BIOGEN IDEC INC. Form 10-Q October 21, 2009

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

#### Form 10-Q

(Mark One)

**DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the quarterly period ended September 30, 2009

OR

o 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

33-0112644

(State or other jurisdiction of incorporation or organization)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes \( \bar{p} \) No o

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 þ

Accelerated filer o Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company o

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

The number of shares of the issuer s Common Stock, \$0.0005 par value, outstanding as of October 14, 2009, was 289,198,517 shares.

# BIOGEN IDEC INC.

# FORM 10-Q Quarterly Report For the Quarterly Period Ended September 30, 2009

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# PART I FINANCIAL INFORMATION

# BIOGEN IDEC INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF INCOME

(unaudited, in thousands, except per share amounts)

	For the Three Months Ended September 30, 2009 2008				Months ber 30, 2008		
Revenues: Product Unconsolidated joint business Other revenues	\$ 801,689 283,919 34,910	\$	758,260 298,979 35,725	\$	2,326,067 838,307 85,918	\$	2,107,816 825,024 95,754
Total revenues	1,120,518		1,092,964		3,250,292		3,028,594
Costs and expenses: Cost of sales, excluding amortization of acquired intangible assets	93,486		107,493		282,404		300,828
Research and development	304,055		268,800		999,986		779,291
Selling, general and administrative	226,755		232,824		669,415		694,342
Collaboration profit sharing	60,697		43,533		152,608		98,368
Amortization of acquired intangible assets	51,347		94,464		233,830		242,114
Acquired in-process research and development	31,347		94,404		233,630		25,000
Total costs and expenses	736,340		747,114		2,338,243		2,139,943
Income from operations	384,178		345,850		912,049		888,651
Other income (expense), net	9,360		(23,713)		30,886		(24,651)
Income before income tax expense	393,538		322,137		942,935		864,000
Income tax expense	113,936		114,337		271,869		282,320
Net income Net income attributable to noncontrolling	279,602		207,800		671,066		581,680
interest, net of tax	1,939		1,012		6,571		5,167
Net income attributable to Biogen Idec Inc.	\$ 277,663	\$	206,788	\$	664,495	\$	576,513
Basic earnings per share attributable to Biogen Idec Inc.	\$ 0.96	\$	0.71	\$	2.30	\$	1.97
Diluted earnings per share attributable to Biogen Idec Inc.	\$ 0.95	\$	0.70	\$	2.28	\$	1.95

Weighted-average shares used in calculating:

Basic earnings per share attributable to

Biogen Idec Inc.

Biogen Idec Inc. 288,917 291,408 288,416 292,613

Diluted earnings per share attributable to

291,037

293,921

290,368

295,515

See accompanying notes to these unaudited consolidated financial statements.

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# BIOGEN IDEC INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

(unaudited, in thousands, except per share amounts)

	Sep	As of otember 30, 2009	Γ	As of December 31, 2008
ASSETS				
Current assets: Cash and cash equivalents Marketable securities	\$	585,788 821,888	\$	622,385 719,586
Collateral received for loaned securities Accounts receivable, net Due from unconsolidated joint business		550,995 193,279		29,991 446,665 206,925
Loaned securities Inventory Other current assets		278,686 141,623		29,446 263,602 139,400
Total current assets		2,572,259		2,458,000
Marketable securities Property, plant and equipment, net Intangible assets, net Goodwill Investments and other assets		1,497,447 1,634,696 1,927,115 1,138,621 256,299		891,406 1,594,754 2,161,058 1,138,621 235,152
Total assets	\$	9,026,437	\$	8,478,991
LIABILITIES AND EQ	HTTV			
Current liabilities:				
Collateral payable on loaned securities Accounts payable Taxes payable Accrued expenses and other Current portion of notes payable and line of credit	\$	108,547 59,961 537,408 15,452	\$	29,991 107,417 223,260 534,887 27,667
Total current liabilities		721,368		923,222
Notes payable and line of credit Long-term deferred tax liability Other long-term liabilities		1,085,844 289,654 331,761		1,085,431 356,017 280,369
Total liabilities		2,428,627		2,645,039
Commitments and contingencies (Notes 12, 14 and 15) Equity:				

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Preferred stock, par value \$0.001 per share		
Common stock, par value \$0.0005 per share	149	149
Additional paid-in capital	6,184,315	6,073,957
Accumulated other comprehensive income (loss)	37,114	(11,106)
Retained earnings	781,321	270,180
Treasury stock, at cost	(438,710)	(527,097)
Total Biogen Idec Inc. shareholders equity	6,564,189	5,806,083
Noncontrolling interest	33,621	27,869
Total equity	6,597,810	5,833,952
Total liabilities and equity	\$ 9,026,437 \$	8,478,991

See accompanying notes to these unaudited consolidated financial statements.

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

(unaudited, in thousands)

	For the Ni Ended Sep 2009	
Cash flows from operating activities:		
Net income	\$ 671,066	\$ 581,680
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization of property, plant and equipment and intangible		
assets	334,761	340,042
Acquired in-process research and development		25,000
Share-based compensation	119,902	104,339
Non-cash interest (income) expense and foreign exchange remeasurement loss		
(gain), net	(12,861)	(11,288)
Deferred income taxes	(72,580)	(57,591)
Realized loss (gain) on sale of marketable securities and strategic investments	(17,185)	3,774
Write-down of inventory to net realizable value	13,431	22,472
Impairment of marketable securities, investments and other assets	9,866	31,502
Excess tax benefit from stock options	(3,194)	(27,424)
Changes in operating assets and liabilities, net:	(0.5.2.1.7)	
Accounts receivable	(96,215)	(95,337)
Due from unconsolidated joint business	13,646	(29,856)
Inventory	(25,195)	(34,376)
Other assets	8,555	24,898
Accrued expenses and other current liabilities	(40,565)	155,437
Other liabilities and taxes payable	(110,706)	121,928
Net cash flows provided by operating activities	792,726	1,155,200
Cash flows from investing activities:		
Purchases of marketable securities	(3,001,156)	(1,801,056)
Proceeds from sales and maturities of marketable securities	2,334,093	2,135,065
Collateral received under securities leading	29,991	30,080
Acquisitions, net of cash acquired		(25,000)
Purchases of property, plant and equipment	(110,129)	(221,961)
Proceeds from the sale of property, plant and equipment		16
Purchases of other investments	(36,519)	(17,260)
Proceeds from the sale of a strategic equity investment	6,067	
Net cash flows (used in) provided by investing activities	(777,653)	99,884
Cash flows from financing activities:		
Purchase of treasury stock	(57,631)	(559,767)
Proceeds from issuance of stock for share-based compensation arrangements	33,236	167,032
Change in cash overdraft	7,497	18,052

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Excess tax benefit from stock options Proceeds from borrowings	3,194	27,424 986,980
Repayment of borrowings	(10,867)	(1,512,474)
Obligation under securities lending	(29,991)	(30,080)
Net cash flows used in financing activities	(54,562)	(902,833)
Net (decrease) increase in cash and cash equivalents	(39,489)	352,251
Effect of exchange rate changes on cash and cash equivalents	2,892	(1,212)
Cash and cash equivalents, beginning of the period	622,385	659,662
Cash and cash equivalents, end of the period	\$ 585,788	\$ 1,010,701

See accompanying notes to these unaudited 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. (Biogen Idec, we, us or the Company) is a global biotechnology company that creates new standa of care in therapeutic areas with high unmet medical needs. We currently have four marketed products: AVONEX®, RITUXAN®, TYSABRI®, and FUMADERM<sup>tm</sup>. Our marketed products are used for the treatment of multiple sclerosis, or MS, non-Hodgkin s lymphoma, or NHL, rheumatoid arthritis, or RA, Crohn s disease and psoriasis.

#### **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, 2008. Our accounting policies are described in Notes to Consolidated Financial Statements in our 2008 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 United States. The results of operations for the three and nine months ended September 30, 2009 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

In June 2009, the Financial Accounting Standards Board, or FASB, issued the FASB Accounting Standards Codification, or Codification. Effective this quarter, the Codification became the single source for all authoritative generally accepted accounting principles, or GAAP, recognized by the FASB and is required to be applied to financial statements issued for interim and annual periods ending after September 15, 2009. The Codification does not change GAAP and did not impact our financial position or results of operations.

Effective January 1, 2009, we adopted a newly issued accounting standard for noncontrolling interests. In accordance with the accounting standard, we changed the accounting and reporting for our minority interests (now called noncontrolling interest) in our consolidated financial statements. Upon adoption, certain prior period amounts have been reclassified to conform to the current period financial statement presentation. These reclassifications did not have a material impact on our previously reported financial position or results of operations. Refer to Note 9, *Equity*, and Note 13, *Other Income (Expense)*, *Net*, of this Form 10-Q for additional information on the adoption of this standard.

#### 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, Biogen Dompé SRL and Biogen Dompé Switzerland Gmbh, respectively. 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 net income attributable to noncontrolling interest (minority interest) in our consolidated statements of income equal to the percentage of ownership of the respective noncontrolling owners. All material intercompany balances and transactions have been eliminated in consolidation.

# Use of Estimates

The preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States requires our management to make estimates and judgments that may affect the

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue recognition and related allowances, marketable securities, derivatives and hedging activities, inventory, impairments of long-lived assets including intangible assets, impairments of goodwill, income taxes including the valuation allowance for deferred tax assets, valuation of investments, research and development expenses, contingencies and litigation, and share-based payments. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

#### Subsequent Events

We evaluated all events and transactions through October 21, 2009, the date we issued these financial statements. During this period we did not have any material recognizable subsequent events. However, we did have the following nonrecognizable subsequent events:

On October 19, 2009, our Board of Directors authorized the repurchase of our common stock in an amount of up to \$1 billion. The Company intends to retire these shares following repurchase on the open market. This repurchase program does not have an expiration date.

On October 16, 2009, we extended our September 21, 2009 tender offer to acquire all of the outstanding shares of Facet Biotech Corporation, or Facet, until December 16, 2009 at the same offering price of \$14.50 per share.

## 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.

The components of inventories are as follows:

(In millions)	Septeml	As of September 30, 2009		
Raw materials Work in process Finished goods	\$	40.6 168.4 69.7	\$	29.8 180.0 53.8
Total Inventory	\$	278.7	\$	263.6

#### 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; the seller s price to the buyer is fixed or determinable; and collectibility is reasonably assured.

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon delivery. However, under the terms of a development and marketing collaboration agreement with Elan Pharma International, Ltd., or Elan, an affiliate of Elan Corporation, plc, we manufacture TYSABRI and collaborate with Elan on the product s marketing, commercial distribution and on-going

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

development activities. Therefore, sales of TYSABRI in the United States are recognized on the sell-through model, that is, upon shipment of the product by Elan to its third party distributor rather than upon shipment to Elan. For sales of TYSABRI outside the United States, we are responsible for distributing TYSABRI to customers and are primarily responsible for all operating activities. Generally, revenue on sales of TYSABRI outside the United States is recognized at the time of product delivery to our customers and distributors, as all revenue recognition criteria have been met.

#### Reserves

Reserves for Discounts and Allowances

Revenues are recorded net of applicable allowances for trade term discounts, wholesaler incentives, Medicaid rebates, Veteran's Administration rebates, managed care rebates, product returns and other applicable allowances. Reserves established for these discounts and allowances are classified as reductions of accounts receivable (if the amount is payable to our customer) or a liability (if the amount is payable to a party other than our customer).

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 requirements, 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.

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

(In millions)		Discounts		tractual istments	R	eturns	Total	
Balance, as of December 31, 2008	\$	9.2	\$	48.1	\$	18.1	\$	75.4
Current provisions relating to sales in current period		54.9		140.2		14.0		209.1
Adjustments relating to prior periods				3.2				3.2
Payments/returns relating to sales in current period		(42.2)		(76.6)		(0.5)		(119.3)
Payments/returns relating to sales in prior periods		(8.7)		(45.1)		(12.3)		(66.1)
Balance, as of September 30, 2009	\$	13.2	\$	69.8	\$	19.3	\$	102.3

The total reserves summarized within the table above were included in our consolidated balance sheets as follows:

	As of	As of
	September 30,	December 31,
(In millions)	2009	2008

Reduction of accounts receivable Current liability		\$ 41.6 60.7	\$ 31.6 43.8
Total reserves		\$ 102.3	\$ 75.4
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#### BIOGEN IDEC INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Reserves for discounts, contractual adjustments and returns reduced gross product revenues as follows:

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
(In millions, except percentages)		2009		2008		2009		2008
Discounts Contractual adjustments Returns	\$	18.7 50.6 4.4	\$	16.2 40.1 5.9	\$	54.9 143.4 14.0	\$	46.5 112.3 14.4
Total allowances	\$	73.7	\$	62.2	\$	212.3	\$	173.2
Gross product revenues	\$	875.4	\$	820.5	\$	2,538.4	\$	2,281.0
Percent of gross product revenues		8.4%		7.6%		8.4%		7.6%

#### Bad Debt Reserves

Bad debt reserves are based on our estimated uncollectible accounts receivable. Given our historical experiences with bad debts, combined with our credit management policies and practices, we do not presently maintain significant bad debt reserves. Reserves for bad debts are reflected as a reduction of accounts receivable.

#### 4. Intangible Assets and Goodwill

Intangible assets and goodwill, net of accumulated amortization, impairment charges and adjustments, are as follows:

		As	of September 2009	As of December 31, 2008						
(In millions)	Estimated Life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net			
Intangible assets:										
Out-licensed patents	12 years	\$ 578.0	\$ (288.6)	\$ 289.4	\$ 578.0	\$ (250.3)	\$ 327.7			
Core/developed technology	15-23 years	3,005.3	(1,434.0)	1,571.3	3,005.3	(1,241.0)	1,764.3			
Trademarks and tradenames	Indefinite	64.0		64.0	64.0		64.0			
In-licensed patents	14 years	3.0	(1.1)	1.9	3.0	(0.9)	2.1			
Assembled workforce	4 years	2.1	(1.6)	0.5	2.1	(1.2)	0.9			
Distribution rights	2 years	12.7	(12.7)		12.7	(10.6)	2.1			

Total intangible assets \$ 3,665.1 \$ (1,738.0) \$ 1,927.1 \$ 3,665.1 \$ (1,504.0) \$ 2,161.1

Goodwill Indefinite \$ 1,138.6 \$ \$ 1,138.6 \$ \$ 1,138.6 \$

## Intangible Assets

Effective January 1, 2009, we implemented an amendment to the accounting and disclosure requirements related to intangible assets. This amendment provides guidance for determining the useful life of a recognized intangible asset and requires enhanced disclosures so that users of financial statements are able to assess the extent to which the expected future cash flows associated with the asset are affected by our intent and ability to renew or extend the arrangement. The adoption of this guidance did not impact our financial position or

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

results of operations as this standard was required to be implemented prospectively; however, this standard may impact us in subsequent periods.

Our intangible assets consist of patents, licenses, core/developed technology, trademarks, tradenames, assembled workforce, and distribution rights, the majority of which arose in connection with the merger of Biogen Inc. and Idec Pharmaceuticals Corporation, or the Merger. These intangible assets were recorded at fair value and are stated net of accumulated amortization and impairments.

The useful lives of our assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent. Our policy is based on the general accounting principles for amortization of intangible assets, which requires that the amortization of intangible assets reflect the pattern that the economic benefits of the intangible assets are consumed.

Intangible assets related to patents, licenses, core/developed technology, assembled workforce, and distribution rights are amortized over their remaining estimated useful lives. Intangible assets related to trademarks and tradenames have indefinite lives, and as a result are not amortized, but are subject to review for impairment. We review our intangible assets with indefinite lives for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Our most significant intangible asset is the core technology related to our AVONEX product which was established at the time of the Merger. The net book value of this asset as of September 30, 2009 was \$1,554.6 million. We believe the economic benefit of this core technology is consumed as revenue is generated from our AVONEX product. An analysis of the anticipated lifetime revenue of AVONEX is performed at least annually during our long range planning cycle. The results of this forecast serve as the basis for our assumptions used in the economic consumption amortization model for our core technology intangible assets. Although we believe this process has allowed us to reliably determine the best estimate of the pattern in which we will consume the economic benefits of our core technology intangible asset, the model could result in deferring amortization charges to future periods in certain instances, due to continued sales of the product at a nominal level after patent expiration or otherwise. In order to ensure amortization charges are not unreasonably deferred to future periods we use the straight-line method to determine the minimum annual amount of amortization expense, or the minimum amortization amount. This minimum amortization amount is recalculated each year based on the remaining unamortized balance of the intangible asset and the remaining estimated useful life of the intangible asset and is compared to the amount of amortization determined under the economic consumption model. We record amortization based upon the higher of the amount of amortization determined under the economic consumption model or the minimum amortization amount determined under the straight-line method.

