

BIOGEN IDEC INC
Form 10-Q
November 08, 2004

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period ended September 30, 2004

Commission File Number 0-19311

BIOGEN IDEC INC.

(Exact name of registrant as specified in its charter)

Delaware	33-0112644
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

14 Cambridge Center, Cambridge, MA 02142
(617) 679-2000
(Address, including zip code, and telephone number, including
area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Yes ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934):

Yes ☒ No ☐

The number of shares of the registrant's Common Stock, \$0.0005 par value, outstanding as of October 1, 2004 was 333,552,272 shares.

BIOGEN IDEC INC.

FORM 10-Q Quarterly Report

For the Quarterly Period Ended September 30, 2004

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Table of Contents**PART I****BIOGEN IDEC INC. AND SUBSIDIARIES**

CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues:				
Product	\$ 359,692	\$ 4,427	\$ 1,095,415	\$ 15,069
Revenue from unconsolidated joint business	159,507	133,960	444,619	363,236
Royalties	23,860		73,371	
Corporate partner	217	143	10,377	1,032
	<hr/>	<hr/>	<hr/>	<hr/>
Total revenues	<hr/> 543,276	<hr/> 138,530	<hr/> 1,623,782	<hr/> 379,337
	<hr/>	<hr/>	<hr/>	<hr/>
Costs and expenses:				
Cost of product revenues	63,110	639	467,051	5,282
Cost of royalty revenues	1,350		3,904	
Research and development	168,889	39,333	498,219	121,384
Selling, general and administrative	132,040	27,157	401,887	74,985
Amortization of acquired intangible assets	107,054		267,222	
	<hr/>	<hr/>	<hr/>	<hr/>
Total costs and expenses	<hr/> 472,443	<hr/> 67,129	<hr/> 1,638,283	<hr/> 201,651
	<hr/>	<hr/>	<hr/>	<hr/>
Income (loss) from operations	70,833	71,401	(14,501)	177,686
Other income (expense), net	(1,573)	1,986	16,566	8,549
	<hr/>	<hr/>	<hr/>	<hr/>
Income before income tax provision	69,260	73,387	2,065	186,235
Income tax provision	32,492	27,887	5,668	70,769
	<hr/>	<hr/>	<hr/>	<hr/>
Net income (loss)	<hr/> \$ 36,768	<hr/> \$ 45,500	<hr/> \$ (3,603)	<hr/> \$ 115,466
	<hr/>	<hr/>	<hr/>	<hr/>
Basic earnings (loss) per share	<hr/> \$ 0.11	<hr/> \$ 0.29	<hr/> \$ (0.01)	<hr/> \$ 0.73
	<hr/>	<hr/>	<hr/>	<hr/>

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Diluted earnings (loss) per share	\$ 0.10	\$ 0.26	\$ (0.01)	\$ 0.67
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Shares used in calculating:				
Basic earnings (loss) per share	334,777	155,498	335,165	155,117
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Diluted earnings (loss) per share	355,232	184,838	335,165	178,877
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

See accompanying notes to condensed consolidated financial statements.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)

	September 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 179,018	\$ 314,850
Marketable securities available-for-sale	266,862	521,109
Accounts receivable, net	237,572	198,524
Due from unconsolidated joint business	124,604	117,342
Deferred tax assets	131,980	123,945
Inventories	246,369	496,349
Other current assets	77,830	66,545
	<hr/>	<hr/>
Total current assets	1,264,235	1,838,664
	<hr/>	<hr/>
Marketable securities available-for-sale	1,672,126	1,502,327
Property and equipment, net	1,415,689	1,252,783
Intangible assets, net	3,370,624	3,638,812
Goodwill	1,151,105	1,151,066
Investments and other assets	146,819	120,293
	<hr/>	<hr/>
	\$9,020,598	\$9,503,945
	<hr/>	<hr/>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 77,493	\$ 63,364
Deferred revenue	14,955	7,155
Current taxes payable	138,376	94,176
Accrued expenses and other	197,777	240,130
	<hr/>	<hr/>
Total current liabilities	428,601	404,825
	<hr/>	<hr/>
Notes payable	845,704	887,270
Long-term deferred tax liability	985,672	1,108,318
Other long-term liabilities	50,359	50,204
Commitments and contingencies		

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Shareholders' equity		
Convertible preferred stock, par value \$0.001 per share		
Common stock, par value \$0.0005 per share	173	166
Additional paid-in capital	8,128,262	7,801,170
Accumulated other comprehensive income (loss)	(3,208)	1,054
Deferred stock-based compensation	(41,882)	(2,141)
Accumulated deficit	(744,499)	(611,921)
	<u> </u>	<u> </u>
	7,338,846	7,188,328
Less treasury stock, at cost	628,584	135,000
	<u> </u>	<u> </u>
Total shareholders' equity	6,710,262	7,053,328
	<u> </u>	<u> </u>
	\$9,020,598	\$9,503,945
	<u> </u>	<u> </u>

See accompanying notes to condensed consolidated financial statements.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

	Nine Months Ended September 30,	
	2004	2003
Cash Flows from Operating Activities		
Net Income (Loss)	\$ (3,603)	\$ 115,466
Adjustments to reconcile net income (loss) to net cash provided from operating activities		
Depreciation and amortization	332,976	9,960
Deferred stock compensation for restricted stock	11,345	
Non-cash interest expense	38,018	29,229
Deferred income taxes	(128,427)	22,079
Tax benefit from stock options	86,996	26,442
Realized loss (gain) on sale of marketable securities available-for-sale	2,999	(2,020)
Write-down of inventory to net realizable value	21,684	
Impact of inventory step-up	285,671	
Impairment of other investments	12,734	
Other	26	(183)
Changes in assets and liabilities, net:		
Accounts receivable	(39,048)	3,787
Due from unconsolidated joint business	(7,262)	(12,392)
Inventories	(57,375)	(4,867)
Other current and other assets	(45,092)	(4,626)
Accrued expenses and other current liabilities	16,829	10,223
Deferred revenue	7,800	(93)
Other long-term liabilities	154	2,254
Net cash flows from operating activities	<u>536,425</u>	<u>195,259</u>
Cash Flows from Investing Activities		
Purchases of marketable securities available-for-sale	(2,892,683)	(754,288)
Proceeds from sales and maturities of marketable securities available-for-sale	2,937,055	751,821
Changes in restricted cash		(2,500)
Acquisitions of property and equipment, net	(227,007)	(188,664)
Net cash flows from investing activities	<u>(182,635)</u>	<u>(193,631)</u>

Cash Flows from Financing Activities		
Purchase of treasury stock	(698,390)	
Issuance of common stock and option exercises	132,941	11,921
Issuance of treasury stock for option exercises and employee stock purchase plan	75,827	
	<u> </u>	<u> </u>
Net cash flows from financing activities	(489,622)	11,921
	<u> </u>	<u> </u>
Net increase (decrease) in cash and cash equivalents	(135,832)	13,549
Cash and cash equivalents, beginning of the period	314,850	350,129
	<u> </u>	<u> </u>
Cash and cash equivalents, end of the period	\$ 179,018	\$ 363,678
	<u> </u>	<u> </u>

See accompanying notes to condensed consolidated financial statements.

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BIOGEN IDEC INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Overview

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. entered into a merger transaction, or the Merger, resulting in Biogen, Inc. becoming a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. The Merger was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc.

Our primary focus is to create new standards of care in oncology and immunology. We currently have four commercial products: AVONEX® (interferon beta-1a) for the treatment of relapsing multiple sclerosis, or MS; RITUXAN® (rituximab) and ZEVALIN® (ibritumomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs; and AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. We acquired AVONEX and AMEVIVE from Biogen, Inc. We also receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control and for sales of RITUXAN outside the U.S. through our collaborator Genentech, Inc., or Genentech. RITUXAN is the trade name for the compound rituximab in the U.S., Canada and Japan. MabThera is the tradename for rituximab in the EU. In this Form 10-Q, we refer to rituximab, RITUXAN, and MabThera collectively as RITUXAN, except where we have otherwise indicated. We are also developing ANTEGREN® (natalizumab) in collaboration with Elan Corporation plc. We submitted applications for approval of ANTEGREN in the U.S. and EU as a treatment for MS in the second quarter of 2004 and submitted an application for approval of ANTEGREN in the EU as a treatment for Crohn's disease in September 2004. The FDA designated ANTEGREN for Priority Review and Accelerated Approval as a treatment for MS. In addition, we have a pipeline of development stage products and a number of research programs in our core therapeutic areas and in other areas of interest.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring accruals, necessary to present fairly our financial position, results of operations and cash flows as well as that of our subsidiaries. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our 2003 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. Interim results are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

The preparation of the condensed consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include our financial statements and those of our wholly owned subsidiaries. We also consolidate a limited partnership investment, in which we are the majority investor. All material intercompany balances and transactions have been eliminated. On November 12, 2003, we completed the Merger and

changed our name to Biogen Idec Inc. (see Note 2, Merger of IDEC Pharmaceuticals Corporation and Biogen, Inc.) Our results of operations for the three and nine months ended September 30, 2003 include only the results of operations of the former IDEC Pharmaceuticals Corporation. Former Biogen, Inc. results of operations have been included in our results of operations since November 13, 2003.

Inventories

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out, or FIFO, method. Included in inventory are raw materials used in the production of pre-clinical and clinical products, which are expensed as research and development costs when consumed.

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The components of inventories are as follows (table in thousands):

	September 30, 2004	December 31, 2003
Raw materials	\$ 43,547	\$ 36,247
Work in process	161,764	443,666
Finished goods	41,058	16,436
	<hr/>	<hr/>
	\$246,369	\$496,349
	<hr/>	<hr/>

We capitalize inventory costs associated with certain products prior to regulatory approval, based on our judgment of probable future commercialization. We would be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies. At September 30, 2004, capitalized inventory related to ANTEGREN, which has not yet received regulatory approval, was \$11.9 million.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are future determinations that inventory will not be marketable based on updated estimates for demand, additional inventory write-downs may be required. For the three and nine months ended September 30, 2004, we wrote down \$9.2 million and \$21.0 million, respectively, of unmarketable inventory which was charged to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. For the nine months ended September 30, 2004, total write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written down to net realizable value when it was determined that the inventory did not meet quality specifications. The write-down of ZEVALIN inventory during the three months ended September 30, 2004 resulted from a determination that the inventory did not meet quality specifications. The remaining write-downs of ZEVALIN inventory resulted from a determination that the inventory will not be marketable based on estimates of demand. For the nine months ended September 30, 2003, we wrote down a total of \$3.1 million of ZEVALIN commercial inventory, which did not meet quality specifications.

Intangible Assets and Goodwill

In connection with the Merger, we recorded intangible assets related to patents, trademarks, and core technology as part of the purchase accounting. These intangible assets were initially recorded at fair value, and at September 30, 2004 and December 31, 2003 are net of accumulated amortization and impairments. Intangible assets related to out-licensed patents and core technology are amortized over their estimated useful lives, ranging from 12 to 21 years, based on the greater of straight-line basis or economic consumption each period. These amortization costs are included in Amortization of acquired intangible assets in the accompanying condensed consolidated statements of income. Intangible assets related to trademarks have indefinite lives, and as a result are not amortized, but are subject to periodic review for impairment. We review our intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset would not be recoverable. As of September 30, 2004, management determined that certain clinical trials would be discontinued or would not be initiated which indicated

that the carrying value of certain core technology intangible assets related to AMEVIVE would not be recoverable. As a result, in the three months ended September 30, 2004, we recorded an impairment charge of approximately \$27.8 million to amortization of intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE.

Goodwill associated with the Merger represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for by the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. Goodwill is reviewed annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. We will be making our required annual goodwill impairment assessment as of October 31, 2004.

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As of September 30, 2004, intangible assets and goodwill, net of accumulated amortization and impairment charges, are as follows (table in thousands):

	Estimated Life	Historical Cost	Accumulated Amortization	Net
Out-licensed patents	12 years 15-21	\$ 578,000	\$ 42,547	\$ 535,453
Core/developed technology	years	3,022,000	257,855	2,764,145
Trademarks & tradenames	Indefinite	64,000		64,000
In-licensed patents	7-12 years	9,482	2,456	7,026
		<hr/>	<hr/>	<hr/>
Total		\$3,673,482	\$302,858	\$3,370,624
		<hr/>	<hr/>	<hr/>
Goodwill	Indefinite	\$1,151,105	\$	\$1,151,105
		<hr/>	<hr/>	<hr/>

Revenue Recognition and Accounts Receivable

SEC Staff Accounting Bulletin No. 104, or SAB 104, provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB 104 establishes the SEC's view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured. This requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. We believe that our revenue recognition policies are in compliance with SAB 104.

For the three and nine months ended September 30, 2003, our product sales consisted solely of sales of ZEVALIN. We have marketing and distribution rights to ZEVALIN in the U.S. and have granted marketing and distribution rights outside the U.S. to Schering AG. As a result of the Merger, our product sales in the three and nine months ended September 30, 2004 also include sales of AVONEX and AMEVIVE.

Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer. Revenues are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. We prepare our estimates for allowances for returns, rebates and other applicable discounts and allowances quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

Revenues from unconsolidated joint business arrangement consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, reimbursement from Genentech of our RITUXAN-related sales force and development expenses and royalties which are paid to Genentech for sales of RITUXAN outside the U.S. by F. Hoffman-LaRoche, or Roche, and Zenyaku Kogyo Ltd., or Zenyaku. Under the copromotion arrangement, all U.S. sales of RITUXAN and associated costs and expenses are recognized by Genentech. We record our share of the pretax copromotion profits on a quarterly basis, as set forth in our collaborative

agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of RITUXAN to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us. Our profit-sharing formula with Genentech has two tiers. We earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. The higher tier was achieved and we began recording our profit share at the higher percentage during the first quarter of 2004. We record our Roche and Zenyaku royalty revenue on a cash basis.

In February 2002, the Financial Accounting Standards Board, or FASB, Emerging Issues Task Force, or EITF, released EITF Issue No. 01-09, or EITF 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products). EITF 01-09 states that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement, rather than a sales and marketing expense. We have various contracts with distributors that provide for discounts and rebates. Discounts and rebates under these contracts are classified as a reduction of revenue. We also maintain select customer service contracts with distributors and other customers in the distribution channel. In accordance with EITF 01-09, we have established that the customer receives an identifiable benefit and

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the fair value of these contracts and, as provided by EITF 01-09, classified these customer service contracts as sales and marketing expense instead of a reduction of revenue. If we had concluded that sufficient evidence of the fair value did not exist for these contracts, we would have been required to classify these costs as a reduction of revenue.

We receive royalty revenues under license agreements with a number of third parties that sell products based on technology we have developed or to which we have rights. The license agreements provide for the payment of royalties to us based on sales of the licensed product. We record these revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties we have been paid (adjusted for any changes in facts and circumstances, as appropriate). We maintain regular communication with our licensees in order to gauge the reasonableness of our estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period which they become known, typically the following quarter. Historically, adjustments have not been material based on actual amounts paid by licensees. There are no future performance obligations on our part under these license agreements. To the extent we do not have sufficient ability to accurately estimate revenue, we record it on a cash basis.

We have deferred recognition of revenue of approximately \$15.0 million at September 30, 2004 related to certain revenue transactions. We have deferred approximately \$10.9 million related to our revenue from unconsolidated joint business and certain corporate partner transactions. These revenues have been deferred as the conditions for revenue recognition had not yet been satisfied or resolved. Additionally, we have also deferred approximately \$3.9 million of revenue related to a launch program to provide for discounts that may, under certain circumstances, be applied against future purchases by a distributor.

