

BIOGEN IDEC INC.  
Form 10-Q  
October 21, 2008

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended September 30, 2008**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**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 a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of shares of the registrant's Common Stock, \$0.0005 par value, outstanding as of October 16, 2008, was 291,752,825 shares.

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**BIOGEN IDEC INC.**

**FORM 10-Q Quarterly Report  
For the Quarterly Period Ended September 30, 2008**

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**PART I FINANCIAL INFORMATION**

**BIOGEN IDEC INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF INCOME**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>In thousands, except per share amounts</b>			
	<b>(Unaudited)</b>			
Revenues:				
Product	\$ 758,260	\$ 529,581	\$ 2,107,816	\$ 1,532,594
Unconsolidated joint business	298,979	234,637	825,024	672,391
Other revenues	35,725	25,013	95,754	73,332
<b>Total revenues</b>	<b>1,092,964</b>	<b>789,231</b>	<b>3,028,594</b>	<b>2,278,317</b>
Costs and expenses:				
Cost of sales, excluding amortization of acquired intangible assets	107,493	81,613	300,828	247,626
Research and development	268,800	286,274	779,291	695,872
Selling, general and administrative	232,824	190,644	694,342	582,373
Collaboration profit (loss) sharing	43,533	5,842	98,368	170
Amortization of acquired intangible assets	94,464	65,689	242,114	186,570
In-process research and development		29,959	25,000	48,364
<b>Total costs and expenses</b>	<b>747,114</b>	<b>660,021</b>	<b>2,139,943</b>	<b>1,760,975</b>
Income from operations	345,850	129,210	888,651	517,342
Other income (expense), net	(24,725)	44,904	(29,818)	98,192
Income before income tax expense	321,125	174,114	858,833	615,534
Income tax expense	114,337	54,733	282,320	178,512
<b>Net income</b>	<b>\$ 206,788</b>	<b>\$ 119,381</b>	<b>\$ 576,513</b>	<b>\$ 437,022</b>
Basic earnings per share	\$ 0.71	\$ 0.41	\$ 1.97	\$ 1.35
Diluted earnings per share	\$ 0.70	\$ 0.41	\$ 1.95	\$ 1.34
Weighted-average shares used in calculating:				
Basic earnings per share	291,408	288,958	292,613	323,006

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Diluted earnings per share	293,921	293,396	295,515	326,743
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See accompanying notes to the consolidated financial statements.

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

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
	<b>(In thousands, except per share amounts) (Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,010,701	\$ 659,662
Marketable securities	217,127	319,408
Cash collateral received for loaned securities	178,129	208,209
Accounts receivable, net	484,636	392,646
Due from unconsolidated joint business	196,542	166,686
Loaned securities	158,971	204,433
Inventory	249,858	233,987
Other current assets	143,116	183,376
Total current assets	2,639,080	2,368,407
Marketable securities	717,182	932,271
Property, plant and equipment, net	1,579,938	1,497,383
Intangible assets, net	2,250,766	2,492,354
Goodwill	1,137,547	1,137,372
Investments and other assets	210,695	201,028
Total assets	\$ 8,535,208	\$ 8,628,815
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Collateral payable on loaned securities	\$ 178,129	\$ 208,209
Accounts payable	123,512	90,672
Taxes payable	176,753	11,274
Accrued expenses and other	497,263	367,885
Current portion of notes payable	10,215	1,511,135
Total current liabilities	985,872	2,189,175
Notes payable	1,042,427	51,843
Long-term deferred tax liability	440,164	521,525
Other long-term liabilities	298,267	331,977
Total liabilities	2,766,730	3,094,520

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Commitments and contingencies (Notes 11 and 13)

Shareholders' equity:

Preferred stock, par value \$0.001 per share		
Common stock, par value \$0.0005 per share	149	147
Additional paid-in capital	6,029,111	5,807,071
Accumulated other comprehensive income	33,431	79,246
Retained Earnings (Accumulated deficit)	75,361	(352,169)
Treasury stock, at cost	(369,574)	
Total shareholders' equity	5,768,478	5,534,295
Total liabilities and shareholders' equity	\$ 8,535,208	\$ 8,628,815

See accompanying notes to the consolidated financial statements.



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**BIOGEN IDEC INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Nine Months Ended</b> <b>September 30,</b> <b>2008                      2007</b> <b>(In thousands)</b> <b>(Unaudited)</b>	
Cash flows from operating activities:		
Net income	\$ 576,513	\$ 437,022
Adjustments to reconcile net income to net cash flows from operating activities		
Depreciation and amortization of fixed & intangible assets	340,042	278,030
In-process research & development	25,000	98,364
Minority interest in subsidiaries	5,167	(25,045)
Share-based compensation	104,339	91,209
Non-cash interest expense	(11,288)	84
Deferred income taxes	(57,591)	(40,366)
Realized loss (gain) on sale of marketable securities and strategic investments	3,774	(17,667)
Write-down of inventory to net realizable value	22,472	19,579
Impairment of investments and other assets	31,502	6,166
Excess tax benefit from stock options	(27,424)	(31,400)
Changes in assets and liabilities, net:		
Accounts receivable	(95,337)	(57,723)
Due from unconsolidated joint business	(29,856)	7,436
Inventory	(34,376)	(70,866)
Other assets	24,898	(71,257)
Accrued expenses and other current liabilities	155,437	42,311
Other liabilities and taxes payable	121,928	8,896
<b>Net cash flows provided by operating activities</b>	<b>1,155,200</b>	<b>674,773</b>
Cash flows from investing activities:		
Purchases of marketable securities	(1,801,056)	(2,201,518)
Proceeds from sales and maturities of marketable debt securities	2,135,065	2,702,841
Collateral received under securities lending	30,080	
Acquisitions, net of cash acquired	(25,000)	(92,289)
Purchases of property, plant and equipment	(221,961)	(175,750)
Proceeds from sale of property, plant, and equipment	16	16,812
Purchases of other investments	(17,260)	(19,522)
Proceeds from the sale of a strategic equity investment		99,489
<b>Net cash flows provided by investing activities</b>	<b>99,884</b>	<b>330,063</b>
Cash flows from financing activities:		
Purchase of treasury stock	(559,767)	(2,991,183)
Proceeds from issuance of stock for share based compensation arrangements	167,032	247,436

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Change in cash overdrafts	18,052	(10,215)
Excess tax benefit from stock options	27,424	31,400
Proceeds from borrowings, net of discounts and expenses	986,980	1,512,296
Repayments of borrowings	(1,512,474)	(12,042)
Obligations under securities lending	(30,080)	
Repayment of long-term debt		(6,563)
Net cash flow (used in) provided by financing activities	(902,833)	(1,228,871)
Net increase (decrease) in cash and cash equivalents	352,251	(224,035)
Effect of exchange rate changes on cash and cash equivalents	(1,212)	(16)
Cash and cash equivalents, beginning of the period	659,662	661,377
Cash and cash equivalents, end of the period	\$ 1,010,701	\$ 437,326

See accompanying notes to the consolidated financial statements.

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**BIOGEN IDEC INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Business Overview**

*Overview*

Biogen Idec Inc. is a global biotechnology company that creates new standards of care in therapeutic areas of high unmet medical needs. We currently have four marketed products: AVONEX<sup>®</sup>, RITUXAN<sup>®</sup>, TYSABRI<sup>®</sup> and FUMADERM<sup>®</sup>.

*Basis of Presentation*

In the opinion of management, the accompanying unaudited 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. The information included in this quarterly report on Form 10-Q should be read in conjunction with our consolidated financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2007. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our 2007 Annual Report on Form 10-K and updated, as necessary, in this Form 10-Q. The year-end consolidated balance sheet data presented for comparative purposes was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the U.S. The results of operations for the three and nine months ended September 30, 2008 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

The preparation of the 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 amounts and results could differ from those estimates.

In 2008, we reclassified amounts within the shareholders' equity section, resulting in an approximately \$78 million correction to Additional Paid-in Capital and Accumulated Deficit, in connection with the reporting of the re-issuance of treasury stock at a loss.

*Principles of Consolidation*

The consolidated financial statements reflect our financial statements, those of our wholly-owned subsidiaries and of our joint ventures in Italy and Switzerland. In accordance with FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, or FIN 46(R), we consolidate variable interest entities in which we are the primary beneficiary. For such consolidated entities in which we own less than a 100% interest, we record minority interest in our statement of income and our balance sheet for the ownership interest of the minority owner. All material intercompany balances and transactions have been eliminated in consolidation.

**2. 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 charged to research and development expense when consumed.



**Table of Contents****BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of inventory are as follows (in millions):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Raw materials	\$ 34.2	\$ 46.4
Work in process	168.8	155.4
Finished goods	46.9	32.2
Total inventory	\$ 249.9	\$ 234.0

During the three months ended September 30, 2008 and 2007, we wrote down \$12.6 million and \$4.7 million, respectively, in unmarketable inventory, which was charged to cost of sales. During the nine months ended September 30, 2008 and 2007, we wrote down \$22.5 million and \$19.6 million, respectively, in unmarketable inventory, which was charged to cost of sales.

During 2007, we had TYSABRI product on hand that had been written down in 2005 due to the uncertainties surrounding the TYSABRI suspension, but which was subsequently used to fill orders in 2007. As a result, in 2007, we recognized lower than normal cost of sales and, therefore, higher margins on our sales of TYSABRI. For the three and nine months ended September 30, 2007, cost of sales was approximately \$4.2 million and \$10.0 million lower, respectively, due to the sale of TYSABRI inventory that had been written down. All TYSABRI inventory that had been previously written down was shipped prior to December 31, 2007.

**3. Revenue Recognition*****Product Revenues***

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; title and risk of loss have passed to the customer; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured.

Revenues from product sales are recognized when the criteria described above have all been met, which is typically upon delivery. However, sales of TYSABRI in the U.S. are recognized on the sell-through model, that is, upon shipment of the product by our collaboration partner, Elan, to the customer.

***Discounts and Allowances***

Revenues are recorded net of applicable allowances for discounts, contractual adjustments and returns.

We establish reserves for these allowances and discounts, which include trade term discounts and wholesaler incentives, contractual adjustments, which include Medicaid rebates, Veteran's Administration rebates, managed care rebates and other applicable allowances and product returns, which include returns made by wholesalers. Such

reserves are classified as reductions of accounts receivable if the amount is payable to a customer and has the effect of reducing the amount they are required to pay us or as a liability if the amount is payable to a party other than a customer.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

An analysis of the amount of, and change in, reserves is as follows (in millions):

	<b>Discounts</b>	<b>Contractual Adjustments</b>	<b>Returns</b>	<b>Total</b>
Beginning balance, January 1, 2008	\$ 6.4	\$ 33.1	\$ 20.4	\$ 59.9
Current provisions relating to sales in current period	46.5	113.9	14.4	174.8
Adjustments relating to sales in prior periods		(1.6)		(1.6)
Payments/returns relating to sales in current period	(38.2)	(64.7)		(102.9)
Payments/returns relating to sales in prior periods	(6.5)	(33.1)	(11.7)	(51.3)
Ending balance, September 30, 2008	\$ 8.2	\$ 47.6	\$ 23.1	\$ 78.9

The total reserves above were included in the consolidated balance sheets as follows (in millions):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Reduction of accounts receivable	\$ 34.7	\$ 28.5
Accrued expenses and other	44.2	31.4
Total reserves	\$ 78.9	\$ 59.9

Reserves for discounts, contractual adjustments and returns reduced gross product revenues as follows (in millions):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Discounts	\$ 16.2	\$ 10.8	\$ 46.5	\$ 31.3
Contractual adjustments	40.1	24.7	112.3	71.6
Returns	5.9	4.0	14.4	17.6
Total allowances	\$ 62.2	\$ 39.5	\$ 173.2	\$ 120.5
Gross product revenues	\$ 820.5	\$ 575.9	\$ 2,281.0	\$ 1,663.3
Percent of gross product revenues	7.6%	6.9%	7.6%	7.2%

Our product revenue reserves are based on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration our historical experience, current contractual and statutory requirements, specific known market events and trends and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.



Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Intangible Assets and Goodwill**

As of September 30, 2008 and December 31, 2007, intangible assets and goodwill, net of accumulated amortization, impairment charges and adjustments, are as follows (in millions):

		As of September 30, 2008			As of December 31, 2007		
	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Out-licensed patents	12 years	\$ 578.0	\$ (238.0)	\$ 340.0	\$ 578.0	\$ (199.1)	\$ 378.9
Core/developed technology	15-20 years	3,003.7	(1,163.5)	1,840.2	3,003.0	(965.2)	2,037.8
Trademarks & tradenames	Indefinite	64.0		64.0	64.0		64.0
In-licensed patents	14 years	3.0	(0.9)	2.1	3.0	(0.7)	2.3
Assembled workforce	4 years	2.1	(1.1)	1.0	2.1	(0.7)	1.4
Distribution rights	2 years	12.1	(8.6)	3.5	11.8	(3.8)	8.0
Total intangible assets		\$ 3,662.9	\$ (1,412.1)	\$ 2,250.8	\$ 3,661.9	\$ (1,169.5)	\$ 2,492.4
Goodwill	Indefinite	\$ 1,137.5	\$	\$ 1,137.5	\$ 1,137.4	\$	\$ 1,137.4

Amortization expense was \$94.5 million and \$65.7 million in the three months ended September 30, 2008 and 2007, respectively. Amortization expense was \$242.1 million and \$186.6 million in the nine months ended September 30, 2008 and 2007, respectively. In the first quarter of 2008, we recorded \$25.0 million of in-process research and development (IPR&D) charges related to an HSP-90 related milestone payment made to the former shareholders of Conforma Therapeutics, Inc., or Conforma, pursuant to our acquisition of Conforma in 2006.

**5. Fair Value Measurements**

Effective January 1, 2008, we implemented Statement of Financial Accounting Standard No. 157, *Fair Value Measurement*, or SFAS 157, for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157*, we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities.

The adoption of SFAS 157 for financial assets and liabilities that are re-measured and reported at fair value at least annually did not have an impact on our financial results.



**Table of Contents****BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability (in millions):

Description	Balance at September 30, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 908.7	\$	\$ 908.7	\$
Marketable debt securities	1,093.3		1,093.3	
Strategic investments	6.3	6.3		
Venture capital investments	28.4			28.4
Derivative contracts	8.3		8.3	
Plan assets for deferred compensation	14.1		14.1	
Total	\$ 2,059.1	\$ 6.3	\$ 2,024.4	\$ 28.4
Liabilities:				
Derivative contracts	1.9		1.9	
Total	\$ 1.9	\$	\$ 1.9	\$

The fair values of our cash equivalents, marketable debt securities, plan assets and derivative instruments are determined through market, observable and corroborated sources. Our strategic investments are investments in publicly traded equity securities where fair value is readily determinable.

The following table is a roll forward of the fair value of our venture capital investments, where fair value is determined by Level 3 inputs (in millions):

Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
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<b>Description</b>	<b>Fair Value</b>		<b>Fair Value</b>	
Beginning Balance	\$	24.6	\$	28.1
Total net unrealized gains (losses) included in earnings		2.2		(2.6)
Purchases, issuances, and settlements		1.6		2.9
Ending Balance	\$	28.4	\$	28.4

The carrying value of the venture capital investments reflect changes in the fair value of the underlying funds' net assets, which is calculated by employing various market, income and cost approaches to determine fair value at each measurement date. Gains and losses (realized and unrealized) included in earnings for the period are reported in other income (expense), net.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Financial Instruments***Marketable Securities, including Strategic Investments*

The following is a summary of marketable securities and investments (in millions):

<b>September 30, 2008:</b>	<b>Fair Value</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Amortized Cost</b>
<i>Available-for-sale</i>				
Corporate debt securities				
Current	\$ 98.8	\$ 0.1	\$	\$ 98.7
Non-current	234.3	1.5	(0.1)	232.9
U.S. Government securities				
Current	118.0	0.3		117.7
Non-current	218.1	3.0		215.1
Other interest bearing securities				
Current	55.6			55.6
Non-current	368.5	2.8	(0.4)	366.1
Total available-for-sale securities	\$ 1,093.3	\$ 7.7	\$ (0.5)	\$ 1,086.1
<i>Other Investments</i>				
Strategic investments, non-current	\$ 6.3	\$ 0.1	\$ (0.4)	\$ 6.6

<b>December 31, 2007:</b>	<b>Fair Value</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Amortized Cost</b>
<i>Available-for-sale</i>				
Corporate debt securities				
Current	\$ 178.3	\$ 0.2	\$ (0.3)	\$ 178.4
Non-current	309.7	3.5	(0.1)	306.3
U.S. Government securities				
Current	192.5	0.2	(0.1)	192.4
Non-current	232.5	4.7		227.8
Other interest bearing securities				
Current	6.1			6.1
Non-current	537.0	5.2	(0.5)	532.3

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Total available-for-sale securities	\$ 1,456.1	\$ 13.8	\$ (1.0)	1,443.3
<i>Other Investments</i>				
Strategic investments, non-current	\$ 16.8	\$ 2.9	\$ (0.1)	\$ 14.0

The table above includes securities we loan from our portfolio to other institutions, as described below.

In the three months ended September 30, 2008 and 2007, we recognized \$14.1 million and \$0.7 million in impairment charges primarily related to mortgage and asset backed securities classified as available-for-sale securities. In the nine months ended September 30, 2008 and 2007, we recognized \$19.3 million and \$6.2 million in impairment charges primarily related to mortgage and asset backed securities classified as available-for-sale securities.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Unrealized losses relate to various debt securities, including U.S. Government issues, corporate bonds and asset-backed securities and strategic investments. We believe that these unrealized losses are temporary. We have the intent and ability to hold these securities to recovery, which may be at maturity.

The proceeds from maturities and sales of marketable securities, which were primarily reinvested, and resulting realized gains and losses were as follows (in millions):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Proceeds from maturities and sales	\$ 743.2	\$ 293.0	\$ 2,135.1	\$ 2,702.8
Realized gains	\$ 0.9	\$ 1.2	\$ 11.6	\$ 3.2
Realized losses	\$ 10.6	\$ 0.4	\$ 15.4	\$ 4.2

The realized losses for the three and nine months ended September 30, 2008 primarily relate to losses on the sale of corporate debt securities.

The amortized cost and estimated fair value of securities available-for-sale at September 30, 2008 by contractual maturity are as follows (in millions):

	<b>Estimated Fair Value</b>	<b>Amortized Cost</b>
Due in one year or less	\$ 266.4	\$ 265.9
Due after one year through five years	458.4	454.0
Mortgage and other asset backed securities	368.5	366.2
Total	\$ 1,093.3	\$ 1,086.1

The average maturity of our marketable securities as of September 30, 2008 and December 31, 2007, was 13 months and 15 months, respectively.

Certain commercial paper and short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the accompanying balance sheet and are not included in the table above. The commercial paper, including accrued interest, has a fair and carrying value of \$268.6 million and \$368.2 million and short-term debt securities has a fair and carrying value of \$640.1 million and \$195.1 million at September 30, 2008 and December 31, 2007, respectively.

***Strategic Investments***

We hold investments in equity securities of certain publicly traded companies. In the three and nine months ended September 30, 2008, we recognized \$2.5 million and \$6.1 million, respectively, in charges for the impairment of strategic investments that were deemed to be other-than-temporary. In the nine months ended September 30, 2007, we recognized no charges for the impairment of strategic investments that were deemed to be other-than-temporary.

***Non-Marketable Securities***

We hold investments in equity securities of certain privately held biotechnology companies and biotechnology oriented venture capital investments. The carrying value of these investments as of September 30, 2008 and December 31, 2007, was \$67.9 million and \$52.4 million, respectively. These investments are included in investments and other assets on the accompanying consolidated balance sheets.

In the three months ended September 30, 2008, we recorded \$2.2 million in unrealized gains due to increases in the fair value of the investments and \$0.3 million in charges for the impairment of investments



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**BIOGEN IDEC INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

that were determined to be other-than-temporary. In the nine months ended September 30, 2008, we recorded \$2.6 million in unrealized losses due to declines in the fair value of the investments and \$1.3 million in charges for the impairment of investments that were determined to be other-than-temporary. In the three and nine months ended September 30, 2007, we recorded \$0.5 million and \$0.9 million in impairment losses.

***Securities Lending***

We loan certain securities from our portfolio to other institutions. Such securities are classified as loaned securities on the accompanying consolidated balance sheet. Collateral for the loaned securities, consisting of cash or other assets, is maintained at a rate of approximately 102% of the market value of each loaned security. We held cash as collateral in the amount of \$178.1 million and \$208.2 million as of September 30, 2008 and December 31, 2007, respectively. The cash collateral is recorded as cash collateral received for loaned securities on the consolidated balance sheet. We have a current obligation to return the collateral, which is reflected as collateral payable on loaned securities on the accompanying consolidated balance sheet. Income received from lending securities is recorded in other income (expense), net.

***Forward Contracts and Interest Rate Swaps***

We have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts in effect at September 30, 2008 have durations of one to nine months. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in accumulated other comprehensive income. Realized gains and losses for the effective portion are recognized with the completion of the underlying hedge transaction. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net.

The notional settlement amount of the foreign currency forward contracts outstanding at September 30, 2008 was approximately \$132.8 million. These contracts had an aggregate fair value of \$5.7 million, representing an unrealized gain, and were included in other current assets at September 30, 2008. The notional settlement amount of the foreign currency forward contracts outstanding at December 31, 2007 was approximately \$409.2 million. These contracts had an aggregate fair value of \$6.4 million, representing an unrealized loss, and were included in other current liabilities at December 31, 2007.

For our foreign currency forward contracts, in the three and nine months ended September 30, 2008, there was \$1.3 million and \$2.4 million, respectively, recognized in earnings as a loss due to hedge ineffectiveness. In the three and nine months ended September 30, 2007, there was \$2.0 million and \$2.6 million recognized in earnings as a loss due to hedge ineffectiveness. We recognized \$2.3 million and \$20.0 million of losses in product revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2008 as compared to \$3.8 million and \$4.9 million in product revenue for the three and nine months ended September 30, 2007. These settlements were recorded in the same period the related forecasted transactions affected earnings.

In connection with the issuance of our Senior Notes in March 2008, as described in Note 7, Indebtedness, we entered into interest rate swaps at the issuance of the Senior Notes and during the second quarter of 2008 with a total aggregate notional amount of \$550.0 million, which expire in March 2018. These interest rate swaps have been

designated as fair value hedges and are being used to manage our exposure to changes in interest rates. These swaps have the effect of changing \$550.0 million of our fixed rate debt to variable rate debt, as we receive a fixed rate and pay a floating rate. In the three and nine months ended September 30, 2008, we recognized a net gain of \$1.3 million and a net loss of \$3.6 million, respectively, in earnings due to hedge ineffectiveness. The fair value of these swaps at September 30, 2008, which incorporates counter party credit risk, is included in other assets and other liabilities was \$2.6 million and \$1.9 million, respectively, net of accrued interest.

**Table of Contents****BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Indebtedness**

Notes payable consists of the following (in millions):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Current portion:		
Term loan facility	\$	\$ 1,500.0
20-year subordinated convertible promissory notes, due 2019 at 5.5%		0.2
Note payable to Fumedica	10.2	10.3
Other		0.6
	\$ 10.2	\$ 1,511.1
Non-current portion:		
6.000% Senior Notes due 2013	\$ 449.5	\$
6.875% Senior Notes due 2018	550.1	
Note payable to Fumedica	25.9	34.3
Credit line from Dompé	16.9	17.5
	\$ 1,042.4	\$ 51.8

On March 4, 2008, we issued \$450.0 million aggregate principal amount of 6.0% Senior Notes due March 1, 2013 and \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 at 99.886% and 99.184% of par, respectively. The discount will be amortized as additional interest expense over the period from issuance through maturity. These notes are senior unsecured obligations. Interest on the notes is payable March 1 and September 1 of each year. The notes may be redeemed at our option at any time at 100% of the principal amount plus accrued interest and a specified make-whole amount. The notes contain a change of control provision that may require us to purchase the notes under certain circumstances. There is also an interest rate adjustment feature that requires us to increase the interest rate on the notes if the rating on the notes declines below investment grade. Offering costs of approximately \$8.0 million have been recorded as debt issuance costs on our consolidated balance sheet and will be amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Additionally, in connection with this issuance, we entered into interest rate swaps, as further described in Note 6, Financial Instruments. The carrying value of the 6.875% Senior Notes due in 2018 has increased by approximately \$4.4 million related to the interest rate swap.