In September 2009, we were issued a U.S. patent for the use of beta interferon for immunomodulation or treating a viral condition, viral disease, cancers or tumors. This patent, expiring in September 2026, covers the treatment of multiple sclerosis with AVONEX, which is our brand of recombinant beta interferon. This patent extends the expected remaining life of our core intangible asset through 2026 and thus, under the straight-line method, reduces the minimum amortization amount.

We completed our most recent long range planning cycle in the third quarter, which includes an analysis of the anticipated product sales of AVONEX. The outcome of this analysis is based on certain assumptions that we evaluate on a periodic basis, such as the expected impact of competitor products and our own pipeline product candidates, as well as the issuance of new patents or extension of existing patents. Based on this year s analysis, we have continued to amortize this asset on the economic consumption model for the third quarter of 2009, and expect to apply the same model for the subsequent three quarters. The results of our

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

analysis were most significantly impacted by the extension of the assumed remaining life of the core intangible asset due to the issuance of the U.S. patent in September 2009.

## Summary of Expense Recognized Related to Intangible Assets

	For the Th	ree Months	For the Nine Months			
	Ended Sep	otember 30,	Ended September 30,			
(In millions)	2009	2008	2009	2008		
Amortization of acquired intangible assets	\$ 51.3	\$ 94.5	\$ 233.8	\$ 242.1		
Acquired in-process research and development	\$	\$	\$	\$ 25.0		

The decrease in amortization related to our acquired intangible assets for the three and nine months ended September 30, 2009, as compared to the prior year comparative periods, was primarily due to the decrease in amortization attributable to our core intangible asset. This decrease in amortization resulted from changes in the estimate of the future revenues of AVONEX which serves as the basis for our calculation of economic consumption for core technology.

Amortization of acquired intangible assets is expected to be approximately \$283.0 million for the twelve months ended December 31, 2009 and between \$160.0 million and \$220.0 million for each of the following five years.

In the first quarter of 2008, we recorded an in-process research and development, or IPR&D, charge of \$25.0 million related to a HSP90-related milestone payment made to the former shareholders of Conforma Therapeutics, Inc., or Conforma, pursuant to the terms of our acquisition of Conforma in 2006.

#### 5. Fair Value Measurements

Effective January 1, 2009, we adopted a newly issued accounting standard for fair value measurements of all nonfinancial assets and nonfinancial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of the accounting standard for these assets and liabilities did not have a material impact on our financial position or results of operations; however, this standard may impact us in subsequent periods and require additional disclosures.

During the quarter ended June 30, 2009, we implemented newly issued accounting standards which provide guidance for determining fair value when the volume and level of activity for the asset or liability have significantly decreased and identifying circumstances that indicate that a transaction is not orderly. Specifically, the new standards provide additional guidelines for making fair value measurements more consistent with the principles presented and provide authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed. This guidance is applicable to all assets and liabilities (i.e. financial and nonfinancial) and requires enhanced disclosures, including interim and annual disclosure of the input and valuation techniques (or changes in techniques) used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of the new standards did not impact our financial position

or results of operations; however, adoption has enhanced disclosures for our investments in marketable debt securities and resulted in the reclassification of certain amounts included within our previously reported disclosures to conform to the presentation adopted in the current year.

During the second quarter of 2009, we also implemented a newly issued accounting standard requiring disclosure about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of this standard has resulted in the disclosure of the fair values attributable to our debt instruments within our interim report. Since this guidance addresses disclosure requirements, the adoption of this standard did not impact our financial position or results of operations.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

#### Summary of Assets and Liabilities Recorded at Fair Value

The tables below present information about our assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2009 and December 31, 2008 and indicate 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 utilize unobservable data points for the asset or liability.

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 typically 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, other industry, and economic events. We validate the prices provided by our third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, and analyzing pricing data in certain instances. The fair values of our cash equivalents, derivative contracts, marketable debt securities, and plan assets for deferred compensation are determined through market and observable sources and have been classified as Level 2. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of September 30, 2009 and December 31, 2008.

Our strategic investments are investments in publicly traded equity securities where fair value is readily determinable and have therefore been classified as Level 1 assets.

Our venture capital investments are the only assets for which we used Level 3 inputs to determine the fair value. Venture capital investments represented approximately 0.3% of total assets as of both September 30, 2009 and December 31, 2008. The underlying assets in these funds are initially measured at transaction prices and subsequently valued using the pricing of recent financing or by reviewing the underlying economic fundamentals and liquidation value of the companies. Gains and losses (realized and unrealized) included in earnings for the period are reported in other income (expense), net.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, due from unconsolidated joint business, other current assets, accounts payable, accrued expenses and other approximate fair value due to their short-term nature.

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# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

The following tables set forth our financial assets and liabilities that were recorded at fair value:

		0	4. J D.:			5	Significant	
Bala	ance as of	Quo	in	_		Unobservable		
September 30, 2009		Active Markets (Level 1)			Inputs (Level 2)	Inputs (Level 3)		
\$	483.5	\$		\$	483.5	\$		
	446.2				446.2			
	1,638.9				1,638.9			
	234.2				234.2			
	4.2		4.2					
	23.1						23.1	
	13.2				13.2			
\$	2,843.3	\$	4.2	\$	2,816.0	\$	23.1	
	26.0				26.0			
	36.0				36.0			
\$	36.0	\$		\$	36.0	\$		
	<b>Sept</b> \$	\$ 483.5 446.2 1,638.9 234.2 4.2 23.1 13.2 \$ 2,843.3	Balance as of  September 30, 2009  \$ 483.5 \$ (I)  \$ 446.2   1,638.9   234.2   4.2   23.1   13.2   \$ 2,843.3 \$  36.0	September 30, 2009       Active Markets (Level 1)         \$ 483.5       \$         446.2 1,638.9       4.2         234.2 4.2 23.1       4.2         13.2       4.2         \$ 2,843.3       \$ 4.2         36.0	Balance as of in Sign September 30, 2009 Active Markets (Level 1)  \$ 483.5 \$ \$ \$  446.2   1,638.9   234.2   4.2   23.1    13.2   \$ 2,843.3 \$ 4.2 \$	Balance as of 2009       in Observable (Level 1)       Significant Other Observable Inputs (Level 2)         \$ 483.5       \$ 483.5         446.2 1,638.9       446.2 1,638.9         234.2 4.2 23.1       234.2 24.2         \$ 2,843.3       \$ 4.2         \$ 2,843.3       \$ 4.2         \$ 2,843.0       36.0	Balance as of 2009       Quoted Prices in Significant Other Observable Inputs (Level 1)       Under Observable Inputs (Level 2)         \$ 483.5	

						Significant
	Bala	nce as of	Quoted Prices in	Signific	cant Other	Unobservable
(In millions)		mber 31, 2008	Active Markets (Level 1)	Observable Inputs (Level 2)		Inputs (Level 3)
Assets: Cash equivalents Marketable debt securities:	\$	500.9	\$	\$	500.9	\$
Corporate debt securities		328.5			328.5	

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Government securities	1,005.0			1,005.0	
Mortgage and other asset backed securities	306.9			306.9	
Strategic investments	4.6		4.6	300.9	
Venture capital investments	23.9				23.9
Derivative contracts	1.9			1.9	
Plan assets for deferred					
compensation	13.3			13.3	
Total	\$ 2,185.0	\$	4.6	\$ 2,156.5	\$ 23.9
Liabilities:					
Derivative contracts	46.0			46.0	
Derivative contracts	40.0			40.0	
Total	\$ 46.0	\$		\$ 46.0	\$
		13			

#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

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

		ree Months tember 30,	For the Nine Months Ended September 30,			
(In millions)	2009	2008	2009	2008		
Beginning Balance	\$ 21.6	\$ 24.6	\$ 23.9	\$ 28.1		
Total net unrealized gains (losses) included in earnings	0.9	2.2	(2.2)	(2.6)		
Purchases, issuances, and settlements	0.6	1.6	1.4	2.9		
Ending Balance	\$ 23.1	\$ 28.4	\$ 23.1	\$ 28.4		

#### Summary of Liabilities Recorded at Carrying Value

The fair values of our debt instruments were estimated using market observable inputs, including quoted prices in active markets, market indices and interest rate measurements. Within the hierarchy of fair value measurements, these are Level 2 fair values.

The fair and carrying value of our debt instruments are detailed as follows:

	As of September 30, 2009				As of December 31, 2008				
(In millions)	Fair Value		Carrying Value		Fair Value		Carrying Value		
Credit line from Dompé	\$	17.5	\$	17.5	\$	16.4	\$	16.8	
Notes payable to Fumedica		31.7		29.7		37.5		38.5	
6.0% Senior Notes due 2013		476.7		449.6		429.8		449.6	
6.875% Senior Notes due 2018		602.1		604.5		562.4		608.2	
Total	\$	1,128.0	\$	1,101.3	\$	1,046.1	\$	1,113.1	

#### 6. Financial Instruments

Financial instruments that potentially subject us to concentrations of credit risk are accounts receivable and marketable securities. The majority of our accounts receivable are payable by wholesale distributors and large pharmaceutical companies and collateral is generally not required from these large customers. We monitor the financial performance and credit worthiness of our large customers so that we can properly assess and respond to

changes in their credit profile. Our portfolio of marketable securities is subject to concentration limits set within our investment policy that help to mitigate our credit exposure.

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## BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

# Marketable Securities, including Strategic Investments

The following tables summarize our marketable securities and strategic investments (in millions):

As of September 30, 2009 (In millions):	Fair Value	Unr	ross ealized ains	Unr	ross ealized osses	Ar	nortized Cost
Available-for-sale							
Corporate debt securities							
Current	\$ 167.1	\$	1.5	\$		\$	165.6
Non-current	279.1		6.7		(0.2)		272.6
Government securities							
Current	650.5		1.5				649.0
Non-current	988.4		6.8		(1.1)		982.7
Mortgage and other asset backed securities							
Current	4.3		0.1				4.2
Non-current	229.9		5.4		(0.1)		224.6
Total available-for-sale securities	\$ 2,319.3	\$	22.0	\$	(1.4)	\$	2,298.7
Other Investments							
Strategic investments, non-current	\$ 4.2	\$	0.9	\$	(0.2)	\$	3.5
					. /		

As of December 31, 2008 (In millions):	Fair Value	Gross Unrealized Gains		Gross Unrealized Losses		Ar	nortized Cost
Available-for-sale							
Corporate debt securities							
Current	\$ 128.2	\$	0.4	\$		\$	127.8
Non-current	200.3		2.6				197.7
Government securities							
Current	582.8		1.5				581.3
Non-current	422.2		8.7				413.5
Mortgage and other asset backed securities							
Current	13.9						13.9
Non-current	293.0		3.3		(0.3)		290.0
Total available-for-sale securities	\$ 1,640.4	\$	16.5	\$	(0.3)	\$	1,624.2

\$

Other Investments
Strategic investments, non-current

4.6 \$ 0.5 \$ (0.1) \$

4.2

In the tables above, as of September 30, 2009 and December 31, 2008, government securities included \$384.1 million and \$139.1 million, respectively, of Federal Deposit Insurance Corporation, or FDIC, guaranteed senior notes issued by financial institutions under the Temporary Liquidity Guarantee Program. In addition, the balances as of December 31, 2008 include amounts related to our loaned securities.

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 consolidated balance sheets and are not included

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

in the tables above. As of September 30, 2009 and December 31, 2008, the commercial paper, including accrued interest, had fair and carrying values of \$95.1 million and \$42.7 million, respectively, and short-term debt securities had fair and carrying values of \$388.4 million and \$458.2 million, respectively.

#### Summary of Contractual Maturities: Available-for-Sale Securities

The estimated fair value and amortized cost of securities, excluding strategic investments, available-for-sale by contractual maturity as of September 30, 2009 and December 31, 2008 were as follows (in millions):

	As of Sep 20	As of December 31, 2008				
	Estimated Fair	Amortized	Estimated Fair	Amortized Cost		
(In millions)	Value	Cost	Value			
Due in one year or less	\$ 731.4	\$ 728.7	\$ 714.9	\$ 713.0		
Due after one year through five years	1,397.2	1,382.8	733.7	722.0		
Due after five years	190.7	187.2	191.8	189.2		
Total	\$ 2,319.3	\$ 2,298.7	\$ 1,640.4	\$ 1,624.2		

The average maturity of our marketable securities as of September 30, 2009 and December 31, 2008, was 15 months and 13 months, respectively.

#### **Impairments**

#### Other-than-Temporary Impairments

In April 2009, we implemented newly issued accounting standards which provided guidance for the recognition, measurement and presentation of other-than-temporary impairments. These newly issued standards amended the other-than-temporary impairment model for debt securities and requires additional disclosures regarding the calculation of credit losses and the factors considered in reaching a conclusion that an investment is not other-than-temporarily impaired. The impairment model for equity securities was not affected.

Prior to our adoption of these new accounting standards in April 2009, we recognized all other-than-temporary impairment amounts related to our debt securities in earnings as required under the previously effective guidance which required that management assert that it had the ability and intent to hold a debt security until maturity or until we recovered the cost of our investment. Under the new accounting standards, an other-than-temporary impairment must be recognized through earnings if an investor has the intent to sell the debt security or if it is more likely than not that the investor will be required to sell the debt security before recovery of its amortized cost basis. However, even if an investor does not expect to sell a debt security, expected cash flows to be received must be evaluated to determine

if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized in income. The amount of losses relating to other factors, including those resulting from changes in interest rates, are recorded in accumulated other comprehensive income. The adoption of this guidance did not have a material impact on our financial position or results of operations.

Evaluating Investments for Other-than-Temporary Impairments

We conduct periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments, as required by the general accounting principles provided under the *Investment for Debt and Equity Securities* Topic of the Codification. An unrealized loss exists when the current fair value of an individual security is less

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in fair value below our cost basis is other-than-temporary, we consider the fair market value of the security, the duration of the security s decline, and the financial condition of the issuer. We then consider our intent and ability to hold the equity security for a period of time sufficient to recover our carrying value. Where we have determined that we lack the intent and ability to hold an equity security to its expected recovery, the security s decline in fair value is deemed to be other-than-temporary and is recorded within earnings as an impairment loss.

Recognition and Measurement of Other-than-Temporary Impairment

During the nine months ended September 30, 2009, we recognized \$3.6 million in charges for the other-than-temporary impairment of available for sale securities primarily related to mortgage and asset backed securities when we lacked the ability and intent to hold the securities to recovery. No impairment losses were recognized through earnings related to available for sale securities during the three months ended September 30, 2009.

For the three and nine months ended September 30, 2008, we recognized \$14.1 million and \$19.3 million, respectively, in charges for the other-than-temporary impairment of available-for-sale securities primarily related to mortgage and asset backed securities.

For the three and nine months ended September 30, 2009 we recorded increases of \$0.6 million and \$4.3 million, respectively, in unrealized net gains accounted for through accumulated other comprehensive income, a component of shareholders—equity. This compares to an increase of \$2.4 million and a decrease of \$5.7 million in unrealized net gains, respectively, in the comparable periods of the prior year.

#### Proceeds from Marketable Securities, excluding Strategic Investments

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

For the Three Months For the Nine Months

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	Ended September 30,					Ended September 30,				
(In millions)		2009		2008		2009		2008		
Proceeds from maturities and sales	\$	696.5	\$	743.2	\$	2,334.1	\$	2,135.1		
Realized gains	\$	3.1	\$	0.9	\$	17.0	\$	11.6		
Realized losses	\$	1.3	\$	10.6	\$	3.4	\$	15.4		

The realized losses for the three and nine months ended September 30, 2009 and 2008 primarily relate to losses on the sale of corporate debt securities and non-agency mortgage-backed securities.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

#### Securities Lending

We previously loaned certain securities from our portfolio to other institutions. We held collateral in the amount of \$30.0 million as of December 31, 2008. The cash collateral was recorded as collateral received for loaned securities on the accompanying consolidated balance sheet. No such loans were outstanding as of September 30, 2009 and accordingly no collateral was held as of September 30, 2009.

#### 7. Derivative Instruments

#### Forward Contracts and Interest Rate Swaps

On January 1, 2009, we adopted a newly issued accounting standard which requires additional disclosure about our objectives for using derivative instruments, the level of derivative activity we engage in, and the effect of derivative instruments and related hedged items on our financial position and performance. The adoption of this standard did not impact our financial position or results of operations.

Our primary market exposure is to interest rates and foreign exchange rates. We use certain derivative instruments to help manage this exposure. We execute these instruments with financial institutions we judge to be creditworthy and the majority of the foreign currencies are denominated in currencies of major industrial countries. We do not hold or issue derivative instruments for trading or speculative purposes.

We recognize all derivative instruments as either assets or liabilities at fair value in our consolidated balance sheets. We classify the cash flows from these instruments in the same category as the cash flows from the hedged items.

#### Forward Contracts

Due to the global nature of our operations, portions of our revenues are in currencies other than the U.S. dollar. The value of revenue measured in U.S. dollars is subject to changes in currency exchange rates. In order to mitigate these changes we use forward contracts to lock in exchange rates. We do not engage in currency speculation.

