prepared.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Transkaryotic Therapies (TKT) and Aventis Litigation

On October 15, 2004, the Massachusetts District Court decided the remaining issues remanded from the U.S. Court of Appeals for the Federal Circuit in the Company s favor. In the October 15 decision, the court ruled that claims 4-9 of the 698 patent are valid and infringed, claims 2-4 of the 080 claims are valid, claim 1 of the 422 is valid and claim 7 of the 349 patent is valid and infringed. TKT stated that it intends to appeal the decision to the Court of Appeals for the Federal Circuit.

Israel Bio-Engineering Project Litigation (IBEP)

The Company and Immunex Corporation (Immunex) filed their appeal brief on July 29, 2004. IBEP filed its reply brief on August 27, 2004. A date for oral argument has not yet been set by the Court of Appeals for the Federal Circuit.

Columbia Litigation

On September 1, 2004, The Trustees of Columbia University (Columbia) filed a covenant not to sue the plaintiffs for infringement of Columbia s U.S. Patent No. 6,455,275 (the 275 patent). On October 12, 2004, Columbia filed an Amended and Restated Covenant. Columbia filed a Motion to Dismiss based upon its covenant, seeking to dismiss claims against the Company and Immunex which it contends relate to the 275 patent and to transfer the remaining claims back to the U.S. District Court for the Central District of California. On November 5, 2004, the Court granted Columbia s Motion to Dismiss claims based upon the 275 patent and requested briefing regarding the schedule for remaining issues.

Average Wholesale Price Litigation

On August 4, 2004 a civil action, *The City of New York v. Abbott Laboratories, Inc., et al.*, was filed in the United States District Court for the Southern District of New York. As of the date of this filing, the Company has not received service of process on this matter. Further, according to press reports, on November 4, 2004 a civil action captioned *Commonwealth of Kentucky v. Alpharma, Inc., et al* was filed in the Franklin Circuit Court in Franklin County, Kentucky. Both actions broadly allege that the Company and Immunex Corporation, together with many other pharmaceutical manufacturers, reported prices for certain products in a manner that allegedly inflated reimbursement under Medicaid laws, including co-payments paid to providers who prescribe and administer the products. These actions are the sixteenth and seventeenth, respectively, such civil actions naming the Company and/or Immunex as defendants, either separately or together.

Tularik Inc. Stockholder Litigation

In re: Tularik Inc. Shareholder Litigation

On August 25, 2004, plaintiffs dismissed this action with prejudice as to the named plaintiffs, Janis Zvokel and Zucker only.

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Mary Kahler v. Tularik, Inc. et al.

On August 10, 2004, the California Superior Court for the County of San Mateo denied plaintiff s request for a preliminary injunction of the proposed transaction. On August 18, 2004, plaintiff requested that the entire action be dismissed with prejudice. On August 19, 2004, the California Superior Court for County of San Mateo entered the dismissal.

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

During the three months ended September 30, 2004, the Company had one outstanding stock repurchase program. The amount the Company spends and the number of shares repurchased varies based on a variety of factors including the stock price and blackout periods in which the Company is restricted from repurchasing shares. Repurchases under the Company s stock repurchase program reflect, in part, the Company s confidence in the long-term value of Amgen common stock. A summary of the Company s repurchase activity for the three months ended September 30, 2004 is as follows:

Total Number	Average	Total Number of Shares Purchased as Part	Maximum \$ Value that May Yet Be
of Shares	Paid per	of Publicly Announced	Purchased Under the
Purchased	Share	Programs	Programs (1)
14,206	\$41.70		\$3,391,368,654
11,519,195	57.65	11,517,788	2,727,420,739
12,498,348	58.74	12,494,951	1,993,416,274
24,031,749(2)	\$58.22	24,012,739	
	0f Shares Purchased 14,206 11,519,195 12,498,348	of Shares Price Paid per Share Purchased \$41.70 11,519,195 57.65 12,498,348 58.74	Total Number Average Price Paid per Share Purchased as Part Purchased as Part Price of Publicly Announced Purchased Purchased Share Programs 14,206 \$41.70 11,519,195 57.65 11,517,788 12,498,348 58.74 12,494,951

- (1) In December 2003, the Board authorized the Company to repurchase up to an additional \$5.0 billion of common stock.
- (2) The difference between total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to 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 the Company for the payment of taxes upon vesting of certain employees restricted stock.

