

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 June 30, 2002**

**Commission File Number 0-12042**

**BIOGEN, INC.**

(Exact name of registrant as specified in its charter)

**Massachusetts**  
(State or other jurisdiction of  
incorporation or organization)

**04-3002117**  
(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

The number of shares of the registrant's Common Stock, \$0.01 par value, outstanding as of July 22, 2002 was 148,527,345 shares.

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# BIOGEN, INC.

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

**PART I – FINANCIAL INFORMATION**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
<b>REVENUES:</b>				
Product	\$250,542	\$243,140	\$516,527	\$463,137
Royalties	18,721	17,445	41,079	34,495
<b>Total revenues</b>	<b>269,263</b>	<b>260,585</b>	<b>557,606</b>	<b>497,632</b>
<b>COSTS AND EXPENSES:</b>				
Cost of revenues	36,209	35,202	75,527	64,348
Research and development	89,348	79,118	171,815	151,888
Selling, general and administrative	91,567	55,189	164,957	103,749
<b>Total costs and expenses</b>	<b>217,124</b>	<b>169,509</b>	<b>412,299</b>	<b>319,985</b>
Income from operations	52,139	91,076	145,307	177,647
Other income, net	8,104	11,533	15,132	27,996
<b>INCOME BEFORE INCOME TAXES</b>	<b>60,243</b>	<b>102,609</b>	<b>160,439</b>	<b>205,643</b>
Income taxes	16,868	30,757	44,923	61,668
<b>NET INCOME</b>	<b>\$ 43,375</b>	<b>\$ 71,852</b>	<b>\$115,516</b>	<b>\$143,975</b>
<b>BASIC EARNINGS PER SHARE</b>	<b>\$ 0.29</b>	<b>\$ 0.48</b>	<b>\$ 0.78</b>	<b>\$ 0.97</b>
<b>DILUTED EARNINGS PER SHARE</b>	<b>\$ 0.29</b>	<b>\$ 0.47</b>	<b>\$ 0.76</b>	<b>\$ 0.94</b>
<b>SHARES USED IN COMPUTING:</b>				
Basic earnings per share	149,231	148,602	148,945	148,395
Diluted earnings per share	152,033	153,337	152,118	153,414

See Notes to Condensed Consolidated Financial Statements.

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

	June 30, 2002	December 31, 2001
	(unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 30,235	\$ 54,042
Marketable securities	763,230	744,065
Accounts receivable, net	181,904	177,582
Deferred tax assets	50,426	44,108
Other current assets	105,331	77,930
	<u>1,131,126</u>	<u>1,097,727</u>
Property, plant and equipment		
Cost	844,522	727,825
Less accumulated depreciation	191,689	171,827
	<u>652,833</u>	<u>555,998</u>
Patents, net	17,179	16,562
Other assets	44,986	50,759
	<u>\$1,846,124</u>	<u>\$1,721,046</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 59,682	\$ 50,944
Current portion of long-term debt	4,888	4,888
Accrued expenses and other	226,645	239,110
	<u>291,215</u>	<u>294,942</u>
Long-term debt, less current portion	39,854	42,297
Other long-term liabilities	32,179	34,975
Commitments and contingencies	—	—
Shareholders' equity		
Common stock	1,517	1,517
Additional paid-in capital	823,393	808,076
Treasury stock, at cost	(125,293)	(176,123)
Retained earnings	780,601	705,893
Accumulated other comprehensive income	2,658	9,469
	<u>1,482,876</u>	<u>1,348,832</u>
	<u>\$1,846,124</u>	<u>\$1,721,046</u>

See Notes to Condensed Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2002	2001
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net income	\$ 115,516	\$ 143,975
Adjustments to reconcile net income to net cash provided from operating activities:		
Depreciation and amortization	20,530	18,200
Deferred income taxes	(105)	86
Tax benefit of stock options	14,294	22,622
Other	3,851	649
Realized loss (gain) on sale of non-current marketable securities	301	(3,321)
Write-down of non-current marketable securities	2,182	—
Changes in:		
Accounts receivable	(833)	(24,785)
Other current and other assets	(43,627)	4,711
Accounts payable, accrued expenses and other current and long-term liabilities	(11,211)	10,792
Net cash flows from operating activities	<u>100,898</u>	<u>172,929</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of current marketable securities	(220,539)	(624,483)
Proceeds from sales and maturities of current marketable securities	201,957	575,863
Proceeds from sales of non-current marketable securities	493	3,652
Acquisitions of property and equipment	(113,436)	(91,204)
Additions to patents	(1,574)	(2,424)
Net cash flows from investing activities	<u>(133,099)</u>	<u>(138,596)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayments on long-term debt	(2,443)	(2,444)
Purchases of treasury stock	(8,384)	(21,443)
Issuance of treasury stock related to stock option exercises	18,406	17,192
Other	84	12
Net cash flows from financing activities	<u>7,663</u>	<u>(6,683)</u>
Effect of exchange rate changes on cash	<u>731</u>	<u>(415)</u>
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	(23,807)	27,235
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>54,042</u>	<u>48,737</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 30,235</u>	<u>\$ 75,972</u>