Accounting for Stock Based Compensation

We have several stock-based compensation plans. We apply APB Opinion No. 25 Accounting for Stock Issued to Employees in accounting for our plans and apply Statement of Financial Accounting Standards No. 123 Accounting for Stock Issued to Employees, or SFAS 123, as amended by Statement of Financial Accounting Standards No. 148 Accounting for Stock-Based Compensation Transition and Disclosure, or SFAS 148, for disclosure purposes only. The SFAS 123 disclosures include pro forma net income and earnings per share as if the fair value-based method of accounting had been used. Stock-based compensation issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.

If compensation cost for awards issued in the three and nine months ended September 30, 2004 and 2003 under the stock-based compensation plans, including costs related to prior years awards, had been determined based on SFAS 123 as amended by SFAS 148, our pro forma net income (loss), and pro forma earnings (loss) per share for the three and nine months ended September 30, would have been as follows (table in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Reported net income (loss)	\$36,768	\$ 45,500	\$ (3,603)	\$115,466
Stock based compensation included in net income (loss)	4,483		12,031	
Pro forma stock compensation expense, net of tax	(9,000)	(12,905)	(24,304)	(37,070)

Pro forma net income (loss)	<u>\$32,251</u>	<u>\$ 32,595</u>	<u>\$(15,876)</u>	<u>\$ 78,396</u>
Reported basic earnings (loss) per share	\$ 0.11	\$ 0.29	\$ (0.01)	\$ 0.73
Pro forma basic earnings (loss) per share	\$ 0.10	\$ 0.21	\$ (0.05)	\$ 0.51
Reported diluted earnings (loss) per share	\$ 0.10	\$ 0.26	\$ (0.01)	\$ 0.67
Pro forma diluted earnings (loss) per share	\$ 0.09	\$ 0.18	\$ (0.05)	\$ 0.44

The fair value of each option granted under our stock based compensation plans and each purchase right granted under our employee stock purchase plan is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Option Grants			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	35%	48%	43%	48%
Risk-free interest rate	3.4%	3.1%	3.4%	2.8%
Expected option life in years	5.4	5.4	5.4	5.8

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The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. SFAS 123 did not apply to awards prior to 1995. Additional awards in future years are anticipated.

Reclassification

Certain reclassifications of prior period amounts have been made to conform to the current period presentation.

2. Merger of IDEC Pharmaceuticals Corporation and Biogen, Inc.

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. entered into the Merger. The Merger was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc.

As a result of the Merger, Biogen, Inc. stockholders received 1.15 shares of Biogen Idec common stock for each share of Biogen, Inc. common stock. As a result, Biogen Idec issued approximately 171.9 million shares at a fair value of approximately \$6.48 billion. In addition, options to purchase Biogen, Inc. common stock outstanding at November 12, 2003 were assumed by Biogen Idec and converted into options to purchase approximately 20.7 million shares of Biogen Idec common stock at a fair value of approximately \$295.0 million. We paid approximately \$19.9 million in fees for banking, legal, accounting and tax related services related to the Merger. Merger-related fees paid by Biogen, Inc. prior to completion of the Merger are not included in this amount as they were expensed as incurred. The total Merger purchase price was approximately \$6.8 billion. The Merger qualified as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

Purchase price

The purchase price was as follows (table in thousands):

Fair value of Biogen Idec common stock	\$6,480,339
Fair value of assumed stock options	295,399
Cash paid for fractional shares	27
Acquisition related costs	19,872
	<hr/>
Total purchase price	\$6,795,637

The fair value of Biogen Idec's shares used in determining the purchase price was \$37.69 per share based on the average of the closing price of IDEC Pharmaceuticals Corporation's common stock for the period two days before through two days after the announcement of the Merger on June 23, 2003. The fair value of assumed stock options was determined using the Black-Scholes option pricing model with the following assumptions: stock price of \$37.69, which is the value ascribed to IDEC Pharmaceuticals Corporation's common stock in determining the purchase price; volatility of 40%; risk-free interest rate of 1.8%; and an expected life of 4.0 years.

Purchase price allocation

The estimated purchase price has been allocated to the acquired tangible and intangible assets and liabilities based on their estimated fair values as of November 12, 2003, the date that the Merger was consummated (table in

thousands):

Inventories	\$ 706,957
Accounts receivable	216,221
Property, plant and equipment	713,719
Acquired identifiable intangible assets	3,664,000
Goodwill	1,151,105
In-process research and development	823,000
Deferred stock-based compensation	2,261
Other current and long-term assets	1,106,112
Assumed liabilities	(424,648)
Increase benefit plan liability to fair value	(26,650)
Deferred tax liabilities arising from fair value adjustments	(1,136,440)
	<u> </u>
Total purchase price	\$ 6,795,637
	<u> </u>

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The allocation of the purchase price was based, in part, on a third-party valuation of the fair value of in-process research and development, identifiable intangible assets, and certain property, plant and equipment. The excess of the purchase price over the fair value of assets and liabilities acquired is allocated to goodwill. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. These assumptions are based on the best available information that we had at the time. Additionally, certain estimates for the purchase price allocation including inventory and taxes may change as subsequent information becomes available.

Identifiable intangible assets

The amount allocated to acquired identifiable intangible assets has been attributed to the following categories (table in thousands):

Patents	\$ 578,000
Trademarks	64,000
Core technology	3,022,000
	<hr/>
	\$3,664,000
	<hr/>

The estimated fair value attributed to core technology, which relates to Biogen, Inc.'s existing FDA-approved products, was determined based on a discounted forecast of the estimated net future cash flows to be generated from the technology. The estimated fair value attributed to core technology is being amortized over 15 to 21 years, which is the estimated period over which cash flows will be generated from the technology.

The estimated fair value attributed to patents represents only those patents from which Biogen, Inc. derived cash flows through contractual third-party out-licensing activity and not patents related to Biogen, Inc.'s current product portfolio or in-process research projects. The estimated fair value was determined based on a discounted forecast of the estimated net future cash flows to be generated from the patents. The estimated fair value attributed to patents is being amortized over 12 years, which is the estimated period over which cash flows will be generated from the patents. The estimated amortization of intangible assets on a straight-line basis is expected to be approximately \$247.5 million for each of the next five years.

The amount allocated to in-process research and development, or IPR&D, represents an estimate of the fair value of purchased in-process technology for research projects that, as of the date of the Merger, had not reached technological feasibility and have no alternative future use. Only those research projects that had advanced to a stage of development where management believed reasonable net future cash flow forecasts could be prepared and a reasonable likelihood of technical success existed were included in the estimated fair value. Accordingly, IPR&D primarily represents the estimated fair value of ANTEGREN, which was in Phase III development for Crohn's disease and MS at the time of the Merger. The estimated fair value of the IPR&D was determined based on a discounted forecast of the estimated net future cash flows for each project, adjusted for the estimated probability of technical success and FDA approval for each research project. IPR&D was expensed immediately following consummation of the Merger.

Pro forma results of operations

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The following unaudited pro forma information presents a summary of the historical consolidated statements of income of IDEC Pharmaceuticals Corporation and Biogen, Inc. for the three and nine months ended September 30, 2003, giving effect to the Merger as if it occurred on January 1, 2003 (table in thousands, except per share amounts):

	Three Months Ended September 30, 2003	Nine Months Ended September 30, 2003
Product sales	\$ 314,536	\$ 896,504
Total revenue	477,195	1,361,211
Net income (loss)	59,606	(177,060)
Pro forma income (loss) per share:		
Basic	\$ 0.18	\$ (0.54)
Diluted	\$ 0.17	\$ (0.54)

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The pro forma net income (loss) and income (loss) per share for the periods presented exclude the acquired IPR&D charge of \$823.0 million. Amortization of the acquired intangibles is included on a straight-line basis. This unaudited pro forma information does not purport to indicate the results that would have actually been obtained had the Merger been completed on the assumed date or for the period presented, or which may be realized in the future. To produce the pro forma financial information, Biogen Idec allocated the purchase price using its best estimates of fair value. These estimates are based on the information that was available at the purchase date.

3. Financial Instruments

Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities, or SFAS 133, requires that all derivatives be recognized on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction. We assess, both at their inception and on an on-going basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We also assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

We have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts have durations of ninety days to fifteen months. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in other comprehensive income. Realized gains and losses for the effective portion are recognized with the underlying hedge transaction. The notional settlement amount of the foreign currency forward contracts outstanding at September 30, 2004 was approximately \$169.8 million. These contracts had a fair value of \$4.3 million, representing an unrealized loss, and were included in other current liabilities at September 30, 2004.

For the three and nine months ended September 30, 2004, there were no significant amounts recognized in earnings due to hedge ineffectiveness or as a result of the discontinuance of cash flow hedge accounting because it was no longer probable that the hedge forecasted transaction would occur. We recognized approximately \$0.9 million and \$2.0 million of losses in product revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2004, respectively. We recognized approximately \$0.1 million of gains and \$0.1 million of losses in royalty revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2004, respectively. These settlements were recorded in the same period as the related forecasted transactions affecting earnings.

4. Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income. Other comprehensive income includes certain changes in equity that are excluded from net income (loss), such as translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities and certain derivative instruments, net of tax. Comprehensive income for the three months ended September 30, 2004 and 2003 was \$49.7 million and \$44.7 million, respectively. Comprehensive income (loss) for the nine months ended September 30, 2004 and 2003 was \$(7.9) million and \$113.9 million, respectively.

5. Earnings (Loss) per Share

We calculate earnings (loss) per share in accordance with Statement of Financial Accounting Standards No. 128, Earnings per Share, or SFAS 128, and EITF 03-06, Participating Securities and the Two-Class Method Under SFAS 128. SFAS 128 and EITF 03-06 together require the presentation of basic earnings (loss) per share and diluted earnings (loss) per share. Basic earnings (loss) per share is computed using the two-class method. Under the two-class method, undistributed net income is allocated to common stock and participating securities based on their respective rights to share in dividends. We have determined that our preferred shares meet the definition of participating securities, and have allocated a portion of net income to our preferred shares on a pro rata basis. Net

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income allocated to preferred shares is excluded from the calculation of basic earnings (loss) per share. For basic earnings (loss) per share, net income (loss) available to holders of common stock is divided by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted earnings (loss) per share, net income (loss) is adjusted for the after-tax amount of interest associated with convertible debt and net income allocable to preferred shares, and the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive common stock equivalents such as stock options and other convertible securities, to the extent they are dilutive.

Basic and diluted earnings (loss) per share for the three and nine months ending September 30 are calculated as follows (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Numerator:				
Net income (loss)	\$ 36,768	\$ 45,500	\$ (3,603)	\$ 115,466
Adjustment for net income allocable to preferred stock	54	627		1,595
Net income (loss) used in calculating basic earnings per share	36,714	44,873	(3,603)	113,871
Adjustment for interest, net of interest capitalized and tax	462	2,883		5,499
Net income (loss) used in calculating diluted earnings (loss) per share	\$ 37,176	\$ 47,756	\$ (3,603)	\$ 119,370
Denominator:				
Weighted average number of common shares outstanding	334,777	155,498	335,165	155,117
Effect of dilutive securities:				
Stock options	9,873	6,744		6,938
Restricted stock awards	1,185			
Convertible promissory notes due 2019	9,397	13,935		13,935
Convertible promissory notes due 2032		8,661		2,887
Dilutive potential common shares	20,455	29,340		23,760
Shares used in calculating diluted earnings (loss) per share	355,232	184,838	335,165	178,877

Included in our net income (loss) for the three and nine months ended September 30, 2004 is \$1.1 million and \$6.4 million, respectively, of interest expense, net of tax, that would adjust net income in calculating diluted earnings per share had certain of our convertible promissory notes due 2032 been dilutive. Excluded from the calculation of diluted earnings per share for the three months ended September 30, 2004 were 8.7 million shares of common stock from the assumed conversion of our 30-year senior convertible promissory notes due 2032, and 0.5 million shares of common stock from the assumed conversion of our convertible preferred stock, and options to acquire 3.4 million shares of common stock, due to the fact that they were anti-dilutive. We had a net loss for the nine months ended September 30, 2004. If we had net income during that period, we would have used the following dilutive securities to calculate diluted earnings per share: options to acquire 7.2 million shares of common stock, 0.8 million shares of restricted stock, 0.3 million shares of common stock from the assumed conversion of our convertible preferred stock, 3.1 million shares of common stock from the assumed conversion of our convertible promissory notes due 2019, and 2.9 million shares of common stock from the assumed conversion of our convertible promissory notes due 2032. For the nine months ended September 30, 2004, options to acquire 5.9 million shares of common stock have been excluded from the calculation of diluted earnings (loss) per share because their effect would be antidilutive, since their exercise price was greater than their market price at September 30, 2004.

For the three and

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nine months ended September 30, 2003, excluded from the calculation of diluted earnings per share were 2.2 million shares of common stock from the assumed conversion of our convertible preferred stock, which were anti-dilutive. For the three and nine months ended September 30, 2003, excluded from the calculation of diluted earnings per share were options to acquire 16.5 million and 18.2 million shares, respectively, of common stock because their effect would be antidilutive since their exercise price was greater than their market price at September 30, 2003.

6. Collaborations

In August 2004, we entered into a collaborative agreement with Sunesis Pharmaceuticals, Inc, or Sunesis, to discover and develop small molecule cancer therapeutics targeting primarily kinases. Under the agreement, we acquired exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Upon signing the agreement, we paid Sunesis a nonrefundable upfront license fee of \$7.0 million, which was recorded in research and development expenses in the third quarter of 2004. Under the terms of this agreement, we purchased approximately 2.9 million shares of preferred stock of Sunesis for \$14.0 million, the fair value of the shares. Our investment in Sunesis is included in other assets. We account for our investment in Sunesis using the cost method of accounting, subject to periodic review of impairment. We have committed to paying Sunesis additional amounts upon the completion of certain future research milestones and first and second indication development milestones. If all the milestones were to be achieved, we would be required to pay up to an additional \$60.5 million over the life of the agreement, excluding royalties.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc, or Vernalis, aimed at advancing research into Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis' lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement may require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. We made an immediate investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis ordinary shares, representing 4.19 percent of Vernalis' post-financing issued share capital, and have committed to purchase an additional \$4.0 million in the event of future Vernalis financing. Our investment in Vernalis is included in other assets. Excluding royalties, total potential payments to Vernalis could exceed \$100.0 million.

In June 2004, we entered into a license agreement with BioWa, Inc., or BioWa, for a worldwide, non-exclusive license for research purposes and a worldwide, exclusive license for development and commercialization purposes for certain BioWa intellectual property rights related to monoclonal antibodies. As part of the agreement, we have committed to paying BioWa amounts upon the achievement of certain research and clinical milestones. If all the milestones were to be achieved, we would be required to pay BioWa a total of \$18.8 million plus royalties over the life of the agreement.

In May 2004, we entered into a limited partnership agreement as a limited partner with MPM Bioventures III GP, LP, to create MPM Bioventures Strategic Fund, LP, or the Strategic Fund. The purpose of the Strategic Fund is to make, manage, and supervise investments in relevant biotechnology companies with novel products or technologies that fit strategically with Biogen Idec. The Strategic Fund takes only minority positions in the equity of its investments, and does not seek to engage in day-to-day management of the entities. We have committed \$65.0 million to the Strategic Fund over a three-year period. Through September 30, 2004, we have contributed \$5.1 million to the Strategic Fund. We have consolidated the Strategic Fund in our condensed consolidated financial statements at September 30, 2004. There were no significant expenses related to the Strategic Fund included in our operating results through September 30, 2004.

