



**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the Quarterly Period ended September 30, 2005

Commission File Number 0-19311

**BIOGEN IDEC INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0112644**

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

**14 Cambridge Center, Cambridge, MA 02142**

**(617) 679-2000**

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: **Yes**  **No**

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934):  
**Yes**  **No**

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934):  
**Yes**  **No**

The number of shares of the registrant's Common Stock, \$0.0005 par value, outstanding as of October 17, 2005, was 339,409,857 shares.

**BIOGEN IDEC INC.**

**FORM 10-Q — Quarterly Report**

**For the Quarterly Period Ended September 30, 2005**

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## PART I

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
<b>Revenues:</b>				
Product	\$ 391,366	\$ 359,692	\$ 1,187,773	\$ 1,095,415
Unconsolidated joint business	181,597	159,507	526,984	444,619
Royalties	23,117	23,860	71,600	73,371
Corporate partner	131	217	3,290	10,377
Total revenues	<u>596,211</u>	<u>543,276</u>	<u>1,789,647</u>	<u>1,623,782</u>
<b>Costs and expenses:</b>				
Cost of product revenues	88,358	63,110	257,083	467,051
Cost of royalty revenues	1,203	1,350	3,179	3,904
Research and development	227,039	168,307	579,357	496,990
Selling, general and administrative	161,410	132,622	475,637	403,116
Amortization of acquired intangible assets	75,990	107,054	228,746	267,222
Facility impairments and loss on sale	21,046	—	102,904	—
Total costs and expenses	<u>575,046</u>	<u>472,443</u>	<u>1,646,906</u>	<u>1,638,283</u>
Income (loss) from operations	21,165	70,833	142,741	(14,501)
Other income (expense), net	11,192	(1,573)	8,318	16,566
Income before income tax provision	32,357	69,260	151,059	2,065
Income tax provision	5,172	32,492	45,910	5,668
Net income (loss)	<u>\$ 27,185</u>	<u>\$ 36,768</u>	<u>\$ 105,149</u>	<u>\$ (3,603)</u>
Basic earnings (loss) per share	<u>\$ 0.08</u>	<u>\$ 0.11</u>	<u>\$ 0.31</u>	<u>\$ (0.01)</u>
Diluted earnings (loss) per share	<u>\$ 0.08</u>	<u>\$ 0.10</u>	<u>\$ 0.31</u>	<u>\$ (0.01)</u>
<b>Shares used in calculating:</b>				
Basic earnings (loss) per share	<u>336,536</u>	<u>334,777</u>	<u>334,819</u>	<u>335,165</u>
Diluted earnings (loss) per share	<u>340,859</u>	<u>355,232</u>	<u>346,581</u>	<u>335,165</u>

See accompanying notes to the condensed consolidated financial statements.

**BIOGEN IDEC INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except per share amounts)**

	September 30, 2005 (unaudited)	December 31, 2004
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 296,492	\$ 209,447
Marketable securities available-for-sale	314,906	848,495
Accounts receivable, net	261,535	278,637
Due from unconsolidated joint business	141,543	137,451
Deferred tax assets	149,187	86,880
Inventory	227,469	251,016
Other current assets	78,894	119,118
Assets held for sale	65,186	—
Total current assets	<u>1,535,212</u>	<u>1,931,044</u>
Marketable securities available-for-sale	1,207,062	1,109,624
Property and equipment, net	1,093,680	1,525,225
Intangible assets, net	3,057,209	3,292,827
Goodwill	1,151,105	1,151,105
Investments and other assets	270,341	155,933
	<u>\$ 8,314,609</u>	<u>\$ 9,165,758</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 48,210	\$ 121,471
Deferred revenue	18,603	13,695
Taxes payable	250,351	129,350
Notes payable	—	748,430
Accrued expenses and other	241,781	247,802
Total current liabilities	<u>558,945</u>	<u>1,260,748</u>
Notes payable	42,925	101,879
Long-term deferred tax liability	856,297	921,771
Other long-term liabilities	58,615	54,959
Commitments and contingencies	—	—
Shareholders' equity		
Convertible preferred stock, par value \$0.001 per share	—	—
Common stock, par value \$0.0005 per share	175	173
Additional paid-in capital	8,246,743	8,184,979
Accumulated other comprehensive loss	(6,189)	(6,767)
Deferred stock-based compensation	(53,836)	(36,280)
Accumulated deficit	(802,311)	(801,094)
	<u>7,384,582</u>	<u>7,341,011</u>
Less treasury stock, at cost	586,755	514,610
Total shareholders' equity	<u>6,797,827</u>	<u>6,826,401</u>
	<u>\$ 8,314,609</u>	<u>\$ 9,165,758</u>

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2005	2004
<b>Cash Flows from Operating Activities</b>		
Net Income (Loss)	\$ 105,149	\$ (3,603)
Adjustments to reconcile net income (loss) to net cash flows from operating activities		
Depreciation and amortization	304,684	332,976
Stock-based compensation	19,465	11,345
Non-cash interest expense and amortization of investment premium	26,728	38,018
Deferred income taxes	(132,211)	(128,427)
Tax benefit from stock options	11,875	86,996
Realized loss on sale of marketable securities available-for-sale	2,983	2,999
Write-down of inventory to net realizable value	65,714	21,684
Impact of inventory step-up	12,313	285,671
Facility impairments and loss on sale	102,904	—
Impairment of property, plant and equipment	3,067	—
Impairment of investments and other assets	32,124	12,734
Other	—	26
Changes in assets and liabilities, net:		
Accounts receivable	11,497	(39,048)
Due from unconsolidated joint business	(4,092)	(7,262)
Inventory	(54,480)	(57,375)
Other current and other assets	11,166	(45,092)
Accrued expenses and other current liabilities	87,313	27,475
Deferred revenue	4,908	7,800
Other long-term liabilities	3,656	154
Net cash flows from operating activities	<u>614,763</u>	<u>547,071</u>
<b>Cash Flows from Investing Activities</b>		
Purchases of marketable securities available-for-sale	(1,122,712)	(2,892,683)
Proceeds from sales and maturities of marketable securities available-for-sale	1,536,475	2,937,055
Acquisitions of property, plant and equipment	(215,950)	(227,007)
Proceeds from sale of manufacturing facility	408,130	—
Purchases of investments and other assets	(117,258)	—
Net cash flows from investing activities	<u>488,685</u>	<u>(182,635)</u>
<b>Cash Flows from Financing Activities</b>		
Purchase of treasury stock	(322,590)	(698,390)
Issuance of common stock for stock-based compensation arrangements	—	132,941
Issuance of treasury stock for stock-based compensation arrangements	88,041	75,827
Repurchase of senior notes	(746,415)	—
Change in cash overdrafts	(35,439)	(10,646)
Net cash flows from financing activities	<u>(1,016,403)</u>	<u>(500,268)</u>
Net increase (decrease) in cash and cash equivalents	87,045	(135,832)
Cash and cash equivalents, beginning of the period	209,447	314,850
Cash and cash equivalents, end of the period	<u>\$ 296,492</u>	<u>\$ 179,018</u>

See accompanying notes to the condensed consolidated financial statements.

**BIAGEN IDEC INC. AND SUBSIDIARIES**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

**Overview**

Biogen Idec creates new standards of care in oncology, neurology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. We currently have five products:

- AVONEX® (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis, or MS.

- RITUXAN® (rituximab) and ZEVALIN® (ibrutinomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. We collaborate with Genentech Inc., or Genentech, on the development and commercialization of RITUXAN. In August 2005, we, along with Genentech, submitted a supplemental Biologics License Application, or sBLA, with the U.S. Food and Drug Administration, or FDA, for a new indication for RITUXAN in patients with active rheumatoid arthritis, or RA, who inadequately respond to an anti-TNF therapy. RITUXAN is the trade name in the United States, or U.S., Canada and Japan for the compound rituximab. MabThera is the trade name for rituximab in the European Union, or EU. In this Form 10-Q, we refer to rituximab, RITUXAN and MabThera collectively as RITUXAN, except where we have otherwise indicated.

- TYSABRI® (natalizumab), formerly known as ANTEGREN®, which was approved by the FDA in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan Corporation plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and RA. These decisions were based on reports of cases of progressive multifocal leukoencephalopathy, or PML, a rare and potentially fatal, demyelinating disease of the central nervous system in patients treated with TYSABRI in clinical studies. We and Elan are consulting with leading experts to better understand the possible risk of PML and have been working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies. The safety evaluation also included the review of any reports of potential PML in MS patients receiving TYSABRI in the commercial setting. In October 2005, we completed our safety evaluation of TYSABRI in MS, Crohn's disease and RA patients and found no new cases of PML. Three confirmed cases of PML were previously reported, two of which were fatal. On September 26, 2005, we submitted an sBLA for TYSABRI to the FDA for the treatment of MS. The sBLA includes: final two-year data from the Phase 3 AFFIRM monotherapy trial and SENTINEL combination trial with AVONEX in MS; the integrated safety assessment of patients treated with TYSABRI in clinical trials; and a revised label and risk management plan. We requested Priority Review status for the sBLA which, if granted, would result in action by the FDA approximately six months from the submission date, rather than 10 months for a standard review. We and Elan have also submitted a similar data package to the European Medicines Agency, or EMEA. This information was supplied as part of the ongoing EMEA review process, which was initiated in the summer of 2004 with the filing for approval of TYSABRI as a treatment for MS. We plan to work with regulatory authorities to determine if dosing in MS and other clinical studies will be re-initiated and the future commercial availability of the product.

- AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. In September 2005, we announced that we will seek to divest AMEVIVE as part of a comprehensive strategic plan which is discussed below.

In September 2005, we began implementing a comprehensive strategic plan designed to position us for long-term growth. The plan builds on the continuing strength of AVONEX and RITUXAN and other expected near-term developments. The plan has three principal elements: reducing operating expenses and enhancing economic flexibility by recalibrating our asset base, geographic site missions, staffing levels and business processes; committing significant additional capital to external business development and research opportunities; and changing our organizational culture to enhance innovation and support the first two elements of the plan. In conjunction with the plan, we are consolidating or eliminating certain internal management layers and staff functions, resulting in the reduction of our workforce by approximately 17%, or approximately 650 positions worldwide. These adjustments will take place across company functions, departments and sites, and are expected to be substantially implemented by the end of 2005. In addition, we are seeking to divest several non-core assets, including AMEVIVE, our NICO clinical manufacturing facility in San Diego, California and certain real property in Oceanside, California.

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In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring accruals, necessary for a fair statement of our financial position, results of operations and cash flows as well as that of our subsidiaries. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our 2004 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. Interim results are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

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

### ***Principles of Consolidation***

The condensed consolidated financial statements include our financial statements and those of our wholly owned subsidiaries, and a joint venture in Italy, in which we are the primary beneficiary. We also consolidate a limited partnership investment, in which we are the majority investor. All material intercompany balances and transactions have been eliminated.

### ***Inventories***

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

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

	September 30, 2005	December 31, 2004
Raw materials	\$ 51,876	\$ 48,465
Work in process	123,124	157,947
Finished goods	52,469	44,604
	<u>\$ 227,469</u>	<u>\$ 251,016</u>

We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict to the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed \$23.2 million of costs related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, as we were working with clinical investigators to understand the possible risks of PML, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense for the three and nine months ended September 30, 2005. We will continue to assess TYSABRI to determine if manufacturing costs need to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realized value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. For the three months ended September 30, 2005, we wrote-down \$16.1 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$9.1 million for AMEVIVE, \$6.4 million for ZEVALIN and \$0.6 million for AVONEX. The write-downs of AMEVIVE inventory consisted of \$4.8 million for expired product and \$4.3 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The ZEVALIN inventory was written-down in the third quarter when it was determined that the inventory will not be marketable based on estimates of demand. The write-downs of AVONEX inventory in the third quarter related to product that failed to meet quality specifications.

For the nine months ended September 30, 2005, we wrote-down \$42.5 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$23.4 million for AMEVIVE, \$10.1 million for AVONEX and \$9.0 million for ZEVALIN. The write-downs for AMEVIVE inventory consisted of \$4.8 million for expired product and \$18.6 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of AVONEX inventory consisted of \$8.4 million for remaining supplies of the alternative presentations of AVONEX that were no longer needed after the FDA approved a new component for the pre-filled syringe formulation of AVONEX in March 2005, and \$1.7 million for product that failed to meet quality specifications. The write-down of ZEVALIN inventory was related to inventory that will not be marketable based on estimates of demand.

For the three months ended September 30, 2004, we wrote-down \$9.2 million of unmarketable inventory to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-down of ZEVALIN inventory resulted from a determination that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA.

For the nine months ended September 30, 2004, we wrote-down \$21.0 million of unmarketable inventory to cost of product revenues. The write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of ZEVALIN inventory consisted of \$3.4 million of inventory that failed to meet the numerous stringent quality specifications agreed upon with the FDA and \$4.7 million of inventory that will not be marketable based on estimates of demand.

### ***Intangible Assets and Goodwill***

In connection with the merger transaction on November 12, 2003 between Biogen, Inc. and IDEC Pharmaceuticals Corporation, or the Merger, we recorded intangible assets related to patents, trademarks, and core technology as part of the purchase price. These intangible assets were recorded at fair value, and at September 30, 2005 and December 31, 2004 are net of accumulated amortization and impairments. Intangible assets related to out-licensed patents and core technology are amortized over their estimated useful lives, ranging from 12 to 20 years, based on the greater of straight-line method or economic consumption each period. These amortization costs are included in "Amortization of acquired intangible assets" in the accompanying condensed consolidated statements of income. Intangible assets related to trademarks have indefinite lives, and as a result are not amortized, but are subject to review for impairment. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

In the third quarter of 2005, we completed a review of our business opportunities in each of the relevant commercial markets in which our products are sold and determined their expected profitability. As a result of this review, in the third quarter of 2005, management determined that certain clinical trials would not continue which indicated that the carrying value of certain technology intangible assets related to future sales of AVONEX in Japan may not be recoverable. As a result, we recorded a charge of approximately \$7.9 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of technology intangible assets related to AVONEX. Additionally, in the third quarter of 2005, we recorded a charge of \$5.7 million to cost of product revenues related to an impairment of certain capitalized ZEVALIN patents, to reflect the adjustment to net realizable value. As part of our decision to divest our AMEVIVE product, we have reassessed our intangible assets related to AMEVIVE, and have determined that there are no impairments related to these assets as a result of our decision to divest AMEVIVE. However, should new information arise, we may be required to take impairment charges related to certain of our intangibles. In the third quarter of 2004, management determined that certain clinical trials would not continue which indicated that the carrying value of certain core technology intangible assets related to AMEVIVE may not be recoverable. As a result, we recorded a charge of approximately \$27.8 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE.

Goodwill associated with the Merger represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for by the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. Goodwill is reviewed annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. As a result of the voluntary suspension of TYSABRI in February 2005, we performed an interim review for impairment of goodwill, intangibles and other long-lived assets. We believe that the fair value of our Biogen reporting unit exceeds its carrying value and therefore, we determined that goodwill was not impaired. However, should new information arise, we may need to reassess goodwill for impairment in light of the new information and we may be required to take impairment charges related to goodwill.



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As of September 30, 2005 and December 31, 2004, intangible assets and goodwill, net of accumulated amortization and impairment charges, were as follows (table in thousands):

	Estimated Life	September 30, 2005			December 31, 2004		
		Historical Cost	Accumulated Amortization	Net	Historical Cost	Accumulated Amortization	Net
Out-licensed patents	12 years	\$ 578,000	\$ 90,714	\$ 487,286	\$ 578,000	\$ 54,589	\$ 523,411
	15-20						
Core/developed technology	years	2,984,000	480,890	2,503,110	2,993,000	297,269	2,695,731
Trademarks & tradenames	Indefinite	64,000	—	64,000	64,000	—	64,000
In-licensed patents	7-14 years	3,000	187	2,813	12,482	2,797	9,685
<b>Total</b>		<b>\$ 3,629,000</b>	<b>\$ 571,791</b>	<b>\$ 3,057,209</b>	<b>\$ 3,647,482</b>	<b>\$ 354,655</b>	<b>\$ 3,292,827</b>
Goodwill	Indefinite	\$ 1,151,105	\$ —	\$ 1,151,105	\$ 1,151,105	\$ —	\$ 1,151,105

### **Revenue Recognition and Accounts Receivable**

SEC Staff Accounting Bulletin No. 101, or SAB 101, superceded in part by SAB 104, 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. SAB 104 also requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. We believe that our revenue recognition policies are in compliance with SAB 101 and SAB 104.

Product revenue consists of sales from four of our products: AVONEX, AMEVIVE, ZEVALIN, and TYSABRI. The timing of distributor orders and shipments can cause variability in earnings. Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Revenues are recorded net of applicable allowances for returns, patient assistance, trade term discounts, Medicaid rebates, Veteran's Administration rebates, and managed care discounts and other applicable allowances. Included in our condensed consolidated balance sheets at September 30, 2005 and December 31, 2004 are allowances for returns, rebates, discounts and other allowances which totaled \$39.7 million and \$33.8 million, respectively. At September 30, 2005, our allowance for product returns, which is a component of allowances for returns, rebates, discounts, and other allowances, was \$1.7 million. In the first nine months of 2005, total discounts and allowances were approximately 3% of total current assets and less than 1% of total assets. We prepare our estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

For the three and nine months ended September 30, 2005, we recorded \$59.1 million and \$167.0 million, respectively, in our condensed consolidated statements of income related to sales returns and allowances, discounts, and rebates compared to \$39.1 million and \$116.7 million, respectively, for the comparable periods in 2004. In the three and nine months ended September 30, 2005, the amount of product returns was approximately 1.0% and 1.7%, respectively, of product revenue for all our products compared to 1.3% and 1.1%, respectively, for the comparable periods in 2004. Product returns, which is a component of allowances for returns, rebates, discounts, and other allowances, were \$4.0 million and \$20.1 million for the three and nine months ended September 30, 2005, respectively, compared to \$4.8 million and \$12.0 million, respectively, to the comparable periods in 2004. The increase of product returns in the nine months ended September 30, 2005 consisted primarily of \$9.7 million due to the voluntary suspension of TYSABRI. Product returns in the first nine months of 2005 included \$9.2 million related to product sales made prior to 2005, which represents less than 1% of total product revenue, of which \$4.7 million was in reserves at December 31, 2004.

In January 2003, we received regulatory approval to market AMEVIVE in the U.S. In connection with the commercialization of AMEVIVE, we implemented an initiative, undertaken in cooperation with one of our distributors which provides discounts on future purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the claim after appeal and where the other requirements of the initiative are met. Under this initiative, our exposure was contractually limited to 5% of the price of all AMEVIVE purchased by the distributor. As a result, we deferred recognition of revenue of 5% of AMEVIVE purchased by the distributor until such time as sufficient history of insurance reimbursement claims became available. As of December 31, 2004, we had approximately \$2.8 million of deferred revenue related to this initiative in accrued expenses and other. Since January 2003, our experience of denials of claims after appeal and where the other requirements of the initiative have been met were substantially below the contractual limit. As a result, in the first quarter of 2005, we recognized approximately \$2.8 million in AMEVIVE product revenue, which had previously been deferred.

In November 2004, we received regulatory approval in the U.S. of TYSABRI for the treatment of MS and paid a \$7.0 million approval-based milestone to Elan. Upon approval, we also became obligated to provide Elan with \$5.3 million in credits against

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reimbursement of commercialization costs. Elan can apply \$1.5 million of the credits per year. The approval and credit milestones were capitalized upon approval in investments and other assets and are being amortized over the remaining patent life of approximately 15 years. The amortization of the approval and credit milestones is being recorded as a reduction of revenue. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. We have reassessed our long-lived assets related to TYSABRI, such as intangibles and manufacturing facilities, and have determined that there are no impairments related to these assets as a result of the suspension of the marketing of TYSABRI. However, should new information arise, we may be required to take impairment charges related to certain of our long-lived assets.

Under our agreement with Elan, we manufacture TYSABRI and, in the U.S. prior to the suspension, sold TYSABRI to Elan who then distributed TYSABRI to third party distributors. Prior to the suspension, we recorded revenue when TYSABRI was shipped from Elan to third party distributors. In the first quarter of 2005, we recorded \$5.9 million of net product revenues related to sales of TYSABRI to Elan that we estimate were ultimately dosed into patients. Additionally, as of March 31, 2005, we deferred \$14.0 million in revenue under our revenue recognition policy with Elan, which has been fully paid by Elan, related to sales of TYSABRI which had not yet been shipped by Elan and remains deferred at September 30, 2005. Through September 30, 2005, we incurred net withdrawal costs of \$7.8 million related to sales returns in connection with the voluntary suspension of TYSABRI.

As of September 30, 2005, Elan owed us \$18.7 million, representing commercialization and development expenses as well as withdrawal costs incurred by us, which is included in other current assets on our condensed consolidated balance sheets.

Revenues from unconsolidated joint business consist of our share of the pretax copromotion profits generated from our copromotion arrangement with Genentech, reimbursement from Genentech of our RITUXAN-related sales force and development expenses and royalties from Genentech for sales of RITUXAN outside the U.S. by Roche and Zenyaku. Under the copromotion arrangement, all U.S. sales of RITUXAN and associated costs and expenses are recognized by Genentech and we record our share of the pretax copromotion profits on a quarterly basis, as defined in our amended and restated collaboration agreement with Genentech. Pretax copromotion profits under the copromotion arrangement are derived by taking U.S. net sales of RITUXAN to third-party customers less cost of sales, third-party royalty expenses, distribution, selling and marketing expenses and joint development expenses incurred by Genentech and us.