See Notes to Condensed Consolidated Financial Statements.

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

**1. BASIS OF PRESENTATION**

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, Inc. and its subsidiaries (the “Company”). The Company’s accounting policies are described in the Notes to the Consolidated Financial Statements in the Company’s 2001 Annual Report on Form 10-K. Interim results are not necessarily indicative of the operating results for the full year.

Effective January 1, 2002, the Company adopted the provisions of Emerging Issues Task Force Issue No. 01-09 (EITF 01-09) “Accounting for Consideration Given by a Vendor to a Customer or Reseller of the Vendor’s Products”. EITF 01-09 requires the cost of certain vendor consideration to be classified as a reduction of revenue rather than a sales and marketing expense. The impact of EITF 01-09 is not significant.

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 and are included in other current assets. 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)	June 30, 2002	December 31, 2001
Raw materials	\$ 20,212	\$ 14,754
Work in process	34,204	17,004
Finished goods	25,713	20,161
	<u>\$ 80,129</u>	<u>\$ 51,919</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 June 30, 2002 and December 31, 2001, capitalized inventory related to AMEVIVE® (alefacept), which has not yet received regulatory approval, was \$20.7 million and \$8.4 million, respectively.

Biogen writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realized value is less than that estimated by Biogen, additional inventory write-downs may be required. The Company has not had any material write-downs of inventory for the three and six months ended June 30, 2002.

**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 June 30, 2002, the Company had \$13.3 million outstanding under a floating rate loan collateralized by one of the Company's laboratory and office buildings in Cambridge, Massachusetts and \$31.4 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 \$3.7 million and \$3.3 million at June 30, 2002 and December 31, 2001, 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 and six months ended June 30, 2002 or in the comparable period of 2001, 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 June 30, 2002 was approximately \$97.3 million. These contracts had a fair value of approximately \$8.9 million, representing an unrealized loss, and were included in other current liabilities at June 30, 2002.

For the three and six months ended June 30, 2002, approximately \$734,000 and \$620,000, respectively, were recognized as expenses due to hedge ineffectiveness. For the three and six months ended June 30, 2001, there were no significant amounts recognized in earnings due to hedge ineffectiveness. For the three and six months ended June 30, 2002 and 2001, 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 \$1.2 million and \$468,000 of losses in product revenue for the settlement of certain effective cash flow hedge instruments for the three and six months ended June 30, 2002, respectively. The Company recognized approximately \$403,000 and \$294,000 of losses in royalty revenue for the settlement of certain effective cash flow hedge instruments for the three and six months ended June 30, 2002, respectively. The Company recognized \$3.7 million and \$6.7 million of gains in product revenue for the settlement of certain effective cash flow hedge instruments for the three and six months ended June 30, 2001, respectively. The Company recognized \$974,000 and \$1.8 million of gains in royalty revenue for the settlement of certain effective cash flow hedge instruments for the three and six months ended June 30, 2001, 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 June 30, 2002 and 2001 was \$42.9 million and \$79.1 million, respectively. Comprehensive income for the six months ended June 30, 2002 and 2001 was \$108.7 million and \$135.3 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". 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.

Shares used in calculating basic and diluted earnings per share for the three and six month periods ending June 30, are as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Weighted average number of shares of common stock outstanding	149,231	148,602	148,945	148,395
Dilutive stock options	2,802	4,735	3,173	5,019
Shares used in calculating diluted earnings per share	<u>152,033</u>	<u>153,337</u>	<u>152,118</u>	<u>153,414</u>

Options to purchase approximately 8.4 million and 2.1 million shares were outstanding at June 30, 2002 and 2001, 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. The put warrants sold in connection with the Company's stock repurchase program did not have a material additional dilutive effect.

#### 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. The Company purchased 145,000 shares through June 30, 2002 at a cost of \$8.4 million. During 2001, the Company repurchased approximately 1.5 million shares of its common stock under this program at a cost of \$88.3 million. Approximately 2.4 million shares remain authorized for repurchase under this program at June 30, 2002.