In April 2004, we became a limited partner in MPM Bioventures III-QP, LP, or the LP, a limited partnership that invests in entities that are engaged in the research, development, manufacture, marketing and/or sale of novel biological products or technologies. We have committed to contribute \$4.0 million to the limited partnership. Through September 30, 2004, we have contributed \$1.6 million into the LP, which is included in other assets in our condensed consolidated balance sheet at September 30, 2004.

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In the first nine months of 2004, we made payments totaling \$17.0 million to Vetter Pharma-Fertigung GmbH & Co. KG, or Vetter, for the achievement of certain milestones achieved under the terms of our supply agreement for reserving certain capacity at Vetter's fill-finish facility. Total payments to date of \$22.7 million are recorded in other assets on our condensed consolidated balance sheets. The asset will be amortized to cost of sales over the units produced upon delivery to Biogen Idec. We have total potential milestone payments of approximately 16 million euros remaining as part of the agreement.

7. Notes Payable

Our notes payable are as follows (table in thousands):

	September 30, 2004	December 31, 2003
	<hr/>	<hr/>
20-year subordinated convertible promissory notes, due 2019 at 5.5%	\$ 100,525	\$ 151,772
30-year senior convertible promissory notes, due 2032 at 1.75%	745,179	735,498
	<hr/>	<hr/>
	\$ 845,704	\$ 887,270
	<hr/>	<hr/>

In the three and nine months ended September 30, 2004, holders of our 2019 subordinated notes with a face value of approximately \$55.5 million and \$125.7 million, respectively, elected to convert their subordinated notes to approximately 2.2 million and 5.1 million shares, respectively, of our common stock.

8. Other Income (Expense), Net

Total other income (expense), net consists of the following (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	<hr/>	<hr/>	<hr/>	<hr/>
Interest income	\$ 13,794	\$ 6,636	\$ 43,058	\$ 22,986
Interest expense	(2,984)	(4,650)	(10,246)	(14,437)
Other expense	(12,383)		(16,246)	
	<hr/>	<hr/>	<hr/>	<hr/>
Total other income (expense), net	\$ (1,573)	\$ 1,986	\$ 16,566	\$ 8,549
	<hr/>	<hr/>	<hr/>	<hr/>

Other expense for the three and nine months ended September 30, 2004 consists primarily of a \$12.7 million charge for the impairment of certain noncurrent marketable securities that were determined to be other than temporary, and \$1.0 million and \$3.0 million, respectively, of realized losses on sales of marketable securities.

9. Income Taxes

Our effective tax rate for the three and nine months ended September 30, 2004 was 46.9% and 274.5%, respectively, compared to 38% for the comparable periods in 2003. Our effective tax rates in the three and nine months ended September 30, 2004 were higher than the normal statutory rates primarily due to the acquisition-related intangible amortization and impairment charges and inventory fair value adjustments arising from purchase accounting related to foreign jurisdictions. These items significantly reduced our pre-tax income for the nine months ended September 30, 2004 and substantially increased our effective tax rate for the period. We did not reflect the benefit of any expected increases in the research tax credit for the three months ended September 30, 2004 as the credit expired on June 30, 2004. On October 4, 2004, the Working Families Tax Relief Act of 2004 reinstated the research credit retroactively to June 30, 2004. The benefit of the reinstated credit will be reflected in our effective tax rate for the year ended December 31, 2004. Our effective tax rates in the three and nine months ended September 30, 2003 were higher than the normal statutory rates primarily due to state taxes. We expect that our effective tax rate in the future will continue to be higher than the normal statutory rate as a result of acquisition-related intangible amortization and state taxes. We have net operating loss and tax credit carryforwards available for federal and state income tax purposes. The utilization of our net operating loss carryforwards and tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate that this annual limitation will result only in a modest delay in the utilization of such net operating loss carryforwards and tax credits.

Table of Contents**10. Unconsolidated Joint Business Arrangement**

In June 2003, we amended our collaboration agreement with Genentech to include the development and commercialization of one or more humanized anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications. The original collaboration agreement was entered into in 1995 for the clinical development and commercialization of RITUXAN. Under the terms of the amended and restated agreement, we continue to receive a share of the pretax operating profits in the U.S. from RITUXAN and will share in pretax operating profits or losses in the U.S. relating to any new products developed under the agreement.

We copromote RITUXAN with Genentech, and share responsibility with Genentech for continued development of RITUXAN, in the U.S. Such continued development includes conducting supportive research and post-approval clinical studies and seeking potential approval for additional indications. Genentech provides the support functions for the commercialization of RITUXAN in the U.S., including marketing, customer service, order entry, distribution, shipping and billing, as well as fulfilling all worldwide manufacturing responsibilities. We share responsibility with Genentech for development in the U.S. of any new products developed under the agreement, and we will also copromote with Genentech any such new products in the U.S.

The amended collaboration agreement provides that, upon the occurrence of a Biogen Idec change-in-control as described in the agreement, Genentech may present an offer to us to purchase our rights to RITUXAN. We must then accept Genentech's offer or purchase Genentech's rights to RITUXAN for an amount proportioned (using the profit sharing ratio between us) to Genentech's offer. If Genentech presents such an offer in such a situation, then Genentech will be deemed concurrently to have exercised a right, in exchange for a share in the operating profits or net sales in the U.S. of any new products developed under the agreement, to purchase our interest in each such product.

Concurrent with the original collaboration agreement, we also entered into an expression technology license agreement with Genentech (for a proprietary gene expression technology developed by us) and a preferred stock purchase agreement providing for certain equity investments in us by Genentech.

Under the terms of separate agreements with Genentech, commercialization of RITUXAN outside the U.S. is the responsibility of Roche, except in Japan where it copromotes RITUXAN in collaboration with Zenyaku. We receive royalties from Genentech on sales by Roche and Zenyaku of RITUXAN outside the U.S., except in Canada. Royalties on sales of RITUXAN in Canada are received directly from Roche (and are included in revenues from unconsolidated joint business arrangement in the accompanying condensed consolidated statements of income).

Revenues from unconsolidated joint business arrangement consist of the following (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Copromotion profits	\$ 118,753	\$ 109,553	\$ 339,612	\$ 301,978
Reimbursement of selling and development expenses	7,999	5,662	17,903	13,898
Royalty revenue on sales of RITUXAN outside the U.S., including royalties received directly from Roche	32,755	18,745	87,104	47,360

<u>\$159,507</u>	<u>\$133,960</u>	<u>\$444,619</u>	<u>\$363,236</u>
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11. Litigation

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York, or Columbia, in the U.S. District Court for the District of Massachusetts, contending that we no longer have any obligation to pay royalties to Columbia on sales of our products under a 1993 license agreement between us and Columbia related to U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017, also referred to as the Original Patents, or under a newly issued patent, U.S. Patent No. 6,455,275, also referred to as the 275 patent (the 2003 action). In our suit, we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the 275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based

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on the 275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. Columbia initially took the position that we still owe it royalties under the license agreement on the basis of the 275 patent, which was issued on September 24, 2002, over two years after the expiration of the Original Patents, and that we are in breach of the license agreement due to an alleged failure to pay royalties under the 275 patent. When Columbia sought to terminate our license agreement on this ground, we moved to have the court preliminarily enjoin such termination until the underlying patent dispute is resolved. In a published decision, the court denied our motion to enjoin termination of the license agreement. In reaching that decision, the court found that we had made a strong showing that we might prevail in proving the 275 patent is invalid under the doctrine of non-statutory double patenting, and, if valid, that the patent is unenforceable because of the equitable doctrine of prosecution laches. Our motion was denied, however, because we did not meet our burden of demonstrating irreparable harm if the license agreement was terminated. The court ordered an expedited schedule for completion of fact and expert discovery, submission of briefs on claim construction, and a hearing on the merits, while staying all other aspects of the case. On September 13, 2004, Columbia informed us that it would not seek to terminate the license agreement for failure to pay royalties on the 275 patent but expressly reserved all other grounds for termination. Columbia then asserted that Biogen Idec MA, Inc. is a licensee in good standing. Columbia then moved for dismissal of the litigation based on their assertion that there is no longer a case or controversy as required by Article III of the U.S. Constitution. We opposed the motion and Columbia, in a hearing on the motion held on October 6, 2004, subsequently covenanted not to sue Biogen Idec MA, Inc. on any claim of the 275 patent and any claim that is the same or substantially the same as the claims of the 275 patent if such claim(s) emerge from the reexamination or reissue proceedings currently pending before the United States Patent and Trademark Office, or USPTO, with respect to the 275 patent. In an order issued on November 5, 2004, the court dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction in view of the covenant not to sue Biogen Idec MA Inc., which was filed with the court by Columbia. At this time, we are unable to predict whether any claims will issue from the USPTO on the reexamination or reissue proceedings concerning the 275 patent, or whether, if any claims do issue, such claims will pose a risk of infringement with respect to our activities.

On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation, filed suit against Columbia in the U.S. District Court for the District of Massachusetts (the 2004 action). In the 2004 action we reasserted some of the contentions made in our complaint in the action filed in 2003 action. For example, that we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the 275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the 275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. In addition to seeking a declaration of invalidity based on non-statutory double-patenting, we have also asserted claims for relief based on abuse of process, breach of contract, violation of Massachusetts laws concerning unfair and deceptive trade practices, prosecution laches and inequitable conduct. We also filed a motion to consolidate the 2004 action with the 2003 action. The court has not yet ruled on the motion. On October 1, 2004, Columbia filed a motion to dismiss the 2004 action, which we have opposed. The motion is currently pending before the court. To date, Columbia has refused to extend its covenant not to sue on the 275 patent to Biogen Idec Inc. The order issued by the court in the 2003 action on November 5, 2004 may affect the pending motion to consolidate the 2004 action with the 2003 action, since that Memorandum and Order will affect the scope of the 2003 action. In the event that we are unsuccessful in the present litigation and Columbia asserts a claim for infringement against Biogen Idec Inc., we may be liable for damages suffered by Columbia with respect to unpaid royalties and such other relief as Columbia may seek and be granted by the Court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, Glaxosmithkline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of

infringement claims are based on allegations that we provided instructions and/or recommendations on a proper immunization schedule for vaccines to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. Under our 1988 license agreement with Glaxosmithkline, Glaxosmithkline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that Glaxosmithkline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court.

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Along with many other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) was named as a defendant in a lawsuit filed by each of the County of Suffolk, New York, the County of Westchester, New York, and the County of Rockland, New York. All three cases are pending in the U.S. District Court for the District of Massachusetts. The complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs, marketed and promoted the sale of Covered Drugs to providers based on the providers ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs, provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs, and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints further allege that the defendants failed to accurately report the best price on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services. The complaints allege that the defendants excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the best price. Plaintiffs brought claims for violation of the Racketeering Influence and Corrupt Organizations Act (RICO) 18 U.S.C. § 1962(c), violation of the Federal Medicaid Rebate Statute, 42 U.S.C. § 1396v-8, violation of New York Social Services Law § 367(A)(7)(d), violation of New York Department of Health Regulations 18 N.Y.CRR § 515(b)(4) and (5), violation of New York Social Services Law § 145-b, breach of contract for breach of the rebate agreement entered into with the Secretary of Health and Human Services, unfair trade practices under New York State law, common law fraud, and unjust enrichment. In September 2003, Biogen joined other named defendants in filing a Joint Motion to Dismiss the complaints. Biogen also filed separately a motion on its own behalf arguing that the plaintiffs made no specific factual allegations against Biogen to connect it with the alleged scheme. In September 2004, the court, in ruling on defendants joint motion to dismiss, allowed the motion, in part, and dismissed the RICO claim, the Medicaid Best Price claim, the breach of contract claim, and the common law fraud claim. The court did not dismiss the claims brought under the New York State Medicaid and Social Services statutes, the unfair trade practices claim, or the claim for unjust enrichment. In October 2004, the court issued a partial decision on Biogen's individual motion to dismiss. The court deferred ruling on Biogen's motion to dismiss the fraud-based claims pending consideration of supporting documentation to be produced by plaintiffs. The extent to which the plaintiffs are allowed to proceed with these claims against Biogen will be affected by any disclosures they make in response to the court's ruling. The court dismissed all of the state law claims against Biogen based in the alleged failure to report Best Prices. Biogen Idec MA, Inc. intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business, results of operations, or financial condition.

12. Share Repurchase Program

In February 2004, our Board of Directors authorized the repurchase of up to 12.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. During the first nine months of 2004, we repurchased all 12.0 million shares at a cost of \$698.4 million.

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. No shares have been repurchased under this program.

13. Segment Information

We operate in one segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment. We currently have four commercial products: AVONEX, RITUXAN, ZEVALIN and AMEVIVE. We also receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control including sales of RITUXAN outside the U.S. Revenues are primarily attributed from external customers to individual countries where earned based on location of the customer or licensee.

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14. Guarantees

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34, or FIN No. 45. FIN No. 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of certain guarantees. The initial recognition and initial measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Since January 1, 2003, we have not issued or modified any guarantees as defined by FIN No. 45.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. Accordingly, we have no liabilities recorded for these agreements as of September 30, 2004.

15. Deferred Stock Based Compensation

In the first nine months of 2004, we granted a total of 1.3 million shares of restricted common stock to employees under our 2003 Omnibus Equity Plan. The restricted stock will vest 100% three years from the grant date, provided the employee remains continuously employed with us. During the vesting period, shareholders have full voting rights, even though the restricted stock remains subject to transfer restrictions and will generally be forfeited upon termination of employment prior to vesting. Approximately 0.1 million grants have been forfeited as of September 30, 2004 due to employee terminations. At September 30, 2004, deferred stock based compensation related to restricted stock was \$40.4 million and was included in shareholders' equity. For the three and nine months ended September 30, 2004, we recorded \$4.3 million and \$11.3 million of stock compensation charges related to the restricted stock.

16. Severance Obligations

In 2003, we accrued \$10.2 million related to restructuring costs associated with the relocation of our European headquarters, and recorded an additional \$0.3 million and \$1.3 million of restructuring costs in selling, general and administrative expense for the three and nine months ended September 30, 2004, respectively. During the three and nine months ended September 30, 2004, we made payments of \$5.3 million and \$10.5 million, respectively, related to this relocation obligation. At September 30, 2004, we had a remaining accrual of approximately \$1.0 million related to this relocation obligation.

In 2003, we accrued \$2.1 million of restructuring costs in selling, general and administrative expense related to severance obligations for certain employees in our Cambridge facilities, and accrued an additional \$0.2 million and \$1.0 million of charges in the three and nine months ended September 30, 2004. At September 30, 2004, we had a remaining accrual of approximately \$1.6 million related to these severance obligations.

During the three and nine months ended September 30, 2004, we recorded charges of \$0.4 million and \$4.4 million in selling, general and administrative expense, respectively, related to severance obligations for certain employees in our San Diego facilities. At September 30, 2004, we had a remaining accrual of approximately \$1.0 million related to these severance obligations.

17. Pension

In connection with the Merger, we assumed Biogen, Inc.'s tax-qualified defined benefit pension plan. Prior to November 13, 2003, we did not have a pension plan. The pension plan provides benefits to all of Biogen, Inc.'s U.S. employees based on compensation credits and interest credits to participants' accounts using a cash balance method.

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We also assumed Biogen, Inc.'s unfunded supplemental retirement benefit plan which covers a select group of highly compensated U.S. employees. The plans are noncontributory with benefit formulas based on employee earnings and credited years of service. Biogen, Inc.'s funding policy for the plans has been to contribute amounts deductible for federal income tax purposes. Funds contributed to the plans have been invested in fixed income and equity securities. At October 31, 2003, Biogen, Inc. ceased allowing new participants into the plans.