Under the amended and restated collaboration agreement, our current pretax copromotion profit-sharing formula, which resets annually, is as follows:

<u>Copromotion Operating Profits</u>	<u>Biogen Idec's Share of Copromotion Profits</u>
First \$50 million	30%
Greater than \$50 million	40%

In both 2004 and 2005, the 40% threshold was met during the first quarter. For each calendar year or portion thereof following the approval date of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products sold by us and Genentech will change to the following:

<u>Copromotion Operating Profits</u>	<u>New Anti-CD20 U.S. Gross Product Sales</u>	<u>Biogen Idec's Share of Copromotion Profits</u>
First \$50 million (1)	N/A	30%
Greater than \$50 million	Until such sales exceed \$150 million in any calendar year (2)	38%
	or	
	After such sales exceed \$150 million in any calendar year and until such sales exceed \$350 million in any calendar year (3)	35%

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<u>Copromotion Operating Profits</u>	<u>New Anti-CD20 U.S. Gross Product Sales</u>	<u>Biogen Idec's Share of Copromotion Profits</u>
	or	
	After such sales exceed \$350 million in any calendar year (4)	30%

- (1) – not applicable in the calendar year the first new anti-CD20 product is approved if \$50 million in copromotion operating profits has already been achieved in such calendar year through sales of RITUXAN.
- (2) – if we are recording our share of RITUXAN copromotion profits at 40%, upon the approval date of the first new anti-CD20 product, our share of copromotion profits for RITUXAN and the new anti-CD20 product will be immediately reduced to 38% following the approval date of the first new anti-CD20 product until the \$150 million new product sales level is achieved.
- (3) – if \$150 million in new product sales is achieved in the same calendar year the first new anti-CD20 product receives approval, then the 35% copromotion profit-sharing rate will not be effective until January 1 of the following calendar year. Once the \$150 million new product sales level is achieved then our share of copromotion profits for the balance of the year and all subsequent years' (after the first \$50 million in copromotion operating profits in such years) will be 35% until the \$350 million new product sales level is achieved.
- (4) – if \$350 million in new product sales is achieved in the same calendar year that \$150 million in new product sales is achieved, then the 30% copromotion profit-sharing rate will not be effective until January 1 of the following calendar year (or January 1 of the second following calendar year if the first new anti-CD20 product receives approval and, in the same calendar year, the \$150 million and \$350 million new product sales levels are achieved). Once the \$350 million new product sales level is achieved then our share of copromotion profits for the balance of the year and all subsequent years' will be 30%.

Currently, we record our share of expenses incurred for the development of new anti-CD20 products in research and development expense until such time as a new product is approved, at which time we will record our share of pretax copromotion profits related to the new product in revenues from unconsolidated joint business. We record our royalty revenue on sales of RITUXAN outside the U.S. on a cash basis. Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products, as compared to royalty revenue received on sales of RITUXAN. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis.

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

### ***Research and Development Expenses***

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development expenses are expensed as incurred. We have entered into certain research agreements in which we share expenses with our collaborator. We have entered into other collaborations where we are reimbursed for work performed on behalf of our collaborative partners. We record these expenses as research and development expenses. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments by the collaborator for their share of the development effort as a reduction of research and development expense. If the arrangement is a reimbursement of research and development expenses, we record the reimbursement as corporate partner revenue.

We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict with the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed

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\$23.2 million of costs related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense in the three and nine months ended September 30, 2005. We will continue to assess TYSABRI to determine if it needs to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards.

### **Reclassification**

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

### **Accounting for Stock-Based Compensation**

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

If compensation cost for awards issued in the three and nine months ended September 30, 2005 and 2004 under the stock-based compensation plans, including costs related to prior years' awards, had been determined based on SFAS 123 as amended by SFAS 148, our pro forma net income (loss), and pro forma earnings (loss) per share for the three and nine months ended September 30, would have been as follows (table in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Reported net income (loss)	\$ 27,185	\$ 36,768	\$ 105,149	\$ (3,603)
Stock-based compensation included in net income (loss), net of tax	2,916	2,779	13,226	7,459
Pro forma stock compensation expense	(17,323)	(7,296)	(59,638)	(19,732)
Pro forma net income (loss)	\$ 12,778	\$ 32,251	\$ 58,737	\$ (15,876)
Reported basic earnings (loss) per share	\$ 0.08	\$ 0.11	\$ 0.31	\$ (0.01)
Pro forma basic earnings (loss) per share	\$ 0.04	\$ 0.10	\$ 0.18	\$ (0.05)
Reported diluted earnings (loss) per share	\$ 0.08	\$ 0.10	\$ 0.31	\$ (0.01)
Pro forma diluted earnings (loss) per share	\$ 0.04	\$ 0.09	\$ 0.17	\$ (0.05)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	35%	35%	35%	43%
Risk-free interest rate	4.2%	3.4%	4.1%	3.4%
Expected option life in years	5.4	5.4	5.4	5.4

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, and additional awards in future years are anticipated. Additionally, in December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123(R), "Share-Based Payments," which replaces FASB Statement No. 123 and supersedes APB Opinion No. 25. SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. In April 2005, the SEC issued a rule amending the compliance date which allows companies to implement SFAS 123(R) at the beginning of their next fiscal year, instead of the next reporting period, that begins after June 15, 2005. As a result, we will implement SFAS 123(R) in the reporting period starting January

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1, 2006. See “Note 19 — New Accounting Pronouncements” for a more complete description of this new accounting guidance and the potential impact it will have on our financial statements.

### ***Assets Held for Sale***

As part of the comprehensive strategic plan that we announced in September 2005, we are seeking to divest several non-core assets, including our NICO clinical manufacturing facility in San Diego, California and certain real property in Oceanside, California. We consider those assets as held for sale, since they meet the criteria of held for sale under SFAS 144, “Accounting for the Impairment or Disposal of Long-Live Assets,” and have reported those assets separately in current assets on the condensed consolidated balance sheet at September 30, 2005.

## **2. Financial Instruments**

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

We have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts have durations of ninety days. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in other comprehensive income. Realized gains and losses for the effective portion are recognized with the underlying hedge transaction. The notional settlement amount of the foreign currency forward contracts outstanding at September 30, 2005 was approximately \$52.8 million. These contracts had a fair value of \$0.8 million, representing an unrealized gain, and were included in other current assets at September 30, 2005. The notional settlement amount of the foreign currency forward contracts outstanding at December 31, 2004 was approximately \$164.3 million. These contracts had a fair value of \$18.1 million, representing an unrealized loss, and were included in other current liabilities at December 31, 2004.

For the nine months ended September 30, 2005, we recognized \$1.0 million of gains in earnings due to hedge ineffectiveness and no significant amounts as a result of the discontinuance of cash flow hedge accounting because it was no longer probable that the hedge forecasted transaction would occur. For the three and nine months ended September 30, 2004, there were no significant amounts recognized in earnings due to hedge ineffectiveness or as a result of the discontinuance of cash flow hedge accounting because it was no longer probable that the hedge forecasted transaction would occur. We recognized approximately \$0.5 million of gains and \$1.8 million of losses in product revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2005, respectively, as compared to approximately \$0.9 million and \$2.0 million of losses for the three and nine months ended September 30, 2004, respectively. We recognized no material amounts and \$0.3 million of losses in royalty revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2005, respectively, as compared to \$0.1 million of gains and \$0.1 million of losses for the three and nine months ended September 30, 2004, respectively. These settlements were recorded in the same period as the related forecasted transactions affecting earnings.

## **3. Comprehensive Income (Loss)**

Comprehensive income (loss) consists of net income (loss) and other comprehensive income. Other comprehensive income includes certain changes in equity that are excluded from net income (loss), such as translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities and certain derivative instruments, net of tax. Comprehensive income (loss) for the three months ended September 30, 2005 and 2004 was \$29.4 million and \$49.7 million, respectively. Comprehensive income (loss) for the nine months ended September 30, 2005 and 2004 was \$105.7 million and \$(7.9) million, respectively.

## **4. Earnings (Loss) per Share**

We calculate earnings (loss) per share in accordance with Statement of Financial Accounting Standards No. 128, “Earnings per Share,” or SFAS 128, and EITF 03-06, “Participating Securities and the Two-Class Method Under SFAS 128.” SFAS 128 and EITF 03-06 together require the presentation of “basic” earnings (loss) per share and “diluted” earnings (loss) per share. Basic earnings

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(loss) per share is computed using the two-class method. Under the two-class method, undistributed net income is allocated to common stock and participating securities based on their respective rights to share in dividends. We have determined that our preferred shares meet the definition of participating securities, and have allocated a portion of net income to our preferred shares on a pro rata basis. Net income allocated to preferred shares is excluded from the calculation of basic earnings (loss) per share. For basic earnings (loss) per share, net income (loss) available to holders of common stock is divided by the weighted average number of shares of common stock outstanding. For purposes of calculating diluted earnings (loss) per share, net income is adjusted for the after-tax amount of interest associated with convertible debt and net income allocable to preferred shares, and the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive other potential common stock such as stock options and other convertible securities, to the extent they are dilutive.

Basic and diluted earnings (loss) per share are calculated as follows (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
<b>Numerator:</b>				
Net income (loss)	\$ 27,185	\$ 36,768	\$ 105,149	\$ (3,603)
Adjustment for net income allocable to preferred stock	40	54	155	—
Net income (loss) used in calculating basic earnings (loss) per share	27,145	36,714	104,994	(3,603)
Adjustment for interest, net of tax	—	462	1,467	—
Net income (loss) used in calculating diluted earnings (loss) per share	\$ 27,145	\$ 37,176	\$ 106,461	\$ (3,603)
<b>Denominator:</b>				
Weighted average number of common shares outstanding	336,536	334,777	334,819	335,165
<b>Effect of dilutive securities:</b>				
Stock options	2,615	9,873	3,527	—
Restricted stock awards	1,708	1,185	1,677	—
Convertible preferred stock	—	—	—	—
Convertible promissory notes due 2019	—	9,397	6,558	—
Dilutive potential common shares	4,323	20,455	11,762	—
Shares used in calculating diluted earnings (loss) per share	340,859	355,232	346,581	335,165

The following amounts were not included in the calculation of net income (loss) per share because their effects were anti-dilutive (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
<b>Numerator:</b>				
Net income allocable to preferred shares	\$ 40	\$ 54	\$ 155	\$ —
Adjustment for interest, net of tax	446	1,069	5,752	1,531
Total	\$ 486	\$ 1,123	\$ 5,907	\$ 1,531
<b>Denominator:</b>				
Stock options	22,991	3,419	17,674	13,022
Restricted stock awards	—	—	—	790
Convertible preferred stock	493	493	493	329
Convertible promissory notes due 2019	3,048	—	—	3,132
Convertible promissory notes due 2032	73	8,661	3,817	2,887
Total	26,605	12,573	21,984	20,160

## 5. Collaborations

In connection with our December 2002 and August 2004 agreements with Sunesis Pharmaceuticals, Inc., or Sunesis, we had purchased approximately 4.2 million shares of Sunesis preferred stock for approximately \$20.0 million and provided Sunesis with a \$4.0 million credit facility. In addition to the previous agreements entered into with Sunesis, in September 2005 we purchased \$5.0 million of common stock of Sunesis as part of their initial public offering, or IPO. Also, in conjunction with the IPO, our preferred stock was converted into shares of Sunesis common stock. As a result of the IPO valuation, we wrote-down the value of our investment in the converted shares and, in the third quarter of 2005, recognized a \$4.6 million charge for the impairment of our Sunesis investment that was determined to be other-than-temporary. Following the IPO, we own approximately 2.9 million shares, or 13.6% of shares outstanding, of Sunesis common stock with a fair value of \$19.5 million, which is included in investments and other assets. We have no commitments or obligations associated with the \$5.0 million investment. Additionally, Sunesis used a portion of their proceeds from the IPO to



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repay \$4.0 million borrowed from us under a credit facility that we provided to Sunesis in connection with our 2002 collaborative agreement. At September 30, 2005, there are no amounts outstanding under the credit facility.

In August 2005, we entered in a collaborative agreement with Protein Design Labs, Inc., or PDL, for the joint development, manufacture and commercialization of three Phase II antibody products. Under this agreement, Biogen Idec and PDL will share in the development and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and the development and commercialization of M200 (volociximab) and HuZAF™ (fontolizumab) in all indications. Both companies will share equally the costs of all development activities and all operating profits from each collaboration product within the U.S. and Europe. We paid PDL an initial payment of \$40.0 million, which is included in research and development expenses in the third quarter of 2005. We also accrued \$10.0 million in research and development expense in the third quarter for future payments that were determined to be unavoidable. In addition, we purchased approximately \$100.0 million of common stock, or 3.6% of shares outstanding, from PDL, which was included in investments and other assets at September 30, 2005. Terms of the collaborative agreement require us to make certain development and commercialization milestone payments upon the achievement of certain program objectives totaling up to \$660 million over the life of the agreement, of which \$560 million relate to development and \$100 million relate to the commercialization of collaboration products.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc, or Vernalis, aimed at advancing research into Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis' lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. In June 2004, we made an investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis common shares. In March 2005, we purchased approximately 1.4 million additional shares under a qualified offering for \$1.8 million, which fully satisfies our investment obligation under the collaboration agreement. We now hold a total of approximately 7.6 million shares representing 3.5% of Vernalis' total shares outstanding. Our investment in Vernalis is included in investments and other assets.

## 6. Notes Payable

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

	September 30, 2005	December 31, 2004
<b>Current liabilities:</b>		
30-year senior convertible promissory notes, due 2032 at 1.75%	\$ —	\$ 748,430
	<u>\$ —</u>	<u>\$ 748,430</u>
<b>Long-term liabilities:</b>		
20-year subordinated convertible promissory notes, due 2019 at 5.5%	\$ 36,525	\$ 101,879
30-year senior convertible promissory notes, due 2032 at 1.75%	6,400	—
	<u>\$ 42,925</u>	<u>\$ 101,879</u>

In April and May 2002, we issued 30-year senior convertible promissory notes, or senior notes, for gross proceeds of approximately \$714.4 million, or \$696.0 million net of underwriting commissions and expenses of \$18.4 million. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. On April 29, 2005, holders of 99.2% of the outstanding senior notes exercised their right under the indenture governing the senior notes to require us to repurchase their senior notes. On May 2, 2005, we paid \$746.4 million in cash to repurchase those senior notes with an aggregate principal amount at maturity of approximately \$1.2 billion. The purchase price for the senior notes paid by the Company was \$624.73 in cash per \$1,000 principal amount at maturity, and was based on the requirements of the indenture and the senior notes. Neither a gain nor a loss resulted from this transaction. Additionally, we will be required to make a cash payment in 2005 of approximately \$56 million for the payment of tax for which deferred tax liabilities had been previously established related to additional deductible interest expense. Following the repurchase, \$6.4 million (\$10.2 million principal amount at maturity) of senior notes remain outstanding.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes issued in February 1999 would have had an aggregate principal face value of \$345.0 million. As of

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September 30, 2005, our remaining indebtedness under the subordinated notes was approximately \$75.4 million at maturity, due to conversion of subordinated notes into common stock. Each \$1,000 aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36 per share. In the first nine months of 2005, holders of subordinated notes with a face value of approximately \$143.8 million elected to convert their subordinated notes to approximately 5.8 million shares of our common stock. Additionally, the holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2009 or 2014 at a price equal to the issue price plus the accrued original issue discount to the date of purchase, with us having the option to repay the subordinated notes plus accrued original issue discount in cash, common stock or a combination of cash and stock. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the subordinated notes for cash at any time.

### 7. Other Income (Expense), Net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Interest income	\$ 16,530	\$ 13,794	\$ 44,636	\$ 43,058
Interest expense	(571)	(2,984)	(10,331)	(10,246)
Other expense	(4,767)	(12,383)	(25,987)	(16,246)
Total other income (expense), net	\$ 11,192	\$ (1,573)	\$ 8,318	\$ 16,566

Other expense for the three months ended September 30, 2005 consists primarily of \$4.6 million for the impairment of certain marketable securities that were determined to be impaired on an other-than-temporary basis and \$1.7 million of realized losses on sales of marketable securities, which were offset by \$2.5 million received from Targeted Genetics as a partial repayment of a loan that had previously been written-off.

Other expense for the nine months ended September 30, 2005 consists primarily of \$16.9 million of expenses related to the impairment of certain marketable securities that were determined to be impaired on an other-than-temporary basis, \$7.8 million of foreign exchange remeasurement losses, \$2.3 million of loan impairments, and \$3.0 million of realized losses on sales of marketable securities. These charges were offset by \$1.0 million of gains related to hedge ineffectiveness and \$2.5 million received from Targeted Genetics as a partial repayment of a loan that had previously been written-off.

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

### 8. Income Taxes

Our effective tax rate for the three and nine months ended September 30, 2005 was 16.0% and 30.4%, respectively, compared to 46.9% and 274.5%, respectively, for the comparable periods in 2004. The effective rate for the three months ended September 30, 2005 was lower than the effective rate for the nine months ended September 30, 2005 primarily due to additional tax benefit recognized discretely during the quarter related to U.S. restructuring expenses. Our effective tax rate for the three and nine months ended September 30, 2005 was lower than the normal statutory rate primarily due to the effect of lower income tax rates (less than the 35% U.S. statutory corporate rate) in certain non-U.S. jurisdictions in which we operate, tax credits allowed for research and experimentation expenditures in the U.S., and the new domestic manufacturing deduction, offset by acquisition-related intangible amortization arising from purchase accounting related to foreign jurisdictions. Our effective tax rate for the three and nine months ended September 30, 2004 was higher than the normal statutory rates primarily due to the acquisition-related intangible amortization expenses and impairment charges and inventory fair value adjustments arising from purchase accounting related to foreign jurisdictions. We have tax credit carryforwards for federal and state income tax purposes available to offset future taxable income. The utilization of our tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate that this annual limitation will result only in a modest delay in the utilization of such tax credits.

On October 22, 2004, the American Jobs Creation Act of 2004, or the Act, was signed into law. The Act creates a temporary incentive, which expires on December 31, 2005, for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate that could be as low as 5.25%. On December 21, 2004, the FASB issued FASB staff position 109-2, "Accounting and Disclosure Guidance for the Foreign



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Earnings Repatriation Provision within the American Jobs Creation Act of 2004”, or FSP 109-2. FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS 109’s exception to recognizing deferred tax liabilities and require explanatory disclosures from those who need the additional time. Through September 30, 2005, we have not recognized deferred taxes on foreign earnings because such earnings were, and continue to be, indefinitely reinvested outside the U.S. Whether we will ultimately take advantage of this temporary tax incentive depends on a number of factors including an assessment of cash requirements outside of the U.S. and reviewing Congressional or other Governmental guidance with respect to certain aspects of the new legislation that required clarification and analysis before an informed decision can be made. We expect to complete this analysis during the fourth quarter of 2005. Until such analysis is completed, we will continue our plan and intention to indefinitely reinvest accumulated earnings of our foreign subsidiaries. If we decide to avail ourselves of this temporary tax incentive, up to \$500 million could be repatriated under the Act, and we could incur a one-time tax charge to our consolidated results of operations of up to approximately \$32 million in the fourth quarter of 2005.

The Act also provides a deduction for domestic manufacturing. We estimate that the deduction will reduce our effective tax rate by approximately 0.81% for the current year and by a higher amount in future years, as the deduction is fully phased-in.

### **9. Unconsolidated Joint Business Arrangement**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Copromotion profits	\$ 129,009	\$ 118,753	\$ 385,843	\$ 339,612
Reimbursement of selling and development expenses	10,807	7,999	35,756	17,903
Royalty revenue on sales of RITUXAN outside the U.S.	41,781	32,755	105,385	87,104
	<u>\$ 181,597</u>	<u>\$ 159,507</u>	<u>\$ 526,984</u>	<u>\$ 444,619</u>

We received royalties on sales of RITUXAN outside of the U.S. of \$41.8 million and \$105.4 million for the three and nine months ended September 30, 2005, respectively, as compared to \$32.8 million and \$87.1 million for the three and nine months ended September 30, 2004, respectively, which we include under “Unconsolidated joint business” revenues in our condensed consolidated statements of income. Our royalty revenue on sales of RITUXAN outside the U.S. is based on Roche and Zenyaku’s net sales to third-party customers and is recorded on a cash basis. Royalty revenues from sales of RITUXAN outside the U.S. increased approximately \$29.6 million, but were offset in the nine months ended September 30, 2005 by an \$11.3 million royalty credit claimed by Genentech.

Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products, as compared to royalty revenue received on sales of RITUXAN. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis.

### **10. Litigation**

On March 2, 2005, we, along with William H. Rastetter, our Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned *Brown v. Biogen Idec Inc., et al.*, filed in the U.S. District Court for the District of Massachusetts (the “Court”). The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product’s distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, costs and attorneys’ fees. Substantially similar actions, captioned *Grill v. Biogen Idec Inc., et al.* and *Lobel v. Biogen Idec Inc., et al.*, were filed on March 10, 2005 and April 21, 2005 in the same court by other purported class representatives. Those actions have been assigned to District Judge Reginald C. Lindsay and Magistrate Judge Marianne C. Bowler. On July 26, 2005, the three cases were consolidated and by Margin Order dated September 23, 2005, Magistrate Judge Bowler appointed lead plaintiffs and approved their selection of co-lead counsel. An objection to the September 23, 2005 order has been filed and briefed by the affected plaintiffs and their counsel, but remains pending with the Court. No date has been set for the filing of an amended, consolidated complaint. We believe that the actions are without merit and intend to contest them vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss.