#### 6. OTHER INCOME, NET

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Interest income	\$10,466	\$10,694	\$21,064	\$22,479
Interest expense	(909)	(1,051)	(1,922)	(2,089)
Other income (expense)	(1,453)	1,890	(4,010)	7,606
Total other income, net	<u>\$ 8,104</u>	<u>\$11,533</u>	<u>\$15,132</u>	<u>\$27,996</u>

Other income (expense) for the three and six months ended June 30, 2002 includes \$2.9 million and \$2.8 million, respectively, of losses attributable to an equity method investee, offset by \$1.9

million of gains from foreign exchange translation. Other income (expense) for the six months ended June 30, 2002 also includes a \$2.2 million write-down on unrealized losses in certain non-current marketable securities that were determined to be other than temporary. Other income (expense) for the three and six months ended June 30, 2001 includes realized gains on the sale of certain non-current marketable securities totaling approximately \$781,000 and \$3.3 million, respectively.

## **7. INCOME TAX EXPENSE**

Income tax expense as a percentage of pre-tax income was 28% for the three and six months ended June 30, 2002 and was 30% for the three and six months ended June 30, 2001. The effective tax rate varied from the U.S. statutory rates for the first six months of 2002 and 2001 primarily due to higher sales in European jurisdictions with lower tax rates and to the utilization of research and development credits. The Company's effective tax rate outside the U.S. is lower than the U.S. tax rate, and the Company expects that the corporate tax rate will decline as international sales increase.

## **8. LITIGATION**

On July 3, 1996, Berlex Laboratories, Inc. ("Berlex") filed suit against Biogen in the United States District Court for the District of New Jersey alleging infringement by Biogen of Berlex's "McCormick" patent (U.S. Patent No. 5,376,567) in the United States in the production of Biogen's AVONEX® (Interferon beta-1a) product. In November 1996, Berlex's New Jersey action was transferred to the United States District Court in Massachusetts and consolidated for pre-trial purposes with a related declaratory judgment action previously filed by Biogen. On August 18, 1998, Berlex filed a second suit against Biogen alleging infringement by Biogen of a patent which was issued to Berlex in August 1998 and which is related to the McCormick patent (U.S. Patent No. 5,795,779). On September 23, 1998, the cases were consolidated for pre-trial and trial purposes. Berlex sought a judgment granting it damages, a trebling of any damages awarded and a permanent injunction restraining Biogen from the alleged infringement. A hearing on the parties' summary judgment motions in the case was completed in March 2000. In September 2000, the District Court rendered final judgment in favor of Biogen and against Berlex determining that Biogen's production of AVONEX did not infringe any of the claims of the Berlex patents. Berlex has appealed this decision with the Court of Appeals for the Federal Circuit. Oral arguments were presented by the parties to the Court of Appeals on November 7, 2001 and a decision is expected in the second half of 2002. In January 2002, Biogen and Berlex reached a settlement of the litigation pursuant to which the parties agreed to end the dispute in return for a payment of \$20 million from Biogen to Berlex and the possibility of a second and final payment from Biogen to Berlex if the Court of Appeals were to reverse the District Court's previous ruling granting summary judgment in favor of Biogen. If the Court of Appeals were to rule against Biogen and return the case to the District Court, Biogen believes that the most likely decision would require it to make a second and final payment of \$55 million to Berlex. In the event the ruling is significantly adverse to Biogen, the second and final payment to Berlex would be \$230 million. As part of the settlement, Biogen and Berlex agreed not to pursue further litigation about these patents. Biogen recorded a \$20 million charge in "Other Income, net" in the fourth quarter of 2001 to account for the first payment to Berlex. The Company has determined that, based on information currently available, the most probable outcome is that no additional payments will be required.

In 1995, the Company filed an opposition with the Opposition Division of the European Patent Office to oppose a European patent (the "Rentschler I Patent") issued to Dr. Rentschler Biotechnologie GmbH ("Rentschler") relating to compositions of matter of beta interferon. In 1997, the European Patent Office issued a decision to revoke the Rentschler I Patent. Rentschler appealed that decision and an oral hearing on the appeal took place in December 2000. At the oral hearing in order to gain reinstatement of the patent, Rentschler narrowed the patent claims so as to claim only a specific cell line. Biogen does not use the specific cell line now claimed. On October 13, 1998, the Company filed another opposition with the Opposition Division of the European Patent Office to oppose a second European patent issued to Rentschler (the "Rentschler II Patent") with certain claims regarding compositions of matter of beta interferon with specific regard to the structure of the glycosylated molecule. A hearing on the Company's opposition previously scheduled for October 2000 has been set for November 6, 2002. While Biogen believes that the Rentschler II Patent will be revoked, if the Rentschler II Patent were to be upheld and if

Rentschler were to obtain, through legal proceedings, a determination that the Company's sale of AVONEX in Europe infringes a valid Rentschler II Patent, such result could have a material adverse effect on the Company's results of operation and financial position.

