

**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 March 31, 2003**

**Commission File Number 0-12042**

**BIAGEN, INC.**

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(Exact name of registrant as specified in its charter)

**Massachusetts**

**04-3002117**

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(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

**14 Cambridge Center, Cambridge, MA 02142**  
**(617) 679-2000**

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(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, \$0.01 par value, outstanding as of April 1, 2003 was 148,457,921 shares.

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Note concerning trademarks: AVONEX® and AMEVIVE® are registered trademarks of Biogen, Inc.	

**BOGEN, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**  
(unaudited)  
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2003	2002
<b>REVENUES:</b>		
Product	\$278,177	\$265,985
Royalties	41,373	22,358
Contract	1,149	—
Total revenues	320,699	288,343
<b>COSTS AND EXPENSES:</b>		
Cost of product revenues	43,853	37,895
Cost of royalty revenues	2,413	1,423
Research and development	85,106	82,467
Selling, general and administrative	95,423	73,390
Total costs and expenses	226,795	195,175
Income from operations	93,904	93,168
Other income (expense), net	(5,664)	7,028
<b>INCOME BEFORE INCOME TAXES</b>	<b>88,240</b>	<b>100,196</b>
Income taxes	24,707	28,055
<b>NET INCOME</b>	<b>\$ 63,533</b>	<b>\$ 72,141</b>
<b>BASIC EARNINGS PER SHARE</b>	<b>\$ 0.42</b>	<b>\$ 0.49</b>
<b>DILUTED EARNINGS PER SHARE</b>	<b>\$ 0.42</b>	<b>\$ 0.47</b>
<b>SHARES USED IN COMPUTING:</b>		
Basic earnings per share	149,611	148,660
Diluted earnings per share	151,494	152,202

See Notes to Condensed Consolidated Financial Statements.

**BIOGEN, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	March 31, 2003	December 31, 2002
	(unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 36,260	\$ 45,113
Marketable securities	776,121	821,996
Accounts receivable, net	177,966	171,067
Deferred tax assets	38,185	38,592
Inventory	93,708	95,378
Other current assets	58,236	43,878
	<u>1,180,476</u>	<u>1,216,024</u>
Property, plant and equipment		
Cost	979,309	953,805
Less accumulated depreciation	230,126	215,746
	<u>749,183</u>	<u>738,059</u>
Patents, net	16,359	15,994
Other assets	29,871	36,911
	<u>\$1,975,889</u>	<u>\$2,006,988</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 42,317	\$ 64,876
Current portion of long-term debt	4,888	4,888
Current taxes payable	88,770	73,824
Accrued expenses and other	135,035	182,745
	<u>271,010</u>	<u>326,333</u>
Long-term debt, less current portion	36,605	37,410
Long-term deferred tax liabilities	33,673	33,678
Other long-term liabilities	15,922	14,146
Commitments and contingencies	—	—
Shareholders' equity		
Common stock	1,517	1,517
Additional paid-in capital	831,479	829,993
Treasury stock, at cost	(123,484)	(90,844)
Retained earnings	892,458	838,756
Accumulated other comprehensive income	16,709	15,999
	<u>1,618,679</u>	<u>1,595,421</u>
	<u>\$1,975,889</u>	<u>\$2,006,988</u>

See Notes to Condensed Consolidated Financial Statements.

**BIOGEN, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited)  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 63,533	\$ 72,141
Adjustments to reconcile net income to net cash provided from operating activities:		
Depreciation and amortization	14,644	10,446
Tax benefit of stock options	1,486	8,395
Other	—	(148)
Realized loss on sale of non-current marketable securities	—	301
Impairment of non-current investments or marketable securities	3,079	2,182
Writedown of inventory to net realizable value	3,384	—
Changes in:		
Accounts receivable	(5,727)	4,585
Inventory	(1,714)	(9,760)
Other current and other assets	(16,441)	(6,398)
Accounts payable, accrued expenses, current taxes payable and other current and long-term liabilities	(55,073)	(20,377)
Net cash flows from operating activities	7,171	61,367
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of current marketable securities	(76,769)	(73,638)
Proceeds from sales and maturities of current marketable securities	121,366	99,932
Proceeds from sales of non-current marketable securities	—	493
Proceeds from withdrawal from an equity fund	7,217	—
Acquisitions of property and equipment, net	(23,560)	(47,962)
Additions to patents	(786)	(980)
Net cash flows from investing activities	27,468	(22,155)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayments on long-term debt	(805)	(805)
Purchases of treasury stock	(45,785)	(8,384)
Issuance of treasury stock related to stock option exercises	3,320	10,538
Other	56	(159)
Net cash flows from financing activities	(43,214)	1,190
Effect of exchange rate changes on cash	(278)	75
<b>NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(8,853)</b>	<b>40,477</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>45,113</b>	<b>54,042</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 36,260</b>	<b>\$ 94,519</b>

See Notes to Condensed Consolidated Financial Statements.

**BIOGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

**1. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES**

Biogen, Inc. (“Biogen” or the “Company”) is a global biopharmaceutical company that develops, manufactures and markets novel human therapeutic products. Biogen’s primary focus is developing pharmaceutical products that meet unmet medical needs particularly in its core therapeutic areas of neurology, dermatology and rheumatology. Biogen currently sells AVONEX® (Interferon beta-1a) for the treatment of relapsing multiple sclerosis (“MS”) and, commencing in 2003, AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. Biogen also receives revenues from royalties on sales by our licensees of a number of products covered under patents that Biogen controls and from contract revenues related to a collaborative agreement.

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 the financial position, results of operations and cash flows of Biogen and its subsidiaries. The Company’s accounting policies are described in the Notes to the Consolidated Financial Statements in the Company’s 2002 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.

The preparation of 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.

**INVENTORIES**

Inventories are stated at the lower of cost or market with cost determined under the first-in/first-out (“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. The components of inventories are as follows:

(in thousands)	March 31, 2003	December 31, 2002
Raw materials	\$28,417	\$27,027
Work in process	24,746	25,892
Finished goods	40,545	42,459
	<u>\$93,708</u>	<u>\$95,378</u>

Biogen capitalizes inventory costs associated with certain products prior to regulatory approval, based on management’s judgment of probable future commercialization. Biogen 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 March 31, 2003 and December 31, 2002, capitalized inventory related to pre-filled syringe formulation of AVONEX, which has not yet received regulatory approval, was \$9 million and \$3.7 million, respectively.