On March 4, 2005, a purported shareholder derivative action, captioned *Halpern v. Rastetter, et al.* (“Halpern”), was filed in the Court of Chancery for the State of Delaware, in New Castle County, on our behalf, against us as nominal defendant, our Board of

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Directors and our former general counsel. The plaintiff derivatively claims breaches of fiduciary duty by our Board of Directors for inadequate oversight of our policies, practices, controls and assets, and for recklessly awarding executive bonuses despite alleged awareness of potentially serious side effects of TYSABRI and the potential for related harm to our financial position. The plaintiff also derivatively claims that our Executive Chairman, former general counsel and a director misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI, and alleges that our Board of Directors did not ensure that appropriate policies were in place regarding the control of confidential information and personal trading in our securities by officers and directors. The plaintiff seeks unspecified damages, profits, the return of all bonuses paid by us, costs and attorneys' fees. A substantially similar action, captioned *Golaine v. Rastetter, et al.* ("Golaine"), was filed on March 14, 2005 in the same court. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. We filed an Answer and Affirmative Defenses in Halpern on March 31, 2005 and our Board of Directors filed an Answer and Affirmative Defenses on April 11, 2005, which was amended as of April 12, 2005. By court order dated April 14, 2005, Halpern and Golaine were consolidated, captioned *In re Biogen Idec Inc. Derivative Litigation* (the "Delaware Action") and the Halpern complaint was deemed the operative complaint in the Delaware Action. On May 19, 2005, we and our Board of Directors filed a motion seeking judgment on the pleadings, and on August 3, 2005, plaintiffs filed a motion seeking voluntary dismissal of the action. On September 27, 2005, the Court entered an Order providing that the plaintiffs in the purported derivative cases pending in the Superior Court of California and the Middlesex Superior Court for the Commonwealth of Massachusetts may file a complaint in intervention in the Delaware Action not later than October 28, 2005 (the "Delaware Order"). If no such complaint in intervention is timely filed, then the Court shall enter a further order and final judgment finding that the Delaware Action has not alleged, as a matter of controlling substantive Delaware law, demand excusal as to the claims raised in the Delaware Action and granting defendants' motions and dismissing the litigation with prejudice on the merits. To date, we have not been served with any proposed complaint(s) in intervention. The consolidated action does not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On March 9, 2005, two additional purported shareholder derivative actions, captioned *Carmona v. Mullen, et al.* ("Carmona") and *Fink v. Mullen, et al.* ("Fink"), were brought in the Superior Court of the State of California, County of San Diego, on our behalf, against us as nominal defendant, our Board of Directors and our chief financial officer. The plaintiffs derivatively claim breach of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment against all defendants. The plaintiffs also derivatively claim insider selling in violation of California Corporations Code § 25402 and breach of fiduciary duty and misappropriation of information against certain defendants who sold our securities during the period of February 18, 2004 to the date of the complaints. The plaintiffs allege that the defendants caused and/or allowed us to issue, and conspired, aided and abetted and acted in concert in concealing that we were issuing, false and misleading press releases about the safety of TYSABRI and its financial prospects which resulted in legal claims being asserted against us, irreparable harm to our corporate image, depression of our stock price and impairment of our ability to raise capital. The plaintiffs also allege that certain defendants sold personally owned shares of our stock while in possession of material, undisclosed, adverse information. The plaintiffs seek unspecified damages, treble damages for the purported insider trading in violation of California Corporate Code § 25402, equitable relief including restriction of the defendants' trading proceeds or other assets, restitution, disgorgement and costs, including attorneys' fees and expenses. Neither of the plaintiffs made presuit demand on the Board of Directors prior to filing their respective actions. On April 11, 2005, all defendants filed a Motion To Stay Proceedings in both Carmona and Fink, which the plaintiffs' opposed, pending resolution of the Delaware Action. On May 11, 2005, the Court consolidated the Carmona and Fink cases. On May 27, 2005, the Court granted defendants' Motion to Stay. On September 27, 2005, plaintiffs were provided a copy of the Delaware Order. These purported derivative actions do not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On June 20, 2005, a purported class action, captioned *Wayne v. Biogen Idec Inc. and Elan Pharmaceutical Management Corp.*, was filed in the U.S. District Court for the Northern District of California. On August 15, 2005, the plaintiff filed an amended complaint. The amended complaint purports to assert claims for strict product liability, medical monitoring and concert of action arising out of the manufacture, marketing, distribution and sale of TYSABRI. The action is purportedly brought on behalf of all persons in the U.S. who have had infusions of TYSABRI and who have not been diagnosed with any medical conditions resulting from TYSABRI use. The plaintiff alleges that defendants, acting individually and in concert, failed to warn the public about purportedly known risks related to TYSABRI use. The plaintiff seeks to recover the cost of periodic medical examinations, restitution, interest, compensatory and punitive damages, and attorneys' fees. Defendants currently have until November 15, 2005 to respond to the amended complaint. A case management conference currently is scheduled for December 15, 2005. We believe that the action is without merit and intend to contest it vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss, if any.

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Our Board of Directors has received letters, dated March 1, 2005, March 15, 2005 and May 23, 2005, respectively, on behalf of purported owners of our securities purportedly constituting demands under Delaware law. A supplement to the March 1 letter was received on March 2, 2005. The letters generally allege that certain of our officers and directors breached their fiduciary duty to us by selling personally held shares of our securities while in possession of material, non-public information about potential serious side effects of TYSABRI. The letters generally request that our Board of Directors take action on our behalf to recover compensation and profits from the officers and directors, consider enhanced corporate governance controls related to the sales of securities by insiders, and pursue other such equitable relief, damages, and other remedies as may be appropriate. A special litigation committee of our Board of Directors was formed, and, with the assistance of independent outside counsel, investigated the allegations set forth in the demand letters. By letters dated August 17, 2005 and October 1, 2005, our Board of Directors informed those shareholders that it would not take action as demanded because it was the Board's determination that such action was not in the best interests of the Company. On June 23, 2005, one of the purported shareholders who made demand filed a purported derivative action in the Middlesex Superior Court for the Commonwealth of Massachusetts, on our behalf, against us as nominal defendant, our former general counsel, a member of our Board of Directors and our Executive Chairman. The plaintiff derivatively claims that our Executive Chairman, former general counsel and the director defendant misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI. The plaintiff seeks disgorgement of profits, costs and attorneys' fees. On September 27, 2005, the plaintiff was provided with a copy of the Delaware Order and responded on September 28, 2005 that he would not be moving to intervene in Delaware. On October 4, 2005, all defendants filed motions seeking dismissal of the action and/or judgment on the pleadings, and the Company also filed a supplemental motion seeking judgment on the pleadings. Also on October 4, 2005, the plaintiff filed a cross-motion seeking leave to amend the complaint, which the Company has opposed. The Court has not yet ruled on those motions. The action does not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On April 21, 2005, we received a formal order of investigation from the Boston District Office of the SEC. The SEC is investigating whether any violations of the federal securities laws occurred in connection with the suspension of marketing and commercial distribution of TYSABRI. We continue to cooperate fully with the SEC in this investigation. We are unable to predict the outcome of this investigation or the timing of its resolution at this time.

On June 9, 2005, we, along with numerous other companies, received a request for information from the U.S. Senate Committee on Finance, or the Committee, concerning the Committee's review of issues relating to the Medicare and Medicaid programs' coverage of prescription drug benefits. We are cooperating fully with the Committee's information request. We are unable to predict the outcome of this review or the timing of its resolution at this time.

On July 20, 2005, a products liability action captioned Walter Smith, as Personal Representative of the Estate of Anita Smith, decedent, and Walter Smith, individually v. Biogen Idec Inc. and Elan Corp., PLC, was commenced in the Superior Court of the Commonwealth of Massachusetts, Middlesex County. The complaint purports to assert statutory wrongful death claims based on negligence, agency principles, fraud, breach of warranties, loss of consortium, conscious pain and suffering, and unfair and deceptive trade practices in violation of Mass. G.L., c. 93A. The complaint alleges that Anita Smith, a participant in a TYSABRI clinical trial, died as a result of PML caused by TYSABRI and that the defendants, individually and jointly, prematurely used TYSABRI in a clinical trial, failed to adequately design the clinical trial, failed to adequately monitor patients participating in the clinical trial, and failed to adequately address and warn of the risks of PML, immunosuppression and risks associated with the pharmacokinetics of TYSABRI when used in combination with AVONEX. The plaintiff seeks compensatory, punitive and multiple damages as well as interest, costs and attorneys' fees. We believe that the action is without merit and intend to contest it vigorously. At this stage of the litigation, we cannot make any estimate of a potential range of loss.

On October 4, 2004, Genentech, Inc. received a subpoena from the U.S. Department of Justice requesting documents related to the promotion of RITUXAN. We market RITUXAN in the U.S. in collaboration with Genentech. Genentech has disclosed that it is cooperating with the associated investigation, which they disclosed that they have been advised is both civil and criminal in nature. The potential outcome of this matter and its impact on us cannot be determined at this time.

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York ("Columbia") in the U.S. District Court for the District of Massachusetts, docket no. 03-11329-MLW ("2003 action") contending that it had no obligation to pay royalties to Columbia under a 1993 license agreement under which it had licensed from Columbia a family of patents and applications ("Axel patents") including U.S. Patent No 6,455,275 ("275 patent"), due to the invalidity and unenforceability of the '275 patent. A third party initiated reexamination proceedings with respect to the '275 patent, and Columbia initiated reissue proceedings with respect to it. These two proceedings were merged in the patent office. Columbia subsequently covenanted not to sue Biogen Idec MA, Inc. on any current claim of the '275 patent or any reissue claim identical to or substantially

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the same as a current claim of the '275 patent if such claim were to emerge from the merged reexamination and reissue proceedings currently pending. Accordingly, on November 5, 2004, the court dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction. On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation filed suit against Columbia in the U.S. District Court for the District of Massachusetts, docket no. 04-12009-MLW ("2004 action"). In the 2004 action, the plaintiffs reasserted some of the contentions made in the 2003 action and also brought other claims for relief. On August 4, 2005, Biogen Idec Inc. and Biogen Idec MA, Inc. arrived at a settlement of the disputes summarized above. Under the settlement, Biogen Idec Inc. and Biogen Idec MA, Inc. are licensed under the Axel patents, including any new or reissued patents in the Axel family that could issue in the future. The other terms of the settlement are confidential and, we believe, not material to investors. On August 5, 2005, Columbia, Biogen Idec Inc., and Biogen Idec MA, Inc. filed stipulations dismissing the 2003 action and the 2004 action with prejudice.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we "provided instructions and/or recommendations on a proper immunization schedule for vaccines" to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. On November 19, 2004, we, along with GlaxoSmithKline, filed a joint motion to dismiss three of the four counts of the complaint. The Court granted that motion on July 22, 2005. On August 1, 2005, Classen filed a motion for reconsideration, which is still pending before the Court. Classen also has filed a Stipulation, seeking to have the third, and final, count against us dismissed with prejudice. Under our 1988 license agreement with GlaxoSmithKline, GlaxoSmithKline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that GlaxoSmithKline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the City of New York and the following Counties of the State of New York: County of Albany, County of Allegany, County of Broome, County of Cattaraugus, County of Cayuga, County of Chautauqua, County of Chenango, County of Columbia, County of Cortland, County of Erie, County of Essex, County of Fulton, County of Genesee, County of Greene, County of Herkimer, County of Jefferson, County of Lewis, County of Madison, County of Monroe, County of Nassau, County of Niagara, County of Oneida, County of Onondaga, County of Orleans, County of Putnam, County of Rensselaer, County of Rockland, County of St. Lawrence, County of Saratoga, County of Steuben, County of Suffolk, County of Tompkins, County of Warren, County of Washington, County of Wayne, County of Westchester, and County of Yates. All of the cases, except for the County of Erie and County of Nassau cases, are the subject of a Consolidated Complaint, which was filed on June 15, 2005 in U.S. District Court for the District of Massachusetts in Multi-District Litigation No. 1456. The County of Nassau, which originally filed its complaint on November 24, 2004, filed an amended complaint on March 24, 2005 and that case is also pending in the U.S. District Court for the District of Massachusetts. The County of Erie originally filed its complaint in Supreme Court of the State of New York on March 8, 2005. On April 15, 2005, Biogen Idec and the other named defendants removed the case to the U.S. District Court for the Western District of New York. On August 11, 2005, the Joint Panel on Multi-District Litigation issued a Transfer Order, transferring the case to the U.S. District Court for the District of Massachusetts. The County of Erie has filed a motion to remand the case back to the Supreme Court of the State of New York, which is currently pending before the District Court in the District of Massachusetts.

All of the complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs; marketed and promoted the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs; and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, all of the complaints, with the exception of the County of Erie complaint, allege that the defendants failed to accurately report the "best price" on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services, and excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the "best price." On April 8, 2005, the court dismissed similar claims, which were brought by Suffolk County against Biogen Idec and eighteen other defendants in a complaint filed on August 1, 2003. The court held that Suffolk County's documentation was insufficient to plead allegations of fraud. Neither Biogen Idec nor the other defendants have answered or responded to the complaints that are currently pending in the U.S. District Court for the District of Massachusetts, as all of the

plaintiffs have agreed to stay the time to respond until a case management order and briefing schedule have been approved by the Court. Biogen Idec intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

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

#### **11. Share Repurchase Program**

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. During the first nine months of 2005, we repurchased approximately 7.5 million shares under this program, at a cost of \$322.6 million. Approximately 11.9 million shares remain authorized for repurchase under this program at September 30, 2005.

#### **12. Segment Information**

We operate in one segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment. We currently have five products: AVONEX and TYSABRI for the treatment of relapsing MS, RITUXAN and ZEVALIN, both of which treat certain B-cell NHLs and AMEVIVE for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. We also receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control including sales of RITUXAN outside the U.S. Revenues are primarily attributed from external customers to individual countries where earned based on location of the customer or licensee.

#### **13. Guarantees**

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. However, to date we have not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of September 30, 2005.

In connection with the relocation from leased facilities to our new research and corporate campus in San Diego, California, we entered into a lease assignment, in January 2005, with Tanox West, Inc., or Tanox, for a manufacturing facility in San Diego for which we have outstanding lease obligations through September 2008. Under the lease assignment, Tanox was assigned all of our rights, title, and interest in the amended lease and assumed all of the terms, covenants, conditions and obligations required to be kept, performed and fulfilled under the amended lease, including the making of all payments under the amended lease. However, if Tanox were to fail to perform under the lease assignment we would be responsible for all obligations under the amended lease through September 2008. At September 30, 2005, our estimate of the maximum potential of future payments under the amended lease through September 2008 is \$14.5 million. Under the lease assignment, Tanox has agreed to indemnify and hold us harmless from and against any and all claims, proceedings and demands and all costs, expenses and liabilities arising out of their performance or failure to perform under the lease assignment.

#### **14. Restricted Stock and Restricted Stock Unit Awards**

In the first nine months of 2005, we granted a total of 0.8 million shares of restricted common stock to employees under our 2003 Omnibus Equity Plan and 2005 Omnibus Equity Plan. In 2004, we granted a total of 1.3 million shares of restricted common stock to employees under our 2003 Omnibus Equity Plan. Substantially all the restricted stock will vest 100% three years from the grant date, provided the employee remains continuously employed with us. During the vesting period, employees have full voting rights, even though the restricted stock remains subject to transfer restrictions and will generally be forfeited upon termination of employment prior to vesting. Approximately 0.5 million and 0.1 million shares have been forfeited as of September 30, 2005 and December 31, 2004, respectively, due to employee terminations. At September 30, 2005 and December 31, 2004, deferred stock based compensation related to restricted stock was \$53.3 million and \$35.1 million, respectively, and was included in shareholders' equity. For the three and nine months ended September 30, 2005, we recorded stock compensation charges of \$2.6 million and \$17.3 million, respectively, related to the restricted stock. Through September 2005, we have recorded \$5.6 million of credits for the reversal of previously recognized compensation associated with approximately 0.5 million of unvested restricted stock cancellations due to employee terminations. For the three and nine months ended September 30, 2004, we recorded stock compensation charges of \$4.3 million and \$11.3 million, respectively, related to the restricted stock.

In the three months ended September 30, 2005, we granted a total of 1.18 million performance-based restricted stock units, or RSUs, to be settled in shares of our common stock to a group of approximately 200 of our employees at the director-level and above. The grants were made under our 2005 Omnibus Equity Plan. The RSUs will convert into shares of Biogen Idec stock, subject to attainment of certain performance goals and the employee's continued employment. If the performance goals are attained and the employee is still in active employment, 70% of the RSUs will vest and convert into shares on September 14, 2006 and the remaining 30% of the RSUs will vest and convert into shares on March 14, 2007. Shares will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. In the three months ended September 30, 2005, we recorded compensation charges of approximately \$1.7 million, using variable accounting under APB 25 because the performance based goals have not yet been met.

#### **15. Pension**

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

We also assumed Biogen, Inc.'s unfunded Supplemental Executive Retirement Plan, or SERP, which covered a select group of highly compensated U.S. employees. The plans are noncontributory. The Retirement Plan's benefit formula was based on employee earnings and age. The SERP provided benefits for covered executives in excess of those permitted under the tax-qualified Retirement Plan. Biogen, Inc.'s funding policy for the plans has been to contribute amounts deductible for federal income tax purposes. Funds contributed to the plans have been invested in fixed income and equity securities. At October 31, 2003, Biogen, Inc. ceased allowing new participants into the plans. Effective December 31, 2003, we amended the plans so that no further benefits would accrue to participants.

We credited participants' cash balance accounts under the Retirement Plan for compensation and interest earned through December 31, 2003. After that date, no further compensation credits will be made, but interest credits will be made until Retirement Plan benefits have been distributed to participants.

We credited participants' accounts under the SERP for compensation and interest earned through December 31, 2003. No further compensation credits will be made, but interest credits will be made until SERP is terminated.

In connection with the termination of the Retirement Plan, we requested an Internal Revenue Service, or IRS, ruling that the Plans' terminations did not adversely affect its tax-qualified status. During 2004, our management decided to accelerate the payment and to pay out participants' benefits as soon as administratively possible. In December 2004, we began distributing to employees their respective Retirement Plan benefits. Participants had the following options with respect to the value of their Plan distribution: (a) to receive an immediate lump sum payment which may be rolled over into the 401(k) Plan or other designated qualified plan or individual retirement account, or (b) to receive an annuity that would begin either immediately or at a deferred date.

At September 30, 2005, we had a liability of \$0.9 million related to these plans, including transition benefits associated with the Retirement Plan terminations.



## 16. Impairment of Long-Lived Assets

In the third quarter of 2005, in connection with our comprehensive strategic plan that we announced in September 2005, we recorded an impairment charge of \$13.1 million to facility impairments and loss on sale, which reflects the adjustment to net realizable value of our NICO clinical manufacturing facility in San Diego, California, and classified the asset as held for sale under SFAS 144. The net realizable value was based in part by an independent third party valuation of the fair value of the manufacturing facility. Additionally, in the third quarter of 2005, we recorded a charge of \$12.9 million to selling, general and administrative expense to write-down any remaining prepaid expense associated with our arrangement with MDS (Canada) related to ZEVALIN, to its net realizable value.

As of March 31, 2005, after our voluntary suspension of TYSABRI, we reconsidered our construction plans and determined that we would proceed with the bulk manufacturing component of our large-scale biologic manufacturing facility in Hillerod. Additionally, we added a labeling and packaging component to the project, and determined that we would no longer proceed with the fill-finish component of the large-scale biological manufacturing facility. As a result, in the first quarter of 2005, we wrote-off \$6.2 million to research and development expense of engineering costs related to the fill-finish component that had previously been capitalized. The original cost of the project was expected to be \$372.0 million. As of September 30, 2005, we had committed approximately \$193.0 million to the project, of which \$117.5 million had been paid. We expect the label and packaging facility to be substantially completed in 2006 and licensed for operation in 2007.

## 17. Sale of Large-Scale Manufacturing Facility

On June 23, 2005, Genentech purchased our large-scale biologics manufacturing facility in Oceanside, California, known as "NIMO," along with approximately 60 acres of real property located in Oceanside, California upon which NIMO is located, together with improvements, related property rights, and certain personal property intangibles and contracts at or related to the real property. Through the first quarter of 2005, we intended to hold and continue using the facility. In June 2005, we determined instead to accept an offer from Genentech to purchase the facility. Total consideration for the purchase was \$408.1 million. For the three and nine months ended September 30, 2005, the loss from this transaction was \$7.7 million and \$83.3 million, respectively, which consisted primarily of the write-down of NIMO to net selling price, sales and transfer taxes, and other associated transaction costs. During the third quarter, we and Genentech finalized plans for the sale of certain equipment. Also, during the quarter, we had changes to estimates previously made for certain construction activities related to the NIMO facility. Following the closing of the sale, we terminated and Genentech offered employment, on an "at-will" basis, to 334 of our employees who were working at NIMO. These employees continued to be employed by us through August 16, 2005.

## 18. Severance and Other Costs from Restructuring Plan

In September 2005, we began implementing a comprehensive strategic plan designed to position us for long-term growth. In conjunction with the plan, we are consolidating or eliminating certain internal management layers and staff functions, resulting in the reduction of our workforce by approximately 17%, or approximately 650 positions worldwide. These adjustments will take place across company functions, departments and sites, and are expected to be substantially implemented by the end of 2005. We have recorded restructuring charges associated with these activities, which consist primarily of severance and other employee termination costs, including health benefits, outplacement, and bonuses. Other costs include write-downs of certain research assets that will no longer be utilized, consulting costs in connection with the restructuring effort, and costs related to the acceleration of restricted stock, offset by the reversal of previously recognized compensation due to unvested restricted stock cancellations. For the three months ended September 30, 2005, \$19.6 million of restructuring charges are included in research and development expenses, and \$7.6 million are included in selling, general and administrative expenses. These remaining costs at September 30, 2005 are included in accrued expenses and other on our condensed consolidated balance sheet. The components of the charges are as follows (table in thousands):

	Costs incurred at September 8, 2005	Paid/Settled through September 30, 2005	Remaining liability at September 30, 2005
Severance and employee termination costs	\$ 24,785	\$ (643)	\$ 24,142
Other costs	2,432	(1,783)	649
	<u>\$ 27,217</u>	<u>\$ (2,426)</u>	<u>\$ 24,791</u>

We may have additional charges related to our comprehensive strategic plan in future periods. The amounts of those charges cannot be determined at this time.

## 19. New Accounting Pronouncements

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections," which replaces APB Opinion No. 20, "Accounting Changes," and supersedes FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements—an amendment of APB Opinion No. 28." SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change.

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When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the provisions of the SFAS 154 will have a significant impact on our results of operations.