We used the proceeds of this borrowing, along with cash and the proceeds from the liquidation of marketable securities, to repay the \$1,500.0 million term loan facility we had entered into in July 2007 in connection with the funding of our June 2007 common stock tender offer.

In June 2007, we entered into a five-year \$400.0 million Senior Unsecured Revolving Credit Facility, which we may use for future working capital and general corporate purposes. The bankruptcy of Lehman Brothers Holdings Inc. has eliminated their \$40 million portion of the credit facility, thereby reducing the availability of the credit facility to \$360 million. This credit facility bears interest at a rate of LIBOR plus 45 basis points. The terms of this revolving credit facility include various covenants, including financial covenants that require us to not exceed a maximum leverage ratio and under certain circumstances, an interest coverage ratio. As of September 30, 2008, we were in compliance with these covenants and there were no borrowings under this credit facility.

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. Comprehensive Income**

The activity in comprehensive income, net of income taxes, was as follows (in millions):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Net income	\$ 206.8	\$ 119.4	\$ 576.5	\$ 437.0
Translation adjustments	(101.8)	25.8	(47.2)	36.9
Unfunded status of pension and post retirement benefit plan	(0.2)			
Net unrealized gains (losses) on available-for-sale marketable securities, net of tax of \$(0.7) million, \$2.6 million, \$2.6 million and \$2.0 million, respectively	1.3	(4.7)	(6.3)	(3.2)
Net unrealized gains (losses) on foreign currency forward contracts, net of tax of \$7.6 million, \$3.0 million, \$4.5 million, and \$4.3 million, respectively	13.0	(5.1)	7.7	(7.4)
Total comprehensive income	\$ 119.1	\$ 135.4	\$ 530.7	\$ 463.3

**9. Earnings per Share**

Basic and diluted earnings per share are calculated as follows (in millions):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Numerator:				
Net income	\$ 206.8	\$ 119.4	\$ 576.5	\$ 437.0
Adjustment for net income allocable to preferred shares	(0.4)	(0.2)	(1.0)	(0.6)
Net income used in calculating basic and diluted earnings per share	\$ 206.4	\$ 119.2	\$ 575.5	\$ 436.4
Denominator:				
Weighted average number of common shares outstanding	291.4	289.0	292.6	323.0
Effect of dilutive securities:				
Stock options and ESPP	1.1	2.7	1.6	2.1

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Restricted stock units	1.4	1.3	1.2	0.8
Performance-based restricted stock units				0.1
Restricted stock awards		0.4	0.1	0.5
Convertible promissory notes				0.2
Dilutive potential common shares	2.5	4.4	2.9	3.7
Shares used in calculating diluted earnings per share	293.9	293.4	295.5	326.7

Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Numerator:				
Net income allocable to preferred shares	\$ 0.4	\$ 0.2	\$ 1.0	\$ 0.6
Denominator:				
Stock options	6.7	7.6	6.4	10.5
Time-vested restricted stock units	1.8	0.1	1.4	0.1
Convertible preferred stock	0.5	0.5	0.5	0.5
Total	9.0	8.2	8.3	11.1

**10. Share-Based Payments**

In the three and nine months ended September 30, 2008 and 2007, share-based compensation expense reduced our results of operations as follows (in millions, except for earnings per share):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>Effect on Net Income</b>		<b>Effect on Net Income</b>	
Income before income taxes	\$ 36.7	\$ 31.8	\$ 104.3	\$ 91.2
Tax effect	(11.4)	(9.9)	(32.2)	(27.8)
Net income	\$ 25.3	\$ 21.9	\$ 72.1	\$ 63.4
Basic earnings per share	\$ 0.09	\$ 0.08	\$ 0.25	\$ 0.20
Diluted earnings per share	\$ 0.09	\$ 0.07	\$ 0.24	\$ 0.19

Share-based compensation expense and cost in the three and nine months ended September 30, 2008 and 2007 is as follows (in millions):

	Three Months Ended September 30, 2008			Three Months Ended September 30, 2007		
	Stock Options & ESPP	Restricted Stock and Restricted Stock Units	Total	Stock Options & ESPP	Restricted Stock and Restricted Stock Units	Total
Research and development	\$ 2.4	\$ 11.6	\$ 14.0	\$ 3.5	\$ 9.7	\$ 13.2
Selling, general and administrative	5.5	19.0	24.5	6.0	13.7	19.7
Total	\$ 7.9	\$ 30.6	\$ 38.5	\$ 9.5	\$ 23.4	\$ 32.9
Capitalized share-based compensation costs			(1.8)			(1.1)
Share-based compensation expense			\$ 36.7			\$ 31.8



Table of Contents**BIOGEN IDEC INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>Nine Months Ended September 30, 2008</b>			<b>Nine Months Ended September 30, 2007</b>		
	<b>Stock Options &amp; ESPP</b>	<b>Restricted Stock and Restricted Stock Units</b>	<b>Total</b>	<b>Stock Options &amp; ESPP</b>	<b>Restricted Stock and Restricted Stock Units</b>	<b>Total</b>
Research and development	\$ 6.2	\$ 39.6	\$ 45.8	\$ 9.5	\$ 27.3	\$ 36.8
Selling, general and administrative	12.7	51.3	64.0	17.5	40.1	57.6
Total	\$ 18.9	\$ 90.9	\$ 109.8	\$ 27.0	\$ 67.4	\$ 94.4
Capitalized share-based compensation costs			(5.5)			(3.2)
Share-based compensation expense			\$ 104.3			\$ 91.2

***Stock Options***

In February of 2008 and 2007, we made our annual awards of stock options. Approximately one million stock options were awarded as part of the annual award in each of February 2008 and 2007 at exercise prices of \$60.56 per share and \$49.31 per share, respectively.

The fair values of the stock option grants awarded in the nine months ended September 30, 2008 and 2007 were estimated as of the date of grant using a Black-Scholes option valuation model that used the following weighted-average assumptions:

	<b>Nine Months Ended September 30, 2008</b>		<b>2007</b>	
Expected dividend yield	0.0%		0.0%	
Expected stock price volatility	34.4%		33.6%	
Risk-free interest rate	2.47%		4.50%	
Expected option life in years	5.10		4.87	
Per share grant-date fair value	\$ 21.12		\$ 18.36	

***Time-Vested Restricted Stock Units***

In February of 2008 and 2007, we made our annual awards of time-vested restricted stock units, or RSUs. Approximately 2.3 million RSUs were awarded as part of the annual grant in each of February 2008 and 2007 at grant date fair values of \$60.56 per share and \$49.31 per share, respectively.

***Performance-Based Restricted Stock Units***

In June 2006, we committed to grant 120,000 performance-based RSUs to an executive. The first tranche of 30,000 RSUs was granted in January 2007 and the remaining 90,000 were granted in June 2007. These tranches are subject to performance conditions established at the time of grant. In February 2008, 27,000 of the first tranche of RSUs vested and was converted into shares of common stock, while the remaining 3,000 RSUs of the tranche expired unvested. The total grant of 120,000 RSUs is being recognized as compensation expense, adjusted as necessary, over the requisite service period of four years as if it were multiple awards, in accordance with FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Options or Award Plans*, or FIN 28.

***Employee Stock Purchase Plan***

In the three months ended September 30, 2008 and 2007, 0.1 million and 0.1 million shares, respectively, were issued under the employee stock purchase plan, or ESPP. In the nine months ended September 30, 2008

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and 2007, 0.4 million and 0.4 million shares, respectively, were issued under the ESPP. In the three months ended September 30, 2008 and 2007, we recorded approximately \$3.0 million and \$2.4 million, respectively, of stock compensation charges related to the ESPP. In the nine months ended September 30, 2008 and 2007, we recorded approximately \$4.6 million and \$3.6 million, respectively, of stock compensation charges related to the ESPP.

**11. Income Taxes*****Tax Rate***

Our effective tax rate was 35.6% on pre-tax income for the three months ended September 30, 2008, compared to 31.4% for the comparable period in 2007. Our effective tax rate was 32.9% on pre-tax income for the nine months ended September 30, 2008, compared to 29.0% for the comparable period in 2007. The effective tax rate in 2008 was unfavorably impacted by a higher proportion of income subject to US taxes and enactment of an amendment to Massachusetts tax laws which will increase payments on timing items which become taxable after January 1, 2009.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the three and nine months ended September 30, 2008 and 2007, respectively, is as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Statutory Rate	35.0%	35.0%	35.0%	35.0%
State Taxes	4.4	4.1	3.0	2.5
Foreign Taxes	(7.4)	(7.7)	(9.0)	(7.7)
Credits and net operating loss utilization	1.1	(2.3)	0.1	(2.5)
Other	(1.3)	(0.6)	(0.8)	(2.6)
Fair Value Adjustment	3.8	3.0	3.6	3.1
IPR&D		(0.1)	1.0	1.2
	35.6%	31.4%	32.9%	29.0%

***Contingency***

On September 12, 2006, we received a Notice of Assessment from the Massachusetts Department of Revenue for \$38.9 million, including penalties and interest, with respect to the 2001, 2002 and 2003 tax years. We believe that we have meritorious defenses to the proposed adjustment and are vigorously opposing the assessment. We believe that the assessment does not impact the level of liabilities for income tax contingencies. However, there is a possibility that we may not prevail in all of our assertions. If this is resolved unfavorably in the future, it could have a material impact on our future effective tax rate and our results of operations in the period the resolution occurs.

We file income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2001. During the second quarter of 2007, the Internal Revenue Service, or IRS, completed its examination of our consolidated federal income tax returns for the fiscal years 2003 and 2004 and issued an assessment. We subsequently paid amounts related to items agreed to with the IRS and are appealing several items.

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

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Interest income	\$ 16.8	\$ 18.8	\$ 55.0	\$ 80.1
Minority interest	(1.0)	29.0	(5.2)	25.0
Interest expense	(8.1)	(19.6)	(37.6)	(21.9)
Other, net	(32.4)	16.7	(42.0)	15.0
Total other income (expense), net	\$ (24.7)	\$ 44.9	\$ (29.8)	\$ 98.2

In the three months ended September 30, 2008, the principal components of other, net, included losses on foreign currency of \$1.8 million and impairments of and net realized losses on the sales of marketable securities of \$23.8 million, as further described in Note 6 Financial Instruments. In the three months ended September 30, 2007, the principal components of other, net included gain on sale of land of \$7.1 million and net realized gains on sales of strategic investments of \$11.0 million, offset by net realized losses on sales of marketable securities of \$0.7 million.

In the nine months ended September 30, 2008, the principal components of other, net, included net impairments on strategic investments of \$10.7 million, losses on foreign currency of \$2.8 million and hedge ineffectiveness of \$2.5 million, impairments of and net realized losses on the sale of marketable securities of \$23.1 million, as further described in Note 6 Financial Instruments. In the nine months ended September 30, 2007, the principal components of other, net, included net realized losses on sales of marketable securities of \$7.1 million, offset by net realized gains on our strategic investments of \$19.0 million and gain on sale of land of \$7.1 million.

**13. Litigation**

We, along with William H. Rastetter, our former Executive Chairman, James C. Mullen, our Chief Executive Officer, Peter N. Kellogg, our former Chief Financial Officer, William R. Rohn, our former Chief Operating Officer, Burt A. Adelman, our former Executive Vice President, Portfolio Strategy, and Thomas J. Bucknum, our former General Counsel are defendants in a consolidated purported class action lawsuit, captioned *Brown v Biogen Idec., et al* ( *Brown* ), first filed in the U.S. District Court for the District of Massachusetts on March 2, 2005. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. 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 plaintiffs allege 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 plaintiffs allege that these statements harmed the purported class by artificially inflating our stock price during the purported class period and that our insiders benefited

personally from the inflated price by selling our stock. The plaintiffs seek unspecified damages, as well as interest, costs and attorneys' fees. On September 14, 2007, the District Court entered an Order allowing the Motions to Dismiss of all defendants. That decision was affirmed on August 7, 2008 by the United States Court of Appeals for the First Circuit. We do not anticipate further action in this matter.

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, and that it has been advised the investigation is both civil and criminal in nature. We are cooperating with the

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**BIOGEN IDEC INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

U.S. Department of Justice in its investigation of Genentech. The potential outcome of this matter and its impact on us cannot be determined at this time.