Biogen writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by Biogen, additional inventory write-downs may be required. The Company wrote down \$3.4 million of unmarketable inventory for the three months ended March 31, 2003, all of which was charged to cost of revenues.

**REVENUE RECOGNITION AND ACCOUNTS RECEIVABLE**

SEC Staff Accounting Bulletin No. 101 (“SAB 101”) provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB 101 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. Further, SAB 101 requires that both title and the risks

and rewards of ownership be transferred to the buyer before revenue can be recognized. The Company believes that its revenue recognition policies are in compliance with SAB 101.

Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer. When customers have inspection and approval rights for products, Biogen defers revenue until lapse of that right. Revenues are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company prepares its estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

In January 2003, Biogen received regulatory approval to market AMEVIVE in the U.S. There is a limited launch period initiative undertaken in cooperation with one of Biogen's distributors which provides a refund on purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the insurance claim after appeal and where the other requirements of the initiative are met. Under this initiative, Biogen's exposure is contractually limited to 10% of all AMEVIVE purchased by the distributor. As a result, Biogen will defer recognition of revenue of 10% of product purchased by the distributor until such time as evidence of insurance claims reimbursement for AMEVIVE becomes available.

In February 2002, the FASB Emerging Issues Task Force ("EITF") released EITF Issue No. 01-09 ("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. The Company has various contracts with distributors that provide for discounts and rebates. These contracts are classified as a reduction of revenue. The Company also maintains select customer service contracts with distributors and other customers in the distribution channel. In accordance with EITF 01-09, the Company has established the fair value of these contracts and, as provided by EITF 01-09, classified these customer service contracts as sales and marketing expense. If the Company should not be able to sustain the fair value of these contracts, the Company would be required to classify these costs as a reduction of revenue. The adoption of EITF 01-09 did not have a significant impact on the Company's financial statements.

The Company receives royalty revenues under license agreements with a number of third parties that sell products based on technology developed by the Company or to which the Company has rights. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records 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 paid to the Company (adjusted for any changes in facts and circumstances, as appropriate). The Company maintains regular communication with its licensees in order to gauge the reasonableness of its 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 the part of the Company under these license agreements.

Revenue is not recognized in any circumstances unless collectibility is reasonably assured.

Biogen maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of Biogen's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which could affect future earnings.

In January 2003, the Company signed a collaboration agreement (the "IDEC Agreement") with IDEC Pharmaceuticals Corporation ("IDEC"), under which Biogen and IDEC will collaborate on the development of three oncology therapeutics from Biogen's pipeline of early-stage product candidates. Under the terms of the IDEC Agreement, IDEC initially will be responsible for the development costs of the product candidates, until that time, if any, when the Company exercises its opt-in rights (which must be done within a certain timeframe) with respect to each specific product candidate. Prior to exercising its opt-in rights, to the extent that the Company incurs any development costs in relation to the programs contained in the IDEC Agreement, they will be recorded as research and development expenses. The reimbursement by IDEC of these costs will be recorded as contract revenue. For the first three months of 2003, the Company recorded \$1.1 million for contract revenues.

## ACCOUNTING FOR STOCK BASED COMPENSATION

The Company has several stock-based compensation plans. The Company applies APB Opinion No. 25 “Accounting for Stock Issued to Employees” in accounting for qualifying options granted to its employees under its plans and applies Statement of Financial Accounting Standards No. 123 “Accounting for Stock Issued to Employees” (“SFAS 123”) 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 issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.

If compensation for employee options had been determined based on SFAS 123, the Company’s pro forma net income, and pro forma earnings per share for the three months ending March 31, would have been as follows:

(in thousands, except per share data)	2003	2002
Reported net income	\$63,533	\$72,141
Pro forma stock compensation expense, net of tax	10,562	11,323
Pro forma net income	\$52,971	\$60,818
Reported basic earnings per share	\$ 0.42	\$ 0.49
Pro forma basic earnings per share	\$ 0.35	\$ 0.41
Reported diluted earnings per share	\$ 0.42	\$ 0.47
Pro forma diluted earnings per share	\$ 0.35	\$ 0.40

The fair value of options granted was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	2003	2002
Expected dividend yield	0%	0%
Expected stock price volatility	45%	44%
Risk-free interest rate	5.75%	5.75%
Expected option term in years	7.4	7.4

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.

## 2. FINANCIAL INSTRUMENTS

Statement of Financial Accounting Standards No. 133, “Accounting for Derivative Instruments and Hedging Activities”, (“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. The Company assesses, both at its 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. The Company assesses hedge ineffectiveness on a quarterly basis and records the gain or loss related to the ineffective portion to current earnings to the extent significant. If the Company determines that a hedged forecasted transaction is no longer probable of occurring, the Company discontinues hedge accounting for the affected portion of the hedge instrument, and any unrealized gain or loss on the contract is recognized in current earnings within other income (expense).

As of March 31, 2003, the Company had \$12.5 million outstanding under a floating rate loan collateralized by one of the Company’s laboratory and office buildings in Cambridge, Massachusetts and \$29 million outstanding under a floating rate loan agreement for financing the construction of its biological manufacturing facility in North Carolina. The Company uses interest rate swap agreements to mitigate the risk associated with its floating rate debt. The fair value of the interest rate swap agreements, representing the cash requirements of the Company to settle the agreements, was approximately \$5.0 million and \$5.1 million at March 31, 2003 and December 31, 2002, respectively, and was included in “accrued expenses and other.” The Company has designated the interest rate swaps as cash flow hedges. There were no amounts of hedge ineffectiveness related to the Company’s interest rate swaps during the three months ended March 31, 2003 or in the comparable period of 2002, and no gains or losses were excluded from the assessment of hedge effectiveness. The Company records the differential to be paid or received on the interest rate swaps as incremental interest



expense.

The Company has foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts have durations of ninety days to nine 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 March 31, 2003 was approximately \$74.8 million. These contracts had a fair value of approximately \$7.3 million, representing an unrealized loss, and were included in other current liabilities at March 31, 2003.