## **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 from sales of its AVONEX product for the treatment of relapsing forms of multiple sclerosis. The Company also derives revenue from royalties on worldwide sales by the Company's licensees of a number of products covered under patents controlled by the Company.

## **10. SIGNIFICANT EVENT**

In the three months ended June 30, 2002, the Company recorded a \$5.8 million charge associated with the retirement of James L. Vincent as Chairman of the Board and as Director of Biogen. The severance and other benefits are consistent with his 1996 employment agreement. In July 2002, the Board elected James C. Mullen as the new Chairman.

## **11. NEW ACCOUNTING PRONOUNCEMENT**

In July 2002, the FASB issued SFAS 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on the Company's financial statements.

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

**OVERVIEW**

Biogen, Inc. (the "Company" or "Biogen") is a biopharmaceutical company principally engaged in the business of developing, manufacturing and marketing drugs for human health care. The Company currently derives revenues from sales of its AVONEX® (Interferon beta-1a) product for the treatment of relapsing forms of multiple sclerosis ("MS"). The Company also derives revenue from royalties on worldwide sales by the Company's licensees of a number of products covered under patents controlled by the Company.

**RESULTS OF OPERATIONS**

Effective January 1, 2002, the Company adopted the provisions of Emerging Issues Task Force Issue No. 01-09 (EITF 01-09) "Accounting for Consideration Given by a Vendor to a Customer or Reseller of the Vendor's Products". EITF 01-09 requires the cost of certain vendor consideration to be classified as a reduction of revenue rather than a sales and marketing expense. The impact of EITF 01-09 is not significant.

For the quarter ended June 30, 2002, the Company reported net income of \$43.4 million or \$0.29 per diluted share as compared to \$71.9 million or \$0.47 per diluted share for the comparable period of 2001. For the six months ended June 30, 2002, the Company reported net income of \$115.5 million or \$0.76 per diluted share as compared to \$144 million or \$0.94 per diluted share for the comparable period of 2001.

Total revenues for the quarter ended June 30, 2002 were \$269.3 million, as compared to \$260.6 million in the same period of 2001, an increase of \$8.7 million or approximately 3%. Total revenues for the six months ended June 30, 2002 were \$557.6 million, as compared to \$497.6 million in the same period of 2001, an increase of \$60 million or approximately 12%.

Product revenues in the current quarter were \$250.5 million as compared to \$243.1 million for the same period of 2001, an increase of \$7.4 million or approximately 3%. Product revenues in the six months ended June 30, 2002 were \$516.5 million as compared to \$463.1 million for the same period of 2001, an increase of \$53.4 million or approximately 12%. Product revenues from AVONEX represent approximately 93% of the Company's total revenues in the three and six months ended June 30, 2002. Product revenues from AVONEX also represented approximately 93% of the Company's total revenues in the three and six months ended June 30, 2001. The growth in product revenues in the three and six months ended June 30, 2002 over the comparable period in 2001 was primarily attributable to increases in the sales volume of AVONEX in the United States and in the fifteen member countries of the European Union ("EU"). Product revenues in the United States were approximately \$175.8 million for the three months ended June 30, 2002 compared to \$173.1 million for the same period in 2001. Product revenues in the United States were approximately \$373.1 million and \$334.9 million for the six months ended June 30, 2002 and 2001, respectively. The slower than expected growth in product revenues in the United States was primarily attributable to inventory reductions by some wholesalers, increased competition and a softening of the MS marketplace in the United States. AVONEX sales outside of the United States were approximately \$74.7 million and \$143.4 million for the three months and six months ended June 30, 2002 as compared to \$70 million and \$128.2 million for the same periods of 2001, respectively.

The Company faces increasing competition in the MS marketplace worldwide from existing and new MS treatments that may impact sales of AVONEX. Biogen 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 possible slowing of growth in the MS market. See "Outlook-Dependence on AVONEX Sales"; see also the Company's Annual Report on Form 10-K for the period ended on December 31, 2001 under the headings "Management's Discussion and Analysis of Financial Condition and Results of Operations — Outlook — Competition."