In December 2004, the FASB issued SFAS 123(R), "Share-Based Payments," which replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. SFAS 123(R) offers alternative methods for determining the fair value. In April 2005, the SEC issued a new rule that allows companies to implement SFAS 123(R) at the beginning of the next fiscal year, instead of the next reporting period, that begins after June 15, 2005. As a result, we will implement SFAS 123(R) in the reporting period starting January 1, 2006. We expect that SFAS 123(R) will have a significant impact on our financial statements. At the present time, we have not yet determined which valuation method we will use.

In July 2005, the FASB published an Exposure Draft of a proposed Interpretation, "Accounting for Uncertain Tax Positions." The Exposure Draft seeks to reduce the significant diversity in practice associated with recognition and measurement in the accounting for income taxes. It would apply to all tax positions accounted for in accordance with SFAS 109, "Accounting for Income Taxes." The Exposure Draft requires that a tax position meet a "probable recognition threshold" for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. The Exposure Draft contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. This proposed Interpretation would clarify the accounting for uncertain tax positions in accordance with SFAS 109. The FASB staff is considering the comment letters that have been received and is determining the plan for redeliberations. The Board expects to issue a final Interpretation, which would include amendments to SFAS 109, in the first quarter of 2006. We are currently evaluating the impact this proposed Interpretation would have on our results of operations.



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

**Overview**

Biogen Idec creates new standards of care in oncology, neurology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. We currently have five products:

- AVONEX® (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis, or MS.
- RITUXAN® (rituximab) and ZEVALIN® (ibrutinomab tiuxetan), both of which treat certain B-cell non-Hodgkin's lymphomas, or B-cell NHLs. We collaborate with Genentech Inc., or Genentech, on the development and commercialization of RITUXAN. In August 2005, we, along with Genentech, submitted a supplemental Biologics License Application, or sBLA, with the U.S. Food and Drug Administration, or FDA, for a new indication for RITUXAN in patients with active rheumatoid arthritis, or RA, who inadequately respond to an anti-TNF therapy. RITUXAN is the trade name in the United States, or U.S., Canada and Japan for the compound rituximab. MabThera is the trade name for rituximab in the European Union, or EU. In this Form 10-Q, we refer to rituximab, RITUXAN and MabThera collectively as RITUXAN, except where we have otherwise indicated.
- TYSABRI® (natalizumab), formerly known as ANTEGREN®, which was approved by the FDA in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan Corporation plc, or Elan, voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. In addition, we suspended dosing in clinical studies of TYSABRI in MS, Crohn's disease and RA. These decisions were based on reports of cases of progressive multifocal leukoencephalopathy, or PML, a rare and potentially fatal, demyelinating disease of the central nervous system in patients treated with TYSABRI in clinical studies. We and Elan are consulting with leading experts to better understand the possible risk of PML and have been working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies. The safety evaluation also included the review of any reports of potential PML in MS patients receiving TYSABRI in the commercial setting. In October 2005, we completed our safety evaluation of TYSABRI in MS, Crohn's disease and RA patients and found no new cases of PML. Three confirmed cases of PML were previously reported, two of which were fatal. On September 26, 2005, we submitted an sBLA for TYSABRI to the FDA for the treatment of MS. The sBLA includes: final two-year data from the Phase 3 AFFIRM monotherapy trial and SENTINEL combination trial with AVONEX in MS; the integrated safety assessment of patients treated with TYSABRI in clinical trials; and a revised label and risk management plan. We requested Priority Review status for the sBLA which, if granted, would result in action by the FDA approximately six months from the submission date, rather than 10 months for a standard review. We and Elan have also submitted a similar data package to the European Medicines Agency, or EMEA. This information was supplied as part of the ongoing EMEA review process, which was initiated in the summer of 2004 with the filing for approval of TYSABRI as a treatment for MS. We plan to work with regulatory authorities to determine if dosing in MS and other clinical studies will be re-initiated and the future commercial availability of the product.
- AMEVIVE® (alefacept) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. In September 2005, we announced that we will seek to divest AMEVIVE as part of a comprehensive strategic plan which is discussed below.

In September 2005, we began implementing a comprehensive strategic plan designed to position us for long-term growth. The plan builds on the continuing strength of AVONEX and RITUXAN and other expected near-term developments. The plan has three principal elements: reducing operating expenses and enhancing economic flexibility by recalibrating our asset base, geographic site missions, staffing levels and business processes; committing significant additional capital to external business development and research opportunities; and changing our organizational culture to enhance innovation and support the first two elements of the plan. In conjunction with the plan, we are consolidating or eliminating certain internal management layers and staff functions, resulting in the reduction of our workforce by approximately 17%, or approximately 650 positions worldwide. These adjustments will take place across company functions, departments and sites, and are expected to be substantially implemented by the end of 2005. In addition, we are seeking to divest several non-core assets, including AMEVIVE, our NICO clinical manufacturing facility in San Diego, California and certain real property in Oceanside, California.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Product sales				
United States	\$ 246,977	\$ 237,482	\$ 744,441	\$ 738,401
Rest of world	144,389	122,210	443,332	357,014
Total product sales	391,366	359,692	1,187,773	1,095,415
Unconsolidated joint business revenue	181,597	159,507	526,984	444,619
Royalties	23,117	23,860	71,600	73,371
Corporate partner	131	217	3,290	10,377
Total revenues	<u>\$ 596,211</u>	<u>\$ 543,276</u>	<u>\$ 1,789,647</u>	<u>\$ 1,623,782</u>

**Product Sales** (table in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
AVONEX	\$ 374,708	\$ 346,248	\$ 1,130,082	\$ 1,047,482
AMEVIVE	11,631	8,222	36,104	33,325
ZEVALIN	5,223	5,222	16,734	14,608
TYSABRI	(196)	—	4,853	—
Total product sales	<u>\$ 391,366</u>	<u>\$ 359,692</u>	<u>\$ 1,187,773</u>	<u>\$ 1,095,415</u>

For the three months ended September 30, 2005, sales of AVONEX generated worldwide revenues of \$374.7 million, of which \$234.7 million was generated in the U.S. and \$140.0 million was generated outside the U.S., primarily the EU. For the three months ended September 30, 2004, sales of AVONEX generated worldwide revenues of \$346.2 million, of which \$224.3 million was generated in the U.S. and \$121.9 million was generated outside the U.S., primarily the EU. The increase in U.S. product sales for AVONEX was primarily due to price increases offset by decreases in volume. Outside of the U.S., AVONEX product sales increased due to higher sales volume, price increases and the effect of foreign exchange. For the nine months ended September 30, 2005, sales of AVONEX generated worldwide revenues of \$1.1 billion, of which \$697.1 million was generated in the U.S. and \$433.0 million was generated outside the U.S., primarily the EU. For the nine months ended September 30, 2004, sales of AVONEX generated worldwide revenues of \$1.0 billion, of which \$691.1 million was generated in the U.S. and \$356.4 million was generated outside the U.S., primarily the EU. In the U.S., product sales from AVONEX increased primarily due to price increases, offset by lower volume of sales year over year. Comparatively, in the first quarter of 2004, we had experienced an increase in the inventories held by our channel partners to normalized levels as a result of recovery from previously encountered problems in manufacturing our pre-filled syringe formulation of AVONEX, and for the reintroduction of an older formulation of AVONEX into the marketplace. Outside the U.S., product sales increased primarily due to increased sales volume year over year. Product sales from AVONEX for the three and nine months ended September 30, 2005 represented approximately 63% of our total revenues for both periods compared to 64% and 65% of our total revenues for the comparable periods in 2004. We expect to face increasing competition in the MS marketplace in and outside the U.S. from existing and new MS treatments, including TYSABRI if it is reintroduced to the market, which may impact sales of AVONEX. We expect future growth in AVONEX revenues to be dependent to a large extent on our ability to compete successfully.

For the three months ended September 30, 2005, AMEVIVE generated revenues of \$11.6 million, of which \$7.9 million was generated in the U.S. and \$3.7 million was generated outside the U.S. For the three months ended September 30, 2004, AMEVIVE generated revenues of \$8.2 million, substantially all in the U.S. For the nine months ended September 30, 2005, AMEVIVE generated revenues of \$36.1 million, of which \$27.1 million was generated in the U.S. and \$9.0 million was generated outside the U.S. As described below, revenues for the first quarter of 2005 included approximately \$2.8 million of revenues which had previously been deferred. For the nine months ended September 30, 2004, AMEVIVE generated revenues of \$33.3 million. Revenue increased as a result of foreign revenue primarily due to the 2004 launch of AMEVIVE in Canada for the three and nine months ended September 30, 2005. In January 2003, we received regulatory approval to market AMEVIVE in the U.S. In connection with the commercialization of AMEVIVE, we implemented an initiative, undertaken in cooperation with one of our distributors which provides discounts on future purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the claim after appeal and where the other requirements of the initiative are met. Under this initiative, our exposure was

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contractually limited to 5% of the price of all AMEVIVE purchased by the distributor. As a result, we deferred recognition of revenue of 5% of AMEVIVE purchased by the distributor until such time as sufficient history of insurance reimbursement claims became available. Since January 2003, our experience of denials of claims after appeal and where the other requirements of the initiative have been met were substantially below the contractual limit. As a result, in the first quarter of 2005, we recognized approximately \$2.8 million in AMEVIVE product revenue, which had previously been deferred. Product sales from AMEVIVE represent approximately 2% of our total revenues in the three and nine months ended September 30, 2005 and 2004, respectively. In September 2005, we announced plans to divest AMEVIVE which we expect to occur in the first quarter of 2006. As a result, we expect that we will derive minimal revenues from AMEVIVE in 2006.

For the three months ended September 30, 2005 and 2004, sales of ZEVALIN generated revenues of \$5.2 million, respectively. Product sales related to ZEVALIN for the nine months ended September 30, 2005 were \$16.7 million and \$14.6 million for the comparable period in 2004. For the nine months ended September 30, 2005, the increase in product sales related to ZEVALIN is attributable to higher sales volumes in the U.S., as well as \$1.4 million of revenue from sales of ZEVALIN in the first nine months of 2005 to Schering AG for distribution in the EU. ZEVALIN was approved by the European Medicines Agency, or EMEA, in 2004. We had no revenue from sales of ZEVALIN outside the U.S. in the first nine months of 2004. Product sales from ZEVALIN represented approximately 1% of our total revenues in the three and nine months ended September 30, 2005 and 2004, respectively.

In November 2004, TYSABRI was approved by the FDA as treatment for relapsing forms of MS to reduce the frequency of clinical relapses. In the U.S., prior to the suspension, we sold TYSABRI to Elan who then distributed TYSABRI to third party distributors and other customers. In the first quarter of 2005, our revenue associated with sales of TYSABRI was \$5.9 million, which consists of revenue from sales which occurred prior to our voluntary suspension. Sales from TYSABRI represent 1% of our total revenues in the first quarter of 2005. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI, and informed physicians that they should suspend dosing of TYSABRI until further notification. We and Elan are consulting with leading experts to better understand the possible risk of PML and have been working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies. The safety evaluation also included the review of any reports of potential PML in MS patients receiving TYSABRI in the commercial setting. In October 2005, we completed our safety evaluation of TYSABRI in MS, Crohn's disease and RA patients and found no new cases of PML. Three confirmed cases of PML were previously reported, two of which were fatal. On September 26, 2005, we submitted an sBLA for TYSABRI to the FDA for the treatment of MS. We and Elan have also submitted a similar data package to the EMEA. We plan to work with regulatory authorities to determine if dosing in MS and other clinical studies will be re-initiated and the future commercial availability of the product. Through September 30, 2005, we incurred net withdrawal costs of \$7.8 million related to sales returns in connection with the voluntary suspension of TYSABRI. Also included as a reduction of TYSABRI revenue is \$0.2 million of amortization related to approval and credit milestones. The approval and credit milestones were capitalized upon approval of TYSABRI in investments and other assets, and are being amortized over the remaining patent life of approximately 15 years.

Additionally, as of March 31, 2005, we deferred \$14.0 million in revenue under our revenue recognition policy with Elan, which has been fully paid by Elan, related to sales of TYSABRI which had not yet been shipped by Elan and remains deferred at September 30, 2005. In July 2005, Elan agreed that we would not share the cost of this inventory if it were ultimately deemed non-salable.

See also the risks affecting revenues described in "Forward-Looking Information and Risk Factors That May Affect Future Results — Our Revenues Rely Significantly on a Limited Number of Products" and "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect Our Growth."

### **Unconsolidated Joint Business Revenue**

RITUXAN is currently marketed and sold worldwide for the treatment of certain B-cell NHLs. We copromote RITUXAN in the U.S. in collaboration with Genentech under a collaboration agreement between the parties. Under the collaboration agreement, we granted Genentech a worldwide license to develop, commercialize and market RITUXAN in multiple indications. In exchange for these worldwide rights, we have copromotion rights in the U.S. and a contractual arrangement under which Genentech shares a portion of the pretax U.S. copromotion profits of RITUXAN with us. This collaboration was created through a contractual arrangement not through a joint venture or other legal entity. In June 2003, we amended and restated our collaboration agreement with Genentech to

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include the development and commercialization of one or more anti-CD20 antibodies targeting B-cell disorders, in addition to RITUXAN, for a broad range of indications.

In the U.S., we contribute resources to selling and the continued development of RITUXAN. Genentech is responsible for worldwide manufacturing of RITUXAN. Genentech also is responsible for the primary support functions for the commercialization of RITUXAN in the U.S. including selling and marketing, customer service, order entry, distribution, shipping and billing. Genentech also incurs the majority of continuing development costs for RITUXAN. Under the arrangement, we have a limited sales force as well as limited development activity.

Under the terms of separate sublicense agreements between Genentech and Roche, commercialization of RITUXAN outside the U.S. is the responsibility of Roche, except in Japan where Roche copromotes RITUXAN in collaboration with Zenyaku. There is no direct contractual arrangement between Biogen Idec and Roche or Zenyaku.

Revenue from unconsolidated joint business consists of our share of pretax copromotion profits which is calculated by Genentech, and includes consideration of our RITUXAN-related sales force and development expenses, and royalty revenue from sales of RITUXAN outside the U.S. by Roche and Zenyaku. Copromotion profit consists of U.S. sales of RITUXAN to third-party customers net of discounts and allowances and less the cost to manufacture RITUXAN, third-party royalty expenses, distribution, selling and marketing expenses, and joint development expenses incurred by Genentech and us.

Under the amended and restated collaboration agreement, our current pretax copromotion profit-sharing formula, which resets annually, is as follows:

<u>Copromotion Operating Profits</u>	<u>Biogen Idec's Share of Copromotion Profits</u>
First \$50 million	30%
Greater than \$50 million	40%

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In both 2004 and 2005, the 40% threshold was met during the first quarter. For each calendar year or portion thereof following the approval date of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products sold by us and Genentech will change to the following:

Copromotion Operating Profits	New Anti-CD20 U.S. Gross Product Sales	Biogen Idec's Share of Copromotion Profits
First \$50 million (1)	N/A	30%
Greater than \$50 million	Until such sales exceed \$150 million in any calendar year (2)	38%
	or	
	After such sales exceed \$150 million in any calendar year and until such sales exceed \$350 million in any calendar year (3)	35%
	or	
	After such sales exceed \$350 million in any calendar year (4)	30%

- (1) – not applicable in the calendar year the first new anti-CD20 product is approved if \$50 million in copromotion operating profits has already been achieved in such calendar year through sales of RITUXAN.
- (2) – if we are recording our share of RITUXAN copromotion profits at 40%, upon the approval date of the first new anti-CD20 product, our share of copromotion profits for RITUXAN and the new anti-CD20 product will be immediately reduced to 38% following the approval date of the first new anti-CD20 product until the \$150 million new product sales level is achieved.
- (3) – if \$150 million in new product sales is achieved in the same calendar year the first new anti-CD20 product receives approval, then the 35% copromotion profit-sharing rate will not be effective until January 1 of the following calendar year. Once the \$150 million new product sales level is achieved then our share of copromotion profits for the balance of the year and all subsequent years' (after the first \$50 million in copromotion operating profits in such years) will be 35% until the \$350 million new product sales level is achieved.
- (4) – if \$350 million in new product sales is achieved in the same calendar year that \$150 million in new product sales is achieved, then the 30% copromotion profit-sharing rate will not be effective until January 1 of the following calendar year (or January 1 of the second following calendar year if the first new anti-CD20 product receives approval and, in the same calendar year, the \$150 million and \$350 million new product sales levels are achieved). Once the \$350 million new product sales level is achieved then our share of copromotion profits for the balance of the year and all subsequent years' will be 30%.

Copromotion profits consist of the following (table in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Product revenues, net	\$ 456,228	\$ 392,999	\$ 1,347,125	\$ 1,144,037
Costs and expenses	126,481	96,139	367,187	282,446
Copromotion profits	\$ 329,747	\$ 296,860	\$ 979,938	\$ 861,591
Biogen Idec's share of copromotion profits	\$ 129,009	\$ 118,753	\$ 385,843	\$ 339,612

Net sales of RITUXAN to third-party customers in the U.S. recorded by Genentech for the three and nine months ended September 30, 2005 were \$456.2 million and \$1.3 billion, respectively, compared to \$393.0 million and \$1.1 billion for the comparable periods in 2004. The increase was primarily due to higher sales for RITUXAN as a treatment for B-cell NHLs and chronic lymphocytic leukemia, offset by increased expenses in 2005.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Copromotion profits	\$ 129,009	\$ 118,753	\$ 385,843	\$ 339,612
Reimbursement of selling and development expenses	10,807	7,999	35,756	17,903
Royalty revenue on sales of RITUXAN outside the U.S.	41,781	32,755	105,385	87,104
	<u>\$ 181,597</u>	<u>\$ 159,507</u>	<u>\$ 526,984</u>	<u>\$ 444,619</u>

For the three and nine months ended September 30, 2005, revenues for our RITUXAN-related sales force and development expenses were \$10.8 million and \$35.8 million, respectively, compared to \$8.0 million and \$17.9 million for the comparable periods in 2004. The increase is primarily due to increased personnel costs, development costs we incurred mainly related to the development of RITUXAN for RA in 2005 and the expansion of the oncology sales force.

We received royalties on sales of RITUXAN outside of the U.S. of \$41.8 million and \$105.4 million for the three and nine months ended September 30, 2005 as compared to \$32.8 million and \$87.1 million for the comparable periods in 2004, which we include under “Unconsolidated joint business” revenues in our condensed consolidated statements of income. Our royalty revenue on sales of RITUXAN outside the U.S. is based on Roche and Zenyaku’s net sales to third-party customers and is recorded on a cash basis. Royalty revenues from sales of RITUXAN outside the U.S. increased approximately \$29.6 million, but were offset in the nine months ended September 30, 2005 by an \$11.3 million royalty credit claimed by Genentech.

Under the amended and restated collaboration agreement, we will receive lower royalty revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products, as compared to royalty revenue received on sales of RITUXAN. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis.

Total unconsolidated joint business revenue represented 30% and 29% of our total revenues for the three and nine months ended September 30, 2005 as compared to 29% and 27% for the comparable periods in 2004.

### **Royalty Revenue**

We receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control. Our royalty revenues on sales of RITUXAN outside the U.S. are included in “Unconsolidated joint business.” For the three and nine months ended September 30, 2005, we earned approximately \$23.1 million and \$71.6 million, respectively, in royalty revenues representing 4% of total revenues in each period. For the three and nine months ended September 30, 2004, we earned approximately \$23.9 million and \$73.4 million, respectively, in royalty revenues representing 4% and 5% of total revenues, respectively.

Royalty revenues may fluctuate as a result of fluctuations in sales levels of products sold by our licensees from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs.

### **Corporate Partner Revenues**

Corporate partner revenues consist of contract revenues and license fees. Corporate partner revenues totaled \$0.1 million and \$0.2 million for the three months ended September 30, 2005 and 2004, respectively, which represented less than 1% of total revenues for the third quarter of 2005 and 2004, respectively. Corporate partner revenues totaled \$3.3 million and \$10.4 million for the nine months ended September 30, 2005 and 2004, respectively, which represented less than 1% and 1% of total revenues for the first nine months of 2005 and 2004, respectively. Corporate partner revenues for the nine months ended September 30, 2005 consists primarily of our collaborative development and license agreement with Seikagaku Corporation, or Seikagaku. Although our agreement with Seikagaku was terminated effective January 2004, we had certain continuing obligations under the agreement that were fulfilled in the first quarter of 2005 and for which we recorded revenue from Seikagaku. Corporate partner revenues for the nine months ended September 30, 2004 consisted primarily of a \$10.0 million payment in March from Schering AG for the EMEA grant of marketing approval of ZEVALIN in the EU. The payment represented, in part, a milestone payment to compensate us for preparing, generating, and collecting data that was critical to the EMEA marketing approval process.

**Operating Costs and Expenses** (table in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Cost of product and royalty revenues	\$ 89,561	\$ 64,460	\$ 260,262	\$ 470,955
Research and development	227,039	168,307	579,357	496,990
Selling, general and administrative	161,410	132,622	475,637	403,116
Amortization of acquired intangibles	75,990	107,054	228,746	267,222
Facility impairments and loss on sale	21,046	—	102,904	—
Total operating costs and expenses	<u>\$ 575,046</u>	<u>\$ 472,443</u>	<u>\$ 1,646,906</u>	<u>\$ 1,638,283</u>

**Cost of Product and Royalty Revenues**

For the three and nine months ended September 30, 2005, total cost of product and royalty revenues was \$89.6 million and \$260.3 million, respectively, consisting of product cost of revenues of \$88.4 million and \$257.1 million, respectively, and cost of royalty revenues of \$1.2 million and \$3.2 million, respectively. In the third quarter of 2005, cost of product revenues consisted of \$56.7 million related to AVONEX, \$17.8 million related to AMEVIVE and \$13.9 million related to ZEVALIN. Approximately \$11.3 million in cost of product revenues represents the difference between the cost of AMEVIVE inventory recorded upon the merger transaction of Biogen, Inc. and IDEC Pharmaceuticals Corporation on November 12, 2003, or the Merger, and its historical manufacturing cost, which was recognized as cost of product revenues when the acquired inventory was sold or written-down in the third quarter of 2005. We expect that cost of product revenues in the remainder of 2005 related to AMEVIVE will include approximately \$4.3 million related to the difference between the cost of AMEVIVE inventory recorded at the Merger date and its historical manufacturing cost, as the acquired inventory is sold or written-down. In 2006 and beyond, we expect this amount will be approximately \$57 million in total and we will record these costs as the AMEVIVE inventory is sold or written-down.