We have requested Internal Revenue Service approval to terminate the pension plan. We credited participants' cash balance accounts under the pension plan for compensation and interest earned through December 31, 2003. No further compensation credits will be made, but interest credits will be made until the pension plan is terminated and benefits are distributed to participants.

We terminated the supplemental retirement benefit plan as of April 1, 2004. We credited participants' accounts under the supplemental retirement benefit plan for compensation and interest earned through December 31, 2003. No further compensation credits will be made, but interest credits will be made until the supplemental retirement benefit plan is terminated.

There were no significant interest or service costs for the three and nine months ended September 30, 2004 related to these plans. As of September 30, 2004 we had a liability of \$24.2 million related to these plans.

18. New Accounting Pronouncements

EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, was issued in February 2004. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. The provisions of EITF 03-01 are effective for fiscal years ending after December 15, 2003. We have complied with the disclosure provisions of EITF 03-01. In September 2004, the FASB staff issued two proposed FASB Staff Positions (FSP): Proposed FSP EITF Issue 03-1-a, which provides guidance for the application of paragraph 16 of EITF Issue 03-1 to debt securities that are impaired because of interest rate and/or sector spread increases, and Proposed FSP EITF Issue 03-1-b, which delays the effective date of Issue 03-1 for debt securities that are impaired because of interest rate and/or sector spread increases. We are currently monitoring these developments to assess the potential impact on our financial position and results of operations.

On March 31, 2004, the FASB issued an Exposure Draft, *Share-Based Payments*, which is a proposed amendment to SFAS No. 123, *Accounting for Stock-Based Compensation*. The Exposure Draft would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion 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 our financial statements. Throughout most of 2004, the FASB has continued to deliberate on different aspects of a new standard, and currently expects to issue a final standard before December 31, 2004. The new standard, as proposed, would be effective for awards that are granted, modified or settled in cash in interim and annual periods beginning after June 15, 2005. We are monitoring developments related to the exposure draft and will adopt the final standards, if any, upon issuance.

The FASB has proposed amending SFAS 128 to make it consistent with International Accounting Standard 33, *Earnings per Share*, and make earnings per share, or EPS, computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly, under the proposed amendment, shares that will be issued upon conversion of a mandatory convertible security

must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard is expected to be issued during the fourth quarter of 2004 and will be effective for all periods ending after December 15, 2004. Accordingly, the changes to EPS calculations will be effective in 2004 for calendar year-end companies. Retrospective application in all periods presented would

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be required, and could require the restatement of previously reported EPS. We are evaluating the impact of this proposed amended standard on our financial statements.

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

Overview

On November 12, 2003, IDEC Pharmaceuticals Corporation and Biogen, Inc. entered into a merger transaction, or the Merger, resulting in Biogen, Inc. becoming a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. The Merger was treated as an acquisition of Biogen, Inc. by IDEC Pharmaceuticals Corporation for accounting purposes. In connection with the Merger, IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc. Biogen Idec combines the complementary strengths of each company to create new standards of care in oncology and immunology. As a global leader in the development, manufacture, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. The Merger provides diversification of our product portfolios and revenue bases, strengthens our research and development capabilities, and diversifies our product pipeline in key therapeutic areas. Additionally, we believe our manufacturing capacity will make us an attractive partner for companies seeking to partner on promising biologic products in development.

Our primary focus is to create new standards of care in oncology and immunology. We currently have four commercial products: AVONEX® (interferon beta-1a) for the treatment of relapsing multiple sclerosis, or MS; RITUXAN® (rituximab) and ZEVALIN® (ibritumomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs; and AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. We acquired AVONEX and AMEVIVE from Biogen, Inc. We also receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control including sales of RITUXAN outside the U.S. RITUXAN is the trade name for the compound rituximab in the U.S., Canada and Japan. MabThera is the trade name for rituximab in the European Union, or the EU. In this Form 10-Q, we refer to rituximab, RITUXAN and MabThera collectively as RITUXAN, except where we have otherwise indicated. We are also developing ANTEGREN® (natalizumab) in collaboration with Elan Corporation plc. We submitted applications for approval of ANTEGREN in the U.S. and EU as a treatment for MS in the second quarter of 2004 and submitted an application for approval of ANTEGREN in the EU as a treatment for Crohn's disease in September 2004. The FDA designated ANTEGREN for Priority Review and Accelerated Approval as a treatment for MS. In addition, we have a pipeline of development stage products and a number of research programs in our core therapeutic areas and in other areas of interest.

As a result of the Merger, Biogen, Inc. stockholders received 1.15 shares of Biogen Idec common stock for each share of Biogen, Inc. common stock. As a result, Biogen Idec issued approximately 171.9 million shares at a fair value of approximately \$6.48 billion (based on the average of the closing price of IDEC Pharmaceuticals Corporation's common stock for the period from two days before through two days after the public announcement of the Merger on June 23, 2003). In addition, options to purchase Biogen, Inc. common stock outstanding at November 12, 2003 were assumed by Biogen Idec and converted into options to purchase approximately 20.7 million shares of Biogen Idec common stock at a fair value of approximately \$295.0 million (based on the Black-Scholes option pricing model). We paid approximately \$19.9 million in fees for banking, legal, accounting and tax related services related to the Merger. Merger-related fees of \$21.5 million paid by Biogen, Inc. prior to completion of the Merger are not included in this amount as they were expensed as incurred. The total Merger purchase price was approximately \$6.8 billion. The Merger qualified as a tax-free reorganization within the meaning of Section 368(a) of the Internal Revenue Code.

Comparisons of the three and nine months ended September 30, 2004 are made to the results of operations of IDEC Pharmaceuticals Corporation for the three and nine months ended September 30, 2003, which only include the historical results of IDEC Pharmaceuticals Corporation.

Table of Contents**Results of Operations****Revenues** *(table in thousands)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Product sales				
United States	\$237,482	\$ 4,427	\$ 738,401	\$ 15,069
Rest of world	122,210		357,014	
Total product sales	359,692	4,427	1,095,415	15,069
Unconsolidated joint business revenue	159,507	133,960	444,619	363,236
Royalties	23,860		73,371	
Corporate partner	217	143	10,377	1,032
Total revenues	\$543,276	\$138,530	\$1,623,782	\$379,337

Product Sales *(table in thousands)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
AVONEX	\$346,248	\$	\$1,047,482	\$
ZEVALIN	5,222	4,427	14,608	15,069
AMEVIVE	8,222		33,325	
Total product sales	\$359,692	\$4,427	\$1,095,415	\$15,069

For the three months ended September 30, 2004, sales of AVONEX generated worldwide revenues of \$346.2 million, of which \$224.3 million was generated in the U.S. and \$121.9 million was generated outside the U.S., primarily the EU. For the nine months ended September 30, 2004, sales of AVONEX generated worldwide revenues of \$1.0 billion, of which \$691.1 million was generated in the U.S. and \$356.4 million was generated outside the U.S., primarily the EU. Product sales from AVONEX for the three and nine months ended September 30, 2004 represent

approximately 64% and 65%, respectively, of our total revenues.

In the third quarter of 2004, sales of ZEVALIN generated revenues of \$5.2 million in the U.S. as compared to \$4.4 million in the third quarter of 2003. Product sales related to ZEVALIN for the nine months ended September 30, 2004 were \$14.6 million and \$15.1 million for the comparable period in 2003. Outside the U.S., we have licensed our marketing rights in ZEVALIN to Schering AG. In January 2004, the European Medicines Agency, or EMEA, the regulatory authority in the EU, granted marketing approval of ZEVALIN in the EU for the treatment of adult patients with CD20+ follicular B-cell NHL who are refractory to or have relapsed following treatment with RITUXAN. We expect to begin recording revenue from sales of ZEVALIN in the EU in the fourth quarter of 2004. Product sales from ZEVALIN represented approximately 1% and 3% of our total revenues in the three months ended September 30, 2004 and 2003, respectively, as compared to 1% and 4% in the nine months ended September 30, 2004 and 2003, respectively.

In the third quarter of 2004, sales of AMEVIVE generated revenues of \$8.2 million, substantially all in the U.S. Product sales from AMEVIVE represent approximately 2% of our total revenues in the third quarter of 2004. Product sales related to AMEVIVE for the nine months ended September 30, 2004 were \$33.3 million, which represented approximately 2% of our total revenues.

Our total product sales in 2004 will be substantially higher than 2003, since revenues from sales of AVONEX and AMEVIVE will be included in our results of operations for all of 2004 as opposed to 2003, when revenues from sales of AVONEX and AMEVIVE were included in our results of operations only for the period from November 13, 2003 through December 31, 2003.

See also the risks affecting revenues described in Forward-Looking Information and Risk Factors That May Affect Future Results Our Revenues Rely Significantly on a Limited Number of Products and Forward-Looking Information and Risk Factors That May Affect Future Results Our Long-Term Success Depends Upon the Successful Development and Commercialization of ANTEGREN and Other Products from Our Research and Development Activities and Collaborations, and Increased Acceptance of ZEVALIN and AMEVIVE.

Table of Contents**Unconsolidated Joint Business Revenue**

We market RITUXAN in the U.S. in collaboration with Genentech, Inc. All U.S. sales of RITUXAN and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis. Our share of pretax copromotion profits from U.S. sales of RITUXAN for the three and nine months ended September 30, 2004 totaled \$118.8 million and \$339.6 million, respectively, compared to \$109.6 million and \$302.0 million for the comparable periods in 2003. F. Hoffman-La Roche Ltd. sells RITUXAN outside the U.S., except in Japan, where it copromotes RITUXAN in collaboration with Zenyaku Kogyo Co. Ltd., or Zenyaku. We received royalties on sales of RITUXAN outside of the U.S. for the three and nine months ended September 30, 2004 totaling \$32.8 million and \$87.1 million, respectively, as compared to \$18.7 million and \$47.4 million for the comparable periods in 2003, which we include under Revenue from unconsolidated joint business in our condensed consolidated statements of income.

Revenues from unconsolidated joint business arrangement consist of the following (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Copromotion profits	\$118,753	\$109,553	\$339,612	\$301,978
Reimbursement of selling and development expenses	7,999	5,662	17,903	13,898
Royalty revenue on sales of RITUXAN outside the U.S., including royalties received directly from Roche	32,755	18,745	87,104	47,360
	<u>\$159,507</u>	<u>\$133,960</u>	<u>\$444,619</u>	<u>\$363,236</u>

Under our agreement with Genentech, our current pretax copromotion profit-sharing formula has two tiers. We earn a higher percentage of the pretax copromotion profits at the upper tier once a fixed pretax copromotion profit level is met. The profit-sharing formula resets annually at the beginning of each year to the lower tier. We began recording our profit share at the higher percentage during the first quarter of 2004.

RITUXAN net sales to third-party customers in the U.S. recorded by Genentech for the three and nine months ended September 30, 2004 amounted to \$393.0 million and \$1.1 billion, respectively, compared to \$354.0 million and \$992.0 million for the comparable periods in 2003. The increase in copromotion profits was primarily due to increased market penetration in treatments of B-cell NHLs and chronic lymphocytic leukemia and increases in the wholesale price of RITUXAN effective March 2004.

Our royalty revenue on sales of RITUXAN outside the U.S. is based on Roche and Zenyaku's net sales to third-party customers and is recorded on a cash basis. The increase in royalty revenues within revenues from our unconsolidated joint business arrangement in the first nine months of 2004 is due to higher sales of RITUXAN outside the U.S. resulting from increased penetration of foreign markets, including Canada and Japan.

Total unconsolidated joint business revenue represented 29% and 27% of our total revenues for the three and nine months ended September 30, 2004 as compared to 97% and 96% for the comparable periods in 2003.

Royalty Revenue

We receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control. Our royalty revenues on sales of RITUXAN outside the U.S. are included in Revenue from unconsolidated joint business instead of royalty revenues in our condensed consolidated statements of income. For the three and nine months ended September 30, 2004, we received approximately \$23.9 million and \$73.4 million in royalty revenues representing 4% and 5% of total revenues, respectively.

Royalty revenues may fluctuate as a result of fluctuations in sales levels of products sold by our licensees from quarter to quarter. Total royalty revenues in 2004 will be substantially higher than 2003, since royalty revenues from former Biogen, Inc. will be included in our results of operations for all of 2004 as opposed to 2003 when royalty revenues from former Biogen, Inc. were included in our results of operations only for the period from November 13, 2003 through December 31, 2003.

Table of Contents**Corporate Partner Revenues**

Corporate partner revenues consist of contract revenues and license fees. Corporate partner revenues totaled \$0.2 million and \$0.1 million for the three months ended September 30, 2004 and 2003, respectively, which represented less than 1% of total revenues for the third quarter of 2004 and 2003, respectively. Corporate partner revenues totaled \$10.4 million and \$1.0 million for the nine months ended September 30, 2004 and 2003, respectively, which represented 1% and less than 1% of total revenues for the first nine months of 2004 and 2003, respectively. The increase in corporate partner revenues for the nine months ended September 30, 2004 as compared to the comparable periods in 2003 is primarily due to a \$10.0 million payment from Schering AG for the EMEA grant of marketing approval of ZEVALIN in the EU in the first quarter of 2004. The payment represented, in part, a milestone payment to compensate us for preparing, generating, and collecting data that was critical to the EMEA marketing approval process.

Operating Costs and Expenses (table in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Cost of sales	\$ 64,460	\$ 639	\$ 470,955	\$ 5,282
Research and development	168,889	39,333	498,219	121,384
Selling, general and administrative	132,040	27,157	401,887	74,985
Amortization of acquired intangibles	107,054		267,222	
Total operating costs and expenses	<u>\$472,443</u>	<u>\$67,129</u>	<u>\$1,638,283</u>	<u>\$201,651</u>

Cost of Sales

For the three and nine months ended September 30, 2004, total cost of sales was \$64.5 million and \$471.0 million, respectively, consisting of product cost of sales of \$63.1 million and \$467.1 million, respectively, and cost of royalty revenues of \$1.4 million and \$3.9 million, respectively. In the third quarter of 2004, product cost of sales consisted of \$48.1 million related to AVONEX, \$4.8 million related to ZEVALIN and \$5.2 million related to AMEVIVE. This includes approximately \$3.3 million in fair market value purchase accounting adjustments related to AMEVIVE. We expect that approximately \$4.0 million in fair market value purchase accounting adjustments related to AMEVIVE will be included in product cost of sales in the remainder of 2004. There will be no additional fair market value purchase accounting adjustments related to AVONEX, as all related inventory has been sold or written-off as of June 30, 2004. In November 2003, we recorded the inventory that we acquired from Biogen, Inc. at its estimated fair value. The increase to fair market value was recognized as cost of product sales when the acquired inventory was sold or written down.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by

us, or if there are future determinations that inventory will not be marketable based on updated estimates for demand, additional inventory write-downs may be required. Also included in product cost of sales were write-downs of commercial inventory that did not meet quality specifications or became obsolete due to dating expiration, in all cases this product inventory was written down to its net realizable value. For the three and nine months ended September 30, 2004, we wrote down \$9.2 million and \$21.0 million, respectively, of unmarketable inventory which was charged to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. For the nine months ended September 30, 2004, total write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written down to net realizable value when it was determined that the inventory did not meet quality specifications. The write-down of ZEVALIN inventory during the three months ended September 30, 2004 resulted from a determination that the inventory did not meet quality specifications. The remaining write-downs of ZEVALIN inventory resulted from a determination that the inventory will not be marketable based on estimates of demand. For the nine months ended September 30, 2003, we wrote down a total of \$3.1 million of ZEVALIN commercial inventory, which did not meet quality specifications.

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In the first nine months of 2003, cost of sales consisted primarily of contractual royalties owed on ZEVALIN sales.