Revenues from royalties in the three months ended June 30, 2002 were \$18.7 million, an increase of \$1.3 million or approximately 7% as compared to \$17.4 million of royalty revenue for the same period in 2001. Revenues from royalties in the six months ended June 30, 2002 were \$41.1 million, an increase of \$6.6 million or approximately 19% as compared to \$34.5 million of royalty revenue for the same period in 2001. Revenues from royalties represented approximately 7% of total revenues for the three and six months ended June 30, 2002. Revenues from royalties also represented approximately 7% for the three and six months ended June 30, 2001. The growth in royalty revenues for the three and six month periods of 2002 over the comparable periods in 2001 was primarily attributable to royalties received on increased sales of alpha interferon products. For a more detailed discussion of royalties, including a discussion on the Company's current arbitration with Schering-Plough Corporation ("Schering-Plough"), see "Outlook – Royalty Revenue".

## **COSTS AND EXPENSES**

Total costs and expenses for the three months ended June 30, 2002 were \$217.1 million as compared to \$169.5 million in the same period of 2001, an increase of approximately 28%. Total costs and expenses for the six months ended June 30, 2002 were \$412.3 million as compared to \$320 million in the same period of 2001, an increase of approximately 29%.

Cost of revenues in the three months ended June 30, 2002 totaled \$36.2 million compared to \$35.2 million in the same period of 2001, an increase of \$1 million or 3%. Cost of revenues in the six months ended June 30, 2002 totaled \$75.5 million compared to \$64.3 million in the same period of 2001, an increase of \$11.2 million or 17%. The increase in cost of revenues was attributable to the higher sales volume of AVONEX. Included in cost of revenues for the three months ended June 30, 2002 and 2001 is \$35 million and \$33.9 million, respectively, of costs related to product revenues and \$1.2 million and \$1.3 million, respectively, of costs related to royalty revenue. Included in cost of revenues for the six months ended June 30, 2002 and 2001 is \$72.9 million and \$62.2 million, respectively, of costs related to product revenues and \$2.6 million and \$2.1 million, respectively, of costs related to royalty revenue. Gross margins on product revenues were approximately 86% for the three months ended June 30, 2002 and 2001. Gross margins on product revenues decreased to approximately 86% for the six months ended June 30, 2002 compared to 87% for the same period in 2001. Gross margins on royalty revenue increased to approximately 94% for the three months ended June 30, 2002 compared to 93% for the same period in 2001. Gross margins on royalty revenue were approximately 94% for the six months ended June 30, 2002 and 2001. The Company expects that gross margins on royalty revenue will fluctuate in the future based on changes in sales volumes for specific products.

Research and development expenses in the current quarter were \$89.3 million, an increase of \$10.2 million, or 13%, as compared to \$79.1 million for the same period of 2001. Research and development expenses for the six months ended June 30, 2002 were \$171.8 million, an increase of \$19.9 million, or 13%, as compared to \$151.9 million for the same period of 2001. The increase was due primarily to an increase in development costs related to the Company's ongoing collaborative development programs and increases in clinical trial costs. 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 work on new formulations for AVONEX.

Selling, general and administrative expenses in the second quarter of 2002 were \$91.6 million, an increase of \$36.4 million or 66% as compared to the same period of 2001. Selling, general and administrative expenses in the six months ended June 30, 2002 were \$165 million, an increase of \$61.2 million or 59% as compared to the same period of 2001. These increases were primarily due to an increase in selling and marketing expenses related to the sale of AVONEX and increased costs in anticipation of the possible approval of AMEVIVE® (alefacept). Selling, general and administrative expenses for the second quarter of 2002 also include approximately \$5.8 million of severance and other benefits related to the retirement of Mr. Vincent as the Chairman of the Board. If the Company receives regulatory approval to market AMEVIVE in the United States and the EU, selling, general and administrative expenses may increase in the near and long term.