All foreign currency forward contracts in effect as of September 30, 2009 and December 31, 2008 had durations of 1 to 12 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 (loss). Realized gains and losses for the effective portion of such contracts are recognized in revenue when the sale of product in the currency being hedged is recognized. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense), net at each reporting date.

Foreign currency forward contracts that were entered into to hedge forecasted revenue were as follows:

Notional Amount
As of September
30. As of December 31.

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Foreign Currency: (In millions)	2009			2008			
Euro Canadian Dollar	\$	399.0 36.7	\$	489.4 34.1			
Total	\$	435.7	\$	523.5			

The portion of the fair value of these contracts that was included in accumulated other comprehensive income (loss) within total equity reflected losses of \$34.7 million and \$44.1 million as of September 30, 2009 and December 31, 2008, respectively. We consider the impact of our and our counterparties credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract. As

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

of September 30, 2009 and December 31, 2008, respectively, credit risk did not materially change the fair value of our foreign currency forward contracts.

In relation to our foreign currency forward contracts, we recognize gains and losses in earnings due to hedge ineffectiveness. During the three and nine months ended September 30, 2009 we recognized net losses of \$0.1 million and \$0.9 million, respectively. During the three and nine months ended September 30, 2008, we recognized net losses of \$1.3 million and \$2.4 million, respectively. In addition, we recognized \$16.3 million and \$28.6 million, respectively, of losses in product revenue for the settlement of certain effective cash flow hedge instruments for the three and nine months ended September 30, 2009 as compared to losses recognized in the amount of \$2.3 million and \$20.0 million, respectively, during the prior year comparative periods. These settlements were recorded in the same period as the related forecasted revenue.

#### Interest Rate Swaps

In connection with the issuance of our 6.0% and 6.875% Senior Notes in March 2008, we entered into interest rate swaps for an aggregate notional amount of \$550.0 million, which were settled in December 2008. Under the settlement we received \$53.9 million. As the interest rate swaps were settled in 2008, no hedge ineffectiveness was recognized for the three and nine months ended September 30, 2009. 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.

Additionally, upon termination of the swaps in December 2008, the carrying amount of the 6.875% Senior Notes increased \$62.8 million. This amount will be recognized as a reduction of interest expense and amortized using the effective interest rate method over the remaining life of the 6.875% Senior Notes. During the three and nine months ended September 30, 2009, approximately \$1.3 million and \$4.0 million, respectively, was recorded as a reduction of interest expense.

Summary of Derivatives designated as Hedging Instruments

The following table summarizes the fair value and presentation in the consolidated balance sheets for derivatives designated as hedging instruments as of September 30, 2009 and December 31, 2008:

	Foreign Currency Contracts									
	<b>Asset Derivatives</b>			Liability Derivatives	S					
	<b>Balance Sheet</b>			<b>Balance Sheet</b>						
		F	`air		]	Fair				
(In millions)	Location	Value		Location	Value					
September 30, 2009	Other Current Assets	\$		Accrued Expenses and Other	\$	34.8				
December 31, 2008	Other Current Assets	\$	1.9	Accrued Expenses and Other	\$	46.0				

As noted above, the interest rate swaps were settled in December 2008.

## BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

The following table summarizes the effect of derivatives designated as hedging instruments on the consolidated statements of income for the three and nine months ended September 30, 2009 and 2008:

	Amount		Amount		
	Recognized		Reclassified		
	in		from		
	Accumulated		Accumulated		
	Other		Other		
	Comprehensiv		Comprehensiv		
	Income	Income	Income	Income	Amount of
	on	<b>G</b>		<b>Q</b>	G 1 10T )
	Derivative	Statement	into Income	Statement	Gain/(Loss)
	Gain/(Loss)	Location	Gain/(Loss)	Location	Recorded
(In millions)	(Effective	(Effective Destina)	(Effective	(In offerting Dention)	(Ineffective
(In millions)	Portion)	(Effective Portion)	Portion)	(Ineffective Portion)	Portion)
For the Three Months Ended September 30, 2009:					
•				Other income	
Foreign currency contracts	\$ (34.7)	Revenue	\$ (16.3)	(expense)	\$ (0.1)
Interest rate swap	\$	Interest expense	\$	Interest expense	\$
<b>September 30, 2008:</b>		-		•	
				Other income	
Foreign currency contracts		Revenue	\$ (2.3)	(expense)	\$ (1.3)
Interest rate swap	\$	Interest expense	\$	Interest expense	\$ 1.3
For the Nine Months Ended September 30, 2009:					
				Other income	
Foreign currency contracts		Revenue	\$ (28.6)	(expense)	\$ (0.9)
Interest rate swap September 30, 2008:	\$	Interest expense	\$	Interest expense	\$
				Other income	
Foreign currency contracts		Revenue	\$ (20.0)	(expense)	\$ (2.4)
Interest rate swap	\$	Interest expense	\$	Interest expense	\$ (3.6)

# Other Derivatives

During the quarter ended September 30, 2009 we entered into several foreign currency forward contracts to mitigate the foreign currency risk related to certain intercompany transactions. We have not elected hedge accounting for these

transactions. As of September 30, 2009 the aggregate notional amount of our outstanding foreign currency contracts was \$115.6 million. The fair value of these contracts was a liability of \$1.2 million. Net losses of \$2.2 million and a de minimis amount, respectively, were recognized as a component of other income (expense), net related to these contracts in the three and nine months ended September 30, 2009.

# 8. Property, Plant and Equipment

Property, plant and equipment are recorded at historical cost, net of accumulated depreciation.

(In millions)		As of September 30, 2009	As of December 31, 2008
Accumulated depreciation		\$ 622.9	\$ 537.0
	20		

# BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

# 9. Equity

The following tables reflect the reconciliation at the beginning and the end of the period of the carrying amount of equity attributable to the shareholders of Biogen Idec Inc., equity attributable to noncontrolling interests, and total equity:

		For the		For the							
	Three Mor	oths Ended Sep 2009	tember 30,	Three Months Ended September 30, 2008							
(In millions)	Biogen Idec Inc. Shareholders Equity	Noncontrolling interest	g Total Equity	Biogen Idec Inc. Shareholders Equity	Noncontrolling interest	Total Equity					
Beginning Balance	\$ 6,212.5	\$ 33.2	\$ 6,245.7	\$ 5,522.9	\$ 26.2	\$ 5,549.1					
Comprehensive income: Net income Unrealized gains(losses) on securities available for sale,	277.7	1.9	279.6	206.8	1.0	207.8					
net of tax of \$0.3 and \$(0.7) Unrealized gains(losses) on foreign currency forward contracts, net of tax of \$0.8	(0.5)		(0.5)	1.3		1.3					
and \$(7.6) Unrealized gains(losses) on pension benefit obligation, net	(2.3)		(2.3)	13.0		13.0					
of tax of \$(0.1) and \$0.0	0.2		0.2	(0.2)		(0.2)					
Translation adjustments	28.4	1.3	29.7	, ,	(2.7)	(104.5)					
Comprehensive income (loss) Distribution to noncontrolling		3.2	306.7	119.1	(1.7)	117.4					
interest		(2.8)	(2.8)	)	(1.4)	(1.4)					
Capital contribution from noncontrolling interest Repurchase of common stock for Treasury, at cost Issuance of common stock from conversion of subordinated notes payable					1.6	1.6					
	8.8		8.8	77.6		77.6					

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Issuance of common stock under stock option and stock							
purchase plans							
Issuance of common stock							
under stock award plans	(2.0)			(2.0)	(1.0)		(1.0)
Compensation expense related							
to share-based payments	42.8			42.8	38.5		38.5
Tax benefit from share-based							
payments	(1.4)			(1.4)	11.4		11.4
Ending Balance	\$ 6,564.2	\$ 3	3.6	\$ 6,597.8	\$ 5,768.5	\$ 24.7	\$ 5,793.2

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

		For the Nine Months Ended September 30, 2009 Biogen Idec Inc.						For the Nine Months Ended September 30 2008 Biogen						
(In millions)	Sha	dec Inc. reholders Equity		ontrolling terest		Total Equity	Sha	dec Inc. areholders Equity		ontrolling iterest	]	Total Equity		
Beginning Balance	\$	5,806.1	\$	27.9	\$	5,834.0	\$	5,534.3	\$	19.7	\$	5,554.0		
Comprehensive income: Net income Unrealized gains(losses) on securities available for sale, ne	t	664.5		6.6		671.1		576.5		5.2		581.7		
of tax of \$(1.7) and \$2.6 Unrealized gains(losses) on foreign currency forward contracts, net of tax of \$0.3	-	3.0				3.0		(6.2)				(6.2)		
and \$(4.5) Unrealized gains on pension benefit obligation, net of tax of	f	9.6				9.6		7.6				7.6		
\$(0.1) and \$0.0		0.2				0.2		(0.1)				(0.1)		
Translation adjustment		35.4		1.9		37.3		(47.1)		(1.0)		(48.1)		
Total comprehensive income Distribution to noncontrolling		712.7		8.5		721.2		530.7		4.2		534.9		
interest				(2.8)		(2.8)	)			(2.8)		(2.8)		
Capital contribution from noncontrolling interest Repurchase of common stock										3.6		3.6		
for Treasury, at cost Issuance of common stock from conversion of		(57.6)				(57.6)	)	(559.8)				(559.8)		
subordinated notes payable Issuance of common stock								0.2				0.2		
under stock option and stock purchase plans Issuance of common stock		33.2				33.2		167.3				167.3		
under stock award plans Compensation expense related		(40.5)				(40.5)	)	(42.8)				(42.8)		
to share-based payments		124.7 (14.4)				124.7 (14.4)	)	109.8 28.8				109.8 28.8		

Tax benefit from share-based payments

Ending Balance \$ 6,564.2 \$ 33.6 \$ 6,597.8 \$ 5,768.5 \$ 24.7 \$ 5,793.2

As noted within Note 1, *Business Overview*, of this Form 10-Q, effective January 1, 2009, we adopted a newly issued accounting standard for noncontrolling interests. The newly issued accounting standard requires enhanced disclosures to clearly distinguish between our interests and the interests of noncontrolling owners.

We changed the accounting and reporting for our minority interests by recharacterizing them as noncontrolling interests and classifying them as a separate component of total equity in our accompanying consolidated balance sheets. Additionally, net income attributable to noncontrolling interest is now shown separately from net income in the consolidated statements of income. As a result, our accompanying consolidated statements of income include net income, which represents net income prior to any allocation to minority shareholders and net income attributable to noncontrolling interest, as well as a new line item titled

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## BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

net income attributable to Biogen Idec Inc., which is the equivalent of the previously reported net income line item. These reclassifications had no effect on our previously reported financial position or results of operations. Refer to Note 1, *Business Overview*, and Note 13, *Other Income (Expense)*, *Net*, of this Form 10-Q for additional information on the adoption of this guidance.

# 10. Earnings per Share

Basic and diluted earnings per share are calculated as follows:

(In millions)	For the aree Months Ended September 30, 2009 2008			For the Nine Months End September 30, 2009 200			
Numerator: Net income attributable to Biogen Idec Inc. Adjustment for net income allocable to preferred stock	\$ 277.7 (0.5)	\$	206.8 (0.4)	\$	664.5 (1.1)	\$	576.5 (1.0)
Net income used in calculating basic and diluted earnings per share	\$ 277.2	\$	206.4	\$	663.4	\$	575.5
Denominator: Weighted average number of common shares outstanding Effect of dilutive securities:	288.9		291.4		288.4		292.6
Stock options and ESPP	0.6		1.1		0.7		1.6
Time-vested restricted stock units	1.5		1.4		1.3		1.2
Performance-vested restricted stock units Restricted stock awards							0.1
Dilutive potential common shares	2.1		2.5		2.0		2.9
Shares used in calculating diluted earnings per share	291.0		293.9		290.4		295.5

The following amounts were not included in the calculation of net income per diluted share because their effects were anti-dilutive or the performance criteria had not been met for the performance-vested restricted stock units:

For the	For the
<b>Three Months</b>	Nine Months
Ended	Ended

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		0,	September 30,					
(In millions)	2009		2008		2009		2008	
Numerator:								
Net income allocable to preferred stock	\$	0.5	\$	0.4	\$	1.1	\$	1.0
Denominator:								
Stock options		8.4		6.7		7.4		6.4
Time-vested restricted stock units		2.3		1.8		2.1		1.4
Performance-vested restricted stock units		0.2				0.1		
Convertible preferred stock		0.5		0.5		0.5		0.5
Total		11.4		9.0		10.1		8.3
2	23							

#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

On January 1, 2009, we adopted a newly issued accounting standard which addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting, and therefore need to be included in the earnings allocation in computing earnings per share under the two-class method. This newly issued accounting standard requires us to include all unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents, whether paid or unpaid, as participating securities and to include them in the number of shares outstanding in our basic and diluted EPS calculations pursuant to the two-class method. Our awards do not have nonforfeitable rights to dividends or dividend equivalents and therefore the adoption of this guidance did not impact our financial position or results of operations.

# 11. Share-Based Payments

The following table summarizes share-based compensation expense included within our consolidated statements of income:

		For the Months Septem	Enc	ded	For the Nine Months Ended September 30,			
(In millions)		2009	2008		2009		2	2008
Research and development Selling, general and administrative	\$	15.6 27.2	\$	14.0 24.5	\$	46.0 78.7	\$	45.8 64.0
Subtotal Capitalized share-based payment costs		42.8 (1.7)		38.5 (1.8)		124.7 (4.8)		109.8 (5.5)
Share-based compensation expense included in total costs and expenses Income tax effect		41.1 (12.6)		36.7 (11.4)		119.9 (36.8)		104.3 (32.2)
Share-based compensation expense included in net income attributable to Biogen Idec, Inc.	\$	28.5	\$	25.3	\$	83.1	\$	72.1

Our share-based compensation programs consist of share-based awards which include stock options, time-vested restricted stock units and performance-vested restricted stock units, as well as our employee stock purchase plan. The following table summarizes share-based compensation expense associated with each of these programs:

	For the	e Three	For the Nine			
	Months	<b>Ended</b>	<b>Months Ended</b>			
	Septem	September 30,				
(In millions)	2009	2008	2009	2008		

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5.5 \$ 4.9 \$ 16.6	\$ 14.3
1.4 30.5 99.9	89.5
0.3) 0.1 3.0	0.8
	0.6
3.2 3.0 5.2	4.6
2.8 \$ 38.5 \$ 124.7	\$ 109.8
(1.8) (4.8)	(5.5)
.1 \$ 36.7 \$ 119.9	\$ 104.3
1 )	.4 30.5 99.9 .3) 0.1 3.0 .2 3.0 5.2 .8 \$ 38.5 \$ 124.7 .7) (1.8) (4.8)

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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## Stock Options

The fair values of our stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the stock options, including the effect of estimated forfeitures, are then expensed over the options vesting periods. A summary of stock options granted during the three and nine months ended September 30, 2009 and 2008 is as follows:

	For the Three Months Ended September 30,				For the Nine Months End September 30,			
	2009	008	2	009	2008			
	Weighted Average Number Exercise Numb		Weighted Average Exercise	Average			Weighted Average Exercise	
(In millions, except share price)	Granted(a) Price	Granted	Price	Granted	Price	Granted	Price	
Stock Options	\$ 47.96	0.1	\$ 65.70	1.0	\$ 50.02	1.4	\$ 60.89	

<sup>(</sup>a) Approximately 14,000 stock options were granted during the quarter ended September 30, 2009.

# Time-Vested Restricted Stock Units

The fair values of our time-vested restricted stock units, or RSUs, are based on the market value of our stock on the date of grant and are recognized over the applicable service period, adjusted for the effect of estimated forfeitures. A summary of RSU activity for the three and nine months ended September 30, 2009 and 2008 is as follows:

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,					
			008 Weighted		009 Weighted	2008 d Weight				
	Number	Average Grant Date Fair	Number	Average Grant Date Fair	Number	Average Grant Date Fair	Number	Average Grant Date Fair		
(In millions, except share price)	Granted	Value	Granted	Value	Granted	Value	Granted	Value		
Time-Vested Restricted Stock Units	0.1	\$ 48.42	0.2	\$ 51.87	2.5	\$ 49.35	2.8	\$ 60.04		

# Performance-Vested Restricted Stock Units

# 2009 Grant Activity

We apply a graded vesting expense methodology when accounting for the performance-vested restricted stock units, or PVRSUs, issued during 2009 in accordance with generally accepted accounting principles for share-based compensation. During the nine months ended September 30, 2009, approximately 321,000 PVRSUs were granted with a weighted average grant date fair value of \$49.46 per share. Approximately 307,000 of these PVRSUs were granted during the first quarter of 2009, primarily in connection with our annual awards made in February; the remainder of the PVRSUs granted during the nine months ended September 30, 2009 were made in conjunction with promotions and new hires.