We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict to the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed \$23.2 million of costs related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, as we are working with clinical investigators to understand the possible risks of PML, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense for the three and nine months ended September 30, 2005. We will continue to assess TYSABRI to determine if manufacturing costs need to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual realizable value is less than that estimated by us, or if there are further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. Also included in cost of product revenues were write-downs of commercial inventory that did not meet quality specifications or became obsolete due to dating expiration, in all cases this product inventory was written-down to its net realizable value. For the three months ended September 30, 2005, we wrote-down \$16.1 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$9.1 million for AMEVIVE, \$6.4 million for ZEVALIN and \$0.6 million for AVONEX. The write-downs of AMEVIVE inventory consisted of \$4.8 million for expired product and \$4.3 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The ZEVALIN inventory was written-down in the third quarter when it was determined that the inventory will not be marketable based on estimates of demand. The write-downs of AVONEX inventory in the third quarter related to product that failed to meet quality specifications.

For the nine months ended September 30, 2005, we wrote-down \$42.5 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$23.4 million for AMEVIVE, \$10.1 million for AVONEX and \$9.0 million for ZEVALIN. The write-downs for AMEVIVE inventory consisted of \$4.8 million for expired product and \$18.6 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of AVONEX inventory consisted of \$8.4 million for remaining supplies of the alternative presentations of AVONEX that were no longer needed after the FDA approved a new component for the pre-filled syringe formulation of AVONEX in March 2005, and \$1.7 million for product that failed to meet quality specifications. The write-down of ZEVALIN inventory was related to inventory that will not be marketable based on estimates of demand.



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For the three months ended September 30, 2004, we wrote-down \$9.2 million of unmarketable inventory to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-down of ZEVALIN inventory resulted from a determination that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA.

For the nine months ended September 30, 2004, we wrote-down \$21.0 million of unmarketable inventory to cost of product revenues. The write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of ZEVALIN inventory consisted of \$3.4 million of inventory that failed to meet the numerous stringent quality specifications agreed upon with the FDA and \$4.7 million of inventory that will not be marketable based on estimates of demand.

Gross margin on product sales, which includes inventory written-down to its net realizable value, for the three and nine months ended September 30, 2005, was approximately 77% and 78%, respectively compared to 82% and 57%, respectively, for the comparable periods in 2004. The decrease of gross margin in the three months ended September 30, 2005 is a result of increased inventory write-downs and unit costs in the third quarter of 2005. The large fluctuation of gross margin for the nine months ended September 30, 2005 on product revenues is due primarily to inventory acquired from Biogen, Inc. through the Merger. During 2003, we recorded the inventory that we acquired from Biogen, Inc. at its estimated fair value. The increase in the inventory's basis to fair market value was recognized as cost of product revenues when the acquired inventory was sold or written-down. During the first half of 2004, we sold or wrote-down all remaining AVONEX inventory acquired through the Merger. As a result, gross margin on product sales increased significantly for the nine months ended September 30, 2005 compared to the same period in 2004. Excluding the increase in fair market value related to purchase accounting, the effect of write-downs of commercial inventory to net realizable value, and costs related to the manufacture of TYSABRI that were included in cost of product revenues, proforma gross margins of product sales would have been 84% and 86% in the three and nine months ended September 30, 2005, respectively, compared to 86%, respectively, for the comparable periods in 2004. We expect that gross margins will fluctuate in the future based on changes in product mix, write-downs of excess or obsolete inventories and new product initiatives.

Gross margin on royalty revenues was approximately 95% and 96%, for the three and nine months ended September 30, 2005. Gross margin on royalty revenues was approximately 94% and 95%, for the three and nine months ended September 30, 2004. We expect that gross margins on royalty revenues will fluctuate in the future based on changes in sales volumes for specific products from which we receive royalties.

### **Research and Development Expenses**

Research and development expenses totaled \$227.0 million in the three months ended September 30, 2005 compared to \$168.3 million in the comparable period of 2004, an increase of \$58.7 million, or 35%. The increase primarily resulted from \$50.0 million related to our collaboration agreement with Protein Design Labs, Inc., or PDL, primarily related to a payment of an upfront licensing fee of \$40.0 million and an accrual of milestone payments of \$10.0 million, and \$6.5 million related to increased depreciation expenses. Research and development expenses totaled \$579.4 million in the nine months ended September 30, 2005 compared to \$497.0 million in the comparable period of 2004, an increase of \$82.4 million, or 17%. The increase primarily resulted from \$34.0 million related to our collaboration agreements, primarily related to an upfront licensing fee paid to PDL, \$23.1 million related to biopharmaceutical operations and global quality initiatives for our manufacturing activities, which includes \$21.0 million of expenses related to the manufacture of TYSABRI, \$15.2 million related to increased depreciation and infrastructure expenses, \$7.4 million for discovery research initiatives and \$10.1 million related to increased pre-clinical research activities offset by a decrease in spend of \$14.8 million related to our ongoing clinical trials. Also included in research and development expense in the first quarter of 2005 were charges of \$6.2 million for engineering costs which had previously been capitalized, related to the write-down of our fill-finish component of large-scale biologic manufacturing facility in Hillerod, Denmark due to our decision not to proceed with the facility.



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We expect that research and development expenses will continue to increase in 2005 for a number of reasons, including our plans to commit significant additional capital to external business development and research opportunities. We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict to the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed \$23.2 million related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense for the three and nine months ended September 30, 2005. We will continually assess our manufacturing needs for TYSABRI in light of our expectations for TYSABRI and, depending upon our expectations, may re-initiate manufacturing of TYSABRI in the near future. In the event we resume production of TYSABRI in subsequent periods, we will continue to assess TYSABRI to determine if manufacturing costs need to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards. We expect to continue incurring additional research and development expenses due to: our plans to commit significant additional capital to external business development and research opportunities; preclinical and clinical testing of our various products under development; the expansion or addition of research and development programs and facilities; technology development and in-licensing; and regulatory-related expenses.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses totaled \$161.4 million for the three months ended September 30, 2005 compared to \$132.6 million in the comparable period of 2004, an increase of \$28.8 million, or 22%. The increase related primarily to \$13.6 million for oncology sales and marketing initiatives primarily due to a charge related to a write-down of remaining prepaid expense associated with our arrangement with MDS (Canada) related to ZEVALIN, \$6.3 million for administrative expenses, primarily related to consulting fees and grant initiatives, \$3.4 million for increased international neurology sales and marketing initiatives and \$2.8 million for joint development expenses related to our TYSABRI collaboration with Elan. Selling, general and administrative expenses totaled \$475.6 million for the nine months ended September 30, 2005 compared to \$403.1 million in the comparable period of 2004, an increase of \$72.5 million, or 18%. The increase related primarily to \$17.8 million for oncology sales and marketing initiatives primarily due to a charge related to the MDS (Canada) write-down described above, \$26.1 million of the neurology sales and marketing for increased marketing initiatives and sales force expansion, \$12.2 million for increased international neurology sales and marketing initiatives, \$11.7 million for administrative expenses, primarily related to consulting fees and grant initiatives, \$8.8 million for customer service initiatives, \$6.3 million for global medical affairs initiatives for Phase IV trials, \$8.7 million for our information technology initiatives offset by a decrease of \$17.8 million in joint development expenses related to our TYSABRI collaboration with Elan and \$7.2 million related to our immunology sales and marketing initiatives.

Our total selling, general, and administrative expense in 2005 will be higher than 2004, due to sales and marketing and other general and administrative expenses to primarily support AVONEX and TYSABRI, despite the voluntary suspension of the marketing and commercial distribution of TYSABRI in February 2005, and legal expenses related to lawsuits, investigations and other matters resulting from the suspension of TYSABRI.

### **Severance and Other Costs from Restructuring Plan**

In September 2005, we began implementing a comprehensive strategic plan designed to position us for long-term growth. In conjunction with the plan, we are consolidating or eliminating certain internal management layers and staff functions, resulting in the reduction of our workforce by approximately 17%, or approximately 650 positions worldwide. These adjustments will take place across company functions, departments and sites, and are expected to be substantially implemented by the end of 2005. We have recorded restructuring charges associated with these activities, which consist primarily of severance and other employee termination costs, including health benefits, outplacement, and bonuses. Other costs include write-downs of certain research assets that will no longer be utilized, consulting costs in connection with the restructuring effort, and costs related to the acceleration of restricted stock, offset by the reversal of previously recognized compensation due to unvested restricted stock cancellations. For the three months ended September 30, 2005, \$19.6 million of restructuring charges are included in research and development expenses, and \$7.6 million are included in selling, general and administrative expenses. These remaining unpaid costs at September 30, 2005 are included in accrued expenses and other on our condensed consolidated balance sheet.

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

	Costs incurred at September 8, 2005	Paid/Settled through September 30, 2005	Remaining liability at September 30, 2005
Severance and employee termination costs incurred	\$ 24,785	\$ (643)	\$ 24,142
Other costs	2,432	(1,783)	649
	<u>\$ 27,217</u>	<u>\$ (2,426)</u>	<u>\$ 24,791</u>

We may have additional charges in future periods related to our comprehensive strategic plan. The amount of those charges cannot be determined at this time.

### **Sale of Large-Scale Manufacturing Facility**

On June 23, 2005, Genentech purchased our large-scale biologics manufacturing facility in Oceanside, California, known as "NIMO," along with approximately 60 acres of real property located in Oceanside, California upon which NIMO is located, together with improvements, related property rights, and certain personal property intangibles and contracts at or related to the real property. Through the first quarter of 2005, we intended to hold and continue using the facility. In June 2005, we determined instead to accept an offer from Genentech to purchase the facility. Total consideration for the purchase was \$408.1 million. For the three and nine months ended September 30, 2005, the loss from this transaction was \$7.7 million and \$83.3 million, respectively, which consisted primarily of the write-down of NIMO to its net selling price, sales and transfer taxes, and other associated transaction costs. During the third quarter, we and Genentech finalized plans for the sale of certain equipment. Also, during the quarter, we had changes to estimates previously made for certain construction activities related to the NIMO facility. Following the closing of the sale, we terminated and Genentech offered employment, on an "at-will" basis, to 334 of our employees who were working at NIMO. These employees continued to be employed by us through August 16, 2005.

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2005	2004	2005	2004
Interest income	\$ 16,530	\$ 13,794	\$ 44,636	\$ 43,058
Interest expense	(571)	(2,984)	(10,331)	(10,246)
Other expense	(4,767)	(12,383)	(25,987)	(16,246)
Total other income (expense), net	<u>\$ 11,192</u>	<u>\$ (1,573)</u>	<u>\$ 8,318</u>	<u>\$ 16,566</u>

Interest income totaled \$16.5 million for the three months ended September 30, 2005 compared to \$13.8 million for the comparable period of 2004. Interest income totaled \$44.6 million for the nine months ended September 30, 2005 compared to \$43.1 million for the comparable period of 2004. The increase in interest income is primarily due to higher yields on our marketable securities portfolio. Interest income levels that may be achieved in the future are, in part, dependent upon market conditions.

Interest expense totaled \$0.6 million for the three months ended September 30, 2005 compared to \$3.0 million for the comparable period of 2004. Interest expense totaled \$10.3 million for the nine months ended September 30, 2005 compared to \$10.2 million for the comparable period of 2004. The decrease in interest expense for the three months ended September 30, 2005 relates to the repurchase of our senior notes due in 2032 in the second quarter of 2005. The increase in interest expense during the nine month period is primarily due to the updated estimation of the life of the senior notes due in 2032, which we repurchased on April 29, 2005.

Other expense for the three months ended September 30, 2005 consists primarily of \$4.6 million for the impairment of certain marketable securities that were determined to be impaired on an other-than-temporary basis and \$1.7 million of realized losses on sales of marketable securities offset by \$2.5 million received from Targeted Genetics as a partial repayment of a loan that had previously been written-off.

Other expense for the nine months ended September 30, 2005 consists primarily of \$16.9 million of expenses related to the impairment of certain marketable securities that were determined to be impaired on an other-than-temporary basis, \$7.8 million of foreign exchange remeasurement losses, \$2.3 million of loan impairments, and \$3.0 million of realized losses on sales of marketable securities offset by \$1.0 million of gains related to hedge ineffectiveness and \$2.5 million received from Targeted Genetics as a partial repayment of a loan that had previously been written-off.

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

## **Amortization of Intangible Assets**

For the three and nine months ended September 30, 2005, we recorded amortization expense of \$76.0 million and \$228.7 million, respectively, compared to \$107.1 million and \$267.2 million, respectively, for the comparable periods in 2004 related to the intangible assets of \$3.7 billion acquired in the Merger with Biogen, Inc. The decrease in the three and nine months ended September 30, 2005 relates to a change in estimate in the calculation of economic consumption for core technology. Intangible assets consist of \$3.0 billion in core technology, \$578.0 million in out-licensed patents and \$64.0 million in trademarks. Amortization of the core technology is provided over the estimated useful lives of the technology ranging from 15 to 20 years, based on the greater of straight-line or economic consumption. Amortization of the out-licensed patents for which we receive royalties is provided over the remaining lives of the patents of 10 years. Trademarks have an indefinite life and, as such, are not amortized.

In the third quarter of 2005, we completed a review of our business opportunities in each of the relevant commercial markets in which our products are sold and determined their expected profitability. As a result of this review, in the third quarter of 2005, management determined that certain clinical trials would not continue which indicated that the carrying value of certain technology intangible assets related to future sales of AVONEX in Japan may not be recoverable. As a result, we recorded a charge of approximately \$7.9 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of technology intangible assets related to AVONEX. Additionally, in the third quarter of 2005, we recorded a charge of \$5.7 million to cost of product revenues related to an impairment of certain capitalized ZEVALIN patents, to reflect the adjustment to net realizable value. As part of our decision to divest our AMEVIVE product, we have reassessed our intangible assets related to AMEVIVE, and have determined that there are no impairments related to these assets as a result of our decision to divest AMEVIVE. However, should new information arise, we may be required to take impairment charges related to certain of our intangibles.

We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If future events or circumstances indicate that the carrying value of these assets may not be recoverable, we may be required to record additional charges to our results of operations.

## **Income Tax Provision**

Our effective tax rate for the three and nine months ended September 30, 2005 was 16.0% and 30.4%, respectively, compared to 46.9% and 274.5%, respectively, for the comparable periods in 2004. The effective rate for the three months ended September 30, 2005 was lower than the effective rate for the nine months ended September 30, 2005 primarily due to additional tax benefit recognized discretely during the quarter related to U.S. restructuring expenses. Our effective tax rate for the three and nine months ended September 30, 2005 was lower than the normal statutory rate primarily due to the effect of lower income tax rates (less than the 35% U.S. statutory corporate rate) in certain non-U.S. jurisdictions in which we operate, tax credits allowed for research and experimentation expenditures in the U.S., and the new domestic manufacturing deduction, offset by acquisition-related intangible amortization arising from purchase accounting related to foreign jurisdictions. Our effective tax rate for the three and nine months ended September 30, 2004 was higher than the normal statutory rates primarily due to the acquisition-related intangible amortization expenses and impairment charges and inventory fair value adjustments arising from purchase accounting related to foreign jurisdictions. We have tax credit carryforwards for federal and state income tax purposes available to offset future taxable income. The utilization of our tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, we anticipate that this annual limitation will result only in a modest delay in the utilization of such tax credits.

On October 22, 2004, the American Jobs Creation Act of 2004, or the Act, was signed into law. The Act creates a temporary incentive, which expires on December 31, 2005, for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate that could be as low as 5.25%. On December 21, 2004, the Financial Accounting Standards Board (FASB) issued FASB staff position 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004", or FSP 109-2. FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS 109's exception to recognizing deferred tax liabilities and require explanatory disclosures from those who need the additional time. Through September 30, 2005, we have not recognized deferred taxes on foreign earnings because such earnings were, and continue to be, indefinitely reinvested outside the U.S. Whether we will ultimately take advantage of this temporary tax incentive depends on a number of factors including an assessment of cash requirements outside of the U.S. and reviewing Congressional or other Governmental guidance with respect to certain aspects of the new legislation that required clarification and analysis before an informed decision can be made. We expect to complete this analysis during the fourth quarter of 2005. Until such analysis is completed, we will continue our plan and intention to indefinitely reinvest accumulated earnings of our foreign subsidiaries. If we decide to avail ourselves of this temporary tax incentive, up to \$500 million could be repatriated under the Act, and we could incur a one-time tax charge to our consolidated results of operations of up to approximately \$32 million in the fourth quarter of 2005.

The Act also provides a deduction for domestic manufacturing. We estimate that the deduction will reduce our effective tax rate by approximately 0.81% for the current year and by a higher amount in future years, as the deduction is fully phased-in.

## Financial Condition

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

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

Cash, cash equivalents and securities available-for-sale totaled \$1.8 billion at September 30, 2005 and \$2.2 billion at December 31, 2004. Our operating activities generated \$614.8 million of cash for the nine months ended September 30, 2005 as compared to \$547.1 million for the comparable period of 2004. Net cash from operating activities includes our net income of \$105.1 million, non-cash charges of \$304.7 million for depreciation and amortization, \$102.9 million related to the loss on sale of our manufacturing facility in Oceanside, CA and write-down of our NICO manufacturing facility in San Diego, CA to fair value, \$26.7 million of interest expense and amortization of investment premium, \$65.7 million related to the write-down of inventory to net realizable value, \$11.9 million of tax benefits related to stock options, \$32.1 million for the impairment of other investments and other long-lived assets, offset by deferred income taxes of \$132.2 million. Our investing activities provided \$488.7 million of cash in the nine months ended September 30, 2005 compared to utilizing \$182.6 million for the comparable period of 2004. Cash generated from investing activities consisted of \$408.1 million of proceeds from the sale of our Oceanside, California manufacturing facility to Genentech on June 23, 2005, previously discussed in our results of operations. Additionally, approximately \$413.8 million of net cash was provided from proceeds from sales of available-for-sale securities. We sold marketable securities in the second quarter of 2005 to fund the repurchase of our senior notes, discussed below. Cash uses for investing activities consisted of \$216.0 million to fund construction projects and purchase property, plant and equipment, including our research and development and administration campus in San Diego and Oceanside manufacturing facility, and \$117.3 million for investments in marketable securities of PDL, Sunesis, and other strategic investments. Cash generated from financing activities included \$88.0 million from the reissuance of treasury stock for stock-based compensation arrangements during the first nine months of 2005, compared to \$208.8 million for the first nine months of 2004. Cash outflows from financing activities included \$746.4 million for the repurchase of our senior notes, discussed in detail below, and \$322.6 million for the repurchase of common stock under our stock repurchase program. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuation in the market value of our stock relative to the price of the options.

In April and May 2002, we raised through the issuance of our senior notes, approximately \$696.0 million, net of underwriting commissions and expenses of \$18.4 million. The senior notes are zero coupon and were priced with a yield to maturity of 1.75% annually. On April 29, 2005 holders of 99.2% of the outstanding senior notes exercised their right under the indenture governing the senior notes to require us to repurchase their senior notes. On May 2, 2005, we paid \$746.4 million in cash to repurchase those senior notes with an aggregate principal amount at maturity of approximately \$1.2 billion. The purchase price for the senior notes paid by the Company was \$624.73 in cash per \$1,000 principal amount at maturity, and was based on the requirements of the indenture and the

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senior notes. Additionally, we will be required to make a cash payment in 2005 of approximately \$56 million for the payment of tax for which deferred tax liabilities had been previously established related to additional deductible interest expense. Following the repurchase, \$6.4 million (\$10.2 million principal amount at maturity) of senior notes remain outstanding.

In February 1999, we raised through the issuance of our subordinated notes, approximately \$112.7 million, net of underwriting commissions and expenses of \$3.9 million. The subordinated notes are zero coupon and were priced with a yield to maturity of 5.5% annually. Upon maturity, the subordinated notes would have had an aggregate principal face value of \$345.0 million. As of September 30, 2005, our remaining indebtedness under the subordinated notes was approximately \$75.4 million at maturity, due to conversion of subordinated notes into common stock.

Each \$1,000 aggregate principal face value subordinated note is convertible at the holders' option at any time through maturity into 40.404 shares of our common stock at an initial conversion price of \$8.36 per share. In the first nine months of 2005, holders of subordinated notes with a face value of approximately \$143.8 million elected to convert their subordinated notes to approximately 5.8 million shares of our common stock. The holders of the subordinated notes may require us to purchase the subordinated notes on February 16, 2009 or 2014 at a price equal to the issue price plus accrued original issue discount to the date of purchase with us having the option to repay the subordinated notes plus accrued original issue discount in cash, common stock or a combination of cash and stock. We have the right to redeem at a price equal to the issue price plus the accrued original issue discount to the date of redemption all or a portion of the subordinated notes for cash at any time.

In August 2004, we restarted construction of our large-scale biologic manufacturing facility in Hillerod, Denmark to be used to manufacture TYSABRI and other products in our pipeline. As of March 31, 2005, after our voluntary suspension of TYSABRI, we reconsidered our construction plans and determined that we would proceed with the bulk manufacturing component of our large-scale biologic manufacturing facility in Hillerod. Additionally, we added a labeling and packaging component to the project. We also determined that we would no longer proceed with the fill-finish component of our large-scale biological manufacturing facility in Hillerod. As a result, in the first quarter of 2005, we wrote-off \$6.2 million to research and development expense of engineering costs related to the fill-finish component that had previously been capitalized. The original cost of the project was expected to be \$372.0 million. As of September 30, 2005, we had committed approximately \$193.0 million to the project, of which \$117.5 million had been paid. We expect the label and packaging facility to be substantially completed in 2006 and licensed for operation in 2007.