For the three months ended March 31, 2003 and 2002, there were no significant amounts recognized in earnings due to hedge ineffectiveness. For the three months ended March 31, 2003 and 2002, there were no significant amounts recognized as a result of the discontinuance of cash flow hedge accounting because it was no longer probable that the hedge forecasted transaction would occur. The Company recognized approximately \$1.9 million of losses and \$0.7 million of gains in product revenue for the settlement of certain effective cash flow hedge instruments for the three months ended March 31, 2003 and 2002, respectively. The Company recognized approximately \$1.3 million of losses and \$0.1 million of gains in royalty revenue for the settlement of certain effective cash flow hedge instruments for the three months ended March 31, 2003 and 2002, respectively. These settlements were recorded in the same period as the related forecasted transactions affecting earnings.

### 3. COMPREHENSIVE INCOME

Comprehensive income is comprised of net income and other comprehensive income. Other comprehensive income includes certain changes in equity that are excluded from net income, such as translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities, net of tax and certain derivative instruments, net of tax. Comprehensive income for the three months ended March 31, 2003 and 2002 was \$64.2 million and \$65.8 million, respectively.

### 4. EARNINGS PER SHARE

The Company calculates earnings per share in accordance with Statement of Financial Accounting Standards No. 128, "Earnings per Share" ("SFAS 128"). SFAS 128 requires the presentation of "basic" earnings per share and "diluted" earnings per share. Basic earnings per share is computed by dividing the net income available to common shareholders by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted earnings per share 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 warrants, as determined using the treasury stock method.

Shares used in calculating basic and diluted earnings per share for the three month periods ending March 31, are as follows:

(in thousands)	Three Months Ended March 31,	
	2003	2002
Weighted average number of shares of common stock outstanding	149,611	148,660
Dilutive stock options and warrants	1,883	3,542
Shares used in calculating diluted earnings per share	151,494	152,202

Options to purchase approximately 13.5 million and 6.5 million shares were outstanding at March 31, 2003 and 2002, respectively, but not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price during the period.

### 5. SHARE REPURCHASE PROGRAM

On December 18, 2000, the Company announced that its Board of Directors had authorized the repurchase of up to 4 million shares of the Company's common stock. The repurchased stock provides the Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. During the first quarter of 2003, the Company repurchased approximately 1.2 million shares of the common stock under this program at a cost of \$45.8 million. The Company purchased 145,000 shares during 2002 at a cost of \$8.4 million. Approximately 1.2 million shares remain authorized for repurchase under this program at March 31, 2003.

## 6. OTHER INCOME (EXPENSE), NET

Other income (expense), net consists of the following (in thousands):

	Three Months Ended March 31,	
	2003	2002
Interest income	\$ 9,439	\$10,598
Interest expense	(645)	(1,013)
Other expense	(14,458)	(2,557)
Total other income (expense), net	\$ (5,664)	\$ 7,028

Other expense for the three months ended March 31, 2003 consists primarily of a \$12.9 million charge related to the settlement of a patent infringement dispute discussed in Note 8. Other expense also included a writedown due to the third party acquisition of Eos Biotechnology Inc. ("EOS") in the first quarter of 2003. Biogen's investment in Eos was written down by approximately \$3.1 million. In addition, the Company recorded \$1.3 million of foreign exchange remeasurement gains during the first three months of 2003.

Other expense for the three months ended March 31, 2002 consisted primarily of a \$2.2 million charge for the impairment of certain noncurrent marketable securities that were determined to be other than temporary.

## 7. INCOME TAX EXPENSE

Income tax expense as a percentage of pre-tax income was 28% for the three months ended March 31, 2003 and 2002. The effective tax rate varied from the U.S. statutory rates for the first three months of 2003 and 2002 primarily due to higher sales in European jurisdictions with lower tax rates and to the utilization of research and development credits. The Company expects its effective tax rate to remain consistent throughout 2003.

## 8. LITIGATION

On October 13, 1998, the Company filed an opposition with the Opposition Division of the European Patent Office opposing the grant of a European patent (the "Rentschler II Patent") issued to Dr. Rentschler Biotechnologie GmbH ("Rentschler") claiming compositions of matter of beta interferon having specific glycosylation patterns. On November 6, 2002, a hearing took place with regard to the Company's opposition of the Rentschler II Patent in the European Patent Office. The Opposition Board of the European Patent Office ruled that the present claims of the Rentschler II Patent should be maintained. Following this decision, Rentschler Biotechnologie GmbH & Co. KG sued our German subsidiary, Biogen GmbH, for infringement of the Rentschler II Patent in Germany. In April 2003, the Company and Rentschler settled their litigation which brought to a close all pending legal proceedings in the German district court and the European Patent Office. Under the Settlement and License Agreement the Company agreed to pay Rentschler \$12.9 million as a one-time payment in settlement of litigation and has agreed to an ongoing royalty of sales of AVONEX in the relevant European countries in which the Rentschler II patent is in effect. As part of the settlement, both parties agreed not to pursue further litigation on these patents, including any appeal of the decision in the European Patent Office.

Because the substantive terms of the Rentschler settlement arrangement were agreed to in the first quarter of 2003, the Company determined that the provisions of SFAS 5, "Accounting for Contingencies," required that the Company account for this settlement in its March 31, 2003 financial statements. As a result, the Company recorded a charge of \$12.9 million related to the settlement in other income (expense), net in its March 31, 2003 financial statements.

Along with most other major pharmaceutical and biotechnology companies, the Company has been named as a defendant in a lawsuit filed by the County of Suffolk, New York, in the U.S. District Court in the Eastern District of New York in January 2003. In March 2003, the case was transferred to the U.S. District Court for the District of Massachusetts. The complaint alleges that the defendants overstated the Average Wholesale Price ("AWP") for drugs for which Medicaid provides reimbursement ("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 prescribe Covered Drugs in place of competing drugs, and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaint further alleges that the defendants failed to accurately report the "best price" on the Covered Drugs to New York's Medicaid program. Under Medicaid, pharmaceutical and biotechnology companies agree to pay Medicaid programs a rebate for each product reimbursed by Medicaid. The amount of the rebate is often the difference between

the average manufacturers price and the best price reported by companies to the Medicaid program. Plaintiff claims that it was harmed because it could have allotted the dollars that it wrongfully spent on Medicaid to other public needs. Plaintiff has brought the action under the Racketeering Influence and Corrupt Organizations Act (RICO), and for breach of contract, unjust enrichment, Medicaid fraud and common law fraud. The Company intends to vigorously defend itself against all of the allegations and claims in this lawsuit. An estimate of any potential loss or range of loss cannot be made at this time.