The number of PVRSUs reflected as granted represents the target number of shares that are eligible to vest in full or in part and are earned subject to the attainment of certain performance criteria established at the beginning of the performance period; the performance period ends December 31, 2009. Participants may ultimately earn up to 200% of the target number of shares granted in the event that the maximum performance thresholds are attained. Accordingly, additional PVRSUs may be issued upon final determination of the number of awards earned.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Once the earned number of performance-vested awards has been determined, the earned PVRSUs will then vest in three equal increments on (1) the later of the first anniversary of the grant date or the date of results determination; (2) the second anniversary of the grant date; and (3) the third anniversary of the grant date. The vesting of these awards is also subject to the respective employees—continued employment. Compensation expense associated with these PVRSUs is initially based upon the number of shares expected to vest after assessing the probability that certain performance criteria will be met and the associated targeted payout level that is forecasted will be achieved, net of estimated forfeitures. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date results are determined.

# 2007 Grant Activity

During 2007, our Board of Directors awarded a total of 120,000 PVRSUs to Dr. Cecil Pickett, our former President, Research and Development. Vesting of these PVRSUs was subject to certain performance criteria established at the beginning of each of four performance periods, beginning January 1 on each of 2007, 2008, 2009 and 2010, and Dr. Pickett s continued employment through the end of the respective performance periods. In February 2008, a total of 27,000 shares were issued based upon the attainment of performance criteria set for 2007. An additional 30,000 shares were issued in February 2009 based on the attainment of performance criteria set for 2008. No additional shares were issued to Dr. Pickett during the three and nine months ended September 30, 2009 and 2008, respectively. Dr. Pickett retired from the position of President, Research and Development effective October 5, 2009. Accordingly, no additional PVRSUs awarded to Dr. Pickett will vest or be issued. Expense previously recognized in relation to unvested awards was reversed during the current quarter.

# Employee Stock Purchase Plan

The purchase price of common stock under the employee stock purchase plan, or ESPP, is equal to 85% of the lower of (i) the market value per share of the common stock on the participant s entry date into an offering period or (ii) the market value per share of the common stock on the purchase date. However, for each participant whose entry date is other than the start date of the offering period, the amount shall in no event be less than the market value per share of the common stock as of the beginning of the related offering period. The fair value of the discounted purchases made under the employee stock purchase plan are calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the purchase period. We apply a graded vesting approach since our ESPP provides for multiple purchase periods and is, in substance, a series of linked awards.

The table below provides a summary of shares issued under our ESPP for the three and nine months ended September 30, 2009 and 2008, respectively:

	For the Three	Months Ended	For the Nine Months Ended September 30,			
	Septem	ber 30,				
	2009	2008	2009	2008		
	Shares	Shares	<b>Shares</b>	Shares		
(In millions)	Issued	<b>Issued</b>	<b>Issued</b>	<b>Issued</b>		

Employee Stock Purchase Plan 0.1 0.1 0.4 0.4

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 12. Income Taxes

The following table provides a comparative summary of our effective tax rates and income tax expense for the three and nine months ended September 30, 2009 and 2008, respectively:

		Three Mont September 3		For the Nine Months Ended September 30,					
(In millions, except percentages)	2009	2008	Change %	2009	2008	Change %			
Effective tax rate	29.0%	35.5%	(18.3)%	28.8%	32.7%	(11.9)%			
Income tax expense	\$ 113.9	\$ 114.3	(0.3)%	\$ 271.9	\$ 282.3	(3.7)%			

Our effective tax rate will fluctuate from period to period due to several factors inherent in the nature of our global operations and business transactions. The factors that most significantly impact our tax rate include the variability of the proportion of our taxable earnings in multiple jurisdictions, changes in tax laws and acquisition and licensing transactions.

Our effective tax rate for the three and nine months ended September 30, 2009 was favorably impacted by certain adjustments to our transfer pricing and other estimates made in conjunction with the filing of our income tax returns during the current quarter. These adjustments had a favorable impact of 1.9% and 0.8% on our tax rate for the three and nine months ended September 30, 2009, respectively. In addition, our tax rate for the nine months ended September 30, 2009, was also favorably impacted by changes in the tax laws of certain states in which we operate. These tax law changes required us to establish deferred tax assets for certain tax credits and adjust certain deferred tax liabilities and reserves for uncertain tax positions resulting in a favorable impact of 3.2% on our effective tax rate for the nine months ended September 30, 2009. As these tax law changes became effective during the first quarter of 2009, these changes did not have an impact on our effective tax rate for the three months ended September 30, 2009.

The favorable impact of these items on our effective tax rate for the nine months ended September 30, 2009 was offset by the impact of the collaboration and license agreement entered into with Acorda Therapeutics, Inc., or Acorda, on June 30, 2009. As there is no income tax benefit associated with the \$110.0 million July 1, 2009 upfront payment made to Acorda and other registrational costs of Fampridine-SR, these payments had a 2.4% and 2.3% unfavorable impact on our effective tax rate for the three and nine months ended September 30, 2009, respectively. Refer to Note 14, *Collaborations*, of this Form 10-Q for additional information related to the Acorda transaction.

In connection with the acquisition of Syntonix Pharmaceuticals, or Syntonix, in January 2007, we agreed to make additional future consideration payments contingent upon the achievement of certain milestone events. In accordance with the acquisition agreement, we expect to make a \$40.0 million milestone payment to the former shareholders of Syntonix in the fourth quarter of 2009. This amount will be recorded as a charge to IPR&D when the related milestone has been achieved. This payment was anticipated in determining our full year effective tax rate. As this amount is not deductible for United States income tax purposes, our 2009 effective tax rate would be favorably impacted in the event that the achievement of these milestones is not met or is delayed beyond the fourth quarter of 2009.

Our effective tax rate for the nine months ended September 30, 2008 was favorably impacted by the restructuring of our operations in foreign jurisdictions as well as other activities and adjustments made.

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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Reconciliation between the U.S. federal statutory tax rate and our effective tax rate for the three and nine months ended September 30, 2009 and 2008 is as follows:

	For t Three M End	For the Nine Months Ended				
	Septemb 2009	er 30, 2008	September 30, 2009 2008			
	2007	2000	<b>2</b> 007	2000		
Statutory rate	35.0%	35.0%	35.0%	35.0%		
State taxes	2.2	4.4	1.6	3.0		
Taxes on foreign earnings	(7.7)	(7.4)	(5.8)	(9.0)		
Credits and net operating loss utilization	(1.5)	1.1	(4.1)	0.1		
Fair value adjustment	0.9	3.8	2.0	3.6		
IPR&D	0.9		1.1	1.0		
Permanent items	(1.0)	(0.9)	(1.5)	(0.8)		
Other	0.2	(0.5)	0.5	(0.2)		
Effective tax rate	29.0%	35.5%	28.8%	32.7%		

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 2002 tax year. Subsequently, we filed a petition with the Massachusetts Appellate Tax Board, seeking among other items, abatements of corporate excise tax for 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 results of operations in the period the resolution occurs. We are subject to examinations by the Massachusetts Department of Revenue for additional tax years and, therefore, may be assessed for a similar proposed adjustment to those additional tax years. Refer to Note 15, *Litigation*, of this Form 10-Q for additional information.

We file income tax returns in the United States 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. During the first quarter of 2009 the IRS completed an examination of our consolidated federal income tax returns for fiscal years 2005 and 2006 and issued an assessment. Our level of liabilities for income tax contingencies approximate the assessment amounts for items agreed to with the IRS; we are appealing several other items. If these items are resolved unfavorably in the future, the outcome could have an adverse impact on our results of operations in the period the resolution occurs.

#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

# 13. Other Income (Expense), Net

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

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,			
(In millions)	2	2009 2008		2008	2	2009	2008		
Interest income	\$	10.9	\$	16.8	\$	37.8	\$	55.0	
Interest expense		(8.5)		(8.1)		(27.6)		(37.6)	
Impairments of investments		(0.5)		(17.4)		(10.1)		(32.0)	
Net gains (losses) on foreign currency transactions		3.2		(1.8)		10.6		(2.8)	
Net realized gains (losses) on marketable securities		1.8		(9.7)		13.7		(3.8)	
Other, net		2.5		(3.5)		6.5		(3.5)	
Total other income (expense), net	\$	9.4	\$	(23.7)	\$	30.9	\$	(24.7)	

# Impairment on Investments

In April 2009, we implemented newly issued accounting standards which provided guidance for recognition and presentation of other-than-temporary impairments. The adoption of the guidance did not have a material impact on our financial position or results of operations; however, this standard amended the other-than-temporary impairment model for debt securities. The impairment model for equity securities was not affected. Refer to Note 6, *Financial Instruments*, of this Form 10-Q for additional information on the adoption of this guidance.

During the three and nine months ended September 30, 2009, we recognized impairment losses of \$0.5 million and \$6.5 million, respectively, on our strategic investments and non-marketable securities. In addition, during the three and nine months ended September 30, 2008, we recognized \$3.3 million and \$12.7 million, respectively, in charges for the impairment of strategic investments and non-marketable securities that were determined to be other-than-temporary.

No impairment losses were recognized through earnings related to available for sale securities during the three months ended September 30, 2009. For the nine months ended September 30, 2009, we recognized \$3.6 million in charges. For the three and nine months ended September 30, 2008, we recognized \$14.1 million and \$19.3 million, respectively, in charges for the other-than-temporary impairment of available for sale securities primarily related to mortgage and asset backed securities.

## Noncontrolling Interest

Effective January 1, 2009, we changed the accounting and reporting for our minority interests by recharacterizing them as noncontrolling interest. Prior year amounts related to noncontrolling interest, historically reflected as a component of other income (expense), net, have been reclassified to conform to current year presentation. Amounts previously reported as minority interest are now shown separately from net income in the accompanying consolidated statements of income and total \$1.9 million and \$6.6 million, respectively, for the three and nine months ended September 30, 2009, as compared to \$1.0 million and \$5.2 million, respectively, in the prior year comparative periods. Refer to Note 1, *Business Overview*, and Note 9, *Equity*, of this Form 10-Q for additional information on the adoption of this guidance.

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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

## 14. Collaborations

In connection with our business strategy, we have entered into various collaboration agreements which provide us with rights to develop, produce and market products using certain know-how, technology and patent rights maintained by our collaborative partners. Terms of the various collaboration agreements may require us to make milestone payments upon the achievement of certain product research and development objectives and pay royalties on future sales, if any, of commercial products resulting from the collaboration.

Effective January 1, 2009, we adopted a newly issued accounting standard for the accounting and disclosure of an entity s collaborative arrangements. This newly issued standard prescribes that certain transactions between collaborators be recorded in the income statement on either a gross or net basis, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. In accordance with this guidance, we must also evaluate our collaborative agreements for proper income statement classification based on the nature of the underlying activity. Amounts due from our collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to our operations. For collaborations with commercialized products, if we are the principal (as defined in reporting revenue as a principal versus net as an agent as required by the Revenue Recognition Topic of the Codification) we record revenue and the corresponding operating costs in their respective line items within our consolidated statements of income. If we are not the principal, we record operating costs as a reduction of revenue. The guidance describes the principal as the party who is responsible for delivering the product or service to the customer, has latitude to determine price, and has the risks and rewards of providing product or service to the customer, including inventory and credit risk. The adoption of this newly issued accounting standard did not impact our financial position or results of operations; however it resulted in enhanced disclosures for our collaboration activities.

#### Genentech

We collaborate with Genentech, Inc., or Genentech, a member of the Roche Group, on the development and commercialization of RITUXAN. We also have rights to collaborate with Genentech on the development and commercialization of (1) anti-CD20 products that Genentech acquires or develops, which we refer to as New Anti-CD20 Products, and (2) anti-CD20 products that Genentech licenses from a third party, which we refer to as Third Party Anti-CD20 Products. Currently, there is only one New Anti-CD20 Product, ocrelizumab, and only one Third Party Anti-CD20 Product, GA101. Our collaboration rights for New Anti-CD20 Products are limited to the United States and our collaboration rights for Third Party Anti-CD20 Products are dependent upon Genentech s underlying license rights. A joint development committee, or JDC, composed of three members from each company must unanimously approve a development plan for each specific indication of certain pharmaceutical products, and Genentech has responsibility for implementation of JDC approved development plans in accordance with the provisions of our collaboration agreement. In the event that we undergo a change in control, as defined in the collaboration agreement, Genentech has the right to present an offer to buy the rights to RITUXAN, and 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 royalty on net sales in the United States of any anti-CD20 product acquired or developed by Genentech or any

anti-CD20 product that Genentech licenses from a third party that is developed under the agreement, to purchase our interest in each such product. Our collaboration with Genentech was created through a contractual arrangement and not through a joint venture or other legal entity.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

While Genentech is responsible for the worldwide manufacturing of RITUXAN, development and commercialization rights and responsibilities under this collaboration are divided as follows:

## **United States**

We share with Genentech co-exclusive rights to develop, commercialize and market RITUXAN and New Anti-CD20 Products in the United States. Although we contribute to the marketing and continued development of RITUXAN, we have a limited sales force dedicated to RITUXAN and limited development activity. Genentech is primarily responsible for the commercialization of RITUXAN in the United States. Its responsibilities include selling and marketing, customer service, order entry, distribution, shipping and billing, and other administrative support. Genentech also incurs the majority of continuing development costs for RITUXAN.

#### Canada

We and Genentech have assigned our rights to develop, commercialize and market RITUXAN, in Canada to F. Hoffmann-La Roche Ltd., or Roche.

# Outside the United States and Canada

We have granted Genentech exclusive rights to develop, commercialize and market RITUXAN outside the United States and Canada. Under the terms of separate sublicense agreements between Genentech and Roche, development and commercialization of RITUXAN outside the United States and Canada is the responsibility of Roche, except in Japan where RITUXAN is co-marketed by Zenyaku Kogyo Co. Ltd., or Zenyaku, and Chugai Pharmaceutical Co. Ltd, or Chugai, an affiliate of Roche. We do not have any direct contractual arrangements with Roche, Zenyaku or Chugai for such development or commercialization.

Revenues from unconsolidated joint business consists of (1) our share of pretax co-promotion profits in the United States (2) reimbursement of selling and development expenses in the United States; and (3) revenue on sales of RITUXAN outside the United States, which consist of our share of pretax co-promotion profits in Canada and royalty revenue on sales of RITUXAN outside the United States and Canada by Roche, Zenyaku and Chugai. Pre-tax co-promotion profits are calculated and paid to us by Genentech in the United States and by Roche in Canada. Pre-tax co-promotion profits consist of United States and Canadian sales of RITUXAN to third-party customers net of discounts and allowances less the cost to manufacture RITUXAN, third-party royalty expenses, distribution, selling, and marketing expenses, and joint development expenses incurred by Genentech, Roche and us. We record our royalty and co-promotion profits revenue on sales of RITUXAN outside the United States on a cash basis.

Revenues from unconsolidated joint business consist of the following:

For the Three For the Nine **Months Ended Months Ended** September 30, September 30, 2009 2008 2009

2008

(In millions)

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\$ 203.3	\$ 192.2	\$ 581.3	\$ 527.9
15.8	16.8	47.5	45.4
64.8	90.0	209.5	251.7
\$ 283.9	\$ 299.0	\$ 838.3	\$ 825.0
	15.8 64.8	15.8 16.8 64.8 90.0	15.8 16.8 47.5 64.8 90.0 209.5

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Under the collaboration agreement, our current pretax co-promotion profit-sharing formula, which resets annually, is stated within the table below. In 2009 and 2008, the 40% threshold was met during the first quarter.

	Biogen Idec Inc. s Share of Co-promotion
<b>Co-promotion Operating Profits</b>	Profits
First \$50 million	30%
Greater than \$50 million	40%

Our agreement with Genentech provides that the successful development and commercialization of the first New Anti-CD20 Product will decrease our percentage of co-promotion profits of the collaboration. Specifically, for each calendar year or portion thereof following the approval date of the first New Anti-CD20 Product, the pretax co-promotion profit-sharing formula for RITUXAN and New Anti-CD20 Products sold by us and Genentech will change as follows:

Co-promotion Operating Profits	First New Anti-CD20 Product U.S. Gross Product Sales	Biogen Idec Inc. s Share of Co-promotion Profits
First \$50 million(1)	Not Applicable	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 co-promotion operating profits has already been achieved in such calendar year through sales of RITUXAN.
- (2) if we are recording our share of RITUXAN co-promotion profits at 40%, upon the approval date of the first New Anti-CD20 Product, our share of co-promotion 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 in first New Anti-CD20 Product sales level is achieved.

- (3) if \$150 million in first New Anti-CD20 Product sales is achieved in the same calendar year the first New Anti-CD20 Product receives approval, then the 35% co-promotion profit-sharing rate will not be effective until January 1 of the following calendar year. Once the \$150 million in first New Anti-CD20 Product sales level is achieved then our share of co-promotion profits for the balance of the year and all subsequent years (after the first \$50 million in co-promotion operating profits in such years) will be 35% until the \$350 million in first New Anti-CD20 Product sales level is achieved.
- (4) if \$350 million in first New Anti-CD20 Product sales is achieved in the same calendar year that \$150 million in new product sales is achieved, then the 30% co-promotion 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 in first New Anti-CD20 Product sales level are achieved). Once the \$350 million in first New Anti-CD20 Product sales level is achieved then our share of co-promotion profits for the balance of the year and all subsequent years will be 30%.