The timing of the completion and anticipated licensing of the Hillerod facility is primarily dependent upon the commercial availability and potential market acceptance of TYSABRI. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth." If TYSABRI were permanently withdrawn from the market, we would need to evaluate our long-term plan for this facility. If we are able to reintroduce TYSABRI to the market, we would need to evaluate our requirements for TYSABRI inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential U.S. market acceptance of TYSABRI in MS, the probability of obtaining marketing approval of TYSABRI in MS in the EU and other jurisdictions, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

In June 2004, we commenced construction to add additional research facilities and administrative space to one of our existing buildings in Cambridge, Massachusetts. The cost of the project is estimated to be \$73.1 million. As of September 30, 2005, we had committed approximately \$58.1 million to the project, of which \$45.7 million had been paid. The project is expected to be substantially complete in late 2005.

In connection with our December 2002 and August 2004 agreements with Sunesis Pharmaceuticals, Inc., or Sunesis, we had purchased approximately 4.2 million shares of Sunesis preferred stock for approximately \$20.0 million and provided Sunesis with a \$4.0 million credit facility. In addition to the previous agreements entered into with Sunesis, in September 2005 we purchased \$5.0 million of common stock of Sunesis as part of their initial public offering, or IPO. Also, in conjunction with the IPO, our preferred stock was converted into shares of Sunesis common stock. As a result of the IPO valuation, we wrote-down the value of our investment in the converted shares and, in the third quarter of 2005, recognized a \$4.6 million charge for the impairment of our Sunesis investment that was determined to be other-than-temporary. Following the IPO, we own approximately 2.9 million shares, or 13.6% of shares outstanding, of Sunesis common stock with a fair value of \$19.5 million, which is included in investments and other assets. We have no commitments or obligations associated with the \$5.0 million investment. Additionally, Sunesis used a portion of their proceeds from the IPO to repay \$4.0 million borrowed from us under a credit facility that we provided to Sunesis in connection with our 2002 collaborative agreement. At September 30, 2005, there are no amounts outstanding under the credit facility.

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In August 2005, we entered in a collaborative agreement with Protein Design Labs, Inc., or PDL, for the joint development, manufacture and commercialization of three Phase II antibody products. Under this agreement, Biogen Idec and PDL will share in the development and commercialization of daclizumab in MS and indications other than transplant and respiratory diseases, and the development and commercialization of M200 (volociximab) and HuZAF™ (fontolizumab) in all indications. Both companies will share equally the costs of all development activities and all operating profits from each collaboration product within the U.S. and Europe. We paid PDL an initial payment of \$40.0 million, which is included in research and development expenses in the third quarter of 2005. We also accrued \$10.0 million in research and development expense in the third quarter for future payments that were determined to be unavoidable. In addition, we purchased approximately \$100.0 million of common stock, or 3.6% of shares outstanding, from PDL, which was included in investments and other assets at September 30, 2005. Terms of the collaborative agreement require us to make certain development and commercialization milestone payments upon the achievement of certain program objectives totaling up to \$660 million over the life of the agreement, of which \$560 million relate to development and \$100 million relate to the commercialization of collaboration products.

In June 2004, we entered into a collaborative research and development agreement with Vernalis plc, or Vernalis, aimed at advancing research into Vernalis' adenosine A2A receptor antagonist program, which targets Parkinson's disease and other central nervous system disorders. Under the agreement, we receive exclusive worldwide rights to develop and commercialize Vernalis' lead compound, V2006. We paid Vernalis an initial license fee of \$10.0 million in July 2004, which was recorded in research and development expenses in the second quarter of 2004. Terms of the collaborative agreement require us to make milestone payments upon the achievement of certain program objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration. In June 2004, we made an investment of \$5.5 million through subscription for approximately 6.2 million new Vernalis ordinary shares. In March 2005, we purchased approximately 1.4 million additional shares under a qualified offering for \$1.8 million, which fully satisfies our investment obligation under the collaboration agreement. We now hold a total of approximately 7.6 million shares representing 3.5% of total shares outstanding. Our investment in Vernalis is included in investments and other assets.

In October 2004, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with treasury shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program will expire no later than October 4, 2006. During the first nine months of 2005, we repurchased approximately 7.5 million shares under this program, at a cost of \$322.6 million. Approximately 11.9 million shares remain authorized for repurchase under this program at September 30, 2005.

### **Legal Matters**

On March 2, 2005, we, along with William H. Rastetter, our Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned *Brown v. Biogen Idec Inc., et al.*, filed in the U.S. District Court for the District of Massachusetts (the "Court"). The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product's distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, costs and attorneys' fees. Substantially similar actions, captioned *Grill v. Biogen Idec Inc., et al.* and *Lobel v. Biogen Idec Inc., et al.*, were filed on March 10, 2005 and April 21, 2005 in the same court by other purported class representatives. Those actions have been assigned to District Judge Reginald C. Lindsey and Magistrate Judge Marianne C. Bowler. On July 26, 2005, the three cases were consolidated and by Margin Order dated September 23, 2005, Magistrate Judge Bowler appointed lead plaintiffs and approved their selection of co-lead counsel. An objection to the September 23, 2005 order has been filed and briefed by the affected plaintiffs and their counsel, but remains pending with the Court. No date has been set for the filing of an amended, consolidated complaint. We believe that the actions are without merit and intend to contest them vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss.

On March 4, 2005, a purported shareholder derivative action, captioned *Halpern v. Rastetter, et al.* ("Halpern"), was filed in the Court of Chancery for the State of Delaware, in New Castle County, on our behalf, against us as nominal defendant, our Board of Directors and our former general counsel. The plaintiff derivatively claims breaches of fiduciary duty by our Board of Directors for inadequate oversight of our policies, practices, controls and assets, and for recklessly awarding executive bonuses despite alleged



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awareness of potentially serious side effects of TYSABRI and the potential for related harm to our financial position. The plaintiff also derivatively claims that our Executive Chairman, former general counsel and a director misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI, and alleges that our Board of Directors did not ensure that appropriate policies were in place regarding the control of confidential information and personal trading in our securities by officers and directors. The plaintiff seeks unspecified damages, profits, the return of all bonuses paid by us, costs and attorneys' fees. A substantially similar action, captioned *Golaine v. Rastetter, et al.* ("Golaine"), was filed on March 14, 2005 in the same court. Neither of the plaintiffs made presuit demand on our Board of Directors prior to filing their respective actions. We filed an Answer and Affirmative Defenses in Halpern on March 31, 2005 and our Board of Directors filed an Answer and Affirmative Defenses on April 11, 2005, which was amended as of April 12, 2005. By court order dated April 14, 2005, Halpern and Golaine were consolidated, captioned *In re Biogen Idec Inc. Derivative Litigation* (the "Delaware Action") and the Halpern complaint was deemed the operative complaint in the Delaware Action. On May 19, 2005, we and our Board of Directors filed a motion seeking judgment on the pleadings, and on August 3, 2005, plaintiffs filed a motion seeking voluntary dismissal of the action. On September 27, 2005, the Court entered an Order providing that the plaintiffs in the purported derivative cases pending in the Superior Court of California and the Middlesex Superior Court for the Commonwealth of Massachusetts may file a complaint in intervention in the Delaware Action not later than October 28, 2005 (the "Delaware Order"). If no such complaint in intervention is timely filed, then the Court shall enter a further order and final judgment finding that the Delaware Action has not alleged, as a matter of controlling substantive Delaware law, demand excusal as to the claims raised in the Delaware Action and granting defendants' motions and dismissing the litigation with prejudice on the merits. To date, we have not been served with any proposed complaint(s) in intervention. The consolidated action does not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On March 9, 2005, two additional purported shareholder derivative actions, captioned *Carmona v. Mullen, et al.* ("Carmona") and *Fink v. Mullen, et al.* ("Fink"), were brought in the Superior Court of the State of California, County of San Diego, on our behalf, against us as nominal defendant, our Board of Directors and our chief financial officer. The plaintiffs derivatively claim breach of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment against all defendants. The plaintiffs also derivatively claim insider selling in violation of California Corporations Code § 25402 and breach of fiduciary duty and misappropriation of information against certain defendants who sold our securities during the period of February 18, 2004 to the date of the complaints. The plaintiffs allege that the defendants caused and/or allowed us to issue, and conspired, aided and abetted and acted in concert in concealing that we were issuing, false and misleading press releases about the safety of TYSABRI and its financial prospects which resulted in legal claims being asserted against us, irreparable harm to our corporate image, depression of our stock price and impairment of our ability to raise capital. The plaintiffs also allege that certain defendants sold personally owned shares of our stock while in possession of material, undisclosed, adverse information. The plaintiffs seek unspecified damages, treble damages for the purported insider trading in violation of California Corporate Code § 25402, equitable relief including restriction of the defendants' trading proceeds or other assets, restitution, disgorgement and costs, including attorneys' fees and expenses. Neither of the plaintiffs made presuit demand on the Board of Directors prior to filing their respective actions. On April 11, 2005, all defendants filed a Motion To Stay Proceedings in both Carmona and Fink, which the plaintiffs' opposed, pending resolution of the Delaware Action. On May 11, 2005, the Court consolidated the Carmona and Fink cases. On May 27, 2005, the Court granted defendants' Motion to Stay. On September 27, 2005, plaintiffs were provided a copy of the Delaware Order. These purported derivative actions do not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On June 20, 2005, a purported class action, captioned *Wayne v. Biogen Idec Inc. and Elan Pharmaceutical Management Corp.*, was filed in the U.S. District Court for the Northern District of California. On August 15, 2005, the plaintiff filed an amended complaint. The amended complaint purports to assert claims for strict product liability, medical monitoring and concert of action arising out of the manufacture, marketing, distribution and sale of TYSABRI. The action is purportedly brought on behalf of all persons in the U.S. who have had infusions of TYSABRI and who have not been diagnosed with any medical conditions resulting from TYSABRI use. The plaintiff alleges that defendants, acting individually and in concert, failed to warn the public about purportedly known risks related to TYSABRI use. The plaintiff seeks to recover the cost of periodic medical examinations, restitution, interest, compensatory and punitive damages, and attorneys' fees. Defendants currently have until November 15, 2005 to respond to the amended complaint. A case management conference currently is scheduled for December 15, 2005. We believe that the action is without merit and intend to contest it vigorously. At this stage of litigation, we cannot make any estimate of a potential loss or range of loss, if any.

Our Board of Directors has received letters, dated March 1, 2005, March 15, 2005 and May 23, 2005, respectively, on behalf of purported owners of our securities purportedly constituting demands under Delaware law. A supplement to the March 1 letter was received on March 2, 2005. The letters generally allege that certain of our officers and directors breached their fiduciary duty to us by

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selling personally held shares our securities while in possession of material, non-public information about potential serious side effects of TYSABRI. The letters generally request that our Board of Directors take action on our behalf to recover compensation and profits from the officers and directors, consider enhanced corporate governance controls related to the sales of securities by insiders, and pursue other such equitable relief, damages, and other remedies as may be appropriate. A special litigation committee of our Board of Directors was formed, and, with the assistance of independent outside counsel, investigated the allegations set forth in the demand letters. By letters dated August 17, 2005 and October 1, 2005, our Board of Directors informed those shareholders that it would not take action as demanded because it was the Board's determination that such action was not in the best interests of the Company. On June 23, 2005, one of the purported shareholders who made demand filed a purported derivative action in the Middlesex Superior Court for the Commonwealth of Massachusetts, on our behalf, against us as nominal defendant, our former general counsel, a member of our Board of Directors and our Executive Chairman. The plaintiff derivatively claims that our Executive Chairman, former general counsel and the director defendant misappropriated confidential company information for personal profit by selling our stock while in possession of material, non-public information regarding the potentially serious side effects of TYSABRI. The plaintiff seeks disgorgement of profits, costs and attorneys' fees. On September 27, 2005, the plaintiff was provided with a copy of the Delaware Order and responded on September 28, 2005 that he would not be moving to intervene in Delaware. On October 4, 2005, all defendants filed motions seeking dismissal of the action and/or judgment on the pleadings, and the Company also filed a supplemental motion seeking judgment on the pleadings. Also on October 4, 2005, the plaintiff filed a cross-motion seeking leave to amend the complaint, which the Company has opposed. The Court has not yet ruled on those motions. The action does not seek affirmative relief from the Company. We believe that there are substantial legal and factual defenses to the claims and intend to pursue them vigorously.

On April 21, 2005, we received a formal order of investigation from the Boston District Office of the SEC. The SEC is investigating whether any violations of the federal securities laws occurred in connection with the suspension of marketing and commercial distribution of TYSABRI. We continue to cooperate fully with the SEC in this investigation. We are unable to predict the outcome of this investigation or the timing of its resolution at this time.

On June 9, 2005, we, along with numerous other companies, received a request for information from the U.S. Senate Committee on Finance, or the Committee, concerning the Committee's review of issues relating to the Medicare and Medicaid programs' coverage of prescription drug benefits. We are cooperating fully with the Committee's information request. We are unable to predict the outcome of this review or the timing of its resolution at this time.

On July 20, 2005, a products liability action captioned Walter Smith, as Personal Representative of the Estate of Anita Smith, decedent, and Walter Smith, individually v. Biogen Idec Inc. and Elan Corp., PLC, was commenced in the Superior Court of the Commonwealth of Massachusetts, Middlesex County. The complaint purports to assert statutory wrongful death claims based on negligence, agency principles, fraud, breach of warranties, loss of consortium, conscious pain and suffering, and unfair and deceptive trade practices in violation of Mass. G.L., c. 93A. The complaint alleges that Anita Smith, a participant in a TYSABRI clinical trial, died as a result of PML caused by TYSABRI and that the defendants, individually and jointly, prematurely used TYSABRI in a clinical trial, failed to adequately design the clinical trial, failed to adequately monitor patients participating in the clinical trial, and failed to adequately address and warn of the risks of PML, immunosuppression and risks associated with the pharmacokinetics of TYSABRI when used in combination with AVONEX. The plaintiff seeks compensatory, punitive and multiple damages as well as interest, costs and attorneys' fees. We believe that the action is without merit and intend to contest it vigorously. At this stage of the litigation, we cannot make any estimate of a potential range of loss.

On October 4, 2004, Genentech, Inc. received a subpoena from the U.S. Department of Justice requesting documents related to the promotion of RITUXAN. We market RITUXAN in the U.S. in collaboration with Genentech. Genentech has disclosed that it is cooperating with the associated investigation, which they disclosed that they have been advised is both civil and criminal in nature. The potential outcome of this matter and its impact on us cannot be determined at this time.

On July 15, 2003, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries), along with Genzyme Corporation and Abbott Bioresearch Center, Inc., filed suit against The Trustees of Columbia University in the City of New York ("Columbia") in the U.S. District Court for the District of Massachusetts, docket no. 03-11329-MLW ("2003 action") contending that it had no obligation to pay royalties to Columbia under a 1993 license agreement under which it had licensed from Columbia a family of patents and applications ("Axel patents") including U.S. Patent No 6,455,275 ("275 patent"), due to the invalidity and unenforceability of the '275 patent. A third party initiated reexamination proceedings with respect to the '275 patent, and Columbia initiated reissue proceedings with respect to it. These two proceedings were merged in the patent office. Columbia subsequently covenanted not to sue Biogen Idec MA, Inc. on any current claim of the '275 patent or any reissue claim identical to or substantially the same as a current claim of the '275 patent if such claim were to emerge from the merged reexamination and reissue proceedings currently pending. Accordingly, on November 5, 2004, the court dismissed Biogen Idec MA Inc.'s claims for declaratory relief for lack of subject matter jurisdiction. On September 17, 2004, Biogen Idec Inc., Biogen Idec MA, Inc., and Genzyme Corporation filed



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suit against Columbia in the U.S. District Court for the District of Massachusetts, docket no. 04-12009-MLW (“2004 action”). In the 2004 action, the plaintiffs reasserted some of the contentions made in the 2003 action and also brought other claims for relief. On August 4, 2005, Biogen Idec Inc. and Biogen Idec MA, Inc. arrived at a settlement of the disputes summarized above. Under the settlement, Biogen Idec Inc. and Biogen Idec MA, Inc. are licensed under the Axel patents, including any new or reissued patents in the Axel family that could issue in the future. The other terms of the settlement are confidential and, we believe, not material to investors. On August 5, 2005, Columbia, Biogen Idec Inc., and Biogen Idec MA, Inc. filed stipulations dismissing the 2003 action and the 2004 action with prejudice.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc., in the U.S. District Court for the District of Maryland, contending that we induced infringement of U.S. patents 6,420,139, 6,638,739, 5,728,385, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. The inducement of infringement claims are based on allegations that we “provided instructions and/or recommendations on a proper immunization schedule for vaccines” to other defendants who are alleged to have directly infringed the patents at issue. We are investigating the allegations, however, we do not believe them to be based in fact. On November 19, 2004, we, along with GlaxoSmithKline, filed a joint motion to dismiss three of the four counts of the complaint. The Court granted that motion on July 22, 2005. On August 1, 2005, Classen filed a motion for reconsideration, which is still pending before the Court. Classen also has filed a Stipulation, seeking to have the third, and final, count against us dismissed with prejudice. Under our 1988 license agreement with GlaxoSmithKline, GlaxoSmithKline is obligated to indemnify and defend us against these claims. In the event that the nature of the claims change such that GlaxoSmithKline is no longer obligated to indemnify and defend us and we are unsuccessful in the present litigation we may be liable for damages suffered by Classen and such other relief as Classen may seek and be granted by the court. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the City of New York and the following Counties of the State of New York: County of Albany, County of Allegany, County of Broome, County of Cattaraugus, County of Cayuga, County of Chautauqua, County of Chenango, County of Columbia, County of Cortland, County of Erie, County of Essex, County of Fulton, County of Genesee, County of Greene, County of Herkimer, County of Jefferson, County of Lewis, County of Madison, County of Monroe, County of Nassau, County of Niagara, County of Oneida, County of Onondaga, County of Orleans, County of Putnam, County of Rensselaer, County of Rockland, County of St. Lawrence, County of Saratoga, County of Steuben, County of Suffolk, County of Tompkins, County of Warren, County of Washington, County of Wayne, County of Westchester, and County of Yates. All of the cases, except for the County of Erie and County of Nassau cases, are the subject of a Consolidated Complaint, which was filed on June 15, 2005 in U.S. District Court for the District of Massachusetts in Multi-District Litigation No. 1456. The County of Nassau, which originally filed its complaint on November 24, 2004, filed an amended complaint on March 24, 2005 and that case is also pending in the U.S. District Court for the District of Massachusetts. The County of Erie originally filed its complaint in Supreme Court of the State of New York on March 8, 2005. On April 15, 2005, Biogen Idec and the other named defendants removed the case to the U.S. District Court for the Western District of New York. On August 11, 2005, the Joint Panel on Multi-District Litigation issued a Transfer Order, transferring the case to the U.S. District Court for the District of Massachusetts. The County of Erie has filed a motion to remand the case back to the Supreme Court of the State of New York, which is currently pending before the District Court in the District of Massachusetts.

All of the complaints allege that the defendants fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, also referred to as Covered Drugs; marketed and promoted the sale of Covered Drugs to providers based on the providers’ ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs; and overcharged Medicaid for illegally inflated Covered Drugs reimbursements. The complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, all of the complaints, with the exception of the County of Erie complaint, allege that the defendants failed to accurately report the “best price” on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements entered into with the Secretary of Health and Human Services, and excluded from their reporting certain drugs offered at discounts and other rebates that would have reduced the “best price.” On April 8, 2005, the court dismissed similar claims, which were brought by Suffolk County against Biogen Idec and eighteen other defendants in a complaint filed on August 1, 2003. The court held that Suffolk County’s documentation was insufficient to plead allegations of fraud. Neither Biogen Idec nor the other defendants have answered or responded to the complaints that are currently pending in the U.S. District Court for the District of Massachusetts, as all of the plaintiffs have agreed to stay the time to respond until a case management order and briefing schedule have been approved by the Court. Biogen Idec intends to defend itself vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

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

### **New Accounting Standards**

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections," which replaces APB Opinion No. 20, "Accounting Changes," and supersedes FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements—an amendment of APB Opinion No. 28." SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. SFAS 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the provisions of the SFAS 154 will have a significant impact on our results of operations.

In December 2004, the FASB issued SFAS 123(R), "Share-Based Payments," which replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123(R) will require all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. SFAS 123(R) offers alternative methods for determining the fair value. In April 2005, the SEC issued a new rule that allows companies to implement SFAS 123(R) at the beginning of the next fiscal year, instead of the next reporting period, that begins after June 15, 2005. As a result, we will implement SFAS 123(R) in the reporting period starting January 1, 2006. We expect that SFAS 123(R) will have a significant impact on our financial statements. At the present time, we have not yet determined which valuation method we will use.

In July 2005, the FASB published an Exposure Draft of a proposed Interpretation, "Accounting for Uncertain Tax Positions." The Exposure Draft seeks to reduce the significant diversity in practice associated with recognition and measurement in the accounting for income taxes. It would apply to all tax positions accounted for in accordance with SFAS 109, "Accounting for Income Taxes." The Exposure Draft requires that a tax position meet a "probable recognition threshold" for the benefit of the uncertain tax position to be recognized in the financial statements. This threshold is to be met assuming that the tax authorities will examine the uncertain tax position. The Exposure Draft contains guidance with respect to the measurement of the benefit that is recognized for an uncertain tax position, when that benefit should be derecognized, and other matters. This proposed Interpretation would clarify the accounting for uncertain tax positions in accordance with SFAS 109. The FASB staff is considering the comment letters that have been received and is determining the plan for redeliberations. The Board expects to issue a final Interpretation, which would include amendments to SFAS 109, in the first quarter of 2006. We are currently evaluating the impact this proposed Interpretation would have on our results of operations.

## CRITICAL ACCOUNTING ESTIMATES

We incorporate by reference the section “Management’s Discussion and Analysis of Financial Condition and Results of Operation — Critical Accounting Estimates” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2004. Significant judgements and/or updates to the policies since December 31, 2004 are included below.