## **9. SEGMENT INFORMATION**

The Company operates in one segment, which is the business of developing, manufacturing and marketing drugs for human health care. The chief operating decision-makers review the profit and loss of the Company on an aggregate basis and manage the operations of the Company as a single operating segment. The Company currently derives product revenues primarily from sales of its AVONEX product for the treatment of relapsing forms of MS, and to a lesser extent, from sales of its AMEVIVE product, approved by the U.S. Food and Drug Administration in January 2003 for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The Company also derives revenue from royalties on sales by the Company's licensees of a number of products covered under patents controlled by the Company and from contract revenues related to a collaborative agreement.

## **10. GUARANTEES**

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 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." FIN 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 measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002.

Under its charter, the Company has agreed to indemnify any person who is made a party to any action or threatened with any action as a result of such person's serving or having served as an officer or director of the Company or having served, at the Company's request, as an officer or director of another company. The indemnification does not apply if the person is adjudicated not to have acted in good faith in the reasonable belief that his or her actions were in the best interests of the Company. The indemnification obligation survives termination of the indemnified party's involvement with the Company but only as to those claims arising from such person's role as an officer or director. The Company has separate indemnification agreements with certain of its officers and directors that do not provide any greater coverage than that found in the charter provisions. The maximum potential amount of future payments that the Company could be required to make under the charter provision and the corresponding indemnification agreements is unlimited; however, the Company has Director and Officer insurance policies that, in most cases, would limit its exposure and enable it to recover a portion of any future amounts paid. The estimated fair value of these indemnification provisions is minimal. Most of these indemnification provisions were grandfathered under the provisions of FIN 45 as they were in effect prior to December 31, 2002. Accordingly, we have no liabilities recorded for these provisions as of March 31, 2003.

The Company enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions the Company generally indemnifies and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2003.

**BIOGEN, INC. AND SUBSIDIARIES**  
**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND**  
**RESULTS OF OPERATIONS**

**OVERVIEW**

Biogen, Inc. ("Biogen" or the "Company") is a global biopharmaceutical company that develops, manufactures and markets novel human therapeutic products. Biogen's primary focus is developing pharmaceutical products that meet unmet medical needs, particularly in its core therapeutic areas of neurology, dermatology and rheumatology. Biogen currently sells AVONEX® (Interferon beta-1a) for the treatment of relapsing multiple sclerosis ("MS") and, commencing in 2003, AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. Biogen also receives revenues from royalties on sales by the Company's licensees of a number of products covered under patents that Biogen controls. In addition, Biogen has a pipeline of development stage products and a number of research programs in our core therapeutic areas and in other areas of interest.

**RESULTS OF OPERATIONS**

For the quarter ended March 31, 2003, the Company reported net income of \$63.5 million or \$0.42 per diluted share as compared to \$72.1 million or \$0.47 per diluted share for the comparable period of 2002.

**Revenues**

(in millions)	Three months ended March 31,		% Change
	2003	2002	
Product revenues			
United States	\$193.2	\$197.3	(2)%
Rest of world	85.0	68.7	24%
Total	278.2	266.0	5%
Royalty revenues	41.4	22.3	86%
Contract revenues	1.1	—	100%
Total revenues	\$320.7	\$288.3	11%

**Product revenues**

Product revenues, consisting primarily of revenues from sales of AVONEX, represented approximately 87% and 92%, respectively, of the Company's total revenues in the three months ended March 31, 2003 and 2002. U.S. product revenues growth was affected by increased competition and a softening of the MS marketplace growth rate. Product revenues outside of the U.S. increased 24% compared to the three months ended March 31, 2002, consisting of an 11% increase based on higher sales volume in 2003 and a 13% increase from the impact of foreign exchange rate changes.

The Company expects to face increasing competition in the MS marketplace in and outside the U.S. from existing and new MS treatments that may impact sales of AVONEX. The Company expects future growth in AVONEX revenues to be dependent to a large extent on the Company's ability to compete successfully. Biogen also expects that future AVONEX sales may be affected by slower growth in the MS market. See "Outlook — Dependence on AVONEX and AMEVIVE Sales" and "Outlook — Competition." The Company expects a substantial portion of its product revenue growth in subsequent quarters to be related to sales of AMEVIVE in the U.S. AMEVIVE was approved by the U.S. Food and Drug Administration ("FDA") in January 2003 for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. For further discussion of AMEVIVE and the factors that may affect the revenues generated by AMEVIVE sales, see "Outlook — Competition" and "Outlook — Dependence on AVONEX and AMEVIVE Sales."

There is a limited launch period initiative undertaken in cooperation with one of Biogen's distributors which provides a refund on purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the insurance claim after appeal and where the other requirements of the initiative are met. Under this initiative, Biogen's exposure is contractually limited to 10% of all AMEVIVE purchased by the distributor. As a result, Biogen will defer recognition of revenue of 10% of product purchased by the distributor until such time as evidence of insurance claims reimbursement for AMEVIVE becomes available.

## Royalty revenues

Revenues from royalties represented approximately 13% and 8%, respectively, of total revenues for the three months ended March 31, 2003 and 2002. The increase in royalty revenues in the first three months of 2003 over the comparable period in 2002 is primarily attributable to the resumption of royalty payments from Schering-Plough Corporation starting in the fourth quarter of 2002 on U.S. sales of its alpha interferon products.

Royalty revenues may fluctuate as a result of fluctuations in sales levels of products sold by the Company's licensees from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs. For a discussion of some of the other factors that may affect royalty revenues in the future, see "Outlook — Royalty Revenue" and "Outlook — Patents and Other Proprietary Rights". The Company expects royalty revenues as a percentage of total revenues to decrease in the long term as the Company continues to market and sell AVONEX worldwide, and begins marketing and selling AMEVIVE. See "Outlook — Royalty Revenue" and "Outlook — Patents and Other Proprietary Rights".

## Contract revenues

In January 2003, the Company signed a collaboration agreement (the "IDEC Agreement") with IDEC Pharmaceuticals Corporation ("IDEC"), under which Biogen and IDEC will collaborate on the development of three oncology therapeutics from Biogen's pipeline of early-stage product candidates. Under the terms of the IDEC Agreement, IDEC initially will be responsible for the development costs of the product candidates, until that time, if any, when the Company exercises its opt-in rights (which must be done within a certain timeframe) with respect to each specific product candidate. Prior to exercising its opt-in rights, to the extent that the Company incurs any development costs in relation to the programs contained in the IDEC Agreement, they will be recorded as research and development expenses. The reimbursement by IDEC of these costs will be recorded as contract revenue. For the first three months of 2003, the Company recorded \$1.1 million for contract revenues.