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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

We will participate in Third Party Anti-CD20 Products on similar financial terms as for ocrelizumab.

Currently, we record our share of the expenses incurred by the collaboration for the development of New Anti-CD20 Products in research and development expense in our consolidated statements of income. After a New Anti-CD20 Product is approved, we will record our share of the development expenses related to that product as a reduction of our share of pretax co-promotion profits in revenues from unconsolidated joint business. We incurred \$14.7 million and \$47.3 million in development expense related to New Anti-CD20 products for the three and nine months ended September 30, 2009, respectively, as compared to \$9.0 million and \$31.6 million, respectively, during the prior year comparative periods. Reimbursement to Genentech for our share of these costs occurs through the net amount of co-promotion profits in the United States remitted to us.

#### Elan

We have a collaboration agreement with Elan to collaborate in the development, manufacture and commercialization of TYSABRI. Under the terms of the agreement, we manufacture TYSABRI and collaborate with Elan on the product s marketing, commercial distribution and on-going development activities. The collaboration with Elan is designed to effect an equal sharing of profits and losses generated by the activities of the collaboration between Elan and us. Under the agreement, however, once sales of TYSABRI exceeded specific thresholds, Elan was required to make milestone payments to us in order to continue sharing equally in the collaboration s results. As of September 30, 2009, Elan has paid to us milestone payments of \$75.0 million in the third quarter of 2008 and \$50.0 million in the first quarter of 2009. We have recorded these amounts as deferred revenue upon receipt and are recognizing the entire \$125.0 million as product revenue in our consolidated statements of income over the term of the collaboration agreement based 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 remaining term of the collaboration. No additional milestone payments are required under the agreement to maintain the current profit sharing split. Our collaboration agreement with Elan provides Elan or us with the option to buy the rights to TYSABRI in the event that the other company was to undergo a change of control (as defined in the collaboration agreement).

In the United States, we sell TYSABRI to Elan who sells the product to third party distributors. Our sales price to Elan in the United States is set prior to the beginning of each quarterly period to effect an approximate equal sharing of the gross margin between Elan and us. We recognize revenue for sales in the United States of TYSABRI upon Elan s shipment of the product to the third party distributors. We incur manufacturing and distribution costs, research and development expenses, commercial expenses, and general and administrative expenses. We record these expenses to their respective line items within our consolidated statements of income when they are incurred. Research and development and sales and marketing expenses are shared equally with Elan and the reimbursement of these expenses is recorded as reductions of the respective expense categories. During the three and nine months ended September 30, 2009, we recorded \$5.2 million and \$16.6 million, respectively, as reductions of research and development expense for reimbursements from Elan as compared to \$4.0 million and \$17.8 million, respectively, of research and development expense recorded for reimbursement from Elan during the prior year comparative periods. In addition, for the three and nine months ended September 30, 2009, we recorded \$14.7 million and \$46.9 million, respectively, as reductions of selling, general and administrative expense for reimbursements from Elan as compared to \$9.3 million and \$26.8 million, respectively, in the prior year comparative periods.

Outside the United States, or rest of world, we are responsible for distributing TYSABRI to customers and are primarily responsible for all operating activities. Generally, we recognize revenue for sales of TYSABRI in the rest of world at the time of product delivery to our customers. Payments are made to Elan for their share of the rest of world net operating profits to effect an equal sharing of collaboration operating profit. These payments also include the reimbursement for our portion of third-party royalties that Elan pays

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

on behalf of the collaboration relating to rest of world sales. These amounts are reflected in the collaboration profit sharing line in our consolidated statements of income. For the three and nine months ended September 30, 2009, \$60.7 million and \$152.6 million, respectively, was reflected in the collaboration profit sharing line for our collaboration with Elan, as compared to \$43.5 million and \$98.4 million, respectively, for the prior year comparative periods. As rest of world sales of TYSABRI increase, our collaboration profit sharing expense is expected to increase.

#### Acorda

On June 30, 2009, we entered into a collaboration and license agreement with Acorda to develop and commercialize products containing Fampridine-SR in markets outside the United States. Fampridine-SR is an oral sustained-release compound, which is being developed to improve walking ability in people with MS. The transaction represents a sublicensing of an existing license agreement between Acorda and Elan. The parties have also entered into a related supply agreement. The \$110.0 million upfront payment made on July 1, 2009 was recorded as research and development expense during the second quarter 2009 as the product candidate has not received regulatory approval.

Under the terms of the agreement, we will commercialize Fampridine-SR and any aminopyridine products developed in our territory and will also have responsibility for regulatory activities and future clinical development of Fampridine-SR in those markets. We may incur additional milestone payments of up to \$400.0 million based upon the successful achievement of regulatory and commercial sales milestones. We will also make tiered royalty payments to Acorda on sales outside of the United States. The consideration that we pay for products will reflect all amounts due from Acorda to Elan for sales in markets outside the United States, including royalties owed. We can also carry out future joint development activities under a cost-sharing arrangement.

Elan will continue to manufacture commercial supply of Fampridine-SR, based upon its existing supply agreement with Acorda. Under the existing agreements with Elan, Acorda will pay Elan 7% of the upfront and milestone payments that Acorda receives from us.

A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
(In millions)	2	009	2008	2009	2008	
Upfront payments made to Acorda Total expense incurred by Biogen Idec Inc., excluding upfront and	\$		\$	\$ 110.0	\$	
milestone payments	\$	0.5	\$	\$ 0.5	\$	
Total expense reflected within our consolidated statements of income	\$	0.5	\$	\$ 110.5	\$	
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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	Septe	As of ember 30, 2009
Total upfront and milestone payments made to Acorda	\$	110.0
Total expense incurred by Biogen Idec Inc., excluding upfront and milestone payments	\$	0.5
Estimate of additional expense to be incurred by us in development of Fampridine-SR	\$	10.0

#### Neurimmune

We have a collaboration agreement with Neurimmune SubOne AG, or Neurimmune, a subsidiary of Neurimmune Therapeutics AG, for the development and commercialization of antibodies for the treatment of Alzheimer's disease. Neurimmune will conduct research to identify potential therapeutic antibodies and we will be responsible for the development, manufacturing and commercialization of all products. We may pay Neurimmune up to \$360.0 million in remaining milestone payments, as well as royalties on sales of any resulting commercial products. Milestone payments are reflected within our consolidated statements of income when achieved. The royalty term for sales in each country will be no less than 12 years from the first commercial sale of product using such compound in such country.

We have determined that we are the primary beneficiary of Neurimmune in accordance with the guidance provided by the *Consolidation* Topic of the Codification. As such, we consolidate the results of Neurimmune. The assets and liabilities of Neurimmune are not significant as it is a research and development organization. We reimburse Neurimmune for all research and development costs incurred in support of the collaboration. These amounts are also reflected in research and development expense in our statements of income. A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

		For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
(In millions)	2	009	2	008	2	2009	2	2008	
Total upfront and milestone payments made to Neurimmune	\$		\$	2.5	\$	7.5	\$	10.5	
Total expense incurred by Neurimmune in support of the collaboration	\$	1.9	\$	1.3	\$	5.5	\$	4.5	
Total expense reflected within our consolidated statements of income	\$	1.9	\$	3.8	\$	13.0	\$	15.0	

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	As of September 30, 2009
Total upfront and milestone payments made to Neurimumune Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone	\$ 20.0
payments	\$ 12.0
Estimate of additional expense to be incurred by us in development of the lead compound	\$ 440.0
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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

#### Cardiokine

We have a collaboration agreement with Cardiokine Biopharma LLC, or Cardiokine, a subsidiary of Cardiokine Inc., for the joint development of Lixivaptan, an oral compound for the potential treatment of hyponatremia in patients with congestive heart failure. The royalty term under the agreement for sales in each country will be no less than 10 years from the first commercial sale of a Lixivaptan product in such country. If successful, we will be responsible for certain development activities, manufacturing and global commercialization of Lixivaptan, and Cardiokine has an option for limited co-promotion in the United States. Under the terms of the agreement, we may pay up to \$150.0 million in remaining development milestone payments as well as royalties on commercial sales.

We have determined that we are the primary beneficiary of Cardiokine in accordance with the guidance provided by the *Consolidation* Topic of the Codification. As such, we consolidate the results of Cardiokine. The assets and liabilities of Cardiokine are not significant as it is a research and development organization. We reimburse Cardiokine for 90% of research and development costs incurred in support of the collaboration. A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2009	2008	2009	2008
Total upfront and milestone payments made to Cardiokine	\$ 20.0		\$ 20.0	
Total expense incurred by the collaboration	\$ 17.2	\$ 15.3	\$ 48.5	\$ 38.9
Biogen Idec Inc. s share of expense reflected within our				
consolidated statements of income	\$ 35.5	\$ 13.8	\$ 63.7	\$ 35.0
Collaboration expense allocated to noncontrolling interests,				
net of tax	\$ 1.7	\$ 1.5	\$ 4.8	\$ 3.9

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	As of September 30, 2009
Total upfront and milestone payments made to Cardiokine	\$ 70.0
Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone payments	\$ 106.8
Estimate of additional expense to be incurred by us in development of the Lixivaptan (all indications)	\$ 430.0

## Biovitrum

We have a collaboration agreement with Biovitrum AB, or Biovitrum, to jointly develop and commercialize Factor VIII and Factor IX for the treatment of hemophilia. Under the agreement, development costs are shared equally. We have commercial rights to North America and Biovitrum has commercial rights to Europe. Each party shares in the other s net sales based on a royalty percentage of up to 33.3%. All other territories are to be managed by a third party with us and Biovitrum sharing equally in all royalties, license fees and other revenues arising from arrangements with third party licenses and distributors.

Amounts incurred by us in the development of the Factor XIII and Factor IX are reflected as research and development expense in our consolidated statements of income, reduced by amounts due from Biovitrum. A

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## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

summary of collective activity related to the Factor VIII and Factor IX programs for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2009	2008	2009	2008
Total expense incurred by the collaboration Biogen Idec Inc. s share of expense reflected within our	\$ 6.8	\$ 8.4	\$ 33.2	\$ 26.9
consolidated statements of income	\$ 3.4	\$ 4.2	\$ 16.6	\$ 13.5

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	As of September 30, 2009
Total upfront and milestone payments received from Biovitrum	\$ 4.0
Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone	
payments	\$ 44.8
Estimate of additional expense to be incurred by the collaboration in development of Factors XIII	
and IX	\$ 95.0

Under the agreement, Biovitrum may pay us an additional \$19.0 million in milestone payments.

#### Mondo

We have an agreement with MondoGen, or Mondo, a subsidiary of MondoBiotech AG, to develop and commercialize Aviptadil, a clinical compound for the treatment of pulmonary arterial hypertension, or PAH. Under the agreement, we are responsible for manufacturing, development, and commercialization of the compound and could incur up to \$30.0 million in milestone payments for successful development and commercialization of the program in the United States and Europe, as well as royalty payments on commercial sales. In February 2009, the parties revised the agreement to clarify that our development funding obligation should not exceed \$13.3 million, inclusive of all amounts incurred during 2009 and the three months ended December 31, 2008, if we decide not to pursue the collaboration beyond 2009.

We have determined that we are the primary beneficiary of Mondo, and as such, we consolidate the results of Mondo. The assets and liabilities of Mondo are not significant as it is a research and development organization. Expenses incurred by the collaboration are reflected in research and development expense in our consolidated statements of

# income.

A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(In millions)	2009	2008	2009	2008
Total expense incurred by the collaboration Total expense reflected within our consolidated statements	\$ 4.0	\$ 2.7	\$ 10.9	\$ 11.7
of income	\$ 4.0	\$ 2.7	\$ 10.9	\$ 11.7
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#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	As of September 30, 2009
Total upfront and milestone payments made to Mondo	\$ 7.5
Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone payments	\$ 40.8

#### **UCB**

In June 2009, UCB, S.A., or UCB, and we announced the discontinuation of the Phase 2 clinical trial for this collaboration s only product candidate due to the absence of clinically relevant efficacy. Since the inception of our collaboration agreement with UCB, we have incurred a total of \$98.0 million in research and development expenses for the development and commercialization of an oral alpha4 integrin, or VLA-4, antagonist for the treatment of relapsing remitting MS.

A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	Month	e Three s Ended aber 30,	For the Nine Months Ended September 30,				
(In millions)	2009	2008	2009	2008			
Total expense incurred by the collaboration Biogen Idec Inc. s share of expense reflected within our	\$ 5.3	\$ 7.2	\$ 27.7	\$ 23.7			
consolidated statements of income	\$ 3.7	\$ 5.0	\$ 18.0	\$ 15.3			

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	As of September 30, 2009
Total upfront and milestone payments made to UCB	\$ 30.0 \$ 68.0

Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone payments

Estimate of additional expense to be incurred by us in development of the compound in this indication

\$ 4.5

## Facet Biotech

We have a collaboration agreement with Facet aimed at advancing the development and commercialization of daclizumab in MS and volociximab in solid tumors. Daclizumab is a humanized monoclonal antibody that binds to the IL-2 receptor on activated T cells. Volociximab is an anti-angiogenic chimeric antibody directed against alpha5 beta1 integrin, or VLA5. Under the agreement, development, and commercialization costs and profits are shared equally. We may incur up to an additional \$650.0 million of payments upon achievement of development and commercial milestones.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	Moi	the Three nths Ended tember 30,	Montl	For the Nine Months Ended September 30,				
(In millions)	2009	2008	2009	2008				
Total expense incurred by the collaboration Biogen Idec Inc. s share of expense reflected within our	\$ 10.6	\$ 13.3	\$ 28.3	\$ 52.9				
consolidated statements of income	\$ 5.3	\$ 6.7	\$ 14.2	\$ 26.4				

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	Sept	As of tember 30, 2009
Total upfront and milestone payments made to Facet	\$	50.0
Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone		
payments	\$	115.1
Estimate of additional expense to be incurred by us in development of current indications of		
daclizumab and volociximab	\$	500.0

On September 21, 2009, we commenced a tender offer to acquire all of the outstanding shares of Facet for approximately \$356.0 million or \$14.50 per share in cash. On October 16, 2009, we extended the offer to December 16, 2009 at the same offering price of \$14.50 per share. Our all-cash proposal is not subject to any financing contingency or approval by Biogen Idec shareholders. We may incur additional costs to complete this transaction in the event that this tender offer is successfully completed. We do not expect these additional transaction costs to be material to our financial position or results of operations.

#### **Vernalis**

We have a collaboration agreement with Vernalis plc, or Vernalis, aimed at advancing the development and commercialization of an adenosine A2a receptor antagonist for treatment of Parkinson's disease. Under the agreement, we received exclusive worldwide rights to develop and commercialize the compound. We are responsible for funding all development costs and may incur up to an additional \$85.0 million of milestone payments upon achievement of certain objectives, as well as royalties on commercial sales.

A summary of activity related to this collaboration for the three and nine months ended September 30, 2009 and 2008, respectively, is as follows:

	Month	e Three s Ended nber 30,	For the Nine Months Ended September 30,		
(In millions)	2009	2008	2009	2008	
Total expense incurred by the collaboration and reflected within our consolidated statements of income	\$ 3.3	\$ 4.4	\$ 10.4	\$ 13.2	
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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

A summary of activity related to this collaboration since inception, along with an estimate of additional future development expense expected to be incurred by us, is as follows:

(In millions)	Sept	As of ember 30, 2009
Total upfront and milestone payments made to Vernalis	\$	13.0
Total development expense incurred by Biogen Idec Inc., excluding upfront and milestone payments	\$	65.3
Estimate of additional expense to be incurred by us in development of the compound in this		
indication	\$	230.0

## 15. Litigation

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in some 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, or the Three County Actions are the subject of a Consolidated Complaint, first filed on September 15, 2005 in the U.S. District Court for the District of Massachusetts in Multi-District Litigation No. 1456, or the MDL proceedings. The complaints allege that the defendants (i) fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement, or the 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, some of the plaintiffs claims were dismissed, and the parties, including Biogen Idec, began a mediation of the outstanding claims 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.

On September 12, 2006, the Massachusetts Department of Revenue, or the DOR, issued a notice of assessment against Biogen Idec MA, Inc. for \$38.9 million of corporate excise tax with respect to the 2002 tax year, which includes associated interest and penalties. On December 6, 2006, we filed an abatement application with the DOR, seeking abatements for 2001, 2002 and 2003 tax years. The abatement application was denied on July 24, 2007. On July 25, 2007, we filed a petition with the Massachusetts Appellate Tax Board, seeking, among other items, abatements of

corporate excise tax for 2001, 2002 and 2003 tax years and adjustments in certain credits and credit carryforwards for 2001, 2002 and 2003 tax years. Issues before the Board include the computation of Biogen Idec MA s sales factor for 2001, 2002 and 2003 tax years, 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 anticipate that the trial will take place in 2010. We intend to contest this matter vigorously.