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 numerous Counties of the State of New York. All of the cases except for cases filed by the County of Erie, County of Oswego and County of Schenectady (the Three County Actions) are the subject of a Consolidated Complaint (Consolidated Complaint), first filed on June 15, 2005 in the U.S. District Court for the District of Massachusetts in Multi-District Litigation No. 1456 (the MDL proceedings). All of the complaints in these cases allege that the defendants (i) fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement (Covered Drugs); (ii) 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; (iii) provided financing incentives to providers to over-prescribe Covered Drugs or to prescribe Covered Drugs in place of competing drugs; and (iv) overcharged Medicaid for illegally inflated Covered Drugs reimbursements. Among other things, the complaints allege violations of New York state law and advance common law claims for unfair trade practices, fraud, and unjust enrichment. In addition, the amended Consolidated Complaint alleges 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, and excluded from their reporting certain discounts and other rebates that would have reduced the best price. With respect to the MDL proceedings, the defendants were successful in having some of the plaintiffs' claims dismissed, and the parties, including Biogen Idec, have agreed to participate in mediation with respect to the outstanding claims, which began on July 1, 2008.

We have not formed an opinion that an unfavorable outcome is either probable or remote in any of these cases, and do not express an opinion at this time as to their likely outcome or as to the magnitude or range of any potential loss. We believe that we have good and valid defenses to each of these complaints and are vigorously defending against them.

Along with several other major pharmaceutical and biotechnology companies, we were also named as a defendant in a lawsuit filed by the Attorney General of Arizona in the Superior Court of the State of Arizona and transferred to the MDL proceedings. The complaint, as amended on March 13, 2007, is brought on behalf of Arizona consumers and other payors for drugs, and alleges that the defendants violated the state consumer fraud statute by fraudulently reporting the Average Wholesale Price for certain drugs covered by various private and public insurance mechanisms and by marketing these drugs to providers based on the providers' ability to collect inflated payments from third-party payors. Biogen Idec and other defendants have filed a motion to dismiss the complaint, which is pending. On December 26, 2007, Biogen Idec and other defendants agreed to participate in mediation. Mediation is underway. We have not formed an opinion that an unfavorable outcome is either probable or remote, and do not express an opinion at this time as to the likely outcome of the matter or as to the magnitude or range of any potential loss. We believe that we have good and valid defenses to the complaint and intend vigorously to defend the case.

On January 6, 2006, we were served with a lawsuit, captioned United States of America ex rel. Paul P. McDermott v. Genentech, Inc. and Biogen Idec, Inc., filed in the U.S. District Court of the District of Maine. The lawsuit was filed under seal on July 29, 2005 by a former employee of our co-defendant Genentech pursuant to the False Claims Act, 31 U.S.C. section 3729 et. seq. On December 20, 2005, the U.S. government elected not to intervene, and the complaint was subsequently unsealed and served. The plaintiff alleges, among other things, that we illegally marketed

off-label uses of RITUXAN for treating rheumatoid arthritis, provided illegal kickbacks to physicians to promote off-label uses, and conspired with Genentech to defraud the government. The plaintiff seeks entry of judgment on behalf of the United States of America against the defendants, an award to the plaintiff as relator, and all costs, expenses, attorneys fees, interest and other



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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

appropriate relief. On July 24, 2007, the District Court granted Biogen Idec's motion to dismiss. Certain of the plaintiff's claims against Genentech are still pending. The District Court subsequently denied the plaintiff's motion to allow an interlocutory appeal of the granting of Biogen Idec's motion to dismiss. We have not formed an opinion that an unfavorable outcome is either probable or remote, and do not express an opinion at this time as to the likely outcome of the matter or as to the magnitude or range of any potential loss. We believe that we have good and valid defenses to the complaint and intend vigorously to defend the case.

On June 17, 2006, Biogen Idec filed a Demand for Arbitration against Genentech, Inc. with the American Arbitration Association (AAA), which Demand was amended on December 5, 2006 and on January 29, 2008. In the Demand, Biogen Idec alleged that Genentech breached the parties' Amended and Restated Collaboration Agreement dated June 19, 2003 (the Collaboration Agreement), by failing to honor Biogen Idec's contractual right to participate in strategic decisions affecting the parties' joint development and commercialization of certain pharmaceutical products, including humanized anti-CD20 antibodies. Genentech filed an Answering Statement in response to Biogen Idec's Demand in which Genentech denied that it had breached the Collaboration Agreement and alleged that Biogen Idec had breached the Collaboration Agreement. In its Answering Statement, Genentech also asserted for the first time that the November 2003 transaction in which Idec Pharmaceuticals acquired Biogen and became Biogen Idec was a change of control under the Collaboration Agreement, a position with which we disagree strongly. It is our position that the Biogen Idec merger did not constitute a change of control under the Collaboration Agreement and that, even if it did, Genentech's rights under the change of control provision, which must be asserted within ninety (90) days of the change of control event, have long since expired. We intend to vigorously assert that position if Genentech persists in making this claim. The hearing commenced on September 15, 2008 and is scheduled to conclude in December, 2008. We anticipate a decision during the first half of 2009. We have not formed an opinion that an unfavorable outcome is either probable or remote, and do not express an opinion at this time as to the likely outcome of the matter or as to the magnitude or range of any potential loss. We believe that we have good and valid defenses to Genentech's allegations in the arbitration and intend vigorously to defend against these allegations.

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. Patent Nos. 6,420,139, 6,638,739, 5,728,383, and 5,723,283, all of which are directed to various methods of immunization or determination of immunization schedules. All counts asserted against us by Classen were dismissed by the District Court. Classen filed an appeal, which has been fully briefed and argued, but not yet decided by the Court of Appeals. We have not formed an opinion that an unfavorable outcome is either probable or remote, and do not express an opinion at this time as to the likely outcome of the matter or as to the magnitude or range of any potential loss. We believe that we have good and valid defenses and intend vigorously to defend the case.

On September 12, 2006, the Massachusetts Department of Revenue (DOR) issued a notice of assessment against Biogen Idec MA, Inc. for \$38.9 million of corporate excise tax for 2002, which includes associated interest and penalties. On December 6, 2006, we filed an abatement application with the DOR, seeking abatements for 2001-2003. The abatement application was denied on July 24, 2007. On July 25, 2007, we filed a petition with the Massachusetts Appellate Tax Board, seeking abatements of corporate excise tax for 2001-2003 and adjustments in certain credits and credit carryforwards for 2001-2003. Issues before the Board include the computation of Biogen Idec MA's sales factor for 2001-2003, computation of Biogen Idec MA's research credits for those same years, and the availability of deductions for certain expenses and partnership flow-through items. We intend to contest this matter vigorously. We

believe that the assessment does not impact the level of liabilities for income tax contingencies.

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**BIOGEN IDEC INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In January 2008, the European Commission ( EC ) began an industry-wide antitrust inquiry into competitive conditions within the pharmaceutical sector. As part of the inquiry, the EC issued detailed questionnaires to approximately 100 companies, including Biogen Idec. The first questionnaire, which we received in April 2008, has been followed by further interaction with the EC and we continue to cooperate with the EC in its inquiry.

In addition, we are involved in product liability claims and 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 conditions.

**14. Segment Information**

We operate in one business segment, which is the business of discovery, development, manufacturing and commercialization of innovative therapies for human health care. Our chief operating decision maker manages our operations as a single operating segment.

**15. New Accounting Pronouncements**

On December 12, 2007, EITF 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of our collaborations existing after January 1, 2009. We are evaluating the impact, if any, this Standard will have on our financial statements.

On December 4, 2007, Statement of Financial Accounting Standard No. 141(R), *Business Combinations*, or SFAS 141(R), was issued. This Standard will require us to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date when we acquire another business. In addition, we will capitalize IPR&D when we acquire another business and either amortize it over the life of the product or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact, if any, this Standard will have on our financial statements.

On December 4, 2007, Statement of Financial Accounting Standard No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160, was issued. This Standard changes the accounting for and reporting of noncontrolling interests (formerly known as minority interests) in consolidated financial statements. This Standard is effective January 1, 2009. When implemented, prior periods will be recast for the changes required by SFAS 160. We do not expect the adoption of this standard to have a material impact on our financial statements or our results of operations.

On March 19, 2008, Statement of Financial Accounting Standard No. 161, *Disclosures About Derivative Instruments and Hedging Activities*, or SFAS 161, was issued. This Standard enhances the disclosure requirements for derivative instruments and hedging activities. This Standard is effective January 1, 2009. Since SFAS No. 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS No. 161 will not affect our

financial condition, results of operations or cash flows.

On May 5, 2008, Statement of Financial Accounting Standard No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162, was issued. This Standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the U.S. We do not expect the adoption of this standard to have a material impact on our financial statements or our results of operations.

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

#### **Forward-Looking Information**

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. These forward-looking statements do not relate strictly to historical or current facts and they may be accompanied by such words as anticipate, believe, estimate, expect, forecast, intend, plan, project, target, and other words and terms of similar meaning. Reference is made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses, contractual obligations, regulatory approvals, our long-term growth, the development and marketing of additional products, the impact of competitive products, the incidence or anticipated outcome of pending or anticipated litigation, patent-related proceedings, tax assessments and other legal proceedings, our effective tax rate for future periods, our ability to finance our operations and meet our manufacturing needs, the completion of our manufacturing facility in Hillerod, Denmark, liquidity, and our plans to spend additional capital on external business development and research opportunities. 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 in the section entitled *Risk Factors* in Part II of this report and elsewhere in this report. Forward-looking statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated). Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.

The following discussion should be read in conjunction with our consolidated financial statements and related notes beginning on page 3 of this quarterly report on Form 10-Q.

#### **Overview**

Biogen Idec Inc. ( We , Biogen Idec or the Company ) is a global biotechnology company that creates new standards of care in therapeutic areas with high unmet medical needs.

We currently have four marketed products:

AVONEX<sup>®</sup> (interferon beta-1a);

RITUXAN<sup>®</sup> (rituximab);

TYSABRI<sup>®</sup> (natalizumab); and,

FUMADERM<sup>®</sup> (dimethylfumarate and monoethylfumarate salts).

Through December 2007, we recorded product revenues from sales of ZEVALIN<sup>®</sup> (ibritumomab tiuxetan). In December 2007, we sold the U.S. marketing, sales, and manufacturing and development rights of ZEVALIN to Cell Therapeutics, Inc., or CTI. As part of the overall agreement, we entered into a supply agreement with CTI to manufacture and supply ZEVALIN product through 2014 and a related services and security agreement under which CTI has agreed to reimburse us for expenses incurred in an ongoing randomized clinical trial for ZEVALIN with respect to aggressive non-Hodgkin's lymphoma, or NHL. Our supply of ZEVALIN to CTI and our sales of ZEVALIN to Bayer Schering Pharma AG, or Schering AG, for distribution in the EU will be recognized as product revenue. We will continue to receive royalty revenues from Schering AG on their sales of ZEVALIN in the EU.

#### **Executive Overview**

Results for the first nine months of 2008 included total revenue of \$3,028.6 million, net income of \$576.5 million and diluted net income per share of \$1.95. These results reflect continued growth in TYSABRI revenue, an increase in RITUXAN revenues from an unconsolidated joint business arrangement as well as the impact of price increases on our AVONEX product. The effect of the increase in revenue was partially offset by an increase in research and development expense due to clinical trials and other projects, and an increase in selling, general and administrative expense related to increased personnel to support the ongoing AVONEX

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sales and TYSABRI growth and realized losses and impairments of \$24.7 million in our marketable securities portfolio primarily related to mortgage and asset backed securities. In July 2008, we disclosed two confirmed cases of progressive multifocal leukoencephalopathy (PML), a known side effect, in patients taking TYSABRI. These patients were the first two confirmed cases of PML reported to us since the reintroduction of TYSABRI in the U.S. and approval in the EU in July 2006. We continue to monitor the growth of TYSABRI in light of these results.