Gross margin on product sales, which includes inventory written down to its net realizable value, for the three and nine months ended September 30, 2004 was approximately 82% and 57%, respectively. Gross margin on product sales was approximately 86% and 65% for the three and nine months ended September 30, 2003. During the fourth quarter of 2003, we recorded the inventory that we acquired from Biogen, Inc. at its estimated fair value. The increase in fair market value was recognized as cost of product sales when the acquired inventory was sold or written down. As a result, gross margin on product sales decreased significantly for the nine months ended September 30, 2004 compared to the same period in 2003. We expect that gross margins will increase during 2004 after remaining inventory acquired from Biogen, Inc. at its estimated fair value is sold. All AVONEX inventory acquired from Biogen, Inc. at its estimated fair value has been sold or written-off as of June 30, 2004. Excluding the increase in fair market value related to purchase accounting for the three and nine months ended September 30, 2004 of \$3.3 million and \$290.7 million, respectively, and the effects of write-downs of commercial inventory to net realizable value of \$9.2 million and \$21.0 million, gross margins of product sales would have been 86% in the three and nine months ended September 30, 2004. We expect that gross margins will fluctuate in the future based on changes in product mix, write-downs of excess or obsolete inventories and new product initiatives. Gross margin on royalty revenues were approximately 94% and 95%, respectively, for the three and nine months ended September 30, 2004. We expect that gross margins on royalty revenues will fluctuate in the future based on changes in sales volumes for specific products from which we receive royalties.

Research and Development Expenses

Research and development expenses totaled \$168.9 million in the three months ended September 30, 2004 compared to \$39.3 million in the comparable period of 2003. Research and development expenses increased \$129.6 million, or 329%. The increase is primarily related to the acquisition of Biogen, Inc., which contributed approximately \$122.1 million of research and development expenses during the three months ended September 30, 2004. Excluding the contribution of expenses related to the acquisition of Biogen, Inc., expenses increased by \$7.5 million in the three months ended September 30, 2004 compared to the comparable period of 2003. This increase primarily resulted from increased depreciation and infrastructure costs of \$9.9 million related to the expansion of our manufacturing and research facilities and \$1.2 million of increased expenses related to our collaboration agreements. These increases were offset by a \$4.3 million decrease in biopharmaceutical operations and global quality initiative expenses due to increased capitalization costs related to inventory and validation costs for the expansion of our manufacturing and research facilities. Included in research and development expenses for the three months ended September 30, 2004 was a \$7.0 million upfront license fee paid to Sunesis in conjunction with a collaboration agreement.

Research and development expenses totaled \$498.2 million in the nine months ended September 30, 2004 compared to \$121.4 million in the comparable period of 2003. The 310% increase in research and development expenses for the nine months ended September 30, 2004 versus the comparable period in 2003 was primarily due to the acquisition of Biogen, Inc., which contributed approximately \$360.1 million of research and development expenses during the nine months ended September 30, 2004. Excluding the contribution of expenses related to the acquisition of Biogen, Inc., expenses increased \$16.7 million in the nine months ended September 30, 2004 compared to the comparable period of 2003. The additional increase primarily resulted from \$3.9 million related to our ongoing clinical trials for oncology development, increased depreciation and infrastructure costs of \$25.4 million related to the expansion of our manufacturing and research facilities and \$4.0 million of increased expenses related to our collaboration agreements. Included in research and development expenses for the nine months ended September 30, 2004 were a \$7.0 million upfront license fee paid to Sunesis in conjunction with a collaboration agreement, a \$7.0 million milestone payment to Elan Corporation, plc under our collaboration agreement on ANTEGREN, and a \$10.0 million upfront license fee paid to Vernalis plc in conjunction with a collaboration agreement to advance

research in Vernalis adenosine A2A receptor antagonist program. Included in research and development expenses for the nine months ended September 30, 2003 was a \$20.0 million initial payment to Genentech for a collaboration agreement.

Research and development expenses will continue to increase significantly in 2004 compared to 2003 as a result of the Merger. Additionally, we expect to incur significant manufacturing and production costs in 2004 as part of the

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regulatory approval process and the anticipated launch of ANTEGREN. In the second quarter of 2004, we submitted applications for approval of ANTEGREN in the U.S. and EU as a treatment for MS. The FDA has designated ANTEGREN for Priority Review and Accelerated Approval as a treatment for MS. In September 2004, we also submitted an application for approval of ANTEGREN in the EU as a treatment for Crohn's disease. We also expect to continue incurring additional research and development expenses due to: preclinical and clinical testing of our various products under development; the expansion or addition of research and development programs; technology in-licensing; and regulatory-related expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses totaled \$132.0 million for the three months ended September 30, 2004 compared to \$27.2 million in the comparable period of 2003. Selling, general and administrative expenses increased \$104.9 million, or 386%, for the three months ended September 30, 2004 and was almost entirely related to the acquisition of Biogen, Inc. which contributed approximately \$109.3 million of selling, general and administrative expenses during the third quarter of 2004. Excluding the contribution of expenses related to the acquisition of Biogen, Inc., expenses decreased by \$4.4 million in the three months ended September 30, 2004 compared to the comparable period of 2003. Selling, general and administrative expenses totaled \$401.9 million for the nine months ended September 30, 2004 compared to \$75.0 million in the comparable period of 2003. Selling, general and administrative expenses increased \$326.9 million, or 436%, for the nine months ended September 30, 2004 from the comparable period in 2003 and was almost entirely related to the acquisition of Biogen, Inc. which contributed approximately \$332.6 million of selling, general and administrative expenses during the first nine months of 2004. Excluding the contribution of expenses related to the acquisition of Biogen, Inc., expenses decreased by \$5.8 million in the nine months ended September 30, 2004 compared to the comparable period of 2003. The decrease in expenses not attributable to the acquisition of Biogen, Inc. in the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003, resulted primarily from lower legal fees in 2004 due to the settlement of the Corixa litigation. Included in the selling, general and administrative expenses for the three and nine months ended September 30, 2004 were \$16.7 million and \$25.4 million of sales and marketing costs related to the anticipated launch of ANTEGREN.

For the three and nine months ended September 30, 2004, we recorded charges of \$0.4 million and \$4.4 million related to severance obligations for certain employees affected by the Merger in our San Diego facilities. At September 30, 2004, we had a remaining accrual of approximately \$1.0 million related to the severance obligations in our San Diego facilities. For the three and nine months ended September 30, 2004, we accrued an additional amount of approximately \$0.3 million and \$1.3 million related to the European relocation-restructuring obligation. Our remaining liability related to the European relocation-restructuring obligation was \$1.0 million at September 30, 2004. In 2003, we accrued \$2.1 million related to restructuring costs related to severance obligations for certain employees in our Cambridge facilities, and accrued an additional \$0.2 million and \$1.0 million of charges in the three and nine months ended September 30, 2004. Our remaining liability at September 30, 2004 related to severance obligations to certain employees affected by the Merger in our Cambridge facilities was \$1.6 million.

Our total selling, general, and administrative expense in 2004 will be substantially higher than 2003, since selling, general and administrative expenses related to support of AVONEX and AMEVIVE will be included in our results of operations for all of 2004 as opposed to 2003 when selling, general and administrative expenses related to support of AVONEX and AMEVIVE were included in our results of operations only for the period from November 13, 2003 through December 31, 2003. Additionally, we expect to incur significant selling, general and administrative costs in 2004 as we prepare for the anticipated launch of ANTEGREN.

Other Income (Expense), Net (table in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Interest income	\$ 13,794	\$ 6,636	\$ 43,058	\$ 22,986
Interest expense	(2,984)	(4,650)	(10,246)	(14,437)
Other expense	(12,383)		(16,246)	
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total other income (expense), net	\$ (1,573)	\$ 1,986	\$ 16,566	\$ 8,549
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

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Interest income totaled \$13.8 million for the three months ended September 30, 2004 compared to \$6.6 million for the comparable period of 2003. Interest income for the nine months ended September 30, 2004 was \$43.1 million as compared to \$23.0 million in the first nine months of 2003. The increase in interest income is primarily due to higher cash balances resulting from our Merger with Biogen, Inc. Interest income levels that may be achieved in the future are, in part, dependent upon market conditions.

Interest expense totaled \$3.0 million for the three months ended September 30, 2004 compared to \$4.7 million for the comparable period of 2003. Interest expense totaled \$10.2 million for the nine months ended September 30, 2004 compared to \$14.4 million for the comparable period of 2003. The decrease in interest expense in the three and nine months ended September 30, 2004 compared to the comparable periods of 2003 is primarily due to the capitalization of interest costs totaling \$2.0 million and \$5.4 million, respectively, largely related to the development of a consolidated research and development and administration campus in San Diego, California and our large-scale manufacturing facility in Oceanside, California. Interest expense was also lower in 2004 due to the partial conversion of the 2019 subordinated notes to common stock during the first nine months of 2004.

Other expense for the three and nine months ended September 30, 2004 consists primarily of a \$12.7 million charge for the impairment of certain noncurrent marketable securities that were determined to be other than temporary and \$1.0 million and \$3.0 million, respectively, realized losses on sales of marketable securities.

Amortization of Intangible Assets

For the three and nine months ended September 30, 2004, we recorded amortization expense of \$107.1 million and \$267.2 million, respectively, related to the intangible assets of \$3.7 billion acquired in the Merger with Biogen, Inc. Intangible assets consist of \$3.0 billion in core technology, \$578.0 million in out-licensed patents and \$64.0 million in trademarks. Amortization of the core technology is provided over the estimated useful lives of the technology ranging from 15 to 21 years, based on the greater of straight-line or economic consumption. Amortization of the patents is provided over the remaining lives of the patents of 12 years. Trademarks have an indefinite life and, as such, are not amortized.

We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. As of September 30, 2004, management determined that certain clinical trials of AMEVIVE would be discontinued or would not be initiated which indicated that the carrying value of certain core technology intangible assets related to AMEVIVE would not be recoverable. As a result, we recorded a charge of approximately \$27.8 million in the three months ended September 30, 2004 to amortization of intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE.

Income Tax Provision

Our effective tax rate for the three and nine months ended September 30, 2004 was 46.9% and 274.5%, respectively, compared to 38% for the comparable periods in 2003. Our effective tax rates in the three and nine months ended September 30, 2004 were higher than the normal statutory rates primarily due to the acquisition-related intangible amortization and impairment charges and inventory fair value adjustments arising from purchase accounting related to foreign jurisdictions. These items significantly reduced our pre-tax income for the nine months ended September 30, 2004 and substantially increased our effective tax rate for the period. We did not reflect the benefit of any expected increases in the research tax credit for the three months ended September 30, 2004 as the credit expired on June 30, 2004. On October 4, 2004, the Working Families Tax Relief Act of 2004 reinstated the research credit retroactively to June 30, 2004. The benefit of the reinstated credit will be reflected in our effective tax rate for the year ended December 31, 2004. Our effective tax rates in the three and nine months ended September 30,

2003 were higher than the normal statutory rates primarily due to state taxes. We expect that our effective tax rate in the future will continue to be higher than the normal statutory rate as a result of acquisition-related intangible amortization and state taxes. We have net operating loss and tax credit carryforwards available for federal and state income tax purposes. The utilization of our net operating loss carryforwards and tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate that this annual limitation will result only in a modest delay in the utilization of such net operating loss carryforwards and tax credits.

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Net Income (Loss)

For the three and nine months ended September 30, 2004, results of operations provided net income of \$36.8 million and a net loss of \$3.6 million, respectively, compared to net income of \$45.5 million and \$115.5 million for the comparable periods of 2003. The decrease in net income for both periods is primarily attributable to the recognition of product cost of sales on AVONEX and AMEVIVE inventory recorded at fair value upon the acquisition of Biogen, Inc., and the amortization of intangible assets.

Financial Condition

We have financed our operating and capital expenditures principally through profits and other revenues from our joint business arrangement with Genentech related to the sale of RITUXAN, sales of AVONEX, AMEVIVE and ZEVALIN, royalty revenues, corporate partner revenues, debt financing transactions and interest income. We expect to finance our current and planned operating requirements principally through cash on hand, which includes the proceeds from the April and May 2002 issuance of our senior notes, and funds from our joint business arrangement with Genentech related to the sale of RITUXAN, commercial sales of AVONEX, AMEVIVE and ZEVALIN, royalties and existing collaborative agreements and contracts. We believe that these funds will be sufficient to meet our operating requirements for the foreseeable future. However, we may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources. Our working capital and capital requirements will depend upon numerous factors, including: the continued commercial success of AVONEX and RITUXAN; the commercial success of AMEVIVE and ZEVALIN; timing and expense of obtaining regulatory approvals for new products including ANTEGREN, the cost of launching such products and the success of those products; funding and timing of payments related to several significant capital projects; the progress of our preclinical and clinical testing; fluctuating or increasing manufacturing requirements and research and development programs; levels of resources that we need to devote to the development of manufacturing, sales and marketing capabilities, including resources devoted to the marketing of AVONEX, RITUXAN, AMEVIVE, ZEVALIN and future products, including ANTEGREN; technological advances; status of products being developed by competitors; our ability to establish collaborative arrangements with other organizations; and working capital required to satisfy the put options related to our senior notes and subordinated notes.

Until required for operations, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, foreign and United States government instruments and other readily marketable debt instruments in accordance with our investment policy.

Cash, cash equivalents and securities available-for-sale totaled \$2.1 billion at September 30, 2004 and \$2.3 billion at December 31, 2003. Our operating activities generated \$536.4 million of cash for the nine months ended September 30, 2004 as compared to \$195.3 million for the comparable period of 2003. Net cash from operating activities includes our net loss of \$3.6 million, which was impacted by non-cash charges of \$21.7 million related to the write-down of inventory to net realizable value, a \$285.7 million impact on sales of inventory recorded at fair value upon the acquisition of Biogen, \$333.0 million of depreciation and amortization, including amortization and a \$27.8 million impairment of acquired intangibles, and \$87.0 million of tax benefits related to stock options, offset by net changes to deferred income taxes of \$128.4 million. Our investing activities utilized \$182.6 million of cash in the nine months ended September 30, 2004 compared to \$193.6 million for the comparable period of 2003, and included uses of \$227.0 million to fund construction projects and purchase real property and equipment, including our research and development and administration campus in San Diego and manufacturing facility in Oceanside, and \$44.4 million of net cash provided from proceeds of available-for-sale securities. Cash generated from financing activities included \$208.8 million from the issuance of common stock and reissuance of treasury stock under employee stock option and stock purchase plans during the first three quarters of 2004, compared to \$11.9 million for the first three quarters of 2003. Cash outflows from financing activities included \$698.4 million for the repurchase of common stock under our

stock repurchase program. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuation in the market value of our stock relative to the price of the options.

In April and May 2002, we raised through the issuance of our senior notes, approximately \$696.0 million, net of underwriting commissions and expenses of \$18.4 million. Simultaneously with the issuance of the senior notes, we

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used a portion of the proceeds to fund the repurchase of \$135.0 million of our outstanding common stock. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. We will pay contingent cash interest to the holders of these senior notes during any nine-month period commencing on or after April 30, 2007 if the average market price of the senior notes for a five-trading-day measurement period preceding such nine-month period equals 120% or more of the sum of the issue price and accrued original issue discount for such senior note. The contingent interest payable per senior note with respect to any quarterly period within such nine-month period where contingent interest is determined to be payable will equal the greater of (1) the amount of regular cash dividends paid by us per share on our common stock during that quarterly period multiplied by the then applicable conversion rate or (2) 0.0625% of the average market price of a senior note for the five-trading-day measurement period preceding such nine-month period, provided that if we do not pay regular cash dividends during a semiannual period, we will pay contingent interest semiannually at a rate of 0.125% of the average market price of a senior note for the five-trading-day measurement period immediately preceding such nine-month period.