### Revenue Recognition and Accounts Receivable

Product revenue consists of sales from four of our products: AVONEX, AMEVIVE, ZEVALIN, and TYSABRI. The timing of distributor orders and shipments can cause variability in earnings. Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Revenues are recorded net of applicable allowances for returns, patient assistance, trade term discounts, Medicaid rebates, Veteran’s Administration rebates, and managed care discounts and other applicable allowances. Included in our condensed consolidated balance sheets at September 30, 2005 and December 31, 2004 are allowances for returns, rebates, discounts and other allowances which totaled \$39.7 million and \$33.8 million, respectively. At September 30, 2005, our allowance for product returns, which is a component of allowances for returns, rebates, discounts and other allowances, was \$1.7 million. In the first nine months of 2005, total discounts and allowances were approximately 3% of total current assets and less than 1% of total assets. We prepare our estimates for sales returns and allowances, discounts and rebates quarterly based primarily on historical experience updated for changes in facts and circumstances, as appropriate.

For the three and nine months ended September 30, 2005, we recorded \$59.1 million and \$167.0 million, respectively, in our condensed consolidated statements of income related to sales returns and allowances, discounts, and rebates compared to \$39.1 million and \$116.7 million, respectively, for the comparable periods in 2004. In the three and nine months ended September 30, 2005, the amount of product returns was approximately 1.0% and 1.7%, respectively, of product revenue for all our products, compared to 1.3% and 1.1%, respectively, for the comparable periods in 2004. Product returns, which is a component of allowances for returns, rebates, discounts and other allowances, were \$4.0 million and \$20.1 million for the three and nine months ended September 30, 2005, respectively, compared to \$4.8 million and \$12.0 million, respectively, in the comparable periods in 2004. The increase of product returns in the nine months ended September 30, 2005 consisted primarily of \$9.7 million, due to the voluntary suspension of TYSABRI. Product returns in the first nine months of 2005 included \$9.2 million related to product sales made prior to 2005, which represents less than 1% of total product revenues, of which \$4.7 million was reserved for at December 31, 2004.

In January 2003, we received regulatory approval to market AMEVIVE in the U.S. In connection with the commercialization of AMEVIVE, we implemented an initiative, undertaken in cooperation with one of our distributors which provides discounts on future purchases of AMEVIVE made after a private payor has initially verified that it will cover the product but later denies the claim after appeal and where the other requirements of the initiative are met. Under this initiative, our exposure was contractually limited to 5% of the price of all AMEVIVE purchased by the distributor. As a result, we deferred recognition of revenue of 5% of AMEVIVE purchased by the distributor until such time as sufficient history of insurance reimbursement claims became available. As of December 31, 2004, we had approximately \$2.8 million of deferred revenue related to this initiative in accrued expenses and other. Since January 2003, our experience of denials of claims after appeal and where the other requirements of the initiative have been met were substantially below the contractual limit. As a result, in the first quarter of 2005, we recognized approximately \$2.8 million in AMEVIVE product revenue, which had previously been deferred.

Under our agreement with Elan, we manufacture TYSABRI and, in the U.S. prior to the suspension, sold TYSABRI to Elan who then distributed TYSABRI to third party distributors. Prior to the suspension, we recorded revenue when TYSABRI was shipped from Elan to third party distributors. In the first quarter of 2005, we recorded \$5.9 million of net product revenues related to sales of TYSABRI to Elan that we estimate were ultimately dosed into patients. Additionally, as of March 31, 2005, we deferred \$14.0 million in revenue under our revenue recognition policy with Elan, which has been fully paid by Elan, related to sales of TYSABRI which had not yet been shipped by Elan and remains deferred at September 30, 2005. Through September 30, 2005, we incurred net withdrawal costs of \$7.8 million related to sales returns in connection with the voluntary suspension of TYSABRI. Should our estimate of expected sales returns and allowances be materially different from actual returns, then we may be required to record adjustments, which could result in additional revenues or further reductions of revenue.

As of September 30, 2005, Elan owed us \$18.7 million, representing commercialization and development expenses as well as withdrawal costs incurred by us, which is included in other current assets on our condensed consolidated balance sheets.

### Income Taxes

Income tax expense includes a provision for income tax contingencies, which we believe is adequate and appropriate.

In preparing our condensed consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our condensed consolidated balance sheets. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and the effects of viable tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates, we adjust our estimates in future periods.

### **Marketable Securities**

We invest our excess cash balances in short-term and long-term marketable securities, principally corporate notes and government securities. At September 30, 2005, substantially all of our securities were classified as “available-for-sale.” All available-for-sale securities are recorded at fair market value and unrealized gains and losses are included in accumulated other comprehensive loss in shareholders’ equity, net of related tax effects. Realized gains and losses and declines in value, if any, judged to be other-than-temporary on available-for-sale securities are reported in other expense. In the first quarter of 2005, we recognized a charge of approximately \$3.1 million for certain unrealized losses on available-for-sale securities that were determined to be other-than-temporary, because we knew the securities would be sold prior to a potential recovery of their decline in value. Any future determinations that unrealized losses are other-than-temporary could have an impact on earnings. The cost of available-for-sale securities sold is based on the specific identification method. We have established guidelines that maintain safety and provide adequate liquidity in our available-for-sale portfolio. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

As part of our strategic product development efforts, we invest in equity securities of certain biotechnology companies with which we have collaborative agreements. Statement of Financial Accounting Standards No. 115, or SFAS 115, “Accounting for Certain Investments in Debt and Equity Securities,” addresses the accounting for investment in marketable equity securities. As a matter of policy, we determine on a quarterly basis whether any decline in the fair value of a marketable security is temporary or other-than-temporary. Unrealized gains and losses on marketable securities are included in accumulated other comprehensive loss in shareholders’ equity, net of related tax effects. If a decline in the fair value of a marketable security below our cost basis is determined to be other-than-temporary, such marketable security is written-down to its estimated fair value with a charge to current earnings. The factors that we consider in our assessments include the fair market value of the security, the duration of the security’s decline, and prospects for the company, including favorable clinical trial results, new product initiatives and new collaborative agreements. In the first three months of 2005, we recognized a \$9.2 million charge for the impairment of an investment that was determined to be other-than-temporary following a decline in value during the first quarter of 2005 due to unfavorable clinical results and the future prospects for the company. Any future determinations that unrealized losses are other-than-temporary could have an impact on earnings. At September 30, 2005, we had no unrealized losses related to these marketable securities. The fair market value of these marketable securities totaled \$8.0 million at September 30, 2005.

We also invest in equity securities of certain companies whose securities are not publicly traded and fair value is not readily available. These investments are recorded using the cost method of accounting and, as a matter of policy, we monitor these investments in private securities on a quarterly basis, and determine whether any impairment in their value would require a charge to current earnings, based on the implied value from any recent rounds of financing completed by the investee, market prices of comparable public companies, and general market conditions. In the three months ended September 30, 2005, we recorded a \$4.6 million charge for the impairment of an investment that completed an initial public offering during the period, when we determined that the offering price and our unrealized loss related to the entity as of September 30, 2005 was not likely to be recovered to our carrying value prior to the company being publicly traded. Additional recognition of impairments for these securities may cause variability in earnings.

### **Inventory**

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

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We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict to the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed \$23.2 million of costs related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense for the three and nine months ended September 30, 2005. In subsequent periods, we will continue to assess TYSABRI to determine if manufacturing costs need to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards.

We periodically review our inventories for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realized value. If the actual realizable value is less than that estimated by us, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write-offs may be required. For the three months ended September 30, 2005, we wrote-down \$16.1 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$9.1 million for AMEVIVE, \$6.4 million for ZEVALIN and \$0.6 million for AVONEX. The write-downs of AMEVIVE inventory consisted of \$4.8 million for expired product and \$4.3 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The ZEVALIN inventory was written-down in the third quarter when it was determined that the inventory will not be marketable based on estimates of demand. The write-downs of AVONEX inventory in the third quarter related to product that failed to meet quality specifications.

For the nine months ended September 30, 2005, we wrote-down \$42.5 million of unmarketable inventory which was charged to cost of product revenues. These write-downs consisted of \$23.4 million for AMEVIVE, \$10.1 million for AVONEX and \$9.0 million for ZEVALIN. The write-downs for AMEVIVE inventory consisted of \$4.8 million for expired product and \$18.6 million for product that failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of AVONEX inventory consisted of \$8.4 million for remaining supplies of the alternative presentations of AVONEX that were no longer needed after the FDA approved a new component for the pre-filled syringe formulation of AVONEX in March 2005, and \$1.7 million for product that failed to meet quality specifications. The write-down of ZEVALIN inventory was related to inventory that will not be marketable based on estimates of demand.

For the three months ended September 30, 2004, we wrote-down \$9.2 million of unmarketable inventory to cost of product revenues. The write-downs for the three months ended September 30, 2004 consisted of \$5.6 million related to AVONEX, \$3.4 million related to ZEVALIN and \$0.2 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-down of ZEVALIN inventory resulted from a determination that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA.

For the nine months ended September 30, 2004, we wrote-down \$21.0 million of unmarketable inventory to cost of product revenues. The write-downs of inventory consisted of \$11.3 million related to AVONEX, \$8.1 million related to ZEVALIN and \$1.7 million related to AMEVIVE. The AVONEX and AMEVIVE inventory was written-down to net realizable value when it was determined that the inventory failed to meet the numerous stringent quality specifications agreed upon with the FDA. The write-downs of ZEVALIN inventory consisted of \$3.4 million of inventory that failed to meet the numerous stringent quality specifications agreed upon with the FDA and \$4.7 million of inventory that will not be marketable based on estimates of demand.

### **Impairment of Long-Lived Assets**

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

In the third quarter of 2005, in connection with our comprehensive strategic plan that we announced in September 2005, we recorded an impairment charge of \$13.1 million to research and development expense, which reflects the adjustment to net realizable value of our NICO clinical manufacturing facility in San Diego, California, and classified the asset as held for sale under SFAS 144. The net realizable value was based in part by an independent third party valuation of the fair value of the manufacturing facility. Additionally, in the third quarter of 2005, we recorded a charge of \$12.9 million to selling,

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general and administrative expense to write-down any remaining prepaid expense associated with our arrangement with MDS (Canada) related to ZEVALIN, to its net realizable value.

In March 2005, we determined that we would no longer proceed with the fill-finish component of our large-scale biologic manufacturing facility in Hillerod. As a result, in the first quarter of 2005, we wrote-down to research and development expense approximately \$6.2 million of engineering costs which had previously been capitalized.

### **Assets Held for Sale**

As part of the comprehensive strategic plan that we announced in September 2005, we are seeking to divest several non-core assets, including our NICO clinical manufacturing facility in San Diego, California and certain real property in Oceanside, California. We consider those assets as held for sale, since they meet the criteria of held for sale under SFAS 144, "Accounting for the Impairment or Disposal of Long-Live Assets," and have reported those assets separately in current assets on the condensed consolidated balance sheet at September 30, 2005. As discussed above, the NICO clinical manufacturing facility was adjusted to its net realizable value, which was based in part by an independent third party valuation of the fair value of the manufacturing facility.

### **Severance and Other Costs from Restructuring Plan**

In September 2005, we began implementing a comprehensive strategic plan designed to position us for long-term growth. In conjunction with the plan, we are consolidating or eliminating certain internal management layers and staff functions, resulting in the reduction of our workforce by approximately 17%, or approximately 650 positions worldwide. These adjustments will take place across company functions, departments and sites, and are expected to be substantially implemented by the end of 2005. We have recorded restructuring charges associated with these activities, which consist primarily of severance and other employee termination costs, including health benefits, outplacement and bonuses. Other costs include write-downs of certain research assets that will no longer be utilized, consulting costs in connection with the restructuring effort and costs related to the acceleration of restricted stock, offset by the reversal of previously recognized compensation due to unvested restricted stock cancellations. For the three months ended September 30, 2005, restructuring charges of \$19.6 million are included in research and development and \$7.6 million are included in selling, general and administrative expenses. The timing and amounts of these charges are based on the estimated termination dates of the employees and the related termination charges. If actual timing is different than planned, our total restructuring charge amount could change. Any remaining unpaid costs at September 30, 2005 are included in accrued expenses and other on our condensed consolidated balance sheet.

### **Research and Development Expenses**

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, contract services and other outside expenses. Research and development expenses are expensed as incurred. We have entered into certain research agreements in which we share expenses with our collaborator. We have entered into other collaborations where we are reimbursed for work performed on behalf of our collaborative partners. We record these expenses as research and development expenses. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments by the collaborator for their share of the development effort as a reduction of research and development expense. If the arrangement is a reimbursement of research and development expenses, we record the reimbursement as corporate partner revenue.

We manufactured TYSABRI during the first and second quarter of 2005 and completed our scheduled production of TYSABRI during July 2005. Because of the uncertain future commercial availability of TYSABRI and our inability to predict with the required degree of certainty that TYSABRI inventory will be realized in commercial sales prior to the expiration of its shelf life, we expensed \$23.2 million of costs related to the manufacture of TYSABRI in the first quarter of 2005 to cost of product revenues. At the time of production, the inventory was believed to be commercially salable. Beginning in the second quarter of 2005, we charged the costs related to the manufacture of TYSABRI to research and development expense. As a result, we expensed \$1.1 million and \$21.0 million, respectively, related to the manufacture of TYSABRI to research and development expense in the three and nine months ended September 30, 2005. We will continue to assess TYSABRI to determine if it needs to continue to be expensed and whether such expenses should be charged to cost of product revenues or research and development expense in light of existing information related to the potential future commercial availability of TYSABRI and applicable accounting standards.

### **Intangible Assets and Goodwill**

In connection with the merger transaction on November 12, 2003 between Biogen, Inc. and IDEC Pharmaceuticals Corporation, or the Merger, we recorded intangible assets related to patents, trademarks, and core technology as part of the purchase price. These intangible assets were recorded at fair value, and at September 30, 2005 and December 31, 2004 are net of accumulated amortization and impairments. Intangible assets related to out-licensed patents and core technology are amortized over their estimated useful lives,



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ranging from 12 to 20 years, based on the greater of straight-line method or economic consumption each period. These amortization costs are included in “Amortization of acquired intangible assets” in the accompanying condensed consolidated statements of income. Intangible assets related to trademarks have indefinite lives, and as a result are not amortized, but are subject to review for impairment. We review our intangible assets for impairment periodically and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In the third quarter of 2005, we completed a review of our business opportunities in each of the relevant commercial markets in which our products are sold and determined their expected profitability as a result of this review.

In the third quarter of 2005, we completed a review of our business opportunities in each of the relevant commercial markets in which our products are sold and determined their expected profitability. As a result of this review, in the third quarter of 2005, management determined that certain clinical trials would not continue which indicated that the carrying value of certain core technology intangible assets related to future sales of AVONEX in Japan may not be recoverable. As a result, we recorded a charge of approximately \$7.9 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AVONEX. Additionally, in the third quarter of 2005, we recorded a charge of \$5.7 million to cost of product revenues related to an impairment of certain capitalized ZEVALIN patents, to reflect the adjustment to net realizable value. As part of our decision to divest our AMEVIVE product, we have reassessed our intangible assets related to AMEVIVE, and have determined that there are no impairments related to these assets as a result of our decision to divest AMEVIVE. However, should new information arise, we may be required to take impairment charges related to certain of our intangibles. In the third quarter of 2004, management determined that certain clinical trials would not continue which indicated that the carrying value of certain core technology intangible assets related to AMEVIVE may not be recoverable. As a result, we recorded a charge of approximately \$27.8 million to amortization of acquired intangible assets, which reflects the adjustment to net realizable value of core technology intangible assets related to AMEVIVE.

Goodwill associated with the Merger represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for by the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. Goodwill is reviewed annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. As a result of the voluntary suspension of TYSABRI in February 2005, we performed an interim review for impairment of goodwill, intangibles and other long-lived assets. We believe that the fair value of our Biogen reporting unit exceeds its carrying value and therefore, we determined that goodwill was not impaired. However, should new information arise, we may need to reassess goodwill for impairment in light of the new information and we may be required to take impairment charges related to goodwill.

### **Contingencies and Litigation**

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

## **CONTROLS AND PROCEDURES**

### *Disclosure Controls and Procedures*

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act) as of September 30, 2005. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2005, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

### *Changes in Internal Control over Financial Reporting*

We have not made any changes in our internal control over financial reporting during the third quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## Use of Non-GAAP Financial Measures

We use pro forma gross margin of product sales measures in the “Cost of Sales” section. These are non-GAAP financial measures. The most directly comparable GAAP financial measures as well as the reconciliation between the non-GAAP financial measures and the GAAP financial measures are presented in the discussion of the non-GAAP financial measures. Management believes that these non-GAAP financial measures provide useful information to investors. In particular, management believes that these non-GAAP financial measures allow investors to monitor and evaluate our ongoing operating results and trends and gain a better understanding of our past performance as well as period-to-period performance.

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

*The SEC encourages public companies to disclose forward-looking information so that investors can better understand a company’s future prospects and make informed investment decisions. In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. Reference is made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses and profits, regulatory approvals, our long-term growth, our ability to continue development of TYSABRI and reintroduce TYSABRI into the market, the re-initiation of manufacturing of TYSABRI, the development and marketing of additional products, including RITUXAN in RA, the impact of competitive products, the anticipated outcome of pending or anticipated litigation and patent-related proceedings, the substantial completion of our Denmark large-scale manufacturing facility, the substantial completion and licensing of our Denmark packaging and labeling facility, our ability to meet our manufacturing needs, the value of investments in certain marketable securities, and our plans to spend additional capital on external business development and research opportunities. These and all other forward-looking statements are made based on our current belief as to the outcome and timing of such future events. Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Although we believe that the risks described below represent all material risks currently applicable to our business, additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.*

### **Our Revenues Rely Significantly on a Limited Number of Products**

Our current and future revenues depend substantially upon continued sales of our commercial products. Revenues related to sales of two of our products, AVONEX and RITUXAN, represented approximately 93% of our total revenues in the third quarter of 2005. We cannot assure you that AVONEX or RITUXAN will continue to be accepted in the U.S. or in any foreign markets or that sales of either of these products will not decline in the future. A number of factors may affect market acceptance of AVONEX, RITUXAN and our other products, including:

- the perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;
- patient and physician satisfaction with these products;
- the effectiveness of our sales and marketing efforts and those of our marketing partners and licensees in the U.S., the EU and other foreign markets;
- the size of the markets for these products;
- unfavorable publicity concerning these products or similar drugs;
- the introduction, availability and acceptance of competing treatments;
- the availability and level of third-party reimbursement;
- adverse event information relating to any of these products;
- changes to product labels to add significant warnings or restrictions on use;

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- the success of ongoing development work on RITUXAN;
- the continued accessibility of third parties to vial, label, and distribute these products on acceptable terms;
- the unfavorable outcome of patent litigation related to any of these products;
- the ability to manufacture commercial lots of these products successfully and on a timely basis; and
- regulatory developments related to the manufacture or continued use of these products.

Any material adverse developments with respect to the commercialization of these products may cause our revenue to grow at a slower than expected rate, or even decrease, in the future.

### ***Safety Issues with TYSABRI Could Significantly Affect our Growth***

TYSABRI was approved by the FDA in November 2004 to treat relapsing forms of MS to reduce the frequency of clinical relapses. In February 2005, in consultation with the FDA, we and Elan voluntarily suspended the marketing and commercial distribution of TYSABRI. We also suspended dosing in all clinical trials of TYSABRI. These decisions were based on reports of cases of PML, a rare and potentially fatal, demyelinating disease of the central nervous system in patients treated with TYSABRI in clinical studies. We and Elan are working with clinical investigators to evaluate patients treated with TYSABRI in clinical studies and consulting with leading experts to better understand the possible risk of PML with TYSABRI. The safety evaluation also included the review of any reports of potential PML in MS patients receiving TYSABRI in the commercial setting. In October 2005, we completed the safety evaluation of TYSABRI in MS, Crohn's disease and RA patients and found no new cases of PML. Three confirmed cases of PML were previously reported, two of which were fatal. On September 26, 2005, we and Elan submitted an sBLA for TYSABRI to the FDA for the treatment of MS. We and Elan have also recently submitted a data package to the EMEA. This information was supplied as part of the ongoing EMEA review process, which was initiated in the summer of 2004 with the filing for approval of TYSABRI as a treatment for MS.

We plan to work with regulatory authorities to determine the path forward for TYSABRI which could range from the permanent withdrawal of TYSABRI from the market and terminating clinical studies of TYSABRI, the need for additional testing, or the re-introduction of TYSABRI to the market in the U.S. If we are allowed to re-introduce TYSABRI to the market in the U.S., it could be for a significantly restricted use. The outcome of our work with the EMEA could result in the withdrawal of our applications for approval of TYSABRI as a treatment for MS and Crohn's disease in the EU, or, if in consultation with the EMEA, we receive marketing approval for TYSABRI in one or both indications, a product label with similar restrictions on use as those that may be required by the FDA. If we are able to re-introduce TYSABRI into the U.S. market or get approval in the EU, we expect that there will be an ongoing extensive patient risk management program and that the label will include blackbox and other significant safety warnings. The success of any reintroduction into the U.S. market and launch in the EU will depend upon its acceptance by the medical community and patients, which cannot be certain given questions regarding the safety of TYSABRI raised by these adverse events, the possibility of significant restrictions on use and the significant safety warnings that we expect to be in the label. Our inability to return TYSABRI to the market in the U.S. or to get TYSABRI approved in the EU or any significant restrictions on use or lack of acceptance of TYSABRI by the medical community or patients would materially affect our growth and impact various aspects of our business and our plans for the future. This could result in, among other things, material write-offs of inventory, intangible assets or goodwill, impairment of capital assets, and additional reductions in our workforce.