## COSTS AND EXPENSES

(in millions)	Three months ended March 31,		% Change
	2003	2002	
Cost of product revenues	\$ 43.9	\$ 37.9	16%
Cost of royalty revenues	2.4	1.4	71%
Research and development	85.1	82.5	3%
Selling, general & administrative	95.4	73.4	30%
	<u>\$226.8</u>	<u>\$195.2</u>	<u>16%</u>

The increase in cost of product revenues in the first three months of 2003 compared to the comparable period of 2002 was primarily attributable to the higher sales volume of AVONEX, and, to a lesser extent, to \$3.4 million of writedowns in 2003 of commercial inventory which did not meet quality specifications to its net realizable value. Gross margins on product sales were approximately 84% for the three months ended March 31, 2003 compared to 86% for the same period in 2002. The Company expects that gross margins on product revenues will fluctuate in the future based on changes in product mix and new product initiatives. The increase in cost of royalty revenues was primarily attributable to increased royalties from sales on alpha interferon products sold in the first quarter of 2003 over the comparable period of 2002. Gross margins on royalty revenue were approximately 94% for the three months ended March 31, 2003 and 2002. The Company expects that gross margins on royalty revenues will fluctuate in the future based on changes in sales volumes for specific products from which the Company receives royalties.

Research and development expenses increased 3% in the first three months of 2003 from the comparable period in 2002. The increase was due primarily to higher clinical trial costs of approximately \$8.6 million primarily related to ANTEGREN® (natalizumab), increased production and development costs of approximately \$5.0 million, and \$6.2 for other research, production and infrastructure costs. These increases were offset by a reduction of approximately \$17.2 million in costs related to collaborative projects. The Company expects that, in the near and long-term, research and development expenses may increase as the Company continues to expand its development efforts with respect to new products, conducts clinical trials of these products and continues to work on new formulations for AVONEX. Costs for upfront fees and milestone payments may cause variability in future research and development expense.

Selling, general and administrative expenses increased 30% in the first three months of 2003 compared to the same period in 2002. The increase was primarily due to an increase in selling and marketing expenses of \$21 million related to both the sale of AVONEX and costs incurred for the launch of AMEVIVE, which received FDA approval in the U.S., in January 2003. AVONEX-related increases were driven by heightened competition in the U.S. market. The Company expects that selling, general and administrative expenses will continue to increase in the near and long term as the Company continues to expand its sales and marketing organizations and efforts necessary to sell AVONEX worldwide in response to increased competition, continues to expand its sales and marketing organizations and efforts necessary to sell AMEVIVE in the U.S., and prepares for the possible future approval of additional products.

## OTHER INCOME (EXPENSE), NET

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

	Three Months Ended March 31,	
	2003	2002
Interest income	\$ 9,439	\$10,598
Interest expense	(645)	(1,013)
Other expense	(14,458)	(2,557)
Total other income (expense), net	\$ (5,664)	\$ 7,028

Total other income (expense), net consists primarily of interest income, offset by interest expenses and other non-operating income and expenses. Total other income (expense), net in the first quarter of 2003 was \$5.7 million in losses as compared to \$7.0 million in income in the first quarter of 2002, a decrease of \$12.7 million.

Interest income for the three months ended March 31, 2003 was \$9.4 million compared to \$10.6 million in the same period of 2002, a decrease of \$1.2 million or 11%. The decrease in interest income for the three months ended March 31, 2003 was due primarily to lower average yields on invested funds. The Company expects interest income to vary based on changes in the amount of funds invested and fluctuations in interest rates.

Interest expense in the three months ended March 31, 2003 was approximately \$0.6 million compared to \$1.0 million for the same period in 2002, a decrease of \$0.4 million or 40%. The decrease in interest expense was due to lower borrowings outstanding.

Other expense for the three months ended March 31, 2003 consists primarily of a \$12.9 million charge related to the settlement of a patent infringement dispute. Other expense also included a writedown due to the third party acquisition of Eos Biotechnology Inc. ("Eos") in the first quarter of 2003. Biogen's investment in Eos was written down by approximately \$3.1 million. In addition, the Company recorded \$1.3 million of foreign exchange remeasurement gains during the first three months of 2003.

Other expense for the three months ended March 31, 2002 consisted primarily of a \$2.2 million charge for the impairment of certain noncurrent marketable securities that were determined to be other than temporary.

## INCOME TAXES

Income tax expense as a percentage of pre-tax income was 28% for the three months ended March 31, 2003 and 2002. The effective tax rate varied from the U.S. statutory rates for the first three months of 2003 and 2002 primarily due to higher sales in European jurisdictions with lower tax rates and to the utilization of research and development credits. The Company expects its effective tax rate to remain consistent throughout 2003.

## FINANCIAL CONDITION

At March 31, 2003, cash, cash equivalents and short-term marketable securities were \$812.4 million compared with \$867.1 million at December 31, 2002, a decrease of \$54.7 million. Working capital increased \$19.8 million to \$909.5 million. Net cash from operating activities which included net income, for the three-month period ending March 31, 2003 was \$7.2 million compared with \$61.4 million for the same period in 2002, and included tax benefits related to stock options of \$1.5 million, the \$3.1 million writedown of the Company's investment in Eos, and a non-cash adjustment of \$3.4 million related to the writedowns of inventory to its net realizable value. Cash outflows from investing activities during the three months ended March 31, 2003 included investments in property and equipment and patents of \$24.3 million and net cash outflows from investing activities related to marketable securities totaling \$44.6 million. Cash inflows from investing consisted of \$7.2 million of proceeds from withdrawal from an equity fund



investment. Significant cash outflows from financing activities included \$45.8 million for purchases of the Company's common stock under its stock repurchase program and \$0.8 million for repayments on loan agreements with banks. Cash inflows from financing included \$3.3 million from common stock option exercises and employee stock purchase plan activity.