## OTHER INCOME, NET

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

	Three Months Ended June 30, 2002		Six Months Ended June 30, 2002	
	2002	2001	2002	2001
Interest income	\$10,466	\$10,694	\$21,064	\$22,479
Interest expense	(909)	(1,051)	(1,922)	(2,089)
Other income (expense)	(1,453)	1,890	(4,010)	7,606
<b>Total other income, net</b>	<b>\$ 8,104</b>	<b>\$11,533</b>	<b>\$15,132</b>	<b>\$27,996</b>

Other income, net consists primarily of interest income, partially offset by interest expenses and other non-operating income and expenses. Other income, net in the current quarter of 2002 was \$8.1 million as compared to \$11.5 million in 2001, a decrease of \$3.4 million. Other income, net in the six months ended June 30, 2002 was \$15.1 million as compared to \$28 million in 2001, a decrease of \$12.9 million. Interest income for the three months ended June 30, 2002 was \$10.5 million compared to \$10.7 million in the same period of 2001, a decrease of \$0.2 million or 2%. Interest income for the first six months of 2002 was \$21.1 million compared to \$22.5 million in the same period of 2001, a decrease of \$1.4 million or 6%. The decreases in interest income for the three and six months were 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 June 30, 2002 was approximately \$0.9 million compared to \$1.1 million for the same period in 2001, a decrease of \$0.2 million or 14%. Interest expense for the six months ended June 30, 2002 was approximately \$1.9 million compared to \$2.1 million for the same period in 2001, a decrease of \$0.2 million or 8% due to lower borrowings outstanding.

Other income (expense) decreased by \$3.3 million for the second quarter of 2002 compared to the same period in 2001. Other income (expense) decreased by \$11.6 million for the six months ended June 30, 2002 compared to the same period in 2001. The decrease in other income (expense) for the six months ended June 30, 2002 is due primarily to the Company's recognition of \$2.8 million of losses attributable to an equity method investee and realization of losses of approximately \$2.5 million from the writedown and sales of certain non-current marketable securities in the first six months of 2002. This compares to realizing \$3.3 million of gains from sales of certain non-current marketable securities in the first six months of 2001.

## INCOME TAXES

Income tax expense as a percentage of pre-tax income was 28% for the three and six months ended June 30, 2002 and was 30% for the three and six months ended June 30, 2001. The effective tax rate varied from the U.S. statutory rates for the first six months of 2002 and 2001 primarily due to higher sales in European jurisdictions with lower tax rates and to the utilization of research and development credits. The Company's effective tax rate outside the U.S. is lower than the U.S. tax rate, and the Company expects that the corporate tax rate will decline as international sales increase.

## FINANCIAL CONDITION

At June 30, 2002, cash, cash equivalents and short-term marketable securities were \$793.5 million compared with \$798.1 million at December 31, 2001, a decrease of \$4.6 million. Working capital increased

\$37.1 million to \$839.9 million. Net cash from operating activities (which included net income) for the six month period ending June 30, 2002 was \$100.9 million compared with \$172.9 million for the same period in 2001, and included tax benefits related to stock options of \$14.3 million, and a non-cash adjustment of \$2.2 million related to the write-down of non-current marketable securities. Cash outflows from investing activities during the six months ended June 30, 2002 included investments in property and equipment and patents of \$115 million and net cash outflows from investing activities related to marketable securities totaling \$18.1 million. Significant cash outflows from financing activities included \$8.4 million for purchases of the Company's common stock under its stock repurchase program and \$2.4 million for repayments on loan agreements with banks. Cash inflows included \$18.4 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. The Company purchased 145,000 shares during the first six months of 2002 at a cost of \$8.4 million. During 2001, the Company repurchased approximately 1.5 million shares of its common stock under this program at a cost of \$88.3 million. Approximately 2.4 million shares remain authorized for repurchase under this program at June 30, 2002.

The Company's construction of the large scale manufacturing plant in Research Triangle Park, North Carolina was substantially completed in the first quarter of 2002. The Company began further expansion of its Research Triangle Park, North Carolina complex in 2001 with commencement of construction of a laboratory office building and additional manufacturing capacity. These additional projects are expected to be completed by the summer of 2003 at a total cost of approximately \$92 million. As of June 30, 2002, the Company had committed \$68 million for construction costs related to these additional projects, of which \$43 million had been spent. The Company is also completing plans to build a manufacturing plant in Denmark. The Company expects that construction will commence in 2003 at an estimated cost of \$250 million. At June 30, 2002, \$32 million had been authorized for costs related to the manufacturing plant in Denmark, of which \$14 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. See also Item 1 – Business, "Patents and Other Proprietary Rights" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 for discussions of these legal proceedings.

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.

## **NEW ACCOUNTING PRONOUNCEMENT**

In July 2002, the FASB issued SFAS 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material effect on the Company's financial statements.