**Results of Operations***Revenues (in millions)*

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008		2007		2008		2007	
Product sales								
U.S.	\$ 380.5	34.9%	\$ 297.4	37.7%	\$ 1,084.8	35.8%	\$ 883.8	38.8%
Rest of world	377.7	34.6%	232.2	29.4%	1,023.0	33.8%	648.8	28.5%
Total product sales	758.2	69.5%	529.6	67.1%	2,107.8	69.6%	1,532.6	67.3%
Unconsolidated joint business	298.9	27.3%	234.6	29.7%	825.0	27.2%	672.4	29.5%
Royalties	35.2	3.2%	23.5	3.0%	87.3	2.9%	69.2	3.0%
Corporate partner	0.6	%	1.5	0.2%	8.5	0.3%	4.1	0.2%
Total revenues	\$ 1,092.9	100.0%	\$ 789.2	100.0%	\$ 3,028.6	100.0%	\$ 2,278.3	100.0%

*Product Revenues (in millions)*

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2008		2007		2008		2007	
AVONEX	\$ 573.5	75.6%	\$ 454.9	85.9%	\$ 1,636.8	77.7%	\$ 1,365.4	89.1%
TYSABRI	171.1	22.6%	62.9	11.9%	433.0	20.5%	140.2	9.1%
FUMADERM	11.1	1.5%	7.4	1.4%	32.8	1.6%	12.5	0.8%
ZEVALIN	2.5	0.3%	4.4	0.8%	5.0	0.2%	14.2	0.9%
AMEVIVE		%		%	0.2	%	0.3	0.1%
Total product revenues	\$ 758.2	100.0%	\$ 529.6	100.0%	\$ 2,107.8	100.0%	\$ 1,532.6	100.0%

*Cost of Sales, excluding Amortization of Intangibles (in millions)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007

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Cost of product revenues	\$ 106.3	98.8%	\$ 80.6	98.8%	\$ 297.2	98.8%	\$ 244.6	98.8%
Cost of royalty revenues	1.2	1.2%	1.0	1.2%	3.6	1.2%	3.0	1.2%
Cost of sales, excluding amortization of intangibles	\$ 107.5	100.0%	\$ 81.6	100.0%	\$ 300.8	100.0%	\$ 247.6	100.0%

During the three months ended September 30, 2008 and 2007, we wrote-down \$12.6 million and \$4.7 million, respectively, in unmarketable inventory, which was charged to cost of sales. During the nine months ended September 30, 2008 and 2007, we wrote-down \$22.5 million and \$19.6 million, respectively, in unmarketable inventory, which was charged to cost of sales.



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Revenues from AVONEX in the three and nine months ended September 30, 2008 and 2007 were as follows (in millions):

	<b>Three Months Ended September 30,</b>				<b>Nine Months Ended September 30,</b>			
	<b>2008</b>		<b>2007</b>		<b>2008</b>		<b>2007</b>	
AVONEX								
U.S.	\$ 321.9	56.1%	\$ 266.4	58.6%	\$ 935.9	57.2%	\$ 806.1	59.0%
Rest of World	251.6	43.9%	188.5	41.4%	700.9	42.8%	559.3	41.0%
Total AVONEX revenues	\$ 573.5	100.0%	\$ 454.9	100.0%	\$ 1,636.8	100.0%	\$ 1,365.4	100.0%

In the three months ended September 30, 2008, compared to the three months ended September 30, 2007, U.S. sales of AVONEX increased \$55.5 million, or 20.8%, due to price increases, partially offset by decreased product demand. In the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, U.S. sales of AVONEX increased \$129.8 million, or 16.1%, due to price increases, partially offset by a decreased product demand.

In the three months ended September 30, 2008, compared to the three months ended September 30, 2007, Rest of World sales of AVONEX increased \$63.1 million, or 33.5% primarily due to increased unit shipments and the impact of exchange rates. In the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, Rest of World sales of AVONEX increased \$141.6 million, or 25.3%, due to increased unit shipments and the impact of exchange rates.

We are facing increasing competition in the multiple sclerosis, or MS, marketplace in both the U.S. and Rest of World from existing and new MS treatments, including TYSABRI, which may have a negative impact on sales of AVONEX. We expect future sales of AVONEX to be dependent, to a large extent, on our ability to compete successfully with the products of our competitors.

**TYSABRI**

Revenues from TYSABRI for the three and nine months ended September 30, 2008 and 2007 were as follows (in millions):

	<b>Three Months Ended September 30,</b>				<b>Nine Months Ended September 30,</b>			
	<b>2008</b>		<b>2007</b>		<b>2008</b>		<b>2007</b>	
TYSABRI								
U.S.	\$ 56.2	32.8%	\$ 28.1	44.7%	\$ 144.0	33.3%	\$ 67.4	48.1%
Rest of World	114.9	67.2%	34.8	55.3%	289.0	66.7%	72.8	51.9%
Total TYSABRI revenues	\$ 171.1	100.0%	\$ 62.9	100.0%	\$ 433.0	100.0%	\$ 140.2	100.0%

In the three months ended September 30, 2008, compared to the three months ended September 30, 2007, sales of TYSABRI increased \$108.2 million, or 172.0%, and in the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, sales of TYSABRI increased \$292.8 million, or 208.8%. These increases are primarily due to an increase in patients using TYSABRI in both the U.S. and Rest of World. Net sales of TYSABRI from our collaboration partner, Elan, to third-party customers in the U.S. for the three months ended September 30, 2008 and 2007 were \$121.5 million and \$58.5 million, respectively. Net sales of TYSABRI to third-party customers in the U.S. for the nine months ended September 30, 2008 and 2007 were \$307.0 million and \$141.1 million, respectively. We recognize revenue for sales of TYSABRI in the U.S. upon Elan's shipment of the product to third party customers. We recognize revenue for sales of TYSABRI outside the U.S. at the time of product delivery to our customers. In July 2008, we disclosed two confirmed cases of PML, a known side effect, in patients taking TYSABRI. These patients were the first two confirmed cases of PML reported to us since the reintroduction of TYSABRI in the U.S. and approval in the EU in July 2006. We continue to monitor the growth of TYSABRI in light of these results. During the three months ended September 30, 2008, pursuant to our collaboration agreement with Elan, Elan paid us a \$75 million milestone payment in order to maintain the current profit sharing split. We will

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recognize this \$75 million as product revenue in our consolidated statement of income over the term of our agreement with Elan on a units of revenue method, whereby the revenue recognized is based on the ratio of units shipped in the current period over the total units expected to be shipped over the collaboration. We have recognized \$0.6 million of this milestone as revenue in the three months ended September 30, 2008. Based on the expected TYSABRI sales levels for the fourth quarter of 2008, we anticipate that Elan will have the option to pay us a second milestone payment of \$50M in the first quarter of 2009 in order to maintain the current profit sharing split.

**FUMADERM**

In connection with our June 2006 acquisition of Fumapharm, we began recognizing revenue on sales of FUMADERM to our distributor, Fumedica, in July 2006. In December 2006, we acquired the right to distribute FUMADERM in Germany from Fumedica effective May 1, 2007. In connection with the acquisition of the FUMADERM distribution rights in Germany, we committed to the repurchase of any inventory Fumedica did not sell by May 1, 2007. As a result of this provision, we deferred the recognition of revenue on shipments made to Fumedica through April 30, 2007. We resumed recognizing revenue on sales of FUMADERM into the German market in May 2007. Accordingly, we recognized no revenue of FUMADERM through April 30, 2007. For the three months ended September 30, 2008 and 2007, we recognized \$11.1 million and \$7.4 million, respectively, of sales of FUMADERM. For the nine months ended September 30, 2008 and 2007, we recognized \$32.8 million and \$12.5 million, respectively, of sales of FUMADERM.

**ZEVALIN**

In the three months ended September 30, 2008, compared to the three months ended September 30, 2007, sales of ZEVALIN decreased from \$4.4 million to \$2.5 million, due to the sale of the rights to market, sell, manufacture and develop ZEVALIN in the U.S. to CTI during the fourth quarter of 2007.

In the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, sales of ZEVALIN decreased from \$14.2 million to \$5.0 million, primarily due to the sale of the rights to market, sell, manufacture and develop ZEVALIN in the U.S. to CTI during the fourth quarter of 2007.

**Unconsolidated Joint Business Revenue**

Revenues from unconsolidated joint business, which consist of our share of pre-tax copromotion profits pursuant to our collaboration agreement with Genentech, Inc., or Genentech, and reimbursement by Genentech of our RITUXAN related expenses as well as royalty revenue, consist of the following (in millions):

	<b>Three Months Ended September 30, 2008</b>		<b>Nine Months Ended September 30, 2008</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Copromotion profits	\$ 192.2	\$ 156.3	\$ 527.9	\$ 446.3
Reimbursement of selling and development expenses	16.7	15.3	45.4	44.4
Royalty revenue on sales of RITUXAN outside the U.S.	90.0	63.0	251.7	181.7
	\$ 298.9	\$ 234.6	\$ 825.0	\$ 672.4

Copromotion profits consist of the following (in millions):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Product revenues, net	\$ 655.4	\$ 572.4	\$ 1,910.8	\$ 1,689.2
Costs and expenses	182.3	181.6	586.1	560.9
Copromotion profits	\$ 473.1	\$ 390.8	\$ 1,324.7	\$ 1,128.3
Biogen Idec's share of copromotion profits	\$ 192.2	\$ 156.3	\$ 527.9	\$ 446.3

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For the three months ended September 30, 2008, compared to the three months ended September 30, 2007, our share of copromotion profits increased \$35.9 million, or 23.0%, due principally to higher sales of RITUXAN. For the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, our share of copromotion profits increased \$81.6 million, or 18.3%, due principally to higher sales of RITUXAN. Effective October 1, 2008, the end user price of RITUXAN increased 2.75%.

Our royalty revenue on sales of RITUXAN outside the U.S. is based on net sales by F. Hoffman-LaRoche Ltd., or Roche, and Zenyaku Kogyo Co. Ltd., or Zenyaku, to third-party customers and is recorded on a cash basis. For the three months ended September 30, 2008, compared to the three months ended September 30, 2007, royalty revenue on sales of RITUXAN outside the U.S. increased \$27.0 million, or 42.9%, due primarily to increased sales outside the U.S., reflecting greater market penetration, as well as the impact of foreign exchange. For the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, royalty revenue on sales of RITUXAN outside the U.S. increased \$70.0 million, or 38.5%, due primarily to increased sales outside the U.S., reflecting greater market penetration, as well as the impact of foreign exchange.

Under our collaboration agreement with Genentech, our current pretax copromotion profit-sharing formula, which resets annually, is as follows:

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

In 2008 and 2007, 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:

<b>Copromotion Operating Profits</b>	<b>New Anti-CD20 U.S. Gross Product Sales</b>	<b>Biogen Idec's Share of Copromotion Profits</b>
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 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

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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.

Under our collaboration agreement with Genentech, we will receive a lower royalty percentage of revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products, as compared to the royalty percentage of revenue 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. For the majority of European countries, the first commercial sale of RITUXAN occurred in the second half of 1998. Therefore, we expect a significant decrease in royalty revenues on sales of RITUXAN outside the US beginning in the latter half of 2009.

**Other Revenues**

Other revenues for the three and nine months ended September 30, 2008 and 2007 were as follows (in millions):

	<b>Three Months Ended September 30,</b>				<b>Nine Months Ended September 30,</b>			
	<b>2008</b>		<b>2007</b>		<b>2008</b>		<b>2007</b>	
Royalties	\$ 35.1	98.3%	\$ 23.5	94.0%	\$ 87.3	91.1%	\$ 69.2	94.4%
Corporate partner	0.6	1.7%	1.5	6.0%	8.5	8.9%	4.1	5.6%
Other revenues	\$ 35.7	100.0%	\$ 25.0	100.0%	\$ 95.8	100.0%	\$ 73.3	100.0%

In the three months ended September 30, 2008, compared to the three months ended September 30, 2007, royalties increased \$11.6 million, or 49.4%. Increased royalties of \$14.8 million were primarily related to increased sales of products licensed by The Medicines Company and GlaxoSmithKline, as well as an increased royalty rate on products licensed by Schering-Plough Corporation. These increases were partially offset by a \$3.2 million decrease, which was primarily due to the expiration of a license agreement with Plant Genetics, as well as decreased sales on products licensed by Merck and Co., Inc.

In the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, royalties increased \$18.1 million, or 26.2%. Increased royalties of \$26.2 million were primarily related to increased sales of products licensed by The Medicines Company and GlaxoSmithKline, as well as an increased royalty rate on products licensed by Schering-Plough Corporation. These increases were partially offset by a \$8.1 million decrease, which was primarily due to the expiration of a license agreement with Shionogi and Co., Ltd., as well as decreased sales on products licensed by Merck and Co., Inc.

Royalty revenues may fluctuate as a result of 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, government-sponsored programs, or loss of patent protection.

Corporate partner revenues consist of contract revenues and license fees.