On December 18, 2000, the Company announced that its Board of Directors had authorized the repurchase of up to 4 million shares of the Company's common stock. The repurchased stock provides the Company with treasury shares for general corporate purposes, such as stock to be issued under employee stock option and stock purchase plans. During the first quarter of 2003, the Company repurchased approximately 1.2 million shares of its common stock under this program at a cost of \$45.8 million. The Company purchased 145,000 shares during 2002 at a cost of \$8.4 million. Approximately 1.2 million shares remain authorized for repurchase under this program at March 31, 2003.

The Company has commenced preliminary work on a large-scale manufacturing facility ("LSM") in Hillerod, Denmark, which is intended to have 90,000 liters of bioreactor capacity. The estimated cost of the 340,000 square foot LSM is \$275 million. At March 31, 2003, approximately \$60 million had been authorized for costs related to the LSM, of which approximately \$43 million had been spent. In addition, the Company is continuing further expansion of its Research Triangle Park, North Carolina complex with ongoing construction of several projects to create additional manufacturing capacity. These additional projects are expected to be completed by the summer of 2003 at a total cost of approximately \$90 million. As of March 31, 2003, the Company had committed approximately \$85 million for construction costs related to these additional projects, of which \$80.1 million had been spent.

Several legal proceedings involving the Company were pending during the current quarter. See Note 8 of the Notes to the Condensed Consolidated Financial Statements and "Legal Proceedings" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 for discussions of these legal proceedings.

The Company currently generates cash from operations primarily due to the sale of AVONEX and AMEVIVE, and from royalties on sales generated by the Company's licensees. In the future, the Company expects to continue generating cash from these sources. The Company believes that existing funds and cash generated from operations are adequate to satisfy its working capital and capital expenditure requirements in the foreseeable future. However, the Company may raise additional capital to take advantage of favorable conditions in the market or in connection with the Company's development activities.

## **CRITICAL ACCOUNTING ESTIMATES**

### **REVENUE RECOGNITION AND ACCOUNTS RECEIVABLE**

SEC Staff Accounting Bulletin No. 101 ("SAB 101") provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB 101 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. Further, SAB 101 requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. The Company believes that its revenue recognition policies are in compliance with SAB 101.

Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer. When customers have inspection and approval rights for products, Biogen defers revenue until lapse of that right. Revenues are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company prepares its estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

In January 2003, Biogen received regulatory approval to market AMEVIVE in the U.S. There is a limited launch period initiative undertaken in cooperation with one of Biogen's distributors which provides a refund on purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the insurance claim after appeal and where the other requirements of the initiative are met. Under this initiative, Biogen's exposure is contractually limited to 10% of all AMEVIVE purchased by the distributor. As a result, Biogen will defer recognition of revenue of 10% of product purchased by the distributor until such time as evidence of insurance claims reimbursement for AMEVIVE becomes available.

In February 2002, the FASB Emerging Issues Task Force ("EITF") released EITF Issue No. 01-09 ("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. The Company has various contracts with distributors that provide for discounts and rebates. These contracts are classified as a reduction of revenue. The Company also maintains select customer service contracts with distributors and other customers in the distribution channel. In accordance with EITF 01-09, the Company has established the fair value of these contracts and, as provided by EITF 01-09, classified these customer service contracts as sales and marketing expense. If the Company should not be able to sustain the fair value of these contracts, the Company would be required to classify these costs as a reduction of revenue. The adoption of EITF 01-09 did not have a significant impact on the Company's financial statements.

The Company receives royalty revenues under license agreements with a number of third parties that sell products based on technology developed by the Company or to which the Company has rights. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records 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 paid to the Company (adjusted for any changes in facts and circumstances, as appropriate). The Company maintains regular communication with its licensees in order to gauge the reasonableness of its 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 the part of the Company under these license agreements.

Revenue is not recognized in any circumstances unless collectibility is reasonably assured.

Biogen maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of Biogen's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which could affect future earnings.

In January 2003, the Company signed a collaboration agreement (the "IDEC Agreement") with IDEC Pharmaceuticals Corporation ("IDEC"), under which Biogen and IDEC will collaborate on the development of three oncology therapeutics from Biogen's pipeline of early-stage product candidates. Under the terms of the IDEC Agreement, IDEC initially will be responsible for the development costs of the product candidates, until that time, if any, when the Company exercises its opt-in rights (which must be done within a certain timeframe) with respect to each specific product candidate. Prior to exercising its opt-in rights, to the extent that the Company incurs any development costs in relation to the programs contained in the IDEC Agreement, they will be recorded as research and development expenses. The reimbursement by IDEC of these costs will be recorded as contract revenue. For the first three months of 2003, the Company recorded \$1.1 million for contract revenues.

## **CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures.** The Company's Chief Executive Officer and Executive Vice President — Finance and Chief Financial Officer, after evaluating the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-14(c) and 15d-14(c)) on April 17, 2003, have concluded that the Company's disclosure controls and procedures were adequate and effective to ensure that material information relating to the Company, including its consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Form 10-Q was being prepared.

**Changes in Internal Controls.** There were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, nor were there any significant deficiencies or material weaknesses in the Company's internal controls. Accordingly, no corrective actions were required or undertaken.

## **OUTLOOK**

### **SAFE HARBOR**

In addition to historical information, this quarterly 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 Company's expectations regarding its level of future product sales, profits, product revenues, royalty revenues, costs and expenses, gross margins on product revenues and royalty revenues, its effective tax rate, regulatory approvals, development and commercialization of additional products, competition and the impact of competitive products,

the outcome of pending or anticipated litigation and patent-related proceedings, facility expansion and the value of investments in certain marketable securities. These and all other forward-looking statements in this report are made based on Biogen's current belief as to the outcome and timing of such future events. Factors which could cause actual results to differ from Biogen's expectations and which could negatively impact Biogen's financial condition and results of operations are discussed below and elsewhere in Management's Discussion and Analysis of Financial Condition and Results of Operations. Unless required by law, Biogen does not undertake any obligation to publicly update any forward-looking statements.

## **DEPENDENCE ON AVONEX AND AMEVIVE SALES**

Biogen's ability to sustain increases in revenues and profitability is primarily dependent on the level of revenues and profitability from AVONEX and AMEVIVE sales.