## **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 anticipated level of future product sales, royalty revenues, expenses and profits, timing of clinical trials, potential outcome of clinical programs, regulatory approvals, marketing of additional products, impact of competitive products, anticipated outcome of pending or anticipated litigation, arbitration and patent-related proceedings, facility expansion and the value of investments in certain marketable securities. These and all other forward-looking statements 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 this Management's Discussion and Analysis of Financial Condition and Results of

Operations. Biogen does not undertake any obligation to publicly update any forward-looking statements.

## **DEPENDENCE ON AVONEX® SALES**

Biogen's ability to sustain increases in revenues and profitability until at least approval and successful launch of a second product will be primarily dependent on the level of revenues and profitability from AVONEX sales. The level of revenues from sales of AVONEX will depend on a number of factors, including: continued market acceptance of AVONEX worldwide; Biogen's ability to maintain a high level of patient satisfaction with AVONEX; the nature of regulatory pricing decisions related to AVONEX worldwide; the level of growth, if any, in the overall MS marketplace; the extent to which AVONEX continues to receive and maintains reimbursement coverage; the nature of legislative actions affecting the pharmaceutical industry; the success of ongoing development related to AVONEX in expanded MS indications; the continued accessibility of third parties to vial, label, and distribute AVONEX on acceptable terms; success in revoking the Rentschler II patent since if the patent were to be upheld and if Rentschler were to obtain, through legal proceedings, a determination that Biogen's sale of AVONEX in Europe infringes a valid Rentschler II patent, such result could have a material adverse effect on the Company's results of operation and financial condition; and the Company's ability to sustain market share of AVONEX in light of the impact of competitive products for the treatment of MS. AVONEX competes in the United States and EU markets primarily with four products: COPAXONE®, sold by Teva Neuroscience, Inc. ("Teva") in the United States and co-promoted by Teva and Aventis Pharma in the EU, BETASERON®, sold by Berlex in the United States and sold under the name of BETAFERON® by Schering A.G. in the EU, NOVANTRONE®, sold by Amgen, Inc. and REBIF® which was launched in the United States by Serono in March 2002. Serono announced in July 2002 that it reached an agreement to co-promote REBIF in the United States with Pfizer Inc. The Company expects there to be aggressive competition among these companies in the MS market worldwide. AVONEX sales may also be affected by a possible slowing in growth of the MS market. See the Company's Annual Report on Form 10-K for the period ended on December 31, 2001 under the headings "Management's Discussion and Analysis of Financial Condition and Results of Operation — Outlook — Competition" and "Business — Patents and Other Proprietary Rights".

## **ROYALTY REVENUE**

Biogen receives royalty revenues which, prior to 2001, contributed a significant amount to its overall profitability. Royalty revenues have decreased significantly in recent years primarily as the result of patent expirations, see "Outlook — Patents and Other Proprietary Rights," and a royalty dispute with Schering-Plough. Biogen is currently in arbitration with Schering-Plough on the issue of whether and to what extent Schering-Plough has an obligation to pay royalties in the United States on sales of its alpha interferon products. Schering-Plough has taken the position that a Court of Appeal's decision affirming a District Court's ruling which narrowed the scope of the claims of Biogen's United States alpha interferon patent (the "901 Patent") allowed it to discontinue royalty payments to Biogen in the United States on sales of its alpha interferon products. The Court of Appeals decision came as part of a suit filed by Schering-Plough, as Biogen's exclusive licensee, against Amgen, Inc. ("Amgen") to enforce the 901 Patent which Schering-Plough claimed was infringed by Amgen's consensus interferon product. Biogen disagrees with Schering-Plough's position and has filed for arbitration to compel payment of unpaid past royalties and to ensure payment of royalties due in the future under the license agreement. Given Schering-Plough's history of taking aggressive positions in contract interpretation, Biogen has included claims in the arbitration which would resolve issues related to future royalty payments to pre-empt any potential challenges by Schering-Plough. These claims include asking the arbitration panel to confirm Schering-Plough's obligation to commence royalty payments in July 2002 (the expiration date of the 901 Patent) based on a patent application owned by F. Hoffman-LaRoche ("Roche") and Genentech, Inc. ("Genentech"). The agreement between Biogen and Schering-Plough extending Schering-Plough's royalty obligation beyond the expiration date of the 901 Patent was part of the settlement of a lawsuit between Biogen and Roche/Genentech. In return for Schering-Plough's agreement to extend its royalty obligation, Biogen settled the lawsuit with Roche/Genentech and Roche granted Schering-Plough an exclusive license for Schering-Plough to sell its products under the Roche/Genentech patent rights that were the subject of the dispute. Biogen intends to vigorously pursue its claims against Schering-Plough, but there is no guarantee that Biogen will be successful in its efforts.