Upon maturity, the senior notes will have an aggregate principal face value of \$1.2 billion. Each \$1,000 aggregate principal face value senior note is convertible at the holder's option at any time through maturity into 7.1881 shares of our common stock at an initial conversion price of \$82.49. In addition, holders of the senior notes may require us to purchase all or a portion of the senior notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, common stock or a combination of cash and stock. In addition, if a change in control in our company occurs on or before April 29, 2007, holders may require us to purchase all or a portion of their senior notes for cash. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the senior notes for cash at any time on or after April 29, 2007.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes are zero coupon and were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes issued in February 1999 had an aggregate principal face value of \$345.0 million. As of September 30, 2004, our remaining indebtedness under the subordinated notes was approximately \$219.2 million at maturity, due to conversion of subordinated notes into common stock. Each \$1,000 aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36. The holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2009 or 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase with us having the option to repay the subordinated notes plus accrued original issue discount in cash, common stock or a combination of cash and stock. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the subordinated notes for cash at any time. In the three and nine months ended September 30, 2004, holders of subordinated notes with a face value of approximately \$55.5 million and \$125.7 million, respectively, elected to convert their subordinated notes to approximately 2.2 million and 5.1 million shares, respectively, of our common stock.

In July 2004, we announced that we will be restarting construction of our large-scale biologic manufacturing facility in Hillerød, Denmark to be used to manufacture products in the pipeline and is expected to expand our large-scale manufacturing capacity to 270,000 liters. The cost of the project is estimated to be \$340.0 million. As of September 30, 2004, we had committed approximately \$45.0 million to the project. The facility is expected to be substantially complete in 2007 and available for commercial production in 2008.

In June 2004, we commenced construction in Cambridge, Massachusetts to add additional research facilities and administrative space to one of our existing buildings. The cost of the project is estimated to be \$65.0 million. As of September 30, 2004, we had committed approximately \$27.3 million to the project, of which \$8.4 million had been paid. The project is expected to be substantially complete in late 2005.

In September 2001, we purchased approximately 42.6 acres of land in San Diego, California for approximately \$31.7 million in cash where we are building a consolidated research and development and administration campus. Construction is expected to be completed in the fourth quarter of 2004 at an estimated total cost of \$170.0 million. As of September 30, 2004, we have committed approximately \$161.9 million and paid approximately \$144.6 million in the construction of this campus.

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In September 2000, we purchased a 60-acre site in Oceanside, California for approximately \$18.9 million. In December 2002, we purchased an additional 27 acres of land at the Oceanside site for \$7.9 million. We are building a large-scale manufacturing facility at this location, which we anticipate using to manufacture commercial products currently in clinical trials if they are approved by the FDA. We anticipate the new facility to be mechanically completed in 2005, followed by commissioning and validation targeted for 2006. Including start-up costs, total costs of this facility upon completion are estimated to be \$480.0 million. As of September 30, 2004, we have committed approximately \$365.0 million, of which approximately \$328.0 million had been paid.

In August 2004, we entered into a collaborative agreement with Sunesis Pharmaceuticals, Inc, or Sunesis, to discover and develop small molecule cancer therapeutics targeting primarily kinases. Under the agreement, we acquired exclusive licenses to develop and commercialize certain compounds resulting from the collaboration. Upon signing the agreement, we paid Sunesis a nonrefundable upfront license fee of \$7.0 million, which was recorded in research and development expenses in the third quarter of 2004. Under the terms of this agreement, we purchased approximately 2.9 million shares of preferred stock of Sunesis for \$14.0 million, the fair value of the shares. Our investment in Sunesis is included in other assets. We account for our investment in Sunesis using the cost method of accounting, subject to periodic review of impairment. We have committed to paying Sunesis additional amounts upon the completion of certain future research milestones and first and second indication development milestones. If all the milestones were to be achieved, we would be required to pay up to an additional \$60.5 million over the life of the agreement, excluding royalties.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc aimed at advancing research into Vernalis adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement may require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. We made an immediate investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis ordinary shares, representing 4.19 percent of Vernalis post-financing issued share capital, and have committed to purchase an additional \$4.0 million in the event of future Vernalis financing. Our investment in Vernalis is included in other assets. We account for our investment in Vernalis using the cost method of accounting, subject to periodic review of impairment. Excluding royalties, total potential payments to Vernalis could exceed \$100.0 million.

In June 2004, we entered into a license agreement with BioWa, Inc. for a worldwide, non-exclusive license for research purposes and a worldwide, exclusive license for development and commercialization purposes to certain BioWa intellectual property rights related to monoclonal antibodies. As part of the agreement, we have committed to paying BioWa certain amounts upon the achievement of certain research and clinical milestones. If all the milestones were to be achieved, we would be required to pay BioWa a total of \$18.8 million plus royalties over the life of the agreement.

In May 2004, we entered into a limited partnership agreement as a limited partner with MPM Bioventures III GP, LP, to create MPM Bioventures Strategic Fund, LP, or the Strategic Fund. The purpose of the Strategic Fund is to make, manage, and supervise investments in relevant biotechnology companies with novel products or technologies that fit strategically with Biogen Idec. The Strategic Fund takes only minority positions in the equity of its investments, and does not seek to engage in day-to-day management of the entities. We have committed \$65.0 million to the Strategic Fund over a three-year period. Through September 30, 2004, we have contributed \$5.1 million to the Strategic Fund. We have consolidated the Strategic Fund in our condensed consolidated financial statements at September 30, 2004. There were no significant expenses related to the Strategic Fund included in our operating results through September 30, 2004.

In April 2004, we became a limited partner in MPM Bioventures III-QP, LP, or the LP, a limited partnership that invests in entities that are engaged in the research, development, manufacture, marketing and/or sale of novel biological products or technologies. We have committed to contribute \$4.0 million to the limited partnership. Through September 30, 2004, we have contributed \$1.6 million into the LP, which is included in other assets in our condensed consolidated balance sheet at September 30, 2004.

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In February 2004, our Board of Directors authorized the repurchase of up to 12.0 million shares of our common stock. The repurchased stock will provide us with treasury shares of general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. During the first nine months of 2004, we repurchased all 12.0 million shares at a cost of \$698.4 million, completing this program.

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. No shares have been repurchased under this program.

In the first nine months of 2004, we made payments totaling \$17.0 million to Vetter Pharma-Fertigung GmbH & Co. KG for the achievement of certain milestones achieved under the terms of our supply agreement for reserving certain capacity at Vetter's fill-finish facility. These payments are recorded in other assets on our condensed consolidated balance sheets. The asset will be amortized to cost of sales over the units produced upon delivery to Biogen Idec. We have total potential milestone payments of approximately 16.0 million euros remaining as part of the agreement.

In July 2004, we and our collaboration partner, Elan Corporation, plc, entered into a license agreement with Genentech for a non-exclusive license to certain Genentech patents related to the manufacture of licensed products, including ANTEGREN. As a part of the agreement, we and Elan paid a \$1.0 million license grant fee upon execution of the agreement and will pay an additional \$1.0 million on the first anniversary of the agreement. In addition, we and Elan may each have to pay a development milestone fee of \$2.5 million, half of which would be paid upon the first marketing approval of a licensed product from the FDA and half of which would be paid on the anniversary of such approval. The agreement also requires that we or Elan pay royalties on net sales of ANTEGREN and other licensed products.

In October 2004, we entered into a development and license agreement with ImmunoGen, Inc., or ImmunoGen, for a worldwide, exclusive license to develop and commercialize anticancer therapeutics that comprise an antibody that we have developed to an undisclosed tumor cell target and ImmunoGen's proprietary Tumor-Activated Prodrug (TAP) technology. As part of the agreement, we will pay ImmunoGen an upfront fee of \$1.0 million as well as additional amounts upon the achievement of certain predetermined milestones. If all the milestones were to be achieved, we would be required to pay ImmunoGen a total of \$42 million plus royalties over the life of the agreement. ImmunoGen will also receive compensation from Biogen Idec for product development research done on its behalf, as well as for the production of preclinical and initial clinical materials.

Legal Matters

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York, or Columbia, in the U.S. District Court for the District of Massachusetts, contending that we no longer have any obligation to pay royalties to Columbia on sales of our products under a 1993 license agreement between us and Columbia related to U.S. Patent Nos. 4,399,216, 4,634,665, and 5,179,017, also referred to as the Original Patents, or under a newly issued patent, U.S. Patent No. 6,455,275, also referred to as the '275 patent (the 2003 action). In our suit, we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the '275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the '275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. Columbia initially took the position that we still owe it royalties under the license agreement on the basis of the '275 patent, which was issued on September 24, 2002, over two years after the expiration of the Original Patents, and that we are in breach of the license agreement due to an alleged failure to pay royalties under the '275 patent. When

Columbia sought to terminate our license agreement on this ground, we moved to have the court preliminarily enjoin such termination until the underlying patent dispute is resolved. In a published decision, the court denied our motion to enjoin termination of the license agreement. In reaching that decision, the court found that we had made a strong showing that we might prevail in proving the 275 patent is invalid under the doctrine of non-statutory double patenting, and, if valid, that the patent is unenforceable because of the equitable doctrine of prosecution laches. Our motion was denied, however, because we did not meet our burden of demonstrating irreparable harm if the license agreement was terminated. The court ordered an expedited

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schedule for completion of fact and expert discovery, submission of briefs on claim construction, and a hearing on the merits, while staying all other aspects of the case. On September 13, 2004, Columbia informed us that it would not seek to terminate the license agreement for failure to pay royalties on the 275 patent but expressly reserved all other grounds for termination. Columbia then asserted that Biogen Idec MA, Inc. is a licensee in good standing. Columbia then moved for dismissal of the litigation based on their assertion that there is no longer a case or controversy as required by Article III of the U.S. Constitution. We opposed the motion and Columbia, in a hearing on the motion held on October 6, 2004, subsequently covenanted not to sue Biogen Idec MA, Inc. on any claim of the 275 patent and any claim that is the same or substantially the same as the claims of the 275 patent if such claim(s) emerge from the reexamination or reissue proceedings currently pending before the United States Patent and Trademark Office, or USPTO, with respect to the 275 patent. In an order issued on November 5, 2004, the court dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction in view of the covenant not to sue Biogen Idec MA Inc., which was filed with the court by Columbia. At this time, we are unable to predict whether any claims will issue from the USPTO on the reexamination or reissue proceedings concerning the 275 patent, or whether, if any claims do issue, such claims will pose a risk of infringement with respect to our activities.

On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation, filed suit against Columbia in the U.S. District Court for the District of Massachusetts (the 2004 action). In the 2004 action we reasserted some of the contentions made in our complaint in the action filed in 2003 action. For example, that we are seeking a declaratory judgment that we have no obligation to pay any further royalties under the license agreement because the Original Patents have expired and the 275 patent is invalid and unenforceable; and that Columbia should be permanently enjoined from demanding any further royalties based on the 275 patent or on any pending continuations, continuations-in-part, or divisional applications of the Original Patents. In addition to seeking a declaration of invalidity based on non-statutory double-patenting, we have also asserted claims for relief based on abuse of process, breach of contract, violation of Massachusetts laws concerning unfair and deceptive trade practices, prosecution laches and inequitable conduct. We also filed a motion to consolidate the 2004 action with the 2003 action. The court has not yet ruled on the motion. On October 1, 2004, Columbia filed a motion to dismiss the 2004 action, which we have opposed. The motion is currently pending before the court. To date, Columbia has refused to extend its covenant not to sue on the 275 patent to Biogen Idec Inc. The order issued by the court in the 2003 action on November 5, 2004 may affect the pending motion to consolidate the 2004 action with the 2003 action, since that Memorandum and Order will affect the scope of the 2003 action. In the event that we are unsuccessful in the present litigation and Columbia asserts a claim for infringement against Biogen Idec Inc., we may be liable for damages suffered by Columbia with respect to unpaid royalties and such other relief as Columbia may seek and be granted by the Court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, Glaxosmithkline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we provided instructions and/or recommendations on a proper immunization schedule for vaccines to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. Under our 1988 license agreement with Glaxosmithkline, Glaxosmithkline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that Glaxosmithkline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court.

Along with many other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) was named as a defendant in a lawsuit filed by each of the County of

Suffolk, New York, the County of Westchester, New York, and the County of Rockland, New York. All three cases are pending in the U.S. District Court for the District of Massachusetts. The complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs, marketed and promoted the sale of Covered Drugs to providers based on the providers ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs, provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs, and overcharged Medicaid for illegally

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inflated Covered Drugs reimbursements. The complaints further allege that the defendants failed to accurately report the best price on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services. The complaints allege that the defendants excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the best price. Plaintiffs brought claims for violation of the Racketeering Influence and Corrupt Organizations Act (RICO) 18 U.S.C. § 1962(c), violation of the Federal Medicaid Rebate Statute, 42 U.S.C. § 1396v-8, violation of New York Social Services Law § 367(A)(7)(d), violation of New York Department of Health Regulations 18 N.Y.C.R.R. § 515(b)(4) and (5), violation of New York Social Services Law § 145-b, breach of contract for breach of the rebate agreement entered into with the Secretary of Health and Human Services, unfair trade practices under New York State law, common law fraud, and unjust enrichment. In September 2003, Biogen joined other named defendants in filing a Joint Motion to Dismiss the complaints. Biogen also filed separately a motion on its own behalf arguing that the plaintiffs made no specific factual allegations against Biogen to connect it with the alleged scheme. In September 2004, the court, in ruling on defendants' motion to dismiss, allowed the motion, in part, and dismissed the RICO claim, the Medicaid Best Price claim, the breach of contract claim, and the common law fraud claim. The court did not dismiss the claims brought under the New York State Medicaid and Social Services statutes, the unfair trade practices claim, or the claim for unjust enrichment. In October 2004, the court issued a partial decision on Biogen's individual motion to dismiss. The court deferred ruling on Biogen's motion to dismiss the fraud-based claims, pending consideration of supporting documentation to be produced by plaintiffs. The extent to which the plaintiffs are allowed to proceed with these claims against Biogen will be affected by any disclosures they make in response to the court's ruling. The court dismissed all of the state law claims against Biogen based on the alleged failure to report Best Prices. Biogen Idec MA, Inc. intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

In addition, we are involved in certain other legal proceedings generally incidental to our normal business activities. While the outcome of any of these proceedings cannot be accurately predicted, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our business, results of operations, or financial condition.

New Accounting Standards

EITF 03-01, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments, was issued in February 2004. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. The provisions of EITF 03-01 are effective for fiscal years ending after December 15, 2003. We have complied with the disclosure provisions of EITF 03-01. In September 2004, the Financial Accounting Standards Board, or FASB, staff issued two proposed FASB Staff Positions (FSP): Proposed FSP EITF Issue 03-1-a, which provides guidance for the application of paragraph 16 of EITF Issue 03-1 to debt securities that are impaired because of interest rate and/or sector spread increases, and Proposed FSP EITF Issue 03-1-b, which delays the effective date of Issue 03-1 for debt securities that are impaired because of interest rate and/or sector spread increases. We are currently monitoring these developments to assess the potential impact on our financial position and results of operations.

On March 31, 2004, the FASB issued an Exposure Draft, Share-Based Payments, which is a proposed amendment to SFAS No. 123, Accounting for Stock-Based Compensation. The Exposure Draft would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion 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 our financial statements. Throughout most of 2004, the FASB has continued to deliberate on different aspects of a new standard, and currently expects to issue a final standard before December 31, 2004. The new standard, as proposed, would be effective for awards that are granted, modified or settled in cash in interim and annual periods beginning after June 15, 2005. We are monitoring

developments related to the exposure draft and will adopt the final standards, if any, upon issuance.