Item 6. Exhibits and Reports on Form 8-K

- (a) Reference is made to the Index to Exhibits included herein.
- (b) Reports on Form 8-K.

The Company also furnished, but did not file, one Current Report on Form 8-K during the three months ended September 30, 2004. The report dated July 28, 2004 contained the Company s press release announcing its earnings for

the three months ended June 30, 2004.

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SIGNATURES

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

Amgen Inc. (Registrant)

Date: 11/09/04 By: /s/ Richard D. Nanula

Richard D. Nanula
Executive Vice President
and Chief Financial Officer,
acting in both his capacity as authorized
signatory on behalf of the registrant and
as principal financial officer

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AMGEN INC.

INDEX TO EXHIBITS

Exhibit No. 3.1	Description 3.1 Restated Certificate of Incorporation as amended. (9)
3.2	Amended and Restated Bylaws of Amgen Inc. (as amended and restated July 13, 2004). (43)
3.3	Certificate of Amendment of Restated Certificate of Incorporation. (17)
3.4	Certificate of Designations of Series A Junior Participating Preferred Stock. (20)
4.1	Indenture dated January 1, 1992 between the Company and Citibank N.A., as trustee. (3)
4.2	First Supplement to Indenture, dated February 26, 1997 between the Company and Citibank N.A., as trustee. (6)
4.3	Officer s Certificate pursuant to Sections 2.1 and 2.3 of the Indenture, as supplemented, establishing a series of securities 8-1/8% Debentures due April 1, 2097. (8)
4.4	8-1/8% Debentures due April 1, 2097. (8)
4.5	Form of stock certificate for the common stock, par value \$.0001 of the Company. (9)
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 Amgen Inc. and Citibank, N.A., as Trustee, establishing a series of securities entitled 6.50% Notes Due December 1, 2007 . (11)
4.7	6.50% Notes Due December 1, 2007 described in Exhibit 4.6. (11)
4.8	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)
4.9	Shareholders Rights Agreement dated as of December 16, 2001 by and among Amgen Inc., Wyeth (formerly American Home Products Corporation), MDP Holdings, Inc., and Lederle Parenterals, Inc. (25)
4.10	Indenture, dated as of March 1, 2002, between Amgen Inc. and LaSalle Bank National Association. (27)
4.11	Form of Liquid Yield Option Note due 2032. (27)
4.12	Registration Rights Agreement, dated as of March 1, 2002, between Amgen Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated. (27)

10.1+	Company s Amended and Restated 1991 Equity Incentive Plan, effective December 2003. (42)
10.2+	Company s Amended and Restated 1997 Equity Incentive Plan, effective July 15, 2002. (40)
10.3	Shareholder s Agreement of Kirin-Amgen, Inc., dated May 11, 1984, between the Company and Kirin Brewery Company, Limited. (20)
10.4	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. (17)

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Exhibit No. 10.5	Description Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated, September 20, 1985 between Agreement Order Pharmacolical Company (17)
	September 30, 1985 between Amgen Inc. and Ortho Pharmaceutical Corporation. (17)
10.6	Product License Agreement, dated September 30, 1985, and Technology License Agreement, dated September 30, 1985 between Kirin-Amgen, Inc. and Ortho Pharmaceutical Corporation. (17)
10.7+	Amended and Restated Employee Stock Purchase Plan of Amgen Inc. (17)
10.8	Research, Development Technology Disclosure and License Agreement PPO, dated January 20, 1986, by and between Amgen Inc. and Kirin Brewery Co., Ltd. (1)
10.9	Amendment Nos. 4 and 5, dated October 16, 1986 (effective July 1, 1986) and December 6, 1986 (effective July 1, 1986), respectively, to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.10	Assignment and License Agreement, dated October 16, 1986, between Amgen Inc. and Kirin-Amgen, Inc. (20)
10.11	G-CSF European License Agreement, dated December 30, 1986, between Kirin-Amgen, Inc. and Amgen Inc. (20)
10.12+	Retirement and Savings Plan of Amgen Inc. (as amended and restated effective January 1, 2003). (41)
10.13+	Amended and Restated 1988 Stock Option Plan of Amgen Inc. (5)
10.14+	First Amendment to the Amgen Inc. Nonqualified Deferred Compensation Plan. (40)
10.15	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)
10.16	ENBREL® Supply Agreement, dated April 12, 2002, between Immunex Corporation and Genentech, Inc. (with certain confidential information deleted therefrom). (31)
10.17	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)
10.18+	Amgen Inc. Supplemental Retirement Plan (As Amended and Restated Effective November 1, 1999). (16)
10.19+	First Amendment to Amgen Inc. Change of Control Severance Plan. (17)
10.20+	Amended and Restated Amgen Performance Based Management Incentive Plan. (15)
10.21	