### ***Our Long-Term Success Depends Upon the Successful Development and Commercialization of Other Products from Our Research and Development Activities and External Growth Opportunities***

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities and external growth opportunities. We continue to expand our development efforts related to RITUXAN and other potential products in our pipeline. The expansion of our pipeline may include increases in spending on internal projects, and is expected to include an increase in spending on external growth opportunities, such as the acquisition and license of third-party technologies or products, collaborations with other companies and universities, the acquisitions of companies with commercial products and/or products in their pipelines, and other types of investments. Product development and commercialization involve a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. In addition, competition for collaborations and the acquisition and in-license of third party technologies and products in the biopharmaceutical industry is intense. We cannot be certain that we will be able to enter into collaborations or agreements for

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desirable and compatible technologies or products on acceptable terms or at all. Many important factors affect our ability to successfully develop and commercialize other products, including the ability to:

- obtain and maintain necessary patents and licenses;
- demonstrate safety and efficacy of drug candidates at each stage of the clinical trial process;
- enroll patients in our clinical trials and complete clinical trials;
- overcome technical hurdles that may arise;
- successful manufacture of products in sufficient quantities to meet demand;
- meet applicable regulatory standards;
- obtain reimbursement coverage for the products;
- receive required regulatory approvals;
- produce drug candidates in commercial quantities at reasonable costs;
- compete successfully against other products and to market products successfully; and
- enter into agreements for desirable and compatible technologies or products on acceptable terms; and
- successfully manage any significant collaborations and/or integrate any significant acquisitions.

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

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

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

AVONEX competes with three other products:

- REBIF® (interferon-beta 1a), which is co-promoted by Serono, Inc. and Pfizer Inc. in the U.S. and sold by Serono AG in the EU;
- BETASERON® (interferon-beta 1a), sold by Berlex in the U.S. and sold under the name BETAFERON® by Schering A.G. in the EU; and
- COPAXONE® (glatiramer acetate injection), sold by Teva Neuroscience, Inc. in the U.S. and co-promoted by Teva and Aventis Pharma in the EU.

In addition, a number of companies, including us, are working to develop products to treat MS that may in the future compete with AVONEX. If we are able to reintroduce TYSABRI to the market, it would compete with the products listed above, including AVONEX. AVONEX also faces competition from off-label uses of drugs approved for other indications. Some of our current

competitors are also working to develop alternative formulations for delivery of their products, which may in the future compete with AVONEX

RITUXAN is typically used after patients fail to respond or relapse after treatment with traditional radiation therapy or standard chemotherapy regimens, such as CVP and CHOP. ZEVALIN is typically used after patients fail to respond or relapse following treatment with RITUXAN. ZEVALIN received designation as an Orphan Drug from the FDA for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell non-Hodgkin's lymphoma, including patients with RITUXAN refractory follicular NHL. Marketing exclusivity resulting from this Orphan Drug designation expires in February 2009. ZEVALIN competes with BEXXAR® (tositumomab, iodine I-131 tositumomab), a radiolabeled molecule developed by Corixa Corporation which is now being developed and commercialized by GlaxoSmithKline. BEXXAR received FDA approval in June 2003 to treat patients with CD20+, follicular, NHL, with and without transformation, whose disease is refractory to RITUXAN and has relapsed following chemotherapy. A number of other companies, including us, are working to develop products to treat B-cell NHLs and other forms of non-Hodgkin's lymphoma that may ultimately compete with RITUXAN and ZEVALIN.

In August 2005, we, along with Genentech, submitted an sBLA with the FDA for a new indication for RITUXAN in patients with active RA who inadequately respond to an anti-tumor necrosis factor, or anti-TNF, therapy. If approved, RITUXAN will compete with several different types of therapies including:

- traditional therapies for RA, including disease-modifying anti-rheumatic drugs, such as steroids, methotrexate and cyclosporin, pain relievers, such as acetaminophen.
- anti-TNF therapies, such as REMICADE® (infliximab), a drug sold worldwide by Centocor, Inc., a subsidiary of Johnson & Johnson, HUMIRA® (adalimumab), a drug sold by Abbott Laboratories, and ENBREL® (etanercept), a drug sold by Amgen, Inc. and Wyeth Pharmaceuticals, Inc.
- drugs in late-stage development for RA, such as ORENCIA® (abatacept), being developed by Bristol-Myers Squibb Company, which was recommended for approval to treat RA in September 2005 by the FDA Arthritis Advisory Committee.
- drugs approved for other indications that are used to treat RA.

In addition, a number of other companies, including us, are working to develop products to treat RA that may ultimately compete with RITUXAN in the RA marketplace.

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

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX, TYSABRI and the ZEVALIN bulk antibody. Our inability to successfully manufacture bulk product and to maintain regulatory approvals of our manufacturing facilities would harm our ability to timely produce sufficient quantities of commercial supplies of AVONEX, TYSABRI and ZEVALIN to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. Any such problem would be exacerbated by unexpected demand for our products. In June 2005, we sold our large-scale manufacturing facility in Oceanside, California to Genentech, Inc. We previously had planned to use the Oceanside facility to manufacture TYSABRI and other commercial products. We currently manufacture TYSABRI at our manufacturing facility in Research Triangle Park, North Carolina. We are building a large-scale manufacturing facility in Hillerod, Denmark. The timing of the completion of construction and anticipated licensing of the Hillerod large-scale manufacturing facility is primarily dependent upon the commercial availability and potential market acceptance of TYSABRI. See "Forward-Looking Information and Risk Factors That May Affect Future Results — Safety Issues with TYSABRI Could Significantly Affect our Growth." If we are able to re-introduce TYSABRI to the market, we expect that we will be able to meet foreseeable manufacturing needs for TYSABRI from the North Carolina facility. We would, however, need to evaluate our requirements for additional manufacturing capacity in light of the approved label and our judgment of the potential U.S. market acceptance of TYSABRI in MS, the probability of obtaining marketing approval of TYSABRI in MS in the EU and other jurisdictions, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

If we cannot produce sufficient commercial requirements of bulk product of our products to meet demand, we would need to rely on third-party manufacturers, of which there are only a limited number capable of manufacturing bulk products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach

agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time. Our ability to supply products in sufficient capacity to meet demand is also dependent upon third party contractors to fill-finish, package and store such products. For a discussion of the risks associated with using third parties to perform manufacturing-related services for our products, see “Forward-Looking Information and Risk Factors That May Affect Future Results — We Rely to a Large Extent on Third Parties in the Manufacturing of Our Products.” In the past, we have had to write down and incur other charges and expenses for products that failed to meet specifications. Similar charges may occur in the future. Any prolonged interruption in the operations of our existing manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. Because our manufacturing processes are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all.

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

We rely on Genentech for all RITUXAN manufacturing. Genentech relies on a third party to manufacture certain bulk RITUXAN requirements. If Genentech or any third party upon which it relies does not manufacture or fill/finish RITUXAN in sufficient quantities and on a timely and cost-effective basis or if Genentech or any third party does not obtain and maintain all required manufacturing approvals, our business could be harmed. We also rely heavily upon third-party manufacturers and suppliers to manufacture and supply significant portions of the product components of ZEVALIN other than the bulk antibody, including chelates necessary for the ZEVALIN therapeutic regimen and the radioisotope yttrium-90 and the indium-111 isotope used with the therapeutic and imaging kits of ZEVALIN, respectively. The radioisotope yttrium-90 is only available from a limited number of suppliers. We made MDS (Canada) our exclusive supplier of the radioisotope yttrium-90 used with ZEVALIN. MDS (Canada) is the only manufacturer of the radioisotope yttrium-90 used with ZEVALIN approved by the FDA. If we were to lose the services of MDS (Canada) or our third party manufacturers of chelates, we would be forced to find other third party providers, which could delay our ability to manufacture and sell ZEVALIN. In addition, radiopharmacies independently purchase the indium-111 isotope required for the imaging use of ZEVALIN. Currently, only two suppliers are approved by the FDA to supply the indium-111 isotope. Our inability to find replacement suppliers for materials used in our marketed products and our primary product candidates that are available only from a single supplier or a limited number of suppliers could significantly impair our ability to sell our products.

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

***The Manufacture of Our Products is Subject to Government Regulation***

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

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

Royalty revenues contribute to our overall profitability. Royalty revenues may fluctuate as a result of disputes with licensees, collaborators and partners, future patent expirations and other factors such as pricing reforms, health care reform initiatives, other legal and regulatory developments and the introduction of competitive products that may have an impact on product sales by our licensees and partners. In addition, sales levels of products sold by our licensees, collaborators and partners may fluctuate from quarter to quarter due to the timing and extent of major events such as new indication approvals or government-sponsored programs. Since we are not involved in the development or sale of products by our licensees, collaborators and partners, we cannot be certain of the timing

or potential impact of factors which may affect their sales. In addition, the obligation of licensees to pay us royalties generally terminates upon expiration of the related patents.

***Our Operating Results Are Subject to Significant Fluctuations***

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

- demand and pricing for our products;
- physician and patient acceptance of our products;
- amount and timing of sales orders for our products;
- our achievement of product development objectives and milestones;
- research and development and manufacturing expenses;
- clinical trial enrollment and expenses;
- our manufacturing performance and capacity and that of our partners;
- percentage of time that our manufacturing facilities are utilized for commercial versus clinical manufacturing;
- rate and success of product approvals;
- costs related to obtain product approvals, launching new products and maintaining market acceptance for existing products;
- timing of regulatory approval, if any, of competitive products and the rate of market penetration of competing products;
- new data or information, positive or negative, on the benefits and risks of our products or products under development;
- expenses related to protecting our intellectual property;
- expenses related to litigation and settlement of litigation;
- payments made to acquire new products or technology;
- write-downs and write offs of inventories, intangible assets, goodwill or investments;
- impairment of assets, such as buildings and manufacturing facilities;
- government or private healthcare reimbursement policies;
- collaboration obligations and copromotion payments we make or receive;
- timing and nature of contract manufacturing and contract research and development payments and receipts;
- interest rate fluctuations;
- foreign currency exchange rates; and
- overall economic conditions.

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

***Our Sales Depend on Payment and Reimbursement from Third-Party Payors, and a Reduction in Payment Rate or Reimbursement Could Result in Decreased Use or Sales of Our Products***

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payers such as state and federal governments, under programs such as Medicare and Medicaid in the U.S., and private insurance plans. In certain foreign markets, the pricing and profitability of our products generally are subject to government controls. In the U.S., there have been, there are, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical and biologic products. Recent Medicare reforms have lowered the reimbursement rate for many of our products. We are not able to predict the full impact of these reforms and its regulatory requirements on our business. However, we believe that legislation that reduces reimbursement for our products could adversely impact our business. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions unilaterally, or in response to such legislation. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, we believe the increasing emphasis on management of the utilization and cost of health care in the U.S. has and will continue to put pressure on the price and usage of our products, which may adversely impact product sales. Further, when a new therapeutic product is approved, the availability of governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at a any stage of development, and current reimbursement policies for marketed products may change at any time. In addition, benefit designs by government and private payers that provide coverage but require more cash outlay from the patient may have the affect of reducing utilization of our products.

Recent Medicare reforms also added a prescription drug reimbursement beginning in 2006 for all Medicare beneficiaries. The temporary drug discount card program that was established for the purpose of providing interim opportunities for discounts to Medicare beneficiaries is being phased out in 2006. Meanwhile, the new Part D pharmacy benefit for Medicare beneficiaries is undergoing enrollment in late 2005 for implementation in 2006. The federal government, through the manner in which they have shaped these programs, is encouraging the new commercial managed care entities that administer them to demand discounts from pharmaceutical and biotechnology companies. The ultimate result of the government's increased purchasing power may be the implicit creation of price controls on prescription drugs. On the other hand, the drug benefit may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts. In addition, Managed Care Organizations, or MCOs, Health Maintenance Organizations, or HMOs, Preferred Provider Organizations, or PPOs, Pharmacy Benefit Managers, or PBM's, institutions and other government agencies continue to seek price discounts. MCOs, HMOs and PPOs and private health plans will administer the Medicare drug benefit, leading to managed care and private health plans influencing prescription decisions for a larger segment of the population. In addition, certain states have proposed and certain other states have adopted various programs to control prices for their seniors' and low-income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products.

In 2003, Congress revised the statutory provisions governing Medicare payment for drugs, biologics and radiopharmaceuticals furnished in outpatient settings. These revisions included a transitional change to the payment methodology in 2004 and 2005, which has lowered payment rates for our products in these years. The methodology will change again in 2006, when the statute provides that rates are to be set based on average acquisition cost. This will affect the reimbursement for products dispensed in the hospital outpatient setting. Some of our products, such as RITUXAN, are not frequently provided in hospital outpatient departments so majority of patients receiving the products should not be affected by these rate changes. However, RITUXAN reimbursement will be affected by the changes in physician outpatient reimbursement described above. Other products, such as ZEVALIN, are used primarily in the hospital outpatient setting and we are uncertain as to whether hospitals will view the 2006 rates favorably and therefore choose to provide ZEVALIN to their patients.

We encounter similar regulatory and legislative issues in most other countries. In the EU and some other international markets, the government provides health care at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored health care system. This international patchwork of price regulation may lead to



inconsistent prices and some third-party trade in our products from markets with lower prices. Such trade exploiting price differences between countries could undermine our sales in markets with higher prices.

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

We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, including a number of our processes and products. Patents have been issued on many of these applications. We have also obtained rights to various patents and patent applications under licenses with third parties, which provide for the payment of royalties by us. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. There is no certainty that our existing patents or others, if obtained, will afford us substantial protection or commercial benefit. Similarly, there is no assurance that our pending patent applications or patent applications licensed from third parties will ultimately be granted as patents or that those patents that have been issued or are issued in the future will prevail if they are challenged in court.

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

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

There has been, and we expect that there may continue to be significant litigation in the industry regarding patents and other intellectual property rights. Litigation, including our current patent litigation with Classen Immunotherapies, and other proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to management. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners, may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or noninfringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights, or, conversely, hinder our ability to market our products.

***Legislative or Regulatory Changes Could Harm Our Business***

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could adversely affect our business, operations or financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

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- new laws, regulations and judicial decisions affecting pricing or marketing; and
- changes in the tax laws relating to our operations.

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

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, 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 or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws. For example, we and a number of other major pharmaceutical and biotechnology companies are named defendants in certain Average Wholesale Price litigation pending in the U.S. District Court for the District of Massachusetts alleging, among other things, violations in connection with Medicaid reimbursement.

Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). We cannot predict with certainty the eventual outcome of any pending litigation. If we were to be convicted of violating laws regulating the sale and marketing of our products in the current proceedings or in new lawsuits or claims brought against us, our business could be materially harmed.

### ***Failure to Prevail in Litigation or Satisfactorily Resolve a Third Party Investigation Could Harm Our Business***

Pharmaceutical and biotechnology companies have been the target of lawsuits relating to product liability claims and disputes over intellectual property rights (including patents). See “Forward-Looking Information and Risk Factors That May Affect Future Results — We May Be Unable to Adequately Protect or Enforce Our Intellectual Property Rights or Secure Rights to Third-Party Patents.” Additionally, the administration of drugs in humans, whether in clinical studies or commercially, can result in lawsuits with product liability claims whether or not the drugs are actually at fault in causing an injury. Our products or product candidates may cause, or may appear to have caused, injury or dangerous drug interactions that we may not learn about or understand until the product or product candidate has been administered to patients for a prolonged period of time. For example, in July 2005, a complaint was filed against us and Elan by the estate and husband of Anita Smith, a patient from the TYSABRI Phase 3 clinical study in combination with AVONEX, known as SENTINEL, who died after developing PML, a rare and potentially fatal, demyelinating disease of the central nervous system. In addition, in August 2005, the plaintiffs in a purported class action in the U.S. District Court for the Northern District of California filed an amended complaint against us and Elan. The amended complaint purports to assert claims for strict product liability, medical monitoring and concert of action arising out of the manufacture, marketing, distribution and sale of TYSABRI. We may face additional lawsuits with product liability and other related claims by patients treated with TYSABRI or related to TYSABRI, including lawsuits filed by patients who have developed PML or other serious adverse events while using TYSABRI.

Public companies may also be the subject of certain other types of claims, including those asserting violations of securities laws and derivative actions. For example, we face several stockholder-derivative actions and class action lawsuits related to our announcement of the suspension of marketing and commercial distribution of TYSABRI in February 2005. In April 2005, we received a formal order of investigation from the Boston District Office of the SEC. The SEC is investigating whether any violations of the federal securities laws occurred in connection with the suspension of marketing and commercial distribution of TYSABRI. We continue to cooperate fully with the SEC in this investigation.

We cannot predict with certainty the eventual outcome of any pending litigation or third-party investigation. We may not be successful in defending ourselves or asserting our rights in the litigation or investigation to which we are currently subject, or in new lawsuits, investigations or claims brought against us, and, as a result, our business could be materially harmed. These lawsuits, investigations or claims may result in large judgments or settlements against us, any of which could have a negative effect on our financial performance and business. Additionally, lawsuits and investigations can be expensive to defend, whether or not the lawsuit or investigation has merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in running our business.

We maintain product liability and director and officer insurance that we regard as reasonably adequate to protect us from potential claims, however we cannot assure you that it will. Also, the costs of insurance have increased dramatically in recent years, and the

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availability of coverage has decreased. As a result, we cannot assure you that we will be able to maintain its current product liability insurance at a reasonable cost, or at all.

### ***Our Business Involves Environmental Risks***

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

### ***We Rely Upon Key Personnel***

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

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

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

- mergers;
- acquisitions;
- strategic alliances;
- licensing and collaboration agreements; and
- copromotion agreements.

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

### ***Volatility of Our Stock Price***

The market prices for our common stock and for securities of other companies engaged primarily in biotechnology and pharmaceutical development, manufacture and distribution are highly volatile. For example, the closing selling price of our common stock fluctuated between \$67.80 per share and \$33.35 per share during the first three quarters of 2005, and \$42.80 and \$34.08 in the third quarter of 2005. The market price of our common stock likely will continue to fluctuate due to a variety of factors, including:

- material public announcements;
- the announcement and timing of new product introductions by us or others;

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- material developments relating to TYSABRI;
- events related to our products or those of our competitors, including the withdrawal or suspension of products from the market;
- technical innovations or product development by us or our competitors;
- regulatory approvals or regulatory issues;
- availability and level of third-party reimbursement;
- developments relating to patents, proprietary rights and orphan drug status;
- results of late-stage clinical trials with respect to our products under development or those of our competitors;
- new data or information, positive or negative, on the benefits and risks of our products or products under development;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic and other external factors, disaster or crisis;
- period-to-period fluctuations in our financial results or results which do not meet or exceed analyst expectations; and
- market trends relating to or affecting stock prices throughout our industry, whether or not related to results or news regarding us or our competitors.

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

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

- we are subject to Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;
- our stockholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors;
- our board of directors has the authority to issue, without vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of common stock;
- our amended and restated collaboration agreement with Genentech provides that, in the event we undergo a change of control, Genentech may present an offer to us to purchase our rights to RITUXAN. We must then accept Genentech's offer or purchase Genentech's rights to RITUXAN. If Genentech presents such an offer, then they will be deemed concurrently to have exercised a right, in exchange for a share in the operating profits or net sales in the U.S. of any other anti CD-20 products developed under the agreement, to purchase our interest in each such product. The rights of Genentech described in this paragraph may limit our attractiveness to potential acquirors;
- our collaboration agreement with Elan provides Elan with the option to buy the rights to TYSABRI in the event that we undergo a change of control, which may limit our attractiveness to potential acquirors;
- our directors are elected to staggered terms, which prevents the entire board from being replaced in any single year;

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- advance notice is required for nomination of candidates for election as a director and for proposals to be brought before an annual meeting of stockholders; and
- our bylaws provide that, until November 12, 2006, the affirmative vote of at least 80% of our board of directors (excluding directors who are serving as an officer or employee) will be required to remove William H. Rastetter, Ph.D. from his position as our Executive Chairman and to remove James C. Mullen as our Chief Executive Officer and President.

**Part II — OTHER INFORMATION**

## Item 1. Legal Proceedings.

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

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

A summary of our stock repurchase activity for the three months ended September 30, 2005 is set forth in the table below:

**Issuer Purchases of Equity Securities**

<b>Period</b>	<b>Total number of shares purchased (#)(a)</b>	<b>Average price paid per share (\$)</b>	<b>Total number of shares purchased as part of publicly announced program (#)(a)</b>	<b>Number of shares that may yet be purchased under our program (#)</b>
<b>July</b>	475	\$ 38.10	—	11,916,400
<b>August</b>	—	—	—	11,916,400
<b>September</b>	4,480	42.51	—	11,916,400
<b>Total</b>	4,955(b)	42.09	—	11,916,400

- (a) In October 2004, our Board of Directors authorized the repurchase of up to 20 million shares of our common stock. This repurchase program will expire no later than October 4, 2006. We publicly announced the repurchase program in our press release dated October 27, 2004 which was furnished to (and not filed with) the SEC as Exhibit 99.1 of our Current Report of Form 8-K filed on October 27, 2004.
- (b) All of these shares are shares that were used by certain employees to pay the exercise price of their stock options in lieu of paying cash or utilizing our cashless option exercise program.

## Item 6. Exhibits

31.1 Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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

**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.

November 2, 2005

BIOGEN IDEC INC.

/s/ Peter N. Kellogg

Peter N. Kellogg

Executive Vice President, Finance and Chief Financial  
Officer



**EXHIBIT 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James C. Mullen, certify that:

1. I have reviewed this quarterly report of Biogen Idec Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2005

/s/ James C. Mullen

James C. Mullen

Chief Executive Officer and President

**EXHIBIT 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter N. Kellogg, certify that:

1. I have reviewed this quarterly report of Biogen Idec Inc.;
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, 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 report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2005

/s/ Peter N. Kellogg

Peter N. Kellogg

Executive Vice President, Finance and Chief Financial  
Officer

**EXHIBIT 32.1**

**CERTIFICATION  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Biogen Idec Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 2, 2005

/s/ James C. Mullen  
James C. Mullen  
Chief Executive Officer and President  
[principal executive officer]

Dated: November 2, 2005

/s/ Peter N. Kellogg  
Peter N. Kellogg  
Executive Vice President - Finance and Chief Financial Officer  
[principal financial officer]

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.