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 United States in collaboration

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

with Genentech. Genentech has disclosed that it is cooperating with the associated investigation, and that it has been advised the investigation is civil in nature. We are cooperating with the 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.

On October 27, 2008, Sanofi-Aventis Deutschland GmbH, or Sanofi, filed suit against Genentech and Biogen Idec in federal court in Texas (E.D. Tex.), which we refer to as the Texas Action claiming that RITUXAN and certain other Genentech products infringe U.S. Patents 5,849,522, or the 522 patent, and 6,218,140, or the 140 patent. Sanofi seeks preliminary and permanent injunctions, compensatory and exemplary damages, and other relief. On October 27, 2008, Genentech and Biogen Idec filed a complaint against Sanofi, Sanofi-Aventis U.S. LLC, and Sanofi-Aventis U.S. Inc. in federal court in California (N.D. Cal.), which we refer to as the California Action seeking a declaratory judgment that RITUXAN and other Genentech products do not infringe the 522 patent or the 140 patent, and a declaratory judgment that those patents are invalid. On May 22, 2009, the United States Court of Appeals for the Federal Circuit granted Genentech s and our petition for a writ of mandamus transferring the Texas Action to the federal court in California, and denied Sanofi s petition for rehearing on August 10, 2009. In addition, on October 24, 2008, Hoechst GmbH filed with the ICC International Court of Arbitration (Paris) a request for arbitration against Genentech, relating to a terminated agreement between Hoechst s predecessor and Genentech that pertained to the above-referenced patents and related patents outside the U.S. Hoechst is seeking payment of royalties on sales of Genentech products, damages for breach of contract, and other relief. 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 matters 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 against the allegations against us.

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.

# 16. Segment Information

We operate in one business segment, which is the business of development, manufacturing and commercialization of novel therapeutics for human health care and therefore, our chief operating decision-maker manages the operation of the Company as a single operating segment.

# 17. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company s management believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

#### Recently Issued Accounting Standards

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, *Measuring Liabilities at Fair Value*, or ASU 2009-05. ASU 2009-05 amends Accounting Standards Codification Topic 820, *Fair Value Measurements*. Specifically, ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of Topic 820 of the

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#### **BIOGEN IDEC INC. AND SUBSIDIARIES**

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

Accounting Standards Codification (e.g. an income approach or market approach). ASU 2009-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. The adoption of this standard did not have an impact on our financial position or results of operations; however, this standard may impact us in future periods.

In September 2009, the FASB issued ASU No. 2009-12, *Fair Value Measurements and Disclosure*, or ASU 2009-12. This standard provides additional guidance on using the net asset value per share, provided by an investee, when estimating the fair value of an alternate investment that does not have a readily determinable fair value and enhances the disclosures concerning these investments. Examples of alternate investments, within the scope of this standard, include investments in hedge funds and private equity, real estate, and venture capital partnerships. This Standard is effective for interim and annual periods ending after December 15, 2009. At of September 30, 2009, our only investments falling within the scope of this Standard are our venture capital investments. For these investments we use the net asset value to assess fair value. Refer to Note 5, *Fair Value Measurements*, of this Form 10-Q for additional disclosure related to our venture capital investments. We are currently evaluating the potential impact of this standard on our financial position and results of operations.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Accounting Standards Codification, or ASC, Subtopic 605-25 (previously included within EITF 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-01, Revenue Arrangements with Multiple Deliverables, or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard on our financial position and results of operations.

# Other Recently Issued Accounting Standards

In June 2009, the FASB issued the following two new accounting standards, which have not yet been integrated into the Codification. Accordingly, these accounting standards will remain authoritative until integrated:

SFAS No. 166, Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140, or SFAS 166; and

SFAS No. 167, Amendments to FASB Interpretation No. 46 (R), or SFAS 167

SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor s continuing involvement in transferred financial assets. Specifically, among other

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

aspects, this standard amends previously issued accounting guidance, modifies the financial-components approach and removes the concept of a qualifying special purpose entity when accounting for transfers and servicing of financial assets and extinguishments of liabilities, and removes the exception from applying the general accounting principles for the consolidation of variable interest entities that are qualifying special-purpose entities. This new accounting standard is effective for transfers of financial assets occurring on or after January 1, 2010. We have not determined the effect that the adoption of SFAS 166 will have on our financial position or results of operations but the effect will generally be limited to future transactions.

SFAS 167 amends previously issued accounting guidance for the consolidation of variable interest entities to require an enterprise to determine whether its variable interest or interests give it a controlling financial interest in a variable interest entity. This amended consolidation guidance for variable interest entities also replaces the existing quantitative approach for identifying which enterprise should consolidate a variable interest entity, which was based on which enterprise is exposed to a majority of the risks and rewards, with a qualitative approach, based on which enterprise has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of the entity that could potentially be significant to the variable interest entity or the right to receive benefits from the entity that could potentially be significant to the variable interest entity. This new standard has broad implications and may affect how we account for the consolidation of common structures, such as joint ventures, equity method investments, collaboration and other agreements and purchase arrangements. Under this revised guidance, more entities may meet the definition of a variable interest entity, and the determination about who should consolidate a variable interest entity is required to be evaluated continuously. We are evaluating all entities that fall within the scope of the amended guidance to determine whether we may be required to consolidate additional entities or deconsolidate existing consolidated entities on January 1, 2010, which is the effective date of SFAS 167; however we have not yet completed our implementation analysis. Accordingly, we have not determined the effect that the adoption of this standard will have on our financial position or results of operation.

#### Recently Adopted Accounting Standards

Effective January 1, 2009, we adopted a newly issued accounting standard for business combinations. This standard requires an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPR&D and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. Due to the fact that this guidance is applicable to acquisitions completed after January 1, 2009 and we did not have any business combinations in the first nine months of 2009, the adoption did not impact our financial position or results of operations. The standard also amended accounting for uncertainty in income taxes as required by the *Income Tax* Topic of the Codification. Previously, accounting standards generally required post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions to be recorded as an increase or decrease to goodwill. This new standard does not permit this accounting and, generally, requires any such changes to be recorded in current period income tax expense. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting, whether the business combination was accounted for under this guidance, will be recognized in current period income tax expense.

In April, 2009, the FASB issued a new accounting standard providing guidance for the accounting of assets acquired and liabilities assumed in a business combination that arise from contingencies, This guidance amends and clarifies previous accounting standards to address application issues regarding the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. Due to the fact that this guidance is applicable to acquisitions completed after January 1, 2009 and we did not have any business combinations in the first nine months of 2009, the adoption did not impact our financial position or results of operations.

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#### BIOGEN IDEC INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, continued)

In June 2009, the SEC issued Staff Accounting Bulletin No. 112, which updates the SEC s rules and regulations to be consistent with the accounting principles and standards established with guidance issued by the FASB during 2009 related to the measurement of assets and liabilities assumed at fair value as of the acquisition date and the reporting of amounts associated with noncontrolling interests. This bulletin did not impact our financial position or results of operations; however, the adoption of this new accounting resulted in the reclassification of certain prior period amounts related to noncontrolling interests to conform to the current financial statement presentation.

In April 2009, the Securities and Exchange Commission, or SEC, issued Staff Accounting Bulletin No. 111 which aligns SEC regulations to the accounting standards issued by the FASB during 2009 on accounting for other-than-temporary impairments for marketable debt securities. Specifically, it amends Topic 5.M., *Other Than Temporary Impairment of Certain Investments in Debt and Equity Securities*, to exclude debt securities from its scope. This bulletin did not impact our financial position or results of operations; however, we conduct periodic reviews to evaluate our investments for the other-than-temporary impairments in accordance with the *Investments Debt and Equity Securities* Topic of the Codification. Refer to Note 1, *Business Overview*, Note 9, *Equity*, and Note 13, *Other Income (Expense)*, *Net*, of this Form 10-Q for additional information on the adoption of the new accounting standard for noncontrolling interests.

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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 are based on our current beliefs and expectations. These statements 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, expect. forecast. intend. mav. plan. project. target. will and other words and terms of similar meaning. l made in particular to forward-looking statements regarding the anticipated level and mix of future product sales, royalty revenues, milestone payments, expenses, liabilities, the impact of competitive products, the incidence, outcome or impact of litigation, proceedings related to patents and other intellectual property rights, tax assessments and other legal proceedings, our effective tax rate for future periods, the impact of accounting standards, the development and timing of programs in our clinical pipeline, our ability to finance our operations, meet our manufacturing needs and source funding for such activities, the completion and use of our manufacturing facility in Hillerød, Denmark, our share repurchase program, and our plans to spend additional capital on external business development and research opportunities. Important factors which could cause actual results to differ from our expectations and which could negatively impact our financial position 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.

# **Executive Summary**

#### **Business Overview**

Biogen Idec Inc. (Biogen Idec, we, us or the Company) is a global biotechnology company that creates new standa of care in therapeutic areas with high unmet medical needs. Our business strategy is focused on discovering and developing first-in-class or best-in-class products that we can deliver to specialty markets globally. Patients around the world benefit from Biogen Idec s significant products that address medical needs in the areas of neurology, oncology and immunology.

We currently have four marketed products. Our marketed products are used for the treatment of multiple sclerosis, or MS, non-Hodgkin s lymphoma, or NHL, rheumatoid arthritis, or RA, Crohn s disease and psoriasis, and are summarized in the table below.

Product AVONEX® (interferon beta-1a)	<b>Indications</b> Relapsing MS
RITUXAN®* (rituximab)	Certain B-cell NHL RA
TYSABRI®** (natalizumab)	Relapsing MS Crohn s disease

# FUMADERM<sup>TM</sup> (dimethylfumarate and monoethylfumarate salts)

Severe psoriasis

- \* Outside the United States, Canada and Japan, MabThera is the trade name for rituximab. We refer to rituximab, RITUXAN and MabThera collectively as RITUXAN.
- \*\* TYSABRI is indicated in the United States for the treatment of some patients with moderately to severely active Crohn s disease.

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As part of our on-going development efforts, we are seeking to expand our marketed products into treatment of other diseases, such as chronic lymphocytic leukemia, or CLL, ANCA-associated vasculitis, multiple myeloma and ulcerative colitis. In addition to the on-going development of our marketed products, we continue to focus our research and development efforts on finding novel therapeutics in areas of high unmet medical needs, both within our current focus areas of neurology, oncology, immunology and cardiology, as well as in new therapeutic areas.

# Financial Highlights

The following table is a summary of results achieved for the three months ended September 30, 2009 and 2008:

		Ended			
(In millions, except per share amounts and percentages)	nts and percentages) 2				Change %
Total revenues	\$	1,120.5	\$	1,093.0	2.5%
Income from operations	\$	384.2	\$	345.9	11.1%
Net income attributable to Biogen Idec Inc.	\$	277.7	\$	206.8	34.3%
Diluted earnings per share attributable to Biogen Idec Inc.	\$	0.95	\$	0.70	35.7%

Eartha Thuas Mantha Endad

As described below under Results of Operations, our operating results for the three months ended September 30, 2009 were primarily driven by:

Continued TYSABRI growth. TYSABRI provided \$207.0 million of revenue during the third quarter 2009, representing an increase of 20.9% over the same period in the prior year.

Increased AVONEX worldwide revenue. Total AVONEX revenues totaled \$580.0 million in the current period, representing a 1.1% increase over the prior year comparable period.

\$283.9 million in revenues from our unconsolidated joint business; driven by net sales of RITUXAN to third-party customers in the United States recorded by Genentech totaling \$670.4 million during the current period, representing a 2.3% increase over the same period in 2008. Our share of co-promotion profits of RITUXAN in the United States totaled \$203.3 million for the third quarter of 2009, representing an increase of 5.8% over the same period in the prior year. These amounts were offset by a \$25.2 million decrease in our share of co-promotion profits in Canada and royalty revenues on sales of RITUXAN outside of the United States primarily driven by royalty expirations in our rest of world markets.

Excluding the impact of amortization related to our acquired intangible assets, total costs and expenses increased 5.0% as compared to the prior year comparable period. This increase was driven by a 13.1% increase in research and development spending primarily related to the continued advancement of our pipeline and a 39.4% increase in collaboration profit sharing expense due to TYSABRI growth. These increases were partially offset by a 13.0% decrease in costs of sales and a reduction in selling, general and administrative expense of 2.6%. Amortization of acquired intangible assets decreased 45.6% which is further described within in Note 4, *Intangible Assets and Goodwill*, in Notes to Consolidated Financial Statements . Including amortization of acquired intangible assets, total costs and expenses decreased 1.4% over the same period in the prior year.

In addition to the strong operating results achieved for the three months ended September 30, 2009, year to date we generated \$792.7 million of net cash flows from operations, which are primarily driven by increases in our earnings.

Cash and cash equivalents and marketable securities totaled approximately \$2,905.1 million as of September 30, 2009.

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## **Business Highlights**

On October 19, 2009, our Board of Directors authorized the repurchase of our common stock in an amount of up to \$1.0 billion. This is in addition to the 6.0 million shares remaining from our previous share repurchase authorization. We have used the prior share repurchase program principally for share stabilization. This new \$1.0 billion authorization is intended to reduce our shares outstanding, with the objective of returning excess cash to shareholders. The Company intends to retire these shares following repurchase on the open market. This repurchase program does not have an expiration date.

On September 21, 2009, we commenced a tender offer to acquire all of the outstanding shares of Facet Biotech, or Facet, for approximately \$356.0 million or \$14.50 per share in cash. On October 16, 2009, we extended the tender offer to December 16, 2009, unless otherwise extended. The tender offer was previously set to expire on October 19, 2009. The offer price remained unchanged at \$14.50 per share in cash. Our all-cash proposal is not subject to any financing contingency or approval by Biogen Idec shareholders.

Under our current collaboration agreement with Facet, we have been jointly developing daclizumab for the treatment of relapsing multiple sclerosis and volociximab for the treatment of solid tumors. Refer to Note 14, *Collaborations*, in Notes to Consolidated Financial Statements , for additional discussion.

On July 1, 2009, we made a \$110.0 million upfront payment to Acorda Therapeutics, Inc., or Acorda, pursuant to our June 30, 2009 collaboration and license agreement to develop and commercialize products containing Fampridine-SR in markets outside the United States.

# Product and Pipeline Highlights

We currently believe that the risk of developing PML increases with the number of TYSABRI infusions received. We continue to believe the overall rate of developing PML with TYSABRI therapy remains consistent with the rate implied in the label. We have proposed and are currently discussing with regulatory authorities a potential label change to reflect this increased risk of PML with increased duration of TYSABRI exposure.

On October 19, 2009, Biovitrum AB and we announced plans to advance the companies long-acting, fully-recombinant Factor IX Fc fusion protein (rFIXFc) into a registrational clinical trial in hemophilia B patients. The decision to advance the program was based on data from a Phase 1/2a open-label, multi-center, safety dose-escalation and pharmacokinetic study of intravenous rFIXFc in severe, previously treated hemophilia B patients. rFIXFc was well tolerated in the study. In addition, rFIXFc demonstrated a prolonged half-life compared to historical data for existing therapies, supporting advancement of the program.

We and Genentech, Inc., or Genentech, a member of the Roche Group, previously submitted a supplemental Biologics License Application, or sBLA, to the U.S. Food and Drug Administration, or FDA, seeking to extend the RITUXAN label to a broader DMARD-IR population. On October 16, 2009, the FDA issued a Complete Response expressing concern related to the prolonged nature of RITUXAN-mediated B-cell depletion and the risk for PML in a less refractory RA population than that covered by our current label. We expect to meet with the FDA to discuss risk-benefit for RITUXAN in a less refractory RA population and determine the appropriate next steps.

In September 2009, we were issued U.S. patent no. 7,588,755 for the use of beta interferon for immunomodulation or treating a viral condition, viral disease, cancers or tumors. The patent expires in September 2026. This patent covers the treatment of multiple sclerosis with AVONEX, which is our brand of

recombinant beta interferon.

In September 2009, Genentech and we announced that a Phase 3 study (PRIMA) met its endpoint during a pre-planned interim analysis, and the study was stopped early on the recommendation of an independent data and safety monitoring board. The primary endpoint was progression-free survival of patients with follicular lymphoma who continued receiving RITUXAN alone after responding to RITUXAN and

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chemotherapy compared to those who did not continue to receive RITUXAN. The safety profile of RITUXAN observed in the study was consistent with that previously reported.

In August 2009, Facet announced its continued plans for the Phase 3 trial of daclizumab high-yield process in MS and that it would request a Special Protocol Assessment from the FDA prior to the initiation of this study. The Phase 3 trial is expected to begin during the first half of 2010. Upon enrollment of the first patient into the Phase 3 study, Facet would receive a \$30.0 million milestone payment from us.