There are a number of other factors which could also cause the actual level of royalty revenue to differ from Biogen's expectations. For example, pricing reforms, health care reform initiatives, other legal and regulatory developments and the introduction of competitive products 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. See "Outlook — Patents and Other Proprietary Rights."

There can be no assurance that the Company will achieve a positive outcome with respect to any of the factors discussed in this Section or that the timing and extent of the Company's success with respect to any combination of these factors will be sufficient to result in sustained increases in revenues or profitability or the sustained profitability of the Company. For a further discussion of risks regarding drug development, patent matters, including the Berlex lawsuit regarding the "McCormick" patents, and regulatory matters, see the Company's Annual Report on Form 10-K for the period ended December 31, 2001 under the headings "Business — Risks Associated with Drug Development", "Business — Patents and Other Proprietary Rights", "Business — Regulation", "Legal Proceedings" and "Management's Discussion and Analysis of Financial Condition and Results of Operations — Outlook."

## **PRODUCTS**

AVONEX is currently the only product 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 expects that its next product on the market will be AMEVIVE. The applications for marketing approval of AMEVIVE are currently under review by both the FDA and regulatory authorities in the EU. On May 23, 2002, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA voted to recommend AMEVIVE for marketing approval. In June 2002, Biogen received a Complete Response Letter from the FDA on the AMEVIVE filing. No new clinical trials of AMEVIVE were requested prior to approval. The FDA proposed post-marketing clinical studies to further profile the safety and effectiveness of AMEVIVE. Biogen is working closely with the FDA to address the questions raised in the letter and move forward rapidly in the approval process. Approval of AMEVIVE is subject to Biogen's ability to work with the FDA to adequately address the questions and provide the clarification and information requested in the Complete Response Letter. Approval is also subject to the other risks and uncertainties inherent in drug development, including the risk of unexpected new data or information. Even if approved, there is no assurance that AMEVIVE will be free from technical issues affecting commercialization, manufacturing, or intellectual property disputes or that it will achieve its market potential.

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, collaborations with third parties, 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 AMEVIVE and 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 the Company'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.

## **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. 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 also filed patent applications and have been granted patents in the United States 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 United States 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. Biogen is also aware of certain patents held by Genentech relating to immunoadhesin technology that Genentech may take the position are valid and infringed by Biogen's future commercial activities with AMEVIVE. Biogen is evaluating these patents to determine if a license should be taken. 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. 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.

PART II – OTHER INFORMATION

Item 4 – Submission of Matters to a Vote of Security Holders

- (a) The information set forth in this Item 4 relates to matters submitted to a vote at the Annual Meeting of Stockholders of Biogen, Inc. on June 14, 2002.
- (b) Not applicable.
- (c) A proposal to elect Thomas F. Keller, Roger H. Morley, James C. Mullen and Phillip A. Sharp as directors to serve for a three year term ending in 2005 and until their successors are duly elected and qualified was approved with the following vote:

Nominee	For	Abstains
Thomas F. Keller	110,079,122	9,111,849
Roger H. Morley	110,692,346	8,498,625
James C. Mullen	110,753,355	8,437,616
Phillip A. Sharp	110,799,693	8,391,278

A proposal to ratify the selection of PricewaterhouseCoopers LLP as the Company’s independent accountants for the fiscal year ending December 31, 2002 was approved with 113,018,285 affirmative votes, 3,243,940 negative votes, and 2,925,456 abstentions.

- (d) Not applicable.

Item 5 – Other Information

None.

Item 6 – Exhibits and Reports on Form 8-K

- (a) Exhibits
  - 3.1 By-Laws (as amended and restated through June 13, 2002).
  - 10.1 1985 Non-Qualified Stock Option Plan (as amended and restated through June 13, 2002, effective as of June 1, 2002).
  - 10.2 Agreement and Amendment to Rights Agreement dated as of May 31, 2002 between the Registrant, State Street Bank and Trust Company, as the old Rights Agent, and EquiServe, Inc., as the new Rights Agent, amending the Rights Agreement, dated as of May 8, 1999, between the Registrant and State Street Bank and Trust Company (successor in interest to First National Bank of Boston) as the Rights Agent.
  - 99.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- (b) Reports on Form 8-K

None.

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, INC.

Dated: August 14, 2002

/s/ Peter N. Kellogg

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Executive Vice President — Finance and  
Chief Financial Officer