	G-CSF United States License Agreement dated June 1, 1987 (effective July 1, 1986) between Kirin-Amgen, Inc. and Amgen Inc. (20)
10.22	Amendment No. 1 dated October 20, 1988 to Kirin-Amgen, Inc./Amgen G-CSF United States License Agreement dated June 1, 1987 (effective July 1, 1986). (20)
10.23	Amendment No. 2 dated October 17, 1991 (effective November 13, 1990) to Kirin-Amgen, Inc./Amgen G-CSF United States License Agreement dated June 1, 1987 (effective July 1, 1986). (20)
10.24	Amendment No. 10 dated March 1, 1996 to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.25+	Amgen Inc. Change of Control Severance Plan effective as of October 20, 1998. (14)
10.26	Preferred Share Rights Agreement, dated as of December 12, 2000, between Amgen Inc. and American Stock Transfer and Trust Company, as Rights Agent. (19) 50

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Exhibit No. 10.27+	Description First Amendment, effective January 1, 1998, to the Amended and Restated Employee Stock Purchase Plan of Amgen Inc. (10)
10.28	Amendment No. 11 dated March 20, 2000 to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.29+	Agreement between Amgen Inc. and Dr. Fabrizio Bonanni, dated March 3, 1999. (16)
10.30	Amendment No. 1 dated June 1, 1987 to Kirin-Amgen, Inc./Amgen G-CSF European License Agreement dated December 30, 1986. (20)
10.31	Amendment No. 2 dated March 15, 1988 to Kirin-Amgen, Inc./Amgen G-CSF European License Agreement dated December 30, 1986. (20)
10.32	Amendment No. 3 dated October 20, 1988 to Kirin-Amgen, Inc./Amgen G-CSF European License Agreement dated December 30, 1986. (20)
10.33	Amendment No. 4 dated December 29, 1989 to Kirin-Amgen, Inc./Amgen G-CSF European License Agreement dated December 30, 1986. (20)
10.34+	Amended and Restated 1987 Directors Stock Option Plan of Amgen Inc. (7)
10.35+	Amgen Inc. Amended and Restated 1993 Equity Incentive Plan (formerly known as the Immunex Corporation 1993 Stock Option Plan). (39)
10.36+	Amgen Inc. Executive Incentive Plan. (28)
10.37+	Promissory Note of Dr. Fabrizio Bonanni, dated October 29, 1999. (16)
10.38+	2002 Special Severance Pay Plan for Amgen Employees. (35)
10.39	Amendment No. 6 dated May 11, 1984 to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.40	Amendment No. 7 dated July 17, 1987 (effective April 1, 1987) to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.41	Amendment No. 8 dated May 28, 1993 (effective November 13, 1990) to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.42	Amendment No. 9 dated December 9, 1994 (effective June 14, 1994) to the Shareholders Agreement of Kirin-Amgen, Inc. dated May 11, 1984. (20)
10.43+	Agreement between Amgen Inc. and Mr. George J. Morrow, dated March 3, 2001. (21)
10.44+	Promissory Note of Mr. George J. Morrow, dated March 11, 2001. (21)