In July 2009, the FDA granted PEGylated interferon beta-1a Fast Track designation for relapsing MS. We are currently enrolling patients in a global Phase 3 study evaluating the efficacy and safety of either bi-weekly or once-monthly injections of PEGylated interferon beta-1a in this patient population. The FDA s Fast Track program is designed to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

In July 2009, Cardiokine enrolled the 300th patient in the Phase 3 clinical trial for Lixivaptan. We made a \$20.0 million payment to Cardiokine upon achievement of this milestone which was included within research and development expense in the quarter ended September 30, 2009.

Acorda previously announced that the European Medicines Agency, or EMEA, notified Acorda that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application via the EMEA s Centralized Procedure as a new active substance.

Additional information about our product pipeline appears under the heading Research and Development in Management s Discussion and Analysis of Financial Condition and Results of Operations of this quarterly report on Form 10-Q.

#### **Results of Operations**

#### Revenues

Revenues were as follows:

	For t	the Three N Septeml	nths Ended 30,	F	or the Nine	e Months I	End	led Septem	ber 30,		
n millions, except percentages)	2009			2008			2009			2008	
oduct revenues											
nited States	\$ 407.8	36.4%	\$	380.6	34.8%	\$	1,223.9	37.7%	\$	1,084.8	35.89
est of world	393.9	35.2%		377.7	34.6%		1,102.2	33.9%		1,023.0	33.89
otal product revenues	\$ 801.7	71.6%	\$	758.3	69.4%	\$	2,326.1	71.6%	\$	2,107.8	69.69
nconsolidated joint business	283.9	25.3%		299.0	27.3%		838.3	25.8%		825.0	27.29
ther revenues	34.9	3.1%		35.7	3.3%		85.9	2.6%		95.8	3.29
otal revenues	\$ 1 120 5	100.0%	\$	1 093 0	100.0%	\$	3 250 3	100.0%	\$	3 028 6	100.09

#### **Product Revenues**

Product revenues were as follows:

(In millions, except percentages)  AVONEX		For th	e Three I Septem		nths Ende	ed	For t	ths Ended 30,				
	2009			2008			2009			2008		
	\$	580.0	72.3%	\$	573.5	75.6%	\$ 1,726.5	74.2%	\$	1,636.8	77.7%	
TYSABRI		207.0	25.8%		171.2	22.6%	559.8	24.1%		433.0	20.5%	
FUMADERM		12.6	1.6%		11.1	1.5%	35.4	1.5%		32.8	1.6%	
Other		2.1	0.3%		2.5	0.3%	4.4	0.2%		5.2	0.2%	
Total product revenues	\$	801.7	100.0%	\$	758.3	100.0%	\$ 2,326.1	100.0%	\$	2,107.8	100.0%	

#### **AVONEX**

We currently market and sell AVONEX for the treatment of relapsing MS, including patients with a first clinical episode and MRI features consistent with MS. AVONEX has been shown in clinical trials in relapsing MS both to slow the accumulation of disability and to reduce the frequency of flare-ups.

Revenues from AVONEX were as follows:

	H			e Month mber 30		For the Nine Months Ended September 30,					
(In millions, except percentages)	2009		2008		Change %		2009		2008	Change %	
AVONEX United States Rest of world	\$	348.5 231.5	\$	321.9 251.6	8.3% (8.0)%	\$	1,054.2 672.3	\$	935.9 700.9	12.6% (4.1)%	
Total AVONEX revenues	\$	580.0	\$	573.5	1.1%	\$	1,726.5	\$	1,636.8	5.5%	

The increase in revenues from the sales of AVONEX in the United States for both the three and nine months ended September 30, 2009, as compared to the prior year comparative periods, was primarily due to price increases, partially offset by decreased patient demand and participation in our AVONEX Access Program, which provides free product to eligible patients.

Revenues from the sale of AVONEX within our rest of world markets decreased for both the three and nine months ended September 30, 2009, as compared to the same periods in the prior year, primarily due to the negative impact of foreign currency exchange rate changes, partially offset by price increases and increased patient demand.

We expect to face increasing competition in the MS marketplace in both the United States and rest of world from existing and new MS treatments, including oral and other alternative formulations developed by our competitors, the

continued growth of TYSABRI and the commercialization of our other pipeline product candidates, which may have a continued negative impact on the unit sales of AVONEX. We expect future unit sales of AVONEX to be dependent to a large extent on our ability to compete successfully with the products of our competitors.

# **TYSABRI**

In August 2000, we entered into a collaboration agreement with Elan Pharma International, Ltd, or Elan, an affiliate of Elan Corporation, plc. Under the terms of the agreement with Elan, we manufacture TYSABRI and collaborate with Elan on the product s marketing, commercial distribution and on-going development activities. TYSABRI is sold as a monotherapy treatment for relapsing MS to slow the progression of disability and reduce the frequency of clinical relapses.

TYSABRI is marketed under risk management or minimization plans as agreed to with local regulatory authorities. In the United States, TYSABRI was reintroduced with a risk minimization action plan known as

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the TOUCH Prescribing Program, a rigorous system intended to educate physicians and patients about the risks involved and help assure appropriate use of the product. Since the reintroduction of TYSABRI to the market in July 2006, we have disclosed cases of progressive multifocal leukoencephalopathy, or PML, a known side effect, in patients taking TYSABRI in the post-marketing setting. We currently believe that the risk of developing PML increases with the number of TYSABRI infusions received. We continue to believe the overall rate of developing PML with TYSABRI therapy remains consistent with the rate implied in the label. We have proposed and are currently discussing with regulatory authorities a potential label change to reflect this increased risk of PML with increased duration of TYSABRI exposure.

We continue to monitor the growth of TYSABRI unit sales in light of these results and we continue to develop protocols to potentially mitigate the outcome of PML in patients being treated with TYSABRI. We believe that the reported cases of PML have slowed the growth of TYSABRI in both the United States and rest of world.

In the United States, we sell TYSABRI to Elan who sells the product to third party distributors. Our sales price to Elan in the United States is set prior to the beginning of each quarterly period to effect an approximate equal sharing of the gross margin on sales in the United States between Elan and us. We recognize revenue for sales of TYSABRI in the United States upon Elan s shipment of the product to the third party distributors. In the rest of world markets, we are responsible for distributing TYSABRI to customers and are primarily responsible for all operating activities. We recognize revenue for sales of TYSABRI in the rest of world at the time of product delivery to our customers.

Revenues from TYSABRI were as follows:

	]	For the Three Months Ended September 30,						For the Nine Months Ended September 30,			
(In millions, except percentages)	2009		2008		Change %		2009		2008	Change %	
TYSABRI United States Rest of world	\$	59.3 147.7	\$	56.2 115.0	5.5% 28.4%	\$	169.7 390.1	\$	144.0 289.0	17.8% 35.0%	
Total TYSABRI revenues	\$	207.0	\$	171.2	20.9%	\$	559.8	\$	433.0	29.3%	

The increase in revenues from the sale of TYSABRI in the United States, as compared to the prior year comparative periods, during the three and nine months ended September 30, 2009, were primarily due to an increase in number of patients using TYSABRI in the United States.

Net sales of TYSABRI from our collaboration partner, Elan, to third-party customers in the United States for the three and nine months ended September 30, 2009 totaled \$130.7 million and \$371.1 million, respectively, as compared to \$121.5 million and \$307.0 million, respectively, in the prior year comparative periods.

Rest of world sales of TYSABRI for the three and nine months ended September 30, 2009, increased as compared to the same periods in the prior year, primarily due to an increase in number of patients using TYSABRI in the United States, partially offset by the negative impact of foreign currency exchange rate changes. TYSABRI rest of world revenues for the three and nine months ended September 30, 2009 also include losses of \$4.2 million recognized in relation to the settlement of certain cash flow hedge instruments.

In accordance with our collaboration agreement, Elan has paid to us milestone payments totaling \$125.0 million. We have recorded these amounts as deferred revenue upon receipt which is being recognized as product revenue in our consolidated statements of income over the term of our collaboration with Elan based 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 remaining term of the collaboration. The following table summarizes the amount of these milestone payments recognized as revenue for the three and nine months ended September 30, 2009 and 2008:

	For the Three Months Ended September 30,					I		the Nine Months Ended September 30,			
(In millions, except percentages)	20	09	2	008	Change %	20	009	2	008	Change %	
Revenue recognized from milestone payments	\$	1.9	\$	0.6	216.7%	\$	5.1	\$	0.6	750.0%	
				50							

#### **Unconsolidated Joint Business Revenue**

We collaborate with Genentech on the development and commercialization of RITUXAN which is approved for treating certain B-cell NHL and RA. While Genentech is responsible for the worldwide manufacturing of RITUXAN, development and commercialization rights and responsibilities under this collaboration are divided between us and Genentech as described in Note 14, *Collaborations*, in Notes to Consolidated Financial Statements

Revenues from unconsolidated joint business consists of (1) our share of pretax co-promotion profits in the United States; (2) reimbursement of selling and development expense in the United States; and (3) revenue on sales of RITUXAN outside the United States, which consist of our share of pretax co-promotion profits in Canada and royalty revenue on sales of RITUXAN outside the United States and Canada by F. Hoffmann-La Roche Ltd., or Roche, Zenyaku Kogyo, Inc., or Zenyaku and Chugai Pharmaceutical Co. Ltd., or Chugai, an affiliate of Roche. Pre-tax co-promotion profits are calculated and paid to us by Genentech in the United States and by Roche in Canada. Pre-tax co-promotion profits consist of United States and Canadian sales of RITUXAN to third-party customers net of discounts and allowances less the cost to manufacture RITUXAN, third-party royalty expenses, distribution, selling and marketing, and joint development expenses incurred by Genentech, Roche and us.

The following table provides a summary of revenues from unconsolidated joint business for the three and nine months ended September 30, 2009 and 2008, respectively:

		For the Three Months Ended For the September 30,					Nine Months Ended September 30,		
<i>a</i>	2000		2000	Change		•000		****	Change
(In millions, except percentages)	2009		2008	%		2009		2008	<b>%</b>
Biogen Idec Inc. s share of co-promotion profits in the United States Reimbursement of selling and development expense in the United States Revenue on sales of RITUXAN	\$ 203.3	\$	192.2 16.8	5.8%	\$	581.3 47.5	\$	527.9 45.4	10.1% 4.6%
outside the United States	64.8		90.0	(28.0)%		209.5		251.7	(16.8)%
Total unconsolidated joint business revenues	\$ 283.9	\$	299.0	(5.1)%	\$	838.3	\$	825.0	1.6%

# Biogen Idec Inc. s Share of Co-promotion Profits in the United States

The following table provides a summary of amounts comprising our share of co-promotion profits in the United States:

	For the Three Months Ended September 30,				r the Nine Months End September 30,		
		· <b>P</b> · · · · · · ·	Change	_	- F	Change	
(In millions, except percentages)	2009	2008	<b>%</b>	2009	2008	<b>%</b>	

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Product revenues, net Costs and expenses	\$ 670.4 167.3	\$ 655.4 182.3	2.3% (8.2)%	\$ 2,008.0 547.2	\$ 1,910.8 586.1	5.1% (6.6)%
Co-promotion profits in the United States	\$ 503.1	\$ 473.1	6.3%	\$ 1,460.8	\$ 1,324.7	10.3%
Biogen Idec Inc. s share of co-promotion profits in the United States	\$ 203.3	\$ 192.2	5.8%	\$ 581.3	\$ 527.9	10.1%
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The increase in net sales of RITUXAN to third-party customers in the United States recorded by Genentech for the three and nine months ended September 30, 2009 as compared to the prior year comparative periods resulted from continued growth for treatment of B-cell NHL and RA, and RITUXAN price increases.

Total collaboration costs and expenses for the three and nine months ended September 30, 2009 as compared to the same periods in the prior year decreased primarily due to higher costs incurred in development of RITUXAN for use in other indications during the prior year.

Under the collaboration agreement, our current pretax co-promotion profit-sharing formula, which resets annually, provides for a 30% share of co-promotion profits on the first \$50.0 million of co-promotion operating profit with our share increasing to 40% if co-promotion operating profits exceed \$50.0 million. In 2009 and 2008, the 40% threshold was met during the first quarter.

In addition, under the collaboration agreement, we also have rights to collaborate with Genentech on the development and commercialization of (1) anti-CD20 products that Genentech acquires or develops, which we refer to as New Anti-CD20 Products, and (2) anti-CD20 products that Genentech licenses from a third party, which we refer to as Third Party Anti-CD20 Products. Our collaboration rights for New Anti-CD20 Products are limited to the United States and our collaboration rights for Third Party Anti-CD20 Products are dependent upon Genentech s underlying license rights. Currently, there is only one New Anti-CD20 Product, ocrelizumab, and only one Third Party Anti-CD20 Product, GA101.

Our agreement with Genentech also provides that the successful development and commercialization of the first New Anti-CD20 Product will decrease our percentage of co-promotion profits of the collaboration. Refer to Note 14, *Collaborations*, in Notes to Consolidated Financial Statements , for a detailed discussion of the pretax co-promotion profit sharing formula for RITUXAN and New Anti-CD20 Products sold by us and Genentech following the approval date of the first New Anti-CD20 Product. We will participate in Third Party Anti-CD20 Products on similar financial terms as for ocrelizumab.

#### Reimbursement of Selling and Development Expense in the United States

As discussed within Note 14, *Collaborations*, in Notes to Consolidated Financial Statements , Genentech incurs the majority of continuing development costs for RITUXAN. Expenses incurred by Genentech in the development of RITUXAN are not recorded as research and development expense, but rather reduce our share of co-promotion profits recorded as a component of unconsolidated joint business revenue.

Selling and development expenses incurred by us in the United States and reimbursed by Genentech for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008 have decreased slightly due to decreases in costs associated with the development of RITUXAN for use in RA.

The increase in selling and development expenses incurred by us in the United States and reimbursed by Genentech for the nine months ended September 30, 2009 as compared to the same period in the prior year are primarily to the result of increased clinical development and marketing expenses.

#### Revenue on sales of RITUXAN outside the United States

Revenues on sales of RITUXAN outside the United States decreased compared to the prior year comparative periods primarily due to royalty expirations in certain of our rest of world markets and the negative impact of foreign currency exchange rate changes.

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 continue to expect a significant decrease in royalty revenues on sales of RITUXAN outside the United States and Canada in the latter half of 2009. Specifically, the royalty periods with respect to sales in France, Spain, Germany and the United Kingdom expire in 2009 and in 2010 with respect to sales in Italy. The royalty periods with respect to sales in other countries will subsequently expire through 2012. As a result of these expirations, we expect a significant decline in royalty

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revenues derived from sales of RITUXAN outside the United States in the fourth quarter of 2009 and in future periods.

We record our royalty revenue and co-promotion profit revenue on sales of RITUXAN outside the United States on a cash basis.

#### Other Revenues

Our product line previously included ZEVALIN (ibritumomab tiuxetan), which is part of a treatment regimen for certain B-cell NHL, and AMEVIVE (alefacept), a treatment for certain moderate to severe psoriasis. We have sold or exclusively licensed the rights to these products to third parties and continue to receive royalty or supply agreement revenues based on those products. We also receive royalties on sales by our licensees of a number of other products covered under patents that we control.

Other revenues were as follows:

		For the Three Months Ended Fo September 30,						he Nine Months Ended September 30,				
(In millions, except percentages)  Royalty revenues		Change							Change			
	2	2009	2	2008	<b>%</b>	2	2009	2	2008	<b>%</b>		
	\$	34.5	\$	35.1	(1.7)%	\$	83.6	\$	87.3	(4.2)%		
Corporate partner revenues		0.4		0.6	(33.3)%		2.3		8.5	(72.9)%		
Total other revenues	\$	34.9	\$	35.7	(2.2)%	\$	85.9	\$	95.8	(10.3)%		

#### Royalty Revenues

We receive revenues from royalties on sales by our licensees of a number of products covered under patents that we control and are dependent upon sales of licensed products which could vary significantly due to competition, manufacturing difficulties and other factors, including the timing and extent of major events such as new indication approvals or government sponsored programs. In addition, the expiration or invalidation of any underlying patents could reduce or eliminate the royalty revenues derived from such patents.

Royalty revenues decreased for the three and nine months ended September 30, 2009 as compared to the prior year comparative periods primarily due to an overall decline in royalties from sales of licensed product as well as the expiration of a license agreement, partially offset by increased sales of ANGIOMAX® (bivalirudin) licensed to The Medicines Company, or TMC.

Our most significant source of royalty revenue is derived from sales of ANGIOMAX by TMC. TMC sells ANGIOMAX in the United States, Europe, Canada, and Latin America for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. Royalty revenues related to the sales of ANGIOMAX are recognized in an amount equal to the level of net sales achieved during a calendar year multiplied by the royalty rate in effect under our royalty agreement with TMC. The royalty rate increases based upon the level of total net sales earned in any calendar year, and the increased rate is applied retroactively to the first dollar of net sales achieved during the year. This formula has the effect of increasing the amount of royalty revenue to be recognized in periods subsequent to the first period of each calendar year in which

increased royalty revenues were recognized. Accordingly, an adjustment is recorded in the period in which a change in royalty rate has been achieved.