The FASB has proposed amending SFAS 128 to make it consistent with International Accounting Standard 33, Earnings per Share, and make earning per share, or EPS, computations comparable on a global basis. Under the proposed amendment, the year-to-date EPS computation would be performed independently from the quarterly computations. Additionally, for all contracts that may be settled in either cash or shares of stock, companies must assume that settlement will occur by the issuance of shares for purposes of computing diluted EPS, even if they intend to settle by paying cash or have a history of cash-only settlements, regardless of who controls the means of settlement. Lastly, under the proposed amendment, shares that will be issued upon conversion of a mandatory

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convertible security must be included in the weighted-average number of shares outstanding used in computing basic EPS from the date that conversion becomes mandatory, using the if-converted method, regardless of whether the result is anti-dilutive. The proposed amended standard is expected to be issued during the fourth quarter of 2004 and will be effective for all periods ending after December 15, 2004. Accordingly, the changes to EPS calculations will be effective in 2004 for calendar year-end companies. Retrospective application in all periods presented would be required, and could require the restatement of previously reported EPS. We are evaluating the impact of this proposed amended standard on our financial statements.

CRITICAL ACCOUNTING ESTIMATES

We incorporate by reference the section Management's Discussion and Analysis of Financial Condition and Results of Operation Critical Accounting Estimates of our Annual Report on Form 10-K for the fiscal year ended December 31, 2003. Changes to the policies since December 31, 2003 are included below.

Biogen, Inc. Purchase Price Allocation

The purchase price related to the Merger with Biogen, Inc. was allocated to tangible and identifiable intangible assets acquired and liabilities assumed based on the estimated fair market values as of the acquisition date. An independent third party valuation firm was engaged to assist in determining the fair values of in-process research and development, identifiable intangible assets, inventory and certain property, plant and equipment, and in determining the useful lives of such tangible and identifiable intangible assets acquired. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, determining the product life and term of estimated future cash flows, and developing appropriate costs, expenses, depreciation and amortization assumptions, tax rates, discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. These assumptions are based on the best available information that we had at the time. Additionally, certain estimates for the purchase price allocation including inventory and taxes may change as subsequent information becomes available.

Inventory Capitalization

Inventories are stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. Included in inventories are raw materials used in the production of pre-clinical and clinical products, which are expensed as research and development expenses when consumed. We capitalize inventory costs associated with certain products prior to regulatory approval, based on management's judgment of probable future commercialization. We could be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies.

We write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are future determinations that inventory will not be marketable based on updated estimates for demand, additional inventory write-downs may be required. For the three and nine months ended September 30, 2004, we wrote down \$9.2 million and \$21.0 million, respectively, of unmarketable inventory which was charged to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. For the nine months ended September 30, 2004, total write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written down to net realizable value when it was determined that the inventory did not meet quality specifications. The write-down of ZEVALIN inventory during the three months ended September 30, 2004 resulted from a determination that the inventory did not meet quality specifications. The

remaining write-downs of ZEVALIN inventory resulted from a determination that the inventory will not be marketable based on estimates of demand. For the nine months ended September 30, 2003, we wrote down a total of \$3.1 million of ZEVALIN commercial inventory, which did not meet quality specifications.

Derivatives and hedging activities

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We have operations in Europe, Japan, Australia and Canada in connection with the sale of AVONEX. We also receive royalty revenues based on worldwide product sales by our licensees. As a result, our financial position, results of operations and cash flows can be affected by fluctuations in foreign currency exchange rates (primarily Euro, Swedish krona, British pound, Japanese yen and Canadian dollar).

We use foreign currency forward contracts to manage foreign currency risk and do not engage in currency speculation. We use these forward contracts to hedge certain forecasted transactions denominated in foreign currencies. SFAS 133, Accounting for Derivative Instruments and Hedging Activities, or SFAS 133, requires that all derivatives be recognized on the balance sheet at their fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction. We assess, both at their inception and on an on-going basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings. Under this policy, and in accordance with SFAS 133, earnings may vary if the forecasted transaction does not occur, or if there is material hedge ineffectiveness or if the hedge ceases to be highly effective.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

As of September 30, 2004, management determined that certain clinical trials would be discontinued or would not be initiated which indicated that the carrying value of certain core technology intangible assets might not be recoverable. As a result, in the three months ended September 30, 2004, we recorded a charge of approximately \$27.8 million to amortization of intangible assets, which reflects the adjustment to the valuation of certain core technology intangible assets related to AMEVIVE to its net realizable value.

Contingencies and Litigation

There has been, and we expect there may be significant litigation in the industry regarding commercial practices, regulatory issues, pricing, and patents and other intellectual property rights. Certain adverse unfavorable rulings or decisions in the future, including in the litigation described under Legal Matters, could create variability or have a material adverse effect on our future results of operations and financial position.

CONTROLS AND PROCEDURES

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of

1934, as amended (the Exchange Act), as of the end of the fiscal quarter covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures,

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our 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 our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

We are evaluating the effectiveness of our internal controls over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004, and to include a management report assessing the effectiveness of our internal controls over financial reporting in all annual reports beginning with our Annual Report on Form 10-K for the fiscal year ending on December 31, 2004. In evaluating our internal controls over financial reporting, we have identified a number of changes that need to be made to our internal controls, primarily related to better documentation of internal controls, and related changes to information systems used in financial reporting. We continued to make these changes during the third quarter of 2004. The changes during the third quarter of 2004 did not, individually or in the aggregate, have a material effect on our internal controls over financial reporting.

Use of Non-GAAP Financial Measures

We use pro forma financial measures in the Cost of Sales, Research and Development Expenses, and Selling, General and Administrative Expenses. In Cost of Sales, we use a pro forma gross margin of product sales measures, and in Research and Development Expenses and Selling, General and Administrative Expenses, we use total expenses measures that exclude expenses contributed by former Biogen, Inc. These are non-GAAP financial measures. The most directly comparable GAAP financial measures as well as the reconciliation between the non-GAAP financial measures and the GAAP financial measures are presented in the discussion of the non-GAAP financial measures. Management believes that these non-GAAP financial measures provide useful information to investors. In particular, management believes that these non-GAAP financial measures allow investors to monitor and evaluate our ongoing operating results and trends and gain a better understanding of our past performance as well as period-to-period performance.

Forward-Looking Information and Risk Factors That May Affect Future Results

The SEC encourages public companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. Reference is made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses and profits, anticipated regulatory filings and product launches, the anticipated outcome of pending or anticipated litigation and patent-related proceedings, facility expansion, the completion and approval of manufacturing facilities, the value of investments in certain marketable securities, and our effective tax rate. These and all other forward-looking statements are made based on our current belief as to the outcome and timing of such future events. Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Although we believe that the risks described below represent all material risks currently applicable to our business, additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

Our Revenues Rely Significantly on a Limited Number of Products

Our current and future revenues depend substantially upon continued sales of our commercial products. Revenues related to sales of two of our products, AVONEX and RITUXAN, represented approximately 93% of our total revenues in the third quarter of 2004. We cannot assure you that these products will continue to be accepted in the U.S. or in any foreign markets or that sales of either of these products will not decline in the future. A number of factors may affect the rate and level of market acceptance of these products, including:

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the perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;

patient and physician satisfaction with these products;

the effectiveness of our sales and marketing efforts and those of our marketing partners and licensees in the U.S., the EU and other foreign markets;

the size of the markets for these products;

unfavorable publicity concerning these products or similar drugs;

the introduction, availability and acceptance of competing treatments, with respect to AVONEX, ANTEGREN and other therapies that we may bring to the market in the future;

the availability and level of third-party reimbursement;

the success of ongoing development work on these products;

new data and adverse event information relating to any of these products;

the continued accessibility of third parties to vial, label, and distribute these products on acceptable terms;

the unfavorable outcome of patent litigation related to any of these products;

the ability to manufacture commercial lots of products successfully and on a timely basis; and

regulatory developments related to the manufacture or continued use of these products.

Given our current reliance on these products as the principal sources of our revenue, any material adverse developments with respect to the commercialization of either of these products may cause our revenue to grow at a slower than expected rate, or even decrease, in the future.

Our Long-Term Success Depends Upon the Successful Development and Commercialization of ANTEGREN and Other Products from Our Research and Development Activities and Collaborations, and Increased Acceptance of ZEVALIN and AMEVIVE

Our long-term viability and growth will depend upon the successful development and commercialization of ANTEGREN and other products from our research and development activities and collaborations, and, to a lesser extent, increased acceptance of ZEVALIN and AMEVIVE. We continue to expand our development and commercialization efforts related to ANTEGREN and our development efforts related to other potential products in our pipeline. We also continue to aggressively market ZEVALIN and AMEVIVE. The expansion of our pipeline may include increases in spending on internal projects, the acquisition of third-party technologies or products or other types of investments. Product development and commercialization involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Many important factors affect our ability to successfully develop and commercialize other products, including the ability to:

obtain and maintain necessary patents and licenses;

demonstrate safety and efficacy of drug candidates at each stage of the clinical trial process;

enroll patients in our clinical trials and to complete clinical trials;

overcome technical hurdles that may arise;

successful manufacture of products in sufficient quantities to meet demand;

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meet applicable regulatory standards;

obtain reimbursement coverage for the products;

receive required regulatory approvals;

produce drug candidates in commercial quantities at reasonable costs; and

compete successfully against other products and to market products successfully.

Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

We have submitted applications for approval of ANTEGREN in the U.S. and EU as a treatment for MS. The FDA has designated ANTEGREN for Priority Review and Accelerated Approval as a treatment for MS. In September 2004, we also submitted an application for approval of ANTEGREN in the EU as a treatment for Crohn's disease. Our efforts to achieve the approvals necessary to launch ANTEGREN could be hindered if unexpected new data arises or if we encounter difficulties in our discussions with the FDA or other regulatory authorities, or if other hurdles arise.

Competition in Our Industry and in the Markets for Our Products is Intensely Competitive

The biotechnology industry is intensely competitive. We compete in the marketing and sale of our products, the development of new products and processes, in the acquisition of rights to new products with commercial potential and in the hiring of personnel. We compete with biotechnology and pharmaceutical companies that have a greater number of products on the market, have greater financial and other resources and have other technological or competitive advantages. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business; will benefit from significantly greater sales and marketing capabilities; or will not develop products that are accepted more widely than ours.

AVONEX competes in the U.S. and EU markets primarily with three products: BETASERON®, sold by Berlex in the U.S. and sold under the name BETAFERON® by Schering A.G. in the EU; REBIF®, which is co-promoted by Serono, Inc. and Pfizer Inc. in the U.S. and sold by Serono AG in the EU; and COPAXONE® glatiramer acetate, sold by Teva Neuroscience, Inc. in the U.S. and co-promoted by Teva and Aventis Pharma in the EU. A number of companies, including us, are working to develop products to treat MS that may in the future compete with AVONEX. We have submitted applications for approval of ANTEGREN in the U.S. and EU as a treatment for MS. The FDA has designated ANTEGREN for Priority Review and Accelerated Approval as a treatment for MS in June 2004 and formally accepted the application for approval in July 2004. AVONEX also faces competition from off-label uses of drugs approved for other indications. Some of our current competitors are also working to develop alternative formulations for delivery of their products, which may in the future compete with AVONEX.

RITUXAN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low-grade or follicular, CD20+ B-cell NHLs. Marketing exclusivity resulting from this Orphan Drug designation expires in November 2004. ZEVALIN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with RITUXAN refractory follicular NHL. Marketing exclusivity resulting from this Orphan Drug designation expires in February 2009. RITUXAN is typically used after patients fail to respond or relapse after treatment with traditional

radiation therapy or standard chemotherapy regimes, such as CVP and CHOP. ZEVALIN is typically used after patients fail to respond or relapse following treatment with RITUXAN. ZEVALIN competes with BEXXAR® (tositumomab, iodine I-131 tositumomab), a radiolabeled molecule developed by Corixa and Glaxo. BEXXAR received FDA approval in June 2003 to treat patients with CD20+, follicular, NHL, with and without transformation, whose disease is refractory to RITUXAN and has relapsed following chemotherapy. A number of other companies,

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including us, are working to develop products to treat B-cell NHLs and other forms of non-Hodgkin's lymphoma that may ultimately compete with RITUXAN and ZEVALIN.

AMEVIVE competes with several different types of therapies including:

traditional therapies for moderate-to-severe chronic plaque psoriasis, such as oral retinoids, steroids, methotrexate, cyclosporin, PUVA and UVB radiation.

RAPTIVA® (efalizumab), a drug co-developed by Genentech and Xoma Corporation that was approved by the FDA to treat moderate-to-severe psoriasis. Serono has an exclusive license to RAPTIVA in the EU and other countries.

ENBREL® (etanercept), a drug sold by Amgen, Inc. and Wyeth Pharmaceuticals, Inc. that was approved by the FDA to treat moderate-to-severe psoriasis in April 2004.

drugs approved for other indications that are used to treat psoriasis. Among these drugs are REMICADE® (infliximab) and HUMIRA® (adalimumab). REMICADE, which is sold worldwide by Centocor, Inc., a subsidiary of Johnson & Johnson, as a treatment for other indications, including rheumatoid arthritis, is currently in clinical studies as a potential treatment for psoriasis. HUMIRA, which is sold by Abbott Laboratories, or Abbott, is approved to treat rheumatoid arthritis. Abbott is undertaking clinical trials in psoriasis and psoriatic arthritis.

In addition, a number of other companies, including us, are working to develop products to treat psoriasis that may ultimately compete with AMEVIVE.

We are Subject to Risks Related to the Products that We Manufacture

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX, AMEVIVE, ANTEGREN and the ZEVALIN bulk antibody. Our inability to successfully manufacture bulk product and to maintain regulatory approvals of our manufacturing facilities would harm our ability to timely produce sufficient quantities of commercial supplies of AVONEX, AMEVIVE, ANTEGREN and ZEVALIN to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products, recall products previously shipped or could impair our ability to supply products at all. In the past, we have had to write down and incur other charges and expenses for products that failed to meet specifications. Similar charges may occur in the future. In addition, any prolonged interruption in the operations of our manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. Because our manufacturing processes are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. To the extent we cannot produce our own biologics, we will need to rely on third-party manufacturers, of which there are only a limited number capable of manufacturing biologics products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time.

We Rely to a Large Extent on Third Parties in the Manufacturing of Our Products

We rely on Genentech for all RITUXAN manufacturing. Genentech relies on a third party to manufacture certain bulk RITUXAN requirements. If Genentech or any third party upon which it relies does not manufacture or fill/finish RITUXAN in sufficient quantities and on a timely and cost-effective basis or if Genentech or any third party does not obtain and maintain all required manufacturing approvals, our business could be harmed. We also rely heavily upon third-party manufacturers and suppliers to manufacture and supply significant portions of the product components of

ZEVALIN other than the bulk antibody, including chelates necessary for the ZEVALIN therapeutic regimen and the radioisotope yttrium-90 and the indium-111 isotope used with the therapeutic and imaging kits of ZEVALIN, respectively. The radioisotope yttrium-90 is only available from a limited number of suppliers. We made MDS (Canada) our exclusive supplier of the radioisotope yttrium-90 used with ZEVALIN. MDS (Canada) is the only manufacturer of the radioisotope yttrium-90 used with ZEVALIN approved by the FDA. If we were to lose the services of MDS (Canada) or our third party manufacturers of chelates, we would be forced to

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find other third party providers, which could delay our ability to manufacture and sell ZEVALIN. In addition, radiopharmacies independently purchase the indium-111 isotope required for the imaging use of ZEVALIN. Currently, only two suppliers are approved by the FDA to supply the indium-111 isotope. Our inability to find replacement suppliers for materials used in our marketed products and our primary product candidates that are available only from a single supplier or a limited number of suppliers could significantly impair our ability to sell our commercial products.