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### **Research and Development Expenses**

Research and development expenses totaled \$268.8 million and \$286.3 million in the three months ended September 30, 2008 and 2007, respectively, a decrease of \$17.5 million, or 6.1%. The decrease is primarily due to lower Lixivaptan expenses of \$46.5 million because of a \$50.0 million upfront collaboration payment made to Cardiokine in Q3 2007. This decrease was offset by \$29.0 million increase driven primarily by the BG-12, Anti-CD23 and Adentri programs.

Research and development expenses totaled \$779.3 million and \$695.9 million in the nine months ended September 30, 2008 and 2007, respectively, an increase of \$83.4 million, or 12.0%. The net increase is primarily due to \$22.4 million increase for BG-12, \$17.7 million increase for Anti CD23, \$14.9 million increase for our BART collaboration with Neurimmune and a \$11.5 million increase for Adentri. The balance of the net increase related to other R&D programs including Rituxan, HSP90, Avonex, Baminercept and BIIB014. These increases were offset by a decrease in expense for Lixivaptan, Tysabri and Zevalin projects.

We anticipate that Research and development expenses in 2008 will continue to be higher than in 2007.

### **In-Process Research and Development, or IPR&D**

In the nine months ended September 30, 2008, we recorded an IPR&D charge of \$25.0 million related to a HSP90-related milestone payment made to the former shareholders of Conforma, pursuant to our acquisition of Conforma in 2006. Through September 30, 2008, research and development expenditures related to in-process research and development projects acquired in prior years are \$36.3 million, \$54.5 million and \$135.9 million related to Syntonix Pharmaceuticals, Inc., or Syntonix, Conforma and Fumapharm, respectively. In the nine months ended September 30, 2007 we recorded an IPR&D charge of \$18.4 million, related to the acquisition of Syntonix and approximately \$30 million related to our collaboration with Cardiokine Biopharma LLC.

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

Selling, general and administrative expenses totaled \$232.8 million and \$190.6 million in the three months ended September 30, 2008 and 2007, respectively, an increase of \$42.2 million, or 22.1%. The increase reflects, principally, a \$19.8 million increase in international sales and marketing activities, primarily for AVONEX and TYSABRI, a \$10.5 million increase in salaries and benefits related to general and administrative personnel and increases in fees and services, including fees related to our proxy contest.

Selling, general and administrative expenses totaled \$694.3 million and \$582.4 million in the nine months ended September 30, 2008 and 2007, respectively, an increase of \$111.9 million, or 19.2%. The increase reflects, principally, a \$54.6 million increase in international sales and marketing activities, primarily for AVONEX and TYSABRI, an \$34.7 million increase in salaries and benefits related to general and administrative personnel and increases in fees and services, including fees related to our proxy contest.

We anticipate that total selling, general, and administrative expenses in 2008 will continue to be higher than 2007 due to sales and marketing and other general and administrative expenses to support global expansion of AVONEX sales and TYSABRI sales growth.

### **Collaboration profit (loss) sharing**

Payments to or from Elan for their share of collaboration net operating profits or losses, including reimbursement for our portion of third-party royalties Elan pays on behalf of the collaboration, relating to sales outside of the U.S. to

effect an equal sharing of operating profit are reflected in the collaboration profit (loss) sharing line in our consolidated statement of income. For the three months ended September 30, 2008 and 2007, the collaboration profit (loss) sharing was \$43.5 million and 5.8 million, respectively. For the nine months ended September 30, 2008 and 2007, the collaboration profit (loss) sharing was \$98.4 million and 0.2 million, respectively. The year-over-year increase in the collaboration profit sharing for the three and nine months ended September 30, 2008 was due to the growth in TYSABRI sales outside the U.S. and the resulting growth in the third-party royalties Elan paid on behalf of the collaboration, which were \$16.8 million and

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\$5.2 million for the three months ended September 30, 2008 and 2007, respectively, and \$42.0 million and \$10.5 million for the nine months ended September 30, 2008 and 2007, respectively. In the prior year, operating costs were greater than profit on sales of TYSABRI outside the U.S.

**Amortization of Intangible Assets**

Amortization of intangible assets totaled \$94.5 million for the three months ended September 30, 2008, compared to \$65.7 million in the comparable period in 2007, an increase of \$28.8 million, or 43.8%. Amortization of intangible assets totaled \$242.1 million for the nine months ended September 30, 2008, compared to \$186.6 million in the comparable period in 2007, an increase of \$55.5 million, or 29.7%. These changes are primarily due to the changes in the estimate of the future revenue of AVONEX, which serves as the basis for the calculation of economic consumption for core technology that occurred as part of our annual reassessment of amortization expense in the third quarters of 2008 and 2007. The change in the estimate of the future revenue of AVONEX is attributable to the expected impact of competitor products, including our own internal pipeline product candidates.

**Income Tax Provision*****Tax Rate***

Our effective tax rate was 35.6% on pre-tax income for the three months ended September 30, 2008, compared to 31.4% for the comparable period in 2007. Our effective tax rate was 32.9% on pre-tax income for the nine months ended September 30, 2008, compared to 29.0% for the comparable period in 2007. The effective tax rate in the three and nine months ended September 30, 2008 was unfavorably impacted by a higher proportion of income subject to US taxes and enactment of an amendment to Massachusetts tax laws which will increase payments on timing items which become taxable after January 1, 2009. We expect our effective tax rate for the full-year ending December 31, 2008 to be in a range of 31% to 33%, which includes an approximate 1% reduction due to the extension of the federal R&D tax credit enacted into law on October 3, 2008. Additionally, we intend to reorganize our current legal structure and move certain organizational functions prior to 2009. This restructuring will impact our amounts subject to taxation in Denmark and Switzerland. We anticipate these changes in the Massachusetts tax laws and our international structure will have a modest unfavorable impact on our effective tax rate for 2009 and beyond. Future changes in federal, state and international tax laws will likely impact our tax rate. Refer to Note 11, Income Taxes, for a detailed income tax rate reconciliation for the three and nine months ended September 30, 2008 and 2007.

**Liquidity and Capital Resources*****Financial Condition***

Our financial condition is summarized as follows (in millions):

	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Cash and cash equivalents	\$ 1,010.7	\$ 659.7
Marketable securities – current and non-current	1,093.2	1,456.1
Total cash, cash equivalents and marketable securities	\$ 2,103.9	\$ 2,115.8
Working capital	\$ 1,653.2	\$ 179.2

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Outstanding borrowings	current and non-current	\$	1,052.6	\$	1,563.0
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Our cash and marketable securities at September 30, 2008, are consistent with the balances at December 31, 2007. However, there were several significant cash flow activities including the net repayment of approximately \$500 million of indebtedness, as well as \$559.8 million used to fund share repurchases and the net impairment of \$19.3 million of marketable securities, offset by cash generated from operations of \$1.16 billion. In addition, during the nine months ended September 30, 2008, we paid approximately \$41.5 million in milestone and other payments pursuant to our research and development programs, including \$25.0 million of contingent purchase price in

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connection with our Conforma acquisition and \$8.0 million related to the development of the Beta-Amyloid antibody under our arrangement with Neurimmune Therapeutics AG.

Until required for use in the business, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, foreign and U.S. government instruments and other interest bearing marketable debt instruments in accordance with our investment policy. The value of these securities may be adversely affected by the instability of the global financial markets which could adversely impact our financial position and our overall liquidity.

As of September 30, 2008, we have certain financial assets and liabilities recorded at fair value. In accordance with Statement of Financial Accounting Standards No. 157, *Fair Value Measurement*, or SFAS 157, we have classified our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability.

As noted in Note 5, Fair Value Measurements, a majority of our financial assets and liabilities have been classified as Level 2. These assets and liabilities have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, and other industry and economic events. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources and challenging pricing data in certain instances.

Excluding cash equivalents, the largest portion of our marketable debt securities is comprised of investments that may be sensitive to changes in economic factors such as interest rates or credit spreads. These risks are further described in Part II, Item 1A, Risk Factors of this Form 10-Q.

The only assets where we used Level 3 inputs to determine the fair value are our venture capital investments, which represent approximately 0.3% of the total assets at September 30, 2008. The underlying assets in these funds are initially measured at transaction prices and subsequently valued using the pricing of recent financing and/or by reviewing the underlying economic fundamentals and liquidation value of the companies.

We have financed our operating and capital expenditures through cash flows from our operations. We financed our common stock tender offer in July 2007 through the use of debt and existing cash. We expect to finance our current and planned operating requirements principally through cash from operations, as well as existing cash resources. 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.

See Part II, Item 1A, Risk Factors of this Form 10-Q for risk factors that could adversely affect our cash position and ability to fund future operations.

***Operating activities***

Cash provided by operating activities is primarily driven by our net income. On an ongoing basis, we expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures. Cash provided by operations was \$1,155.2 million and \$674.8 million in the nine months ended September 30, 2008 and 2007, respectively. The increase is due to higher earnings, offset by lower non-cash charges and a higher investment in working capital.



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### ***Investing activities***

Cash provided by investing activities was \$99.9 million and \$330.1 million in the nine months ended September 30, 2008 and 2007, respectively. This decrease was primarily due to a reduction in net proceeds from our sales and purchases of marketable securities. Purchases of property, plant and equipment totaled \$221.9 million in the nine months ended September 30, 2008, as compared to \$175.8 million in the nine months ended September 30, 2007. Payments pursuant to acquisitions and licenses were \$25.0 million in the nine months ended September 30, 2008, which related to our 2006 acquisition of Conforma, and \$92.3 million in the nine months ended September 30, 2007, which related to our acquisition of Syntonix and agreement with Cardiokine Biopharma LLC.

### ***Financing activities***

Cash used in financing activities in the nine months ended September 30, 2008 was \$902.8 million compared to cash provided of \$1,228.9 million in the nine months ended September 30, 2007. The increase in use of cash was due, principally, to the repayment of our term loan facility of \$1.5 billion, and the purchase of our common stock of \$559.8 million, offset in part by the issuance of long-term debt, net, of \$987.0 million, and proceeds of \$167.0 million relating to the exercise of stock options and purchases of our stock under our employee stock purchase plan.

### ***Borrowings***

On March 4, 2008, we issued \$450.0 million aggregate principal amount of 6.0% Senior Notes due March 1, 2013 and \$550.0 million aggregate principal amount of 6.875% Senior Notes due March 1, 2018 for proceeds of \$987.0 million, net of issuance costs. Additionally, in connection with the note issuance, we entered into interest rate swaps which are further described in Note 6, Financial Instruments.

We used the proceeds of this offering, along with cash and the proceeds from the liquidation of marketable securities, to repay the \$1.5 billion term loan facility we had entered into in July 2007 in connection with the funding of our June 2007 tender offer.

In June 2007, we also entered into a five-year \$400.0 million Senior Unsecured Revolving Credit Facility, which we may use for working capital and general corporate purposes. The bankruptcy of Lehman Brothers Holdings Inc. in September 2008 has eliminated their \$40 million portion of the credit facility, thereby reducing the availability of the credit facility to \$360 million. As of September 30, 2008, there were no borrowings outstanding under this credit facility.

### ***Working capital***

At September 30, 2008, our working capital, which we define as current assets less current liabilities, was \$1,653.2 million, as compared to \$179.2 million at December 31, 2007, an increase of \$1,474 million. This primarily reflects use of cash and cash equivalents and the issuance of long-term debt to repay our short-term loan facility of \$1.5 billion.

### ***Commitments***

As of September 30, 2008, we have completed the first phase of construction of our large-scale biologic manufacturing facility in Hillerod, Denmark, which included partial completion of a bulk manufacturing component, a labeling and packaging component, and installation of major equipment. We are proceeding with the second phase of the project, including the completion of the large scale bulk manufacturing component and construction of a warehouse. As of September 30, 2008, we had contractual commitments of approximately \$240.4 million for the

second phase, of which approximately \$227 million had been paid. This second phase of the project is expected to be in commercial production in 2010.

The timing of the completion and anticipated licensing of the bulk manufacturing facility is in part dependent upon market acceptance of TYSABRI. See Risk Factors Our near-term success depends on the market acceptance and successful sales growth of TYSABRI. Now that TYSABRI has been approved for the



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treatment of relapsing forms of MS in the U.S. and other countries, we are in the process of evaluating our requirements for TYSABRI inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential market acceptance of TYSABRI in MS, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

**Share Repurchase Program**

In the nine months ended September 30, 2008, we repurchased approximately 9.0 million shares of our common stock for \$559.8 million under the share repurchase program that our Board of Directors authorized in October 2006.