10.45+	Agreement between Amgen Inc. and Dr. Roger M. Perlmutter, M.D., Ph.D., dated March 5, 2001. (21)
10.46+	Agreement between Amgen Inc. and Mr. Brian McNamee, dated May 5, 2001. (22)
10.47+	Agreement between Amgen Inc. and Mr. Richard Nanula, dated May 15, 2001. (22)
10.48+	Promissory Note of Mr. Richard Nanula, dated June 27, 2001. (22)
10.49+	Promissory Note of Dr. Roger M. Perlmutter, dated June 29, 2001. (22)
10.50	Amendment No. 1 to ENBREL® Supply Agreement, effective as of September 20, 2002 (with certain confidential information deleted therefrom). (41)
10.51+	Second Amendment to the Amgen Inc. Change of Control Severance Plan. (23)
10.52+	First Amendment to the Amgen Supplemental Retirement Plan as amended and restated effective November 1, 1999. (23)
10.53+	Promissory Note of Mr. Brian McNamee, dated May 30, 2001. (23)
10.54+	Restricted Stock Purchase Agreement between Amgen Inc. and Mr. Richard Nanula, dated May 16, 2001. (23)
10.55+	Restricted Stock Purchase Agreement between Amgen Inc. and Dr. Roger M. Perlmutter, dated January 8, 2001. (23)
10.56+	Agreement between Amgen Inc. and Dr. Beth C. Seidenberg, dated December 21, 2001. (26) 51

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Exhibit No.	Description
10.57+	Amendment to Agreement between Amgen Inc. and Dr. Beth C. Seidenberg, dated December 21, 2001. (26)
10.58+	Second Amendment to the Amgen Supplemental Retirement Plan (As Amended and Restated Effective November 1, 1999), effective January 1, 2002. (26)
10.59	Amendment No. 2 to ENBREL® Supply Agreement, effective as of July 16, 2002. (41)
10.60+	Amgen Inc. Executive Nonqualified Retirement Plan, effective January 1, 2001. (26)
10.61+	Nonqualified Deferred Compensation Plan, effective January 1, 2002. (26)
10.62	Shareholder voting agreement dated as of December 16, 2001 by and among Amgen Inc., Wyeth (formerly American Home Products Corporation), MDP Holdings, Inc., and Lederle Parenterals, Inc. (24)
10.63+	Agreement between Amgen Inc. and Dr. Joseph Miletich, dated March 22, 2002. (29)
10.64+	Restricted Stock Purchase Agreement between Amgen Inc. and Dr. Joseph Miletich, dated April 1, 2002. (29)
10.65	Amended and Restated Promotion Agreement by and between Immunex Corporation, Wyeth (formerly American Home Products Corporation) and Amgen Inc. dated December 16, 2001 (with certain confidential information deleted therefrom). (28)
10.66	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). (28)
10.67+	Amgen Inc. Supplemental Retirement Plan (As Amended and Restated Effective January 1, 2005). (45)
10.68+	Amgen Inc. Amended and Restated 1999 Stock Purchase Plan (formerly known as the Immunex Corporation 1999 Stock Purchase Plan). (32)
10.69	ENBREL® 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). (33)
10.70	Amendment No. 1 to the ENBREL® Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated June 27, 2000 (with certain confidential information deleted therefrom). (34)
10.71	Amendment No. 2 to the ENBREL® 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)