We also source all of our fill-finish and final product storage operations, along with a substantial portion of our packaging operations of the components used with our products, to a concentrated group of third party contractors. The manufacture of products and product components, fill-finish, packaging and storage of our products require successful coordination among ourselves and multiple third-party providers. Our inability to coordinate these efforts, the lack of capacity available at the third party contractor or any other problems with the operations of these third party contractors could require us to delay shipment of saleable products, recall products previously shipped or could impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation. Any third party we use to fill-finish, package or store our products to be sold in the U.S. must be licensed by the FDA. As a result, alternative third party providers may not be readily available on a timely basis.

The Manufacture of Our Products is Subject to Government Regulation

We and our third party providers are generally required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm this compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and ultimate amendment acceptance by the FDA prior to release of product to the market place. Our inability or the inability of our third party service providers to demonstrate ongoing cGMP compliance could require us to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our commercial products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to sell our commercial products. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

Royalty Revenues Contribute to Our Overall Profitability and Are Not Within Our Control

Royalty revenues contribute to our overall profitability. Royalty revenues may fluctuate as a result of disputes with licensees, collaborators and partners, future patent expirations and other factors such as pricing reforms, health care reform initiatives, other legal and regulatory developments and the introduction of competitive products that may have an impact on product sales by our licensees and partners. In addition, sales levels of products sold by our licensees, collaborators and partners may fluctuate from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs. Since we are not involved in the development or sale of products by our licensees, collaborators and partners, we cannot be certain of the timing or potential impact of factors which may affect their sales. In addition, the obligation of licensees to pay us royalties generally terminates upon expiration of the related patents. For a further discussion of future patent expirations affecting certain royalty revenues, see Business Principal Licensed Products and Business Patents and Other Proprietary Rights sections of Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

Our Operating Results Are Subject to Significant Fluctuations

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, including:

demand and pricing for our products;

physician and patient acceptance of our products;

amount and timing of sales orders for our products;

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our achievement of product development objectives and milestones;

research and development and manufacturing expenses;

clinical trial enrollment and expenses;

our manufacturing performance and capacity and that of our partners;

percentage of time that our manufacturing facilities are utilized for commercial versus clinical manufacturing;

rate and success of product approvals;

costs related to obtain product approvals and launching new products;

timing of regulatory approval, if any, of competitive products and the rate of market penetration of competing products;

expenses related to protecting our intellectual property;

expenses related to litigation and settlement of litigation;

payments made to acquire new products or technology;

write-downs and write offs of inventories;

government or private healthcare reimbursement policies;

collaboration obligations and copromotion payments we make or receive;

timing and nature of contract manufacturing and contract research and development payments and receipts;

interest rate fluctuations;

foreign currency exchange rates; and

overall economic conditions.

Our operating results during any one quarter do not necessarily suggest the anticipated results of future quarters.

Our Sales Depend on Payment and Reimbursement from Third-Party Payors, and a Reduction in Payment Rate or Reimbursement Could Result in Decreased Use or Sales 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 U.S., and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the U.S., there have been, there are, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. The Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA, was signed into law in December 2003. We are not able to predict the full impact of the MMA and its regulatory requirements on our business. However, we believe that legislation that

reduces reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions in response to such legislation. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, we believe the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further,

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when a new therapeutic product is approved, the availability of governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. 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.

The MMA also added a prescription drug reimbursement beginning in 2006 for all Medicare beneficiaries. In the meantime, a temporary drug discount card program is being established for Medicare beneficiaries. The federal government, through its purchasing power under these programs, is likely to demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, Managed Care Organizations, or MCOs, Health Maintenance Organizations, or HMOs, Preferred Provider Organizations, or PPOs, institutions and other government agencies continue to seek price discounts. MCOs, HMOs and PPOs and private health plans will administer the Medicare drug benefit, leading to managed care and private health plans influencing prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for their seniors and low income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other 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.

On November 7, 2003, CMS released a Hospital Outpatient Prospective Payment System, or HOPPS, final rule that included new payment rates for all outpatient services effective January 1, 2004. Prior to January 1, 2004, Congress revised the statutory provisions governing payment for drugs and biologicals, including RITUXAN and ZEVALIN, under HOPPS. CMS implemented the statutory changes in a rule issued on January 6, 2004, and the 2004 payment rates for RITUXAN and ZEVALIN were announced in that rule. Although most patients do not receive RITUXAN in the outpatient setting and so the majority of RITUXAN patients will not be affected, these new rules could cause hospitals to decide not to provide RITUXAN under certain circumstances. ZEVALIN, in contrast to RITUXAN, is used primarily in the outpatient setting and we are uncertain as to whether hospitals will view the new rules favorably and therefore choose to prescribe ZEVALIN to their patients.

We encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored health care system. This international patchwork of price regulation may lead to inconsistent prices and some third-party trade in our products from markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices.

We May Be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents

We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, including a number of our processes and products. Patents have been issued on many of these applications. We have also obtained rights to various patents and patent applications under licenses with third parties, which provide for the payment of royalties by us. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent

offices, courts and lawmakers in these countries. There is no certainty that our existing patents or others, if obtained, will afford us substantial protection or commercial benefit. Similarly, there is no assurance that our pending patent applications or patent applications licensed from third parties will ultimately be granted as patents or that those patents that have been issued or are issued in the future will prevail if they are challenged in court.

A substantial number of patents have already been issued to other biotechnology and biopharmaceutical companies. Competitors may have filed applications for, or have been issued patents and may obtain additional

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patents and proprietary rights that may relate to products or processes competitive with or similar to our products and processes. Moreover, the patent laws of the U.S. and foreign countries are distinct and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries. In general, we obtain licenses to third party patents, which we deem necessary or desirable for the manufacture, use and sale of our products. We are currently unable to assess the extent to which we may wish or be required to acquire rights under such patents and the availability and cost of acquiring such rights, or whether a license to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder our ability to market our products.

We are aware that others, including various universities and companies working in the biotechnology field, have filed patent applications and have been granted patents in the U.S. and in other countries claiming subject matter potentially useful to our business. Some of those patents and patent applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry. There is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world, and, to date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products

There has been, and we expect that there may continue to be significant litigation in the industry regarding patents and other intellectual property rights. Litigation, including our current patent litigation with Columbia University, and other proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to management. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or noninfringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights, or, conversely, hinder our ability to market our products. See **Forward Looking Information and Risk Factors that May Affect Future Results** **Failure to Comply with Government Regulations or Prevail in Litigation Could Harm Our Business** ; see also the section entitled **Legal Matters** elsewhere in **Managements Discussion and Analysis of Financial Condition and Results of Operations** for a description of litigation regarding our patents and other proprietary rights.

Failure to Comply with Government Regulations or Prevail in Litigation Could Harm Our Business

Pharmaceutical companies have been the target of lawsuits and investigations including: those with claims asserting antitrust violations, claims asserting violations of the Federal False Claim Act, Anti-Kickback Act, the Prescription Drug Marketing Act or other violations in connection with Medicare and/or Medicaid reimbursement, derivative actions, product liability claims, disputes over intellectual property rights (including patents), and claims under state laws, including state anti-kickback and fraud laws. Public companies may also be the subject of certain other types of claims, including those asserting violations of securities laws or related to environmental matters. If lawsuits, investigations or claims of this type are brought against us and we are not successful in defending ourselves or asserting our rights, our business could be harmed. For example, we may not be successful in defending ourselves or asserting our rights in our current Average Wholesale Price litigation in the U.S. District Court for the District of Massachusetts, and our current patent litigation with Columbia University and Classen Immunotherapies. See the section entitled **Litigation** in **Notes to Condensed Consolidated Financial Statements** in Part I of this Quarterly Report

on Form 10-Q for a description of litigation regarding our patents and other proprietary rights.

Our business is also subject to extensive government regulation and oversight. We may also become subject to other governmental actions which could adversely affect our business or financial condition, including:

new laws, regulations and judicial decisions related to health care availability, method of delivery and payment for health care products and services;

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changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

new laws, regulations and judicial decisions affecting pricing or marketing; and

changes in the tax laws relating to our operations.

Our Business Involves Environmental Risks

Our business and the business of several of our strategic partners, including Genentech, involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Biologics manufacturing is extremely susceptible to product loss due to microbial or viral contamination, material equipment failure, or vendor or operator error. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, microbial or viral contamination may cause the closure of a manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently store radioactive materials from our California operation on-site because the approval of a disposal site in California for all California-based companies has been delayed indefinitely. If and when a disposal site is approved, we may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could harm our business.

We Rely Upon Key Personnel

Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers and key scientific personnel. If we lose the services of any of these individuals, our business could be harmed. We currently have employment agreements with William H. Rastetter, Ph.D, our Executive Chairman, and James C. Mullen, our Chief Executive Officer and President. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales and manufacturing personnel and our ability to develop and maintain relationships with qualified clinical researchers. Competition to obtain the services of these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We may not be able to continue to attract and retain qualified personnel or develop and maintain relationships with clinical researchers.

Future Transactions May Harm Our Business or the Market Price of Our Stock

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

mergers;

acquisitions;

strategic alliances;

licensing agreements; and

copromotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations to the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also harm the market price of our common stock.

Volatility of Our Stock Price

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The market prices for our common stock and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, the market price of our common stock fluctuated between \$53.06 per share and \$63.50 per share during the quarter ended September 30, 2004. The market price of our common stock likely will continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the announcement and timing of new product introductions by us or others;
- events related to our commercial products or those of our competitors;
- technical innovations or product development by us or our competitors;
- regulatory approvals or regulatory issues;
- availability and level of third-party reimbursement;
- developments relating to patents, proprietary rights and orphan drug status;
- results of late-stage clinical trials with respect to our products under development or those of our competitors;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic and other external factors, disaster or crisis;
- hedge and/or arbitrage activities by holders of our convertible promissory notes;
- period-to-period fluctuations in our financial results or results which do not meet or exceed analyst expectations;
- and
- market trends relating to or affecting stock prices throughout our industry, whether or not related to results or news regarding us or our competitors.

Our Outstanding Convertible Promissory Notes Leverage Us Considerably

As a result of issuing our subordinated notes due 2019 in February 1999 and issuing our senior notes due 2032 in April and May 2002, we incurred indebtedness of approximately \$345.0 million at maturity in 2019 and approximately \$1.2 billion at maturity in 2032. As of September 30, 2004, our remaining indebtedness under the subordinated notes was approximately \$219.2 million at maturity, due to conversion of subordinated notes into common stock in accordance with the conversion features of the notes. Holders of the subordinated notes may require us to purchase all or a portion of the notes on February 16, 2009 and 2014 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, common stock or a combination of cash and stock. Holders of the senior notes may require us to purchase all or a portion of the notes on April 29, 2005, 2007, 2012 and 2017 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, payable at our option in cash, common stock or a combination of cash and stock. The degree to which we are leveraged could harm our ability to obtain future financing and could make us more vulnerable to industry downturns and competitive pressures. Our ability to meet our debt obligations will be dependent upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

We Have Adopted Several Anti-takeover Measures As Well As Other Measures to Protect Certain Members of Our Management Which May Discourage or Prevent a Third Party From Acquiring Us

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A number of factors pertaining to our corporate governance discourage a takeover attempt that might be viewed as beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. For example:

we are subject to Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;

our stockholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors;

our board of directors has the authority to issue, without vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of common stock;

our collaboration agreement with Genentech provides Genentech with the option to buy the rights to RITUXAN and retain control of any additional anti-CD20 products developed under the collaboration in the event that we undergo a change of control, which may limit our attractiveness to potential acquirors;

our collaboration agreement with Elan Corporation, or Elan, provides Elan with the option to buy the rights to ANTEGREN in the event that we undergo a change of control, which may limit our attractiveness to potential acquirors;

under the terms of our convertible promissory notes any acquiror would be required to repurchase the notes for cash in connection with an acquisition of us before 2007;

our directors are elected to staggered terms, which prevents the entire board from being replaced in any single year; and

our bylaws provide that, until November 12, 2006, the affirmative vote of at least 80% of our board of directors (excluding directors who are serving as an officer or employee) will be required to remove William H. Rastetter, Ph.D. from his position as our Executive Chairman and to remove James C. Mullen as our Chief Executive Officer and President.

Part II OTHER INFORMATION

Item 1. Legal Proceedings.

The section entitled "Litigation" in "Notes to Condensed Consolidated Financial Statements" in Part I of this Quarterly Report on Form 10-Q is incorporated into this item by reference.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

A summary of our stock repurchase activity for the three months ended September 30, 2004 is set forth in the table below :

Issuer Purchases of Equity Securities

Period	Total number of shares purchased (#)(a)	Average price paid per share (\$)	Total number of shares purchased as part of publicly announced program (#)(a)	Number of shares that may yet be purchased under our programs (#)
July 1, 2004 July 31, 2004	132	58.06		6,133,634
August 1, 2004 August 31, 2004	6,139,734	57.81	6,133,634	
September 1, 2004 September 30, 2004	4,967	62.08		
Total	6,144,833(b)	57.81	6,133,634	20,000,000(c)

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- (a) Our Board of Directors authorized the repurchase of up to 12 million shares of common stock in February 2004. All of the shares have been repurchased under the program. This repurchase program was originally set to expire no later than February 6, 2006. We publicly announced the repurchase program in our press release dated March 2, 2004 which was furnished (and not filed) to the SEC as Exhibit 99.1 of our Current Report on Form 8-K filed on March 4, 2004.
- (b) 6,133,634 of these shares were repurchased as part our publicly announced repurchase program. The remaining shares are shares that were used by certain employees to pay the exercise price of their stock options in lieu of paying cash or utilizing our cashless option exercise program.
- (c) Our Board of Directors authorized the repurchase of up to 20 million shares of common stock in October 2004. This repurchase program will expire no later than October 4, 2006. No shares have been repurchased under this program. We publicly announced the repurchase program in our press release dated October 27, 2004 which was furnished (and not filed) to the SEC as Exhibit 99.1 of our Current Report of Form 8-K filed on October 27, 2004.

Item 6. Exhibits and Reports on Form 8-K

- (a) Exhibits
 - 10.1 Lease agreement between Biogen Idec BV, a wholly-owned subsidiary of the registrant, and TUG Vastgoed B.V., dated as of September 24, 2004 (incorporated by reference from an exhibit filed with our Current Report on Form 8-K filed on September 29, 2004).
 - 31.1 Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2 Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 32.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (b) Reports on Form 8-K
 - (i) On July 23, 2004, we filed a Current Report on Form 8-K (old Item 5) announcing that Michael Gilman, our Executive Vice President, Research, entered into a Rule 10b5-1 Sales Plan.
 - (ii) On July 28, 2004, we filed a Current Report on Form 8-K to furnish a press release under Item 12 of Form 8-K that included non-GAAP financial measures for completed fiscal periods.
 - (iii) On September 22, 2004, we filed a Current Report on Form 8-K (Item 8.01) announcing that Mark Wiggins, our Executive Vice President, Business Development, and William C. Rohn, Chief Operating Officer, entered into Rule 10b5-1 Sales Plans.
 - (iv) On September 29, 2004, we filed a Current Report on Form 8-K (Item 1.01) announcing that Biogen Idec BV, one of our wholly-owned subsidiaries, entered into a lease agreement with TUG Vastgoed B.V.

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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.

BIOGEN IDEC INC.

November 5, 2004

/s/ Peter N. Kellogg
Peter N. Kellogg
Executive Vice President, Finance and
Chief Financial Officer