**Contractual Obligations and Off-Balance Sheet Arrangements**

We have funding commitments as of September 30, 2008 of up to approximately \$26.6 million as part of our investment in biotechnology-oriented venture capital investments. In addition, we have committed to make potential future milestone payments to third-parties as part of our various collaborations including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of September 30, 2008, such contingencies have not been recorded in our financial statements.

We do not have any significant relationships with entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships. We consolidate entities falling within the scope of FIN 46(R) if we are the primary beneficiary.

The following summarizes our contractual obligations (excluding funding and contingent milestone payments as described above and construction commitments disclosed above under Commitments ) as of September 30, 2008, including debt issued in March 2008, and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

	Total	Payments Due by Period			
		Remainder of 2008	2009- 2010	2011- 2012	After 2012
Non-cancellable operating leases	\$ 104.5	\$ 6.8	\$ 47.0	\$ 32.2	\$ 18.5
Notes payable(1)	1,469.1	15.0	154.1	121.6	1,178.4
Other long-term obligations	8.3	2.4	5.9		
Total contractual cash obligations	\$ 1,581.9	\$ 24.2	\$ 207.0	\$ 153.8	\$ 1,196.9

(1) Includes estimated interest payable

This table also excludes any liabilities pertaining to uncertain tax positions, as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. In connection with the adoption of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109, or

FIN 48, we reclassified approximately \$113 million in reserves for uncertain tax positions from current taxes payable to long-term liabilities. At September 30, 2008, we have approximately \$129 million of long-term liabilities associated with uncertain tax positions.

**Legal Matters**

Refer to Note 13, Litigation, for a discussion of legal matters as of September 30, 2008.

**New Accounting Standards**

Refer to Note 15, New Accounting Pronouncements, for a discussion of new accounting standards.

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### **Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the 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. On an ongoing basis, management evaluates its critical estimates and judgments, including, among others, those related to revenue recognition, investments, purchase accounting, goodwill impairment, fair value, fair value hierarchies, income taxes, and stock-based compensation. Those critical estimates and assumptions are based on our historical experience, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances and form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Refer to Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10-K for the year ended December 31, 2007 for a discussion of the Company's critical accounting estimates.

### **Item 3. *Quantitative and Qualitative Disclosures about Market Risk***

Our market risks, and the ways we manage them, are summarized in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007. In response to the instability in the global financial markets, we have regularly reviewed our marketable securities holdings and reduced investments deemed to have increased risk. Apart from such adjustments to our investment portfolio, there have been no material changes in the first nine months of 2008 to our market risks or to our management of such risks.

### **Item 4. *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, 2008. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2008, 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 three months ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



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**Part II OTHER INFORMATION**

**Item 1. *Legal Proceedings***

Refer to Note 13, Litigation, in Notes to Consolidated Financial Statements in Part I of this quarterly report on Form 10-Q, which is incorporated into this item by reference.

**Item 1A. *Risk Factors***

***We are substantially dependent on revenues from our two principal products***

Our current and future revenues depend substantially upon continued sales of our two principal products, AVONEX and RITUXAN, which represented approximately 81% of our total revenues for the first nine months of 2008. Any significant negative developments relating to these two products, such as safety or efficacy issues, the introduction or greater acceptance of competing products (including greater than anticipated substitution of TYSABRI for AVONEX) or adverse regulatory or legislative developments, would have a material adverse effect on our results of operations. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from these two products for many years. A decline in sales from either of these two products would adversely affect our business.

***Our near-term success depends on the market acceptance and successful sales growth of TYSABRI***

A substantial portion of our growth in the near-term is dependent on anticipated sales of TYSABRI. TYSABRI is expected to diversify our product offerings and revenues, and to drive additional revenue growth over the next several years. If we are not successful in growing sales of TYSABRI, that would result in a significant reduction in diversification and expected revenues, and adversely affect our business.

Achievement of anticipated sales growth of TYSABRI will depend upon its acceptance by the medical community and patients, which cannot be certain given the significant restrictions on use and the significant safety warnings in the label. In July 2008, we disclosed two confirmed cases of progressive multifocal leukoencephalopathy (PML), a known side effect, in patients taking TYSABRI. These patients were the first two confirmed cases of PML reported to us since the reintroduction of TYSABRI in the U.S. and approval in the EU in July 2006. The occurrence of PML or the occurrence of other side effects could harm acceptance and limit TYSABRI sales. Any significant lack or diminution of acceptance of TYSABRI by the medical community or patients would materially and adversely affect our growth and our plans for the future.

As a relatively new entrant to a maturing multiple sclerosis (MS) market, TYSABRI sales may be more sensitive to additional new competing products. A number of such products are expected to be approved for use in MS in the coming years. If these products have a similar or more attractive overall profile in terms of efficacy, convenience and safety, future sales of TYSABRI could be limited.

***Our long-term success depends upon the successful development and commercialization of other products from our research and development activities***

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities. Product development and commercialization are very expensive and involve a high degree of risk. Only a small number of research and development programs result in the

commercialization of a product. 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 remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may 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.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol

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design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current good clinical practice requirements. We have recently opened clinical sites and are enrolling patients in a number of new countries where our experience is more limited, and we are in many cases using the services of third-party contract clinical trial providers. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and diverse clinical trials, our studies and ultimately our regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether.

***Adverse safety events can negatively affect our assets, product sales, operations, products in development and stock price***

Even after we receive marketing approval for a product, adverse event reports may have a negative impact on our commercialization efforts. Our voluntary withdrawal of TYSABRI from the market in February 2005 following reports of cases of PML resulted in a significant reduction in expected revenues as well as significant expense and management time required to address the legal and regulatory issues arising from the withdrawal, including revised labeling and enhanced risk management programs. Later discovery of safety issues with our products that were not known at the time of their approval by the FDA could cause product liability events, additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market and the imposition of fines or criminal penalties. Any of these actions could result in, among other things, material write-offs of inventory and impairments of intangible assets, goodwill and fixed assets. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our stock price to decline or experience periods of volatility.

***If we fail to compete effectively, our business and market position would suffer***

The biotechnology and pharmaceutical 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 and retention 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 not benefit from significantly greater sales and marketing capabilities, or will not develop products that are accepted more widely than ours. The introduction of alternatives to our products that offer advantages in efficacy, safety or ease of use could negatively affect our revenues and reduce the value of our product development efforts. In addition, potential governmental action in the future could provide a means for competition from developers of follow-on biologics, which could compete on price and differentiation with products that we now or could in the future market.

In addition to competing directly with products that are marketed by substantial pharmaceutical competitors, AVONEX, RITUXAN and TYSABRI also face 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 ours.

***If we do not successfully execute our strategy of growth through the acquisition, partnering and in-licensing of products, technologies or companies, our future performance could be adversely affected***

In addition to the expansion of our pipeline through spending on internal development projects, we plan to grow through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to complete or manage these external growth opportunities successfully, we will not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to

identify suitable candidates or complete transactions on terms that are acceptable to us. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets and the reduction of our revolving credit facility from



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\$400 million to \$360 million as a result of the bankruptcy of Lehman Brothers Holdings Inc. In addition, even if we are able to successfully identify and complete acquisitions, we may not be able to integrate them or take full advantage of them and therefore may not realize the benefits that we expect. If we are unsuccessful in our external growth program, we may not be able to grow our business significantly and we may incur asset impairment charges as a result of acquisitions that are not successful.

***We depend, to a significant extent, on reimbursement from third party payors and a reduction in the extent of reimbursement could negatively affect our product sales and revenue***

Sales of our products are dependent, in large part, on the availability and extent of reimbursement from government health administration authorities, private health insurers and other organizations. U.S. and foreign government regulations mandating price controls and limitations on patient access to our products impact our business and our future results could be adversely affected by changes in such regulations.

In the U.S., at both the federal and state levels, the government regularly proposes legislation to reform healthcare and its cost, any of which may impact our ability to successfully commercialize our products. In the last few years, there have been a number of legislative changes that have affected the reimbursement for our products, including, but not limited to, the Medicare Prescription Drug Improvement and Modernization Act of 2003 and most recently, the Deficit Reduction Act of 2005. The Deficit Reduction Act made significant changes to the Medicaid prescription drug provisions of the Social Security Act, including changes that impose the monthly reporting of price information and that may have an impact on the Medicaid rebates we pay. In addition, states may more aggressively seek Medicaid rebates as a result of legislation enacted in 2006, which rebate activity could adversely affect our results of operations.

Pricing pressures in the U.S. may increase as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Managed care organizations as well as Medicaid and other government health administration authorities continue to seek price discounts. Government efforts to reduce Medicaid expenses may continue to increase the use of managed care organizations. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. In addition, some states have implemented and other states are considering price controls or patient-access constraints under the Medicaid program and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid eligible. Other matters also could be the subject of U.S. federal or state legislative or regulatory action that could adversely affect our business, including the importation of prescription drugs that are marketed outside the U.S. and sold at lower prices as a result of drug price limitations imposed by the governments of various foreign countries.

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 cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. This international patchwork of price regulations may lead to inconsistent prices. Within the EU and other countries, some third party trade in our products occurs from markets with lower prices thereby undermining our sales in some markets with higher prices. Additionally, certain countries reference the prices in other countries where our products are marketed. Thus, inability to secure adequate prices in a particular country may also impair our ability to obtain acceptable prices in existing and potential new markets. This may create the opportunity for the third party cross border trade previously mentioned or our decision not to sell the product thus affecting our geographic expansion plans.

When a new medical product is approved, the availability of government and 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 product candidates.



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***We depend on collaborators for both product and royalty revenue and the clinical development of future collaboration products, which are outside of our full control***

Collaborations between companies on products or programs are a common business practice in the biotechnology industry. Out-licensing typically allows a partner to collect up front payments and future milestone payments, share the costs of clinical development and risk of failure at various points, and access sales and marketing infrastructure and expertise in exchange for certain financial rights to the product or program going to the in-licensing partner. In addition, the obligation of in-licensees to pay royalties or share profits generally terminates upon expiration of the related patents. We have a number of collaborators and partners, and have both in-licensed and out-licensed several products and programs. These collaborations include several risks:

we are not fully in control of the royalty or profit sharing revenues we receive from collaborators, and we cannot be certain of the timing or potential impact of factors including patent expirations, pricing or health care reforms, other legal and regulatory developments, failure of our partners to comply with applicable laws and regulatory requirements, the introduction of competitive products, and new indication approvals which may affect the sales of collaboration products;

where we co-promote and co-market products with our collaboration partners, any failure on their part to comply with applicable laws in the sale and marketing of our products could have an adverse effect on our revenues as well as involve us in possible legal proceedings; and

collaborations often require the parties to cooperate, and failure to do so effectively could have an impact on product sales by our collaborators and partners, as well as an impact on the clinical development of shared products or programs under joint control.

In addition, the successful development and commercialization of new anti-CD20 product candidates in our collaboration with Genentech (which also includes RITUXAN) will decrease our participation in the operating profits from the collaboration (including as to RITUXAN).

***Our business is subject to extensive governmental regulation and oversight and changes in laws could adversely affect our revenues and profitability***

Our business is in a highly regulated industry. As a result, governmental actions may 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;

changes in FDA and foreign regulations that may require additional safety monitoring after the introduction of our products to market, which could increase our costs of doing business and adversely affect the future permitted uses of approved products;

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

changes in the tax laws relating to our operations.

The enactment in the U.S. of the Medicare Prescription Drug Improvement and Modernization Act of 2003, possible legislation which could ease the entry of competing follow-on biologics in the marketplace, and importation of lower-cost competing drugs from other jurisdictions are examples of changes and possible changes in laws that could adversely affect our business. In addition, the Food and Drug Administration Amendments Act of 2007 included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for FDA to impose civil monetary penalties on companies that fail to meet certain commitments.

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***If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business***

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, causing false claims to be submitted for government reimbursement as well as antitrust violations, or other violations related to environmental matters. Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government.

Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

The federal Medicare/Medicaid anti-kickback law prohibits payments intended to induce any entity either to purchase, order, or arrange for or recommend the purchase of healthcare products or services paid for under federal health care programs. There are similar laws in a number of states. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and biologics, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologics. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from federal health care programs, including Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

***Problems with manufacturing or with inventory planning could result in our inability to deliver products, inventory shortages or surpluses, product recalls and increased costs***

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX and TYSABRI. Our products are difficult to manufacture and problems in our manufacturing processes can occur. Our inability to successfully manufacture bulk product and to obtain and maintain regulatory approvals of our manufacturing facilities would harm our ability to produce timely sufficient quantities of commercial supplies of AVONEX and TYSABRI to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures that could require us to delay shipment of products or recall or withdraw products previously shipped, which could result in inventory write-offs and impair our ability to expand into new markets or supply products in existing markets. In the past, we have had to write down and incur other charges and expenses for products that failed to meet specifications. Similar charges may occur in the future. In addition, lower than expected demand for our products, including suspension of sales, or a change in product mix may result in less than optimal utilization of our manufacturing facilities and lower inventory turnover, which could result in abnormal manufacturing variance charges, facility impairment charges and charges for excess and obsolete inventory.

We rely solely on our manufacturing facility in Research Triangle Park, North Carolina, or RTP, for the production of TYSABRI. We have applied to the FDA and the European Medicines Agency, or the EMEA, for approval of a production process, known as a second generation high-titer process, which has higher yields of TYSABRI than the process we currently use. If we do not obtain approval for that process, to meet anticipated demand for TYSABRI we would need to increase our capital spending to add capacity at our RTP manufacturing facility and at the Hillerod,

Denmark facility we are completing. Such an increase in capital spending would affect our business, cash position and results of operations.

If we cannot produce sufficient commercial requirements of bulk product to meet demand, we would need to rely on third party contract manufacturers, of which there are only a limited number capable of manufacturing

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bulk products of the type we require. 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. 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 on third parties to provide services in connection with the manufacture of our products and, in some instances, the manufacture of the product itself***

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 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 us and multiple third party providers. Our inability to coordinate these efforts, the lack of capacity available at a 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 impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share, diminish our profitability 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.

Due to the unique nature of the production of our products, there are several single source providers of raw materials. We make every effort to qualify new vendors and to develop contingency plans so that production is not impacted by short-term issues associated with single source providers. Nonetheless, our business could be materially impacted by long term or chronic issues associated with single source providers.

***If we fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales***

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 such compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and acceptance of the change by the FDA prior to release of product to the marketplace. 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 non-compliance could increase our costs, cause us to lose revenue or market share and damage our reputation.

***The current credit and financial market conditions may exacerbate certain risks affecting our business.***

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and



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Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. For example, we source portions of our product manufacturing to a concentrated group of third-party contractors, we depend upon collaborators for both product and royalty revenue and the clinical development of future collaboration products, we use third-party contract research organizations for many of our clinical trials, and we rely upon several single source providers of raw materials for our products. Due to the recent tightening of global credit and the disruption in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

***Our investments in marketable securities are significant and are subject to market, interest and credit risk that may reduce their value***

We maintain a significant portfolio of investments in marketable securities. Our earnings may be adversely affected by changes in the value of this portfolio. In particular, the value of our investments may be adversely affected by increases in interest rates, downgrades in the corporate bonds included in the portfolio, instability in the global financial markets that reduces the liquidity of securities included in the portfolio, declines in the value of collateral underlying the mortgage- and asset-backed securities included in the portfolio, and by other factors which may result in other than temporary declines in value of the investments. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost. We attempt to mitigate these risks with the assistance of our investment advisors by investing in high quality securities and continuously monitoring the overall risk profile of our portfolio.

***We have made a significant investment in constructing a manufacturing facility the success of which depends upon the completion and licensing of the facility and continued demand for our products***

We are building a large-scale biologic manufacturing facility in Hillerod, Denmark, in which we have invested approximately \$611.0 million. We anticipate that the facility will be ready for commercial production in 2010. If we fail to manage the project, or other unforeseen events occur, we may incur additional costs to complete the project. Depending on the timing of the completion and licensing of the facility, and our other estimates and assumptions regarding future product sales, the carrying value of all or part of the manufacturing facility or other assets may not be fully recoverable and could result in the recognition of an impairment in the carrying value at the time that such effects are identified. The recognition of impairment in the carrying value, if any, could have a material and adverse affect on our results of operations. For example, if the anticipated demand for TYSABRI does not materialize, the carrying values of our Hillerod, Denmark facility could be impaired, which would negatively impact our results of operations.

***If we are unable to attract and retain qualified personnel and key relationships, the growth of our business could be harmed***

Our success will depend, to a great extent, upon our ability to attract and retain qualified scientific, manufacturing, sales and marketing and executive personnel and our ability to develop and maintain relationships with qualified clinical researchers and key distributors. Competition for these people and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. Any inability we experience to continue to attract and retain qualified personnel or develop and maintain key relationships could have an adverse effect on our ability to accomplish our research, development and external growth objectives.

***Our sales and operations are subject to the risks of doing business internationally***

We are increasing our presence in international markets, which subjects us to many risks, such as:

economic problems that disrupt foreign healthcare payment systems;

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fluctuations in currency exchange rates;

the imposition of governmental controls;

less favorable intellectual property or other applicable laws;

the inability to obtain any necessary foreign regulatory or pricing approvals of products in a timely manner;

restrictions on direct investments by foreign entities and trade restrictions;

changes in tax laws and tariffs;

difficulties in staffing and managing international operations; and

longer payment cycles.

Our operations and marketing practices are also subject to regulation and scrutiny by the governments of the other countries in which we operate. In addition, the Foreign Corrupt Practices Act, or FCPA, prohibits U.S. companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the healthcare professionals we regularly interact with meet the definition of a foreign official for purposes of the FCPA. Additionally, we are subject to other U.S. laws in our international operations. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and the imposition of civil or criminal sanctions.

A portion of our business is conducted in currencies other than our reporting currency, the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period in which we incur those gains or losses. As a result, currency fluctuations among the U.S. dollar and the currencies in which we do business will affect our operating results, often in unpredictable ways.

***Our business could be negatively affected as a result of the actions of activist shareholders***

During the first half of 2008, we defended against a proxy contest waged by Icahn Partners and certain of its affiliates that nominated three individuals for election to our Board of Directors at our 2008 Annual Meeting of Stockholders. Although we were successful in having our Board's nominees elected as directors, the proxy contest was disruptive to our operations and caused us to incur substantial costs. If Icahn Partners or any other activist shareholders wage a subsequent proxy contest, our business could be adversely affected because:

Responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;

Perceived uncertainties as to our future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

If individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

***Our operating results are subject to significant fluctuations***

Our quarterly revenues, expenses and net income (loss) have fluctuated in the past and are likely to fluctuate significantly in the future due to the timing of charges and expenses that we may take. In recent periods, for instance, we have recorded charges that include:

acquired in-process research and development at the time we make an acquisition;

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impairments that we are required to take with respect to investments;

impairments that we are required to take with respect to fixed assets, including those that are recorded in connection with the sale of fixed assets;

inventory write-downs for failed quality specifications, charges for excess or obsolete inventory and charges for inventory write downs relating to product suspensions; and

the cost of restructurings.

Our quarterly revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. Although we have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies, our efforts to reduce currency exchange losses may not be successful. As a result, changes in currency exchange rates may have an adverse impact on our future operating results and financial condition. Additionally, our net income may fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher charges from hedge ineffectiveness than we expect or from the termination of a hedge relationship.

These examples are only illustrative and other risks, including those discussed in these Risk Factors, could also cause fluctuations in our reported earnings. In addition, our operating results during any one quarter do not necessarily suggest the anticipated results of future quarters.

***If we are unable to adequately protect and enforce our intellectual property rights, our competitors may take advantage of our development efforts or our acquired technology***

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. Our patents may not afford us substantial protection or commercial benefit. Similarly, our pending patent applications or patent applications licensed from third parties may not ultimately be granted as patents and we may not prevail if patents that have been issued to us are challenged in court. In addition, pending legislation to reform the patent system could also reduce our ability to enforce our patents. We do not know when, or if, changes to the U.S. patent system will become law. If we are unable to protect our intellectual property rights and prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect.

***If our products infringe the intellectual property rights of others, we may incur damages and be required to incur the expense of obtaining a license***

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 that 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 manufacture and market our products.

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***Uncertainty over intellectual property in the biotechnology industry has been the source of litigation, which is inherently costly and unpredictable***

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 and administrative 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 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 manufacture and market our products.

***Pending and future product liability claims may adversely affect our business and our reputation***

The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our products or product candidates may cause, or may appear to have caused, injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time. For example, lawsuits have been filed by patients who have had serious adverse events while using TYSABRI, and we may face lawsuits with other product liability and related claims by patients treated with TYSABRI or other products.

We cannot predict with certainty the eventual outcome of any pending or future litigation. We may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

***Our effective tax rate may fluctuate and we may incur liabilities to tax authorities in excess of amounts that have been accrued***

As a global biotechnology company, we are subject to taxation in numerous countries, states and other jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various countries, states and other jurisdictions in which we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of the countries, states and other jurisdictions in which we operate. Our effective tax rate,

however, may be lower or higher than those experienced in the past due to numerous factors, including a change in the mix of our business from country to country, the cessation or termination of agreements we have with various taxing authorities, recently enacted and future changes in tax laws in jurisdictions in which we operate, unfavorable results of audits of our tax filings, and changes in accounting for income taxes. Any of these factors could cause us to experience an effective tax rate



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significantly different from previous periods or our current expectations and we may incur significant liabilities to tax authorities in excess of amounts that have been accrued in our financial statements, which could have an adverse effect on our business and results of operations.

***We have recently incurred substantial indebtedness that could adversely affect our business and limit our ability to plan for or respond to changes in our business***

We have recently incurred a substantial amount of indebtedness and we may also incur additional debt in the future. This indebtedness could have significant consequences to our business, for example, it could:

increase our vulnerability to general adverse economic and industry conditions;

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts and mergers and acquisitions; and

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that may have less debt.

***Our business involves environmental risks, which include the cost of compliance and the risk of contamination or injury***

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 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 laboratory 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. Biologics manufacturing also requires permits from government agencies for water supply and wastewater discharge. If we do not obtain appropriate permits, or permits for sufficient quantities of water and wastewater, we could incur significant costs and limits on our manufacturing volumes that could harm our business.

***Several aspects of our corporate governance and our collaboration agreements may discourage a third party from attempting to acquire us***

Several factors might discourage a takeover attempt that could 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 a 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;

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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 acquirers;

our amended and restated collaboration agreement with Genentech provides that, in the event we undergo a change of control, within 90 days Genentech may present an offer to us to purchase our rights to RITUXAN. In an arbitration proceeding brought by Biogen Idec relating to the collaboration agreement, Genentech alleged that the November 2003 transaction in which Idec Pharmaceuticals acquired Biogen and became Biogen Idec constituted such a change of control, an assertion with which we strongly disagree. It is our position that the Biogen Idec merger did not constitute a change of control under our agreement with Genentech and that, even if it did, Genentech's rights under the change of control provision have long since expired. We continue to vigorously assert this position. If the arbitrators decide this issue in favor of Genentech, or if a change of control were to occur in the future and Genentech were to present an offer for the RITUXAN rights, we must either accept Genentech's offer or purchase Genentech's rights to RITUXAN on the same terms as its offer. 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.

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

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.

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

On October 13, 2006 the Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with authorized shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program does not have an expiration date. We publicly announced the repurchase program in our press release dated October 31, 2006, which was furnished to the SEC as Exhibit 99.1 of our Current Report on Form 8-K filed on October 31, 2006. We did not repurchase any shares pursuant to this program during the three months ended September 30, 2008.

**Item 6. *Exhibits***

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

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**SIGNATURES**

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

BIOGEN IDEC INC.

/s/ Paul J. Clancy

Paul J. Clancy  
Executive Vice President and Chief  
Financial Officer

October 21, 2008

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**EXHIBIT INDEX**

<b>Exhibit Number*</b>	<b>Description of Exhibit</b>
3.1+	Second Amended and Restated Bylaws
10.1+	Annual Retainer Summary for Board of Directors
10.2	Form of restricted stock unit award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.1 to Biogen Idec's Current Report on Form 8-K filed on August 1, 2008.
10.3	Form of nonqualified stock option award agreement under the Biogen Idec Inc. 2008 Omnibus Equity Plan. Filed as Exhibit 10.2 to Biogen Idec's Current Report on Form 8-K filed on August 1, 2008.
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.

\* Unless otherwise indicated, exhibits were previously filed with the Securities and Exchange Commission under Commission File Number 0-19311 and are incorporated herein by reference.

+ Filed herewith

++ Furnished herewith