10.72	Asset Purchase Agreement, dated May 2, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft (with certain confidential information deleted therefrom). (35)
10.73	Amendment No. 1 to the Asset Purchase Agreement dated as of September 25, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft. (35)
10.74	Amendment No. 2 to the Asset Purchase Agreement dated as of July 17, 2002, by and between Immunex Corporation and Schering Aktiengesellschaft. (35)
10.75+	Promissory Note of Ms. Beth Seidenberg, dated March 20, 2002. (35)
10.76+	Agreement between Amgen Inc. and Edward Fritzky, dated July 15, 2002. (35)
10.77+	Amgen Nonqualified Deferred Compensation Plan (As Amended and Restated Effective January 1, 2005). (45)
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Exhibit No. 10.78+	Description Stock Option Agreement between Amgen Inc. and Edward Fritzky, dated July 15, 2002. (35)
10.79+	Promissory Note of Dr. Hassan Dayem, dated July 10, 2002. (35)
10.80	Amendment No. 3 to the ENBREL® Supply Agreement among Immunex Corporation, American Home Products Corporation and Boehringer Ingelheim Pharma KG, dated December 18, 2002 (with certain confidential information deleted therefrom). (38)
10.81+	Amgen Limited Sharesave Plan. (37)
10.82+	Amgen Limited 2000 UK Company Employee Share Option Plan. (38)
10.83+	Restricted Stock Purchase Agreement between Amgen Inc. and Dr. Beth C. Seidenberg, dated January 14, 2002 and First Amendment thereto dated September 20, 2002. (38)
10.84+	Restricted Stock Purchase Agreement between Amgen Inc. and Brian M. McNamee, dated March 3, 2003. (40)
10.85	Amendment No. 3 to ENBREL® Supply Agreement, effective as of March 26, 2003 (with certain confidential information deleted therefrom). (41)
10.86	Amendment No. 4 to ENBREL® Supply Agreement, effective as of October 31, 2003 (with certain confidential information deleted therefrom). (41)
10.87	Description of Amendment No. 1 to Amended and Restated Promotion Agreement, effective as of July 8, 2003 (with certain confidential information deleted therefrom). (41)
10.88+	Amended and Restated Agreement between Amgen Inc. and David J. Scott, dated February 16, 2004. (41)
10.89+	Amgen Inc. Director Equity Incentive Program, effective as of December 9, 2003. (41)
10.90+	Form of Restricted Stock Unit Agreement. (41)
10.91+	Amgen Inc. Performance Award Program, effective as of December 9, 2003. (41)
10.92+	Form of Performance Unit Agreement. (41)
10.93	Description of Amendment No. 2 to Amended and Restated Promotion Agreement, effective as of April 20, 2004. (43)
10.94	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. (44)
10.95+	Third Amendment of the Amgen Retirement and Savings Plan (As Amended and Restated Effective as of January 1, 2003). (45)

- 10.96+* Forms of Option Grant Agreements under the Company s Amended and Restated 1991 Equity Incentive Plan, effective December 2003.
 - 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.

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- (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 Form 10-Q for the quarter ended June 30, 1999 on August 3, 1999 and incorporated herein by reference.
- (16) 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.
- (17) 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.
- (18) 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.

- (19) Filed as an exhibit to the Form 8-K Current Report dated December 13, 2000 on December 18, 2000 and incorporated herein by reference.
- (20) 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.
- (21) 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.
- (22) 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.
- (23) 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.
- (24) Filed as an exhibit to the Form 8-K Current Report dated December 16, 2001 on December 17, 2001 and incorporated herein by reference.
- (25) Filed as an exhibit to the Form S-4 Registration Statement dated January 31, 2002 and incorporated herein by reference.
- (26) 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.

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- (27) Filed as an exhibit to the Form 8-K Current Report dated February 21, 2002 on March 1, 2002 and incorporated herein by reference.
- (28) Filed as an exhibit to Amendment No. 1 to the Form S-4 Registration Statement dated March 22, 2002 and incorporated herein by reference.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) Filed as an exhibit to the Form S-8 dated July 16, 2002 and incorporated herein by reference.
- (33) Filed as an exhibit to the Annual Report on Form 10-K of Immunex Corporation for the year ended December 31, 1998.
- (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 S-8 dated March 17, 1999 and incorporated herein by reference.
- (38) 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.
- (39) Filed as an exhibit to the Form 10-Q for the quarter ended March 31, 2003 on May 2, 2003 and incorporated herein by reference.
- (40) 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.
- (41) 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.
- (42) Filed as an exhibit to the Form S-4 dated April 26, 2004 and incorporated herein by reference.
- (43) Filed as an exhibit to the Form S-4/A dated June 29, 2004 and incorporated herein by reference.
- (44) 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.

(45) Filed as an exhibit to the Form 8-K Current Report dated October 5, 2004 on October 12, 2004 and incorporated herein by reference.

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