Under the terms of the royalty agreement, TMC is obligated to pay us royalties earned, on a country-by-country basis, until the later of (1) twelve years from the date of the first commercial sale of ANGIOMAX in such country and (2) the date upon which the product is no longer covered by a patent in such country. The annual royalty rate is reduced by a specified percentage in any country where the product is no longer covered by a patent and has been reduced to a certain volume-based market share. TMC began selling ANGIOMAX in the United States in January 2001. The principal U.S. patent that covers ANGIOMAX expires in March 2010. Marketing exclusivity is due to expire in September 2010, due to a grant of pediatric exclusivity.

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## Corporate Partner Revenues

Corporate partner revenues represent contract revenues, such as those generated by ZEVALIN and AMEVIVE, and license fees.

## **Costs and Expenses**

# Cost of Sales, Excluding Amortization of Acquired Intangible Assets

	For the	e Three Mon September :		For the Nine Months Ended September 30,			
(In millions, except percentages)	2009	2008	Change %	2009	2008	Change %	
Cost of sales, excluding amortization of acquired intangible assets	\$ 93.5	\$ 107.5	(13.0)%	\$ 282.4	\$ 300.8	(6.1)%	

The decrease in cost of sales, excluding amortization of intangible assets for both the three and nine months ended September 30, 2009 as compared to the comparative periods in the prior year was primarily due to decreased write-downs from unmarketable inventory and decreased royalty payments, partially offset by higher sales volume.

## Write-downs from Unmarketable Inventory

Amounts written down related to unmarketable inventory are charged to cost of sales, excluding amortization of acquired intangible assets. Amounts written-down related to unmarketable inventory were as follows:

	For th	e Three Moi September		For th	For the Nine Months Ended September 30,			
(In millions, except percentages)	2009	2008	Change %	2009	2008	Change %		
Write-downs from unmarketable inventory	\$ 2.0	\$ 12.6	(84.1)%	\$ 13.4	\$ 22.5	(40.4)%		

# **Research and Development**

		Three Month September 30			For the Nine Months En September 30,			
(In millions, except percentages)	2009	2008	Change %	2009	2008	Change %		
Research and development	\$ 304.1	\$ 268.8	13.1%	\$ 1,000.0	\$ 779.3	28.3%		

We devote significant resources to research and development programs focusing our efforts on finding novel therapeutics in areas of high unmet medical need, both within our current core focus areas of neurology, oncology, immunology and cardiology as well as in new therapeutic areas. Over the past few years, we have incurred significant expenditures related to the development of new product candidates and exploring the utility of our existing products in treating disorders beyond those currently approved in their labels. Costs associated with later stage clinical trials are,

in most cases, more significant than those incurred in earlier stages of our pipeline. As of September 30, 2009, including our RITUXAN product candidates, we had more than 20 pipeline products in Phase 2 trials or beyond.

Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities including salaries and benefits, facilities expenses, overhead expenses, clinical trial and related clinical manufacturing expenses, fees paid to clinical research organizations, or CROs, and other outside expenses. Research and development expenses are expensed as incurred. The timing of upfront fees and milestone payments in the future may cause variability in future research and development expense.

The increase in research and development expense for the three and nine months ended September 30, 2009 as compared to the comparable periods in the prior year was driven by the continued advancement of

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several of our later stage product candidates, partially offset by a reduction in spending across several other programs including Baminercept in RA which we terminated in October of 2008. The increase in expense for the nine months ended September 30, 2009, as compared to the same period in the prior year is also attributable to the \$110.0 million upfront payment made to Acorda under a recent collaboration and license agreement.

A summary of milestone and upfront payments made to our collaboration partners and included within research and development expense were as follows:

	-			e Months ember 30,			For the Nine Months Ended September 30,			
(In millions)	2	2009	2	2008	Change %		2009	2	2008	Change %
Total milestone and upfront payments reflected within research and development	,	22.0	<b>d</b>		200.05	Φ.	151.0	Φ.	161	007.00
expense	\$	22.0	\$	5.5	300.0%	\$	151.0	\$	16.1	837.9%

We have a number of pipeline products in registrational stage development, including:

BG-12 for relapsing MS;

Humanized Anti-Cd20 MAb (ocrelizumab) for RA;

Lixivaptan for hyponatremia commonly seen in acute decompensated heart failure; and

PEGylated interferon beta 1 a for relapsing MS.

In addition to the registrational product indications listed above:

Acorda, our collaboration partner in the development and commercialization of products containing Fampridine-SR in markets outside the United States, previously announced that the EMEA has communicated that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application via the EMEA s Centralized Procedure as a new active substance.

In August 2009, Facet, our collaboration partner in the development of daclizumab, announced its continued plans for the Phase 3 trial of daclizumab high-yield process in MS and that it would request a Special Protocol Assessment from the FDA, prior to the initiation of this study. The Phase 3 trial is expected to begin during the first half of 2010. Upon enrollment of the first patient into the Phase 3 study, Facet would receive a \$30.0 million milestone payment from us.

On October 19, 2009, Biovitrum and we announced plans to advance the companies long-acting, fully-recombinant Factor IX Fc fusion protein (rFIXFc) into a registrational clinical trial in hemophilia B patients. The decision to advance the program is based on data from a Phase 1/2a open-label, multi-center, safety dose-escalation and pharmacokinetic study of intravenous rFIXFc in severe, previously treated hemophilia B patients. rFIXFc was well tolerated in the study. In addition, rFIXFc demonstrated a prolonged half-life compared to historical data for existing therapies, supporting advancement of the program.

In October 2009, a safety review of ocrelizumab data in RA and lupus nephritis, or LN, clinical trials was performed revealing an apparent imbalance in opportunistic infections among ocrelizumab-treated RA and LN patients in these clinical trials. Based upon this review, the ocrelizumab FILM study in methotrexate-naïve RA patients was placed on clinical hold and dosing was stopped. We also decided to close the ocrelizumab BELONG study in LN. The other ocrelizumab RA and RRMS studies remain ongoing. We plan to work with regulators to determine the next step for these programs.

In October 2009, after a strategic review of our Anti-CD80 MAb (galiximab) and Anti-CD23 MAb (lumiliximab) programs, we decided to stop recruitment in the lumiliximab LUCID trial in CLL and prematurely end the galiximab TARGET trial in NHL. Neither decision was a consequence of any safety concerns. We are evaluating our options for these programs and are working on a path forward.

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## Selling, General and Administrative

	For the	<b>Three Mont</b>	hs Ended	For the Nine Months Ended			
(In millions, except percentages)	;	September 3	0,	September 30,			
	2009	2008	Change %	2009	2008	Change %	
Selling, general and administrative	\$ 226.8	\$ 232.8	(2.6)%	\$ 669.4	\$ 694.3	(3.6)%	

Selling, general and administrative expenses are primarily comprised of salaries and benefits associated with sales and marketing, finance, legal and other administrative personnel, outside marketing and legal expenses and other general and administrative costs. The decreases in selling, general and administrative expenses were primarily driven by the positive impact of foreign currency exchange rate changes.

# **Collaboration Profit Sharing**

(In millions, except percentages)		Three Mon September		For the Nine Months Ended September 30,			
	2009	2008	Change %	2009	2008	Change %	
Collaboration profit sharing	\$ 60.7	\$ 43.5	39.4%	\$ 152.6	\$ 98.4	55.1%	

Payments are made to Elan for their share of the rest of world net operating profits to effect an equal sharing of collaboration operating profit. These payments include the reimbursement of our portion of third-party royalties that Elan pays on behalf of the collaboration, relating to sales outside of the United States. These amounts are reflected in the collaboration profit sharing line in our consolidated statements of income. As rest of world sales of TYSABRI increase, our collaboration profit sharing expense will increase.

The increases for both the three and nine months ended September 30, 2009 as compared to the prior year comparative periods were due to the increase in TYSABRI rest of world sales resulting in a higher rest of world net operating profits to be shared with Elan and causing growth in the third-party royalties Elan paid on behalf of the collaboration. For the three and nine months ended September 30, 2009, our collaboration profit sharing expense included \$10.7 million and \$28.5 million, respectively, related to the reimbursement of Elan s royalty payments as compared to \$8.0 million and \$20.9 million during the prior year comparable periods.

# **Amortization of Acquired Intangible Assets**

(In millions, except percentages)	For the Three Months Ended September 30,			For the Nine Months Ended September 30,		
	2009	2008	Change %	2009	2008	Change %
Amortization of acquired intangible assets	\$ 51.3	\$ 94.5	(45.6)%	\$ 233.8	\$ 242.1	(3.4)%

Our most significant intangible asset is the core technology related to our AVONEX product. We believe the economic benefit of our core technology is consumed as revenue is generated from our AVONEX product, which we

refer to as the economic consumption amortization model. An analysis of the anticipated product sales of AVONEX is performed annually during our long range planning cycle each year. This analysis serves as the basis for the calculation of economic consumption for the core technology intangible asset.

We completed our most recent long range planning cycle in the third quarter, which includes an analysis of the anticipated product sales of AVONEX. The outcome of this analysis is based on certain assumptions that we evaluate on a periodic basis, such as the expected impact of competitor products and our own pipeline product candidates, as well as the issuance of new patents or extension of existing patents. Based on this year s analysis, we have continued to amortize this asset on the economic consumption model for the third quarter of 2009, and expect to apply the same model for the subsequent three quarters. The results of our analysis were most significantly impacted by the extension of the assumed remaining life of the core intangible asset due to the issuance of the U.S. patent in September 2009.

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As a result of these favorable changes in the total expected lifetime revenues of AVONEX, amortization recorded in relation to our core intangible asset for the current and three subsequent quarters will be significantly less than those amounts recorded during the prior four quarters.

Amortization of acquired intangible assets is expected to be approximately \$283.0 million for the twelve months ended December 31, 2009 and between \$160.0 million and \$220.0 million for each of the following five years.

## **Acquired In-Process Research and Development (IPR&D)**

	For the Three Months Ended September 30,			For the Nine Months Ende September 30,					
(In millions, except percentages)	2009	2008	Change %	2009	2008	Change %			
Acquired in-process research and development	\$	\$	0.0%	\$	\$ 25.0	(100.0)%			

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 Therapeutics, Inc., or Conforma, pursuant to the terms of our acquisition of Conforma in 2006.

In connection with the acquisition of Syntonix Pharmaceuticals, or Syntonix, in January 2007, we agreed to make additional future consideration payments contingent upon the achievement of certain milestone events. In accordance with the acquisition agreement, we expect to make a \$40.0 million milestone payment to the former shareholders of Syntonix in the fourth quarter of 2009. This amount will be recorded as a charge to IPR&D when the related milestone has been achieved.

## Other Income (Expense), Net

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,				
					Change					Change
(In millions, except percentages)	2	2009		2008	%		2009		2008	%
Interest income	\$	10.9	\$	16.8	(35.1)%	\$	37.8	\$	55.0	(31.3)%
Interest expense		(8.5)		(8.1)	4.9%		(27.6)		(37.6)	(26.6)%
Impairments of investments		(0.5)		(17.4)	(97.1)%		(10.1)		(32.0)	(68.4)%
Net realized gains (losses) on foreign										
currency contracts		3.2		(1.8)	(277.8)%		10.6		(2.8)	(478.6)%
Net realized gains (losses) on										
marketable securities		1.8		(9.7)	(118.6)%		13.7		(3.8)	(460.5)%
Other, net		2.5		(3.5)	(171.4)%		6.5		(3.5)	(285.7)%
Total other income (expense), net	\$	9.4	\$	(23.7)	(139.7)%	\$	30.9	\$	(24.7)	(225.1)%

#### Interest Income

Interest income decreased for the three and nine months ended September 30, 2009 as compared to the prior year comparative periods primarily due to lower yields on cash, cash equivalents, and marketable securities, partially offset by higher average cash balances.

# Interest Expense

As discussed in Note 7, *Derivative Instruments*, in Notes to Consolidated Financial Statements , during the three and nine months ended September 30, 2009, approximately \$1.3 million and \$4.0 million, respectively, was recorded as a reduction of interest expense due to the amortization of the deferred gain associated with the termination of an interest rate swap in December 2008.

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Interest expense increased for the three months ended September 30, 2009 as compared to the same period in the prior year primarily due to the ineffectiveness of the swap recorded in 2008. Interest expense decreased for the nine months ended September 30, 2009 as compared to the prior year comparative period primarily due to decreased average debt balances in 2009 as compared to 2008.

# Impairment on Investments

In April 2009, we implemented newly issued accounting standards which provided guidance for recognition and presentation of other-than-temporary impairments. The adoption of this guidance did not have a material impact on our financial position or results of operations; however, this standard amended the other-than-temporary impairment model for debt securities. The impairment model for equity securities was not affected. Refer to Note 6, *Financial Instruments*, of this Form 10-Q for additional information on the adoption of this guidance.

During the three and nine months ended September 30, 2009, we recognized impairment losses of \$0.5 million and \$6.5 million, respectively, on our strategic investments and non-marketable securities. In addition, during the three and nine months ended September 30, 2008, we recognized \$3.3 million and \$12.7 million, respectively, in charges for the impairment of strategic investments and non-marketable securities that were determined to be other-than-temporary.

No impairment losses were recognized through earnings related to available for sale securities during the three months ended September 30, 2009. For the nine months ended September 30, 2009, we recognized \$3.6 million in charges. For the three and nine months ended September 30, 2008, we recognized \$14.1 million and \$19.3 million, respectively, in charges for the other-than-temporary impairment of available for sale securities primarily related to mortgage and asset backed securities.

# **Income Tax Provision**

#### Tax Rate

	For the Three Months Ended September 30,			ed	For the Nine Months I September 30,					Ended		
(In millions, except percentages)		2009	,	2008		ange ‰		2009	:	2008		ange %
Effective tax rate Income tax expense	\$	29.0% 113.9	\$	35.5% 114.3	(	(18.3)% (0.3)%	\$	28.8% 271.9	\$	32.7% 282.3		(11.9)% (3.7)%

Our effective tax rate will fluctuate from period to period due to several factors inherent in the nature of our global operations and business transactions. The factors that most significantly impact our tax rate include the variability of the proportion of our taxable earnings in multiple jurisdictions, changes in tax laws and acquisition and licensing transactions.

Our effective tax rate for the three and nine months ended September 30, 2009 was favorably impacted by certain adjustments to our transfer pricing and other estimates made in conjunction with the filing of our income tax return during the current quarter. These adjustments had a favorable impact of 1.9% and 0.8% on our tax rate for the three and nine months ended September 30, 2009, respectively. In addition, our tax rate for the nine months ended September 30, 2009, was also favorably impacted by changes in the tax laws of certain states in which we operate.

These tax law changes required us to establish deferred tax assets for certain tax credits and adjust certain deferred tax liabilities and reserves for uncertain tax positions resulting in a favorable impact of 3.2% on our effective tax rate for the nine months ended September 30, 2009. As these tax law changes became effective during the first quarter of 2009, these changes did not have an impact on our effective tax rate for the three months ended September 30, 2009.

The favorable impact of these items on our effective tax rate for the nine months ended September 30, 2009, was offset by the impact of the collaboration and license agreement entered into with Acorda on June 30, 2009. As there is no income tax benefit associated with the July 1, 2009 upfront payment made to Acorda and our on-going spending on Fampridine-SR outside the United States. These payments had a 2.4% and 2.3% unfavorable impact on our effective tax rate for the three and nine months ended September 30, 2009, respectively.

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In connection with the acquisition of Syntonix, in January 2007, we agreed to make additional future consideration payments-contingent upon the achievement of certain milestone events. In accordance with the acquisition agreement, we expect to make a \$40.0 million milestone payment to the former shareholders of Syntonix in the fourth quarter of 2009. This amount will be recorded as a charge to IPR&D when the related milestone has been achieved. This payment was anticipated in determining our full year effective tax rate. As this amount is not deductible for United States income tax purposes our 2009 effective tax rate would be favorably impacted by approximately 3.4% in the event that the achievement of these milestones is not met or is delayed beyond the fourth quarter of 2009.

Our effective tax rate for the nine months ended September 30, 2008 was favorably impacted by the restructuring of our operations in foreign jurisdictions as well as other activities and adjustments made.

We expect our effective tax rate for the full-year ending December 31, 2009 to be in a range of 29% to 31%. Refer to Note 12, *Income Taxes*, in Notes to Consolidated Financial Statements for detailed income tax rate reconciliation for the three and nine months ended September 30, 2009 and 2008.

### **Financial Condition and Liquidity**

Our financial condition is summarized as follows:

	Sep	As of tember 30,	Dec	As of ember 31,	C)
(In millions, except percentages)	2009			2008	Change %
Financial