The level of revenues from sales of AVONEX will depend on a number of factors, including: Biogen's ability to sustain market share of AVONEX in light of competitive products for the treatment of MS, continued market acceptance of AVONEX worldwide; Biogen's ability to maintain a high level of physician and patient satisfaction with AVONEX; the nature of regulatory and pricing decisions related to AVONEX worldwide; the overall growth of the MS market; the extent to which AVONEX continues to receive and maintains reimbursement coverage; the success of ongoing development related to AVONEX in expanded MS indications; the success of ongoing development of the pre-filled syringe formulation of AVONEX; and the continued accessibility of third parties to vial, label, and distribute AVONEX on acceptable terms.

AMEVIVE was approved in the U.S. in January 2003. The level of revenues from sales of AMEVIVE in the U.S. will depend on a number of factors, including: the ability to gain and to sustain market share and to continue to increase market share of AMEVIVE as the competitive landscape for AMEVIVE becomes more challenging; Biogen's ability to maintain a high level of physician and patient satisfaction with AMEVIVE; the nature of regulatory and pricing decisions related to AMEVIVE; the extent to which AMEVIVE receives and maintains adequate reimbursement coverage; and the accessibility of third parties to vial, label, and distribute AMEVIVE on acceptable terms. In February 2003, Biogen withdrew its application for approval to market AMEVIVE in the EU. Biogen's decision was based on a determination by the Committee for Proprietary Medicinal Products, the scientific advisory board of the regulatory authority in the EU, that more clinical information is needed to approve AMEVIVE. Biogen plans to develop the additional information necessary to obtain approval of AMEVIVE for psoriasis patients in the EU. Developing the data and re-filing the application may take several years and there is no assurance that Biogen will ever obtain approval of AMEVIVE in the EU. There is also no assurance that our commercial efforts in the U.S. will be successful.

## **COMPETITION**

AVONEX competes in the U.S. and EU markets primarily with four products: COPAXONE® glatiramer acetate, sold by Teva Neuroscience, Inc. ("Teva") in the U.S. and co-promoted in by Teva and Aventis Pharma in the EU; BETASERON®, sold by Berlex in the U.S. and sold under the name BETA FERON® by Schering A.G. in the EU; NOVANTRONE® (mitoxantrone for injection) sold by Amgen, Inc. ("Amgen") and Serono S.A. in the U.S. and sold by Amgen in the EU; and REBIF®, sold in the EU by Serono and sold in the U.S. by Serono, with Pfizer Inc. as a co-promotion partner. A number of companies, including Biogen, are working to develop products to treat MS which may in the future compete with AVONEX. AVONEX also faces competition from off-label uses of drugs approved for other indications. Some of Biogen's current competitors are also working to develop alternative formulations for delivery of their products which may in the future compete with AVONEX. Biogen believes that competition among treatments for MS will be based on product performance, service and price.

AMEVIVE competes with existing therapies for moderate-to-severe psoriasis, such as oral retinoids, steroids, methotrexate and cyclosporin, along with other drugs, as discussed below, approved for other indications. In the future, AMEVIVE will also compete with new drugs currently in development for psoriasis, drugs now approved for other indications that may be approved for psoriasis, and off-label uses of drugs approved for other indications. Genentech and Xoma Corporation are co-developing RAPTIVA® (efalizumab), an antibody designed to block certain immune cells as a potential treatment for moderate-to-severe psoriasis. Genentech has filed for regulatory approval of the drug in the U.S. Serono has an exclusive license to RAPTIVA in the EU and other countries and has filed for regulatory approval of the drug in the EU. ENBREL® (etanercept), a drug sold by Amgen, has been approved by the FDA as a treatment for psoriatic arthritis, a joint disease that can be associated with the skin plaques of moderate to severe chronic plaque psoriasis. In January 2003, Amgen announced positive results from a Phase 3 clinical study of ENBREL in the treatment of moderate to severe plaque psoriasis and is conducting a second Phase 3 clinical study in psoriasis. Centocor, Inc., a subsidiary of Johnson & Johnson, sells REMICADE® (infliximab) worldwide as a treatment for other indications, including rheumatoid arthritis, and has completed a Phase 2 proof of concept study for REMICADE as a potential treatment for psoriasis.

HUMIRA® (adalimumab), a drug sold by Abbott Laboratories, was also recently approved by the FDA as a treatment for rheumatoid arthritis. Abbott is undertaking clinical trials in psoriasis and psoriatic arthritis. In addition, a number of other companies are working to develop products to treat psoriasis which may ultimately compete with AMEVIVE.

See the “Competition” section of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## **ROYALTY REVENUE**

Biogen receives royalty revenues which, prior to 2001, contributed a significant amount to its overall profitability. Royalty revenues decreased significantly in recent years and through the third quarter of 2002 primarily as the result of patent expirations and a royalty dispute with Schering-Plough Corporation, which was settled in October 2002. Royalty revenues increased in the fourth quarter of 2002 and the first quarter of 2003, and the Company expects that royalty revenues will continue to increase in the near future. However, royalty revenues may fluctuate as a result of 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 Biogen’s licensees. In addition, sales levels of products sold by Biogen’s licensees 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 Biogen is not involved in the development or sale of products by its licensees, it cannot be certain of the timing or potential impact of factors which may affect sales by licensees. For a further discussion of risks regarding drug development, patent matters, including future patent expirations affecting royalty revenues, and regulatory matters, see — “Outlook — Patents and Other Proprietary Rights,” “Outlook — Litigation and Government Regulation,” and the “Business — Risks Associated with Drug Development,” “Business — Patents and Other Proprietary Rights,” and “Business — Regulation” sections of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## **PATENTS AND OTHER PROPRIETARY RIGHTS**

Biogen has numerous issued patents and patent applications pending on a number of its processes and products. Biogen has also obtained rights to certain patents under licenses with third parties, which provide for the payment of royalties by Biogen. There can be no assurances that Biogen’s existing patents or others, if obtained, will substantially protect or commercially benefit Biogen. In addition, Biogen does not know to what extent its pending patent applications or patent applications licensed from third parties will be granted or whether any of Biogen’s patents will prevail if they are challenged in litigation. Also, there is also no assurance that third parties have not or will not be granted patents claiming subject matter necessary to Biogen’s business. Biogen is 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 or necessary to Biogen’s 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. For example, Genentech has been granted patents and is prosecuting other patent applications in the U.S. and certain other countries, which it may allege are currently used by Biogen and the rest of the biotechnology industry to produce recombinant proteins in host cells. Genentech has offered to Biogen and others in the industry non-exclusive licenses under some of those patents and patent applications for various proteins and in various fields of use, but not for others. The ultimate scope and validity of Genentech’s patents, of other existing patents, or of patents which may be granted to third parties in the future, and the extent to which Biogen may wish or be required to acquire rights under such patents and the availability and cost of acquiring such rights, currently cannot be determined by Biogen. Biogen is also aware that Genentech has been granted patents and is presently prosecuting other patent applications in the U.S. and certain other countries pertaining to technology referred to as immunoadhesion technology. Genentech may allege that its patents on such immunoadhesion technology are infringed by Biogen’s commercial activities with AMEVIVE. Biogen has had discussions with Genentech and is evaluating these patents to determine if a license should be taken. The ultimate scope and validity of Genentech’s immunoadhesion patents and the availability and ultimate cost of acquiring such rights currently cannot be determined.

There has been, and Biogen expects that there may continue to be significant litigation in the industry regarding patents and other intellectual property rights. Such litigation could create uncertainty and consume substantial resources. See “Outlook — Litigation and Government Regulation,” and the “Business — Risks Associated with Drug Development” and “Business — Patents and Other Proprietary Rights” sections of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## **PRODUCTS**

AVONEX and AMEVIVE are currently the only products sold by Biogen. Biogen’s long-term viability and growth will depend on the successful development and commercialization of other products from its research and development activities and collaborations.

Biogen continues to expand its development efforts related to other potential products in its pipeline. The expansion of the pipeline may include increases in spending on internal projects, the acquisition of third-party technologies or products or other types of investments. Product development 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 Biogen's ability to successfully develop and commercialize its other potential products, including the ability to obtain and maintain necessary patents and licenses, to demonstrate safety and efficacy of drug candidates at each stage of the clinical trial process, to overcome technical hurdles that may arise, to meet applicable regulatory standards, to obtain reimbursement coverage for the products, to receive required regulatory approvals, to be capable of producing drug candidates in commercial quantities at reasonable costs, to 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 analysis of data or from additional data 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 Biogen's view of the data or require additional data or information or additional studies. There can be no assurance that Biogen will be successful in its efforts to develop and commercialize new products.

## **PRICING PRESSURES**

In the U.S., many pharmaceutical and biologic products are subject to increasing pricing pressures, which could be significantly impacted by the outcome of the current national debate over Medicare reform. If the Medicare program provided outpatient pharmaceutical coverage for its beneficiaries, the federal government, through its enormous purchasing power under the program, could demand discounts from pharmaceutical and biotechnology companies that may implicitly create price controls on prescription drugs. On the other hand, a Medicare drug reimbursement provision may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, Managed Care Organizations ("MCOs"), institutions and other government agencies continue to seek price discounts. Government efforts to reduce Medicare and Medicaid expenses are expected to increase the use of MCOs. This may result in managed care's 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' drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries and bulk purchasing of drugs. Biogen encounters 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 Biogen's products from markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices. See the "Business — Regulation" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## **MANUFACTURING**

Biogen currently produces all of its bulk drug products at its manufacturing facilities located in Cambridge, Massachusetts and Research Triangle Park, North Carolina. Problems with manufacturing processes could result in product defects, which could require Biogen to delay shipment of products, recall products previously shipped or be unable to supply products at all. In addition, any prolonged interruption in the operations of Biogen's manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. Because Biogen's 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. Biogen sources all of its fill-finish and final product storage operations, along with a substantial portion of its packaging operations, to a concentrated group of third party contractors. Problems with the operations of these third party contractors could also require Biogen to delay shipment of saleable products, recall products previously shipped or be unable to supply products at all. Difficulties or delays in Biogen's manufacturing of existing or new products, including difficulties or delays in the operations of third party contractors retained by Biogen to perform fill-finish, packaging and storage of saleable products, could increase Biogen's costs, cause Biogen to lose revenue or market share and damage Biogen's reputation. See the "Business — Manufacturing and Raw Materials" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## **LITIGATION AND GOVERNMENT REGULATION**

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 and disputes

over intellectual property rights (including patents). 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. There is no assurance that if Biogen were to be involved in any such lawsuits or investigation, that Biogen would be successful in defending itself or asserting its rights. There is also no assurance, for example, that Biogen will be successful in defending itself in the current AWP litigation. Biogen's business is also subject to extensive government regulation and oversight. Biogen may also become subject to other governmental actions which could adversely affect its business or financial condition, including: (i) new laws, regulations and judicial decisions related to health care availability, method of delivery and payment for health care products and services, (ii) changes in the Federal Food and Drug Administration and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity, (iii) new laws, regulations and judicial decisions affecting pricing or marketing and (iv) changes in the tax laws relating to Biogen's operations. See "Outlook — Patents and Other Proprietary Rights," and the "Business — Risks Associated with Drug Development," "Business - Patents and Other Proprietary Rights," and "Business — Legal Proceedings" sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## Part II — OTHER INFORMATION

### Item 1. Legal Proceedings.

The section "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 6. Exhibits and Reports on Form 8-K

(a) Exhibits

99.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

- (i) On January 31, 2003, the Company filed a Current Report on Form 8-K to publicly disseminate a press release announcing the approval of AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy.
- (ii) On February 20, 2003, the Company filed a Current Report on Form 8-K to publicly disseminate a press release announcing that the Company decided to withdraw its application for approval of AMEVIVE® (alefacept) for psoriasis in the European Union because the Committee for Proprietary Medicinal Products, the scientific advisory body of the European Medicines Evaluation Agency, determined that more clinical information was needed to approve the product.
- (iii) On March 14, 2003, the Company filed a Current Report on Form 8-K to furnish the written statement of the Company's principal executive officer and principal financial officer required by Section 906 of the Sarbanes-Oxley Act of 2002 in connection with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

## 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.

Dated: April 17, 2003

BIOGEN, INC.

/s/ Peter N. Kellogg

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Executive Vice President-Finance and  
Chief Financial Officer

## CERTIFICATIONS

Certifications:

I, James C. Mullen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biogen, Inc.:
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 17, 2003

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James C. Mullen  
Chairman, Chief Executive Officer and  
President

I, Peter N. Kellogg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biogen, Inc.:
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 17, 2003

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Peter N. Kellogg  
Executive Vice President — Finance  
and Chief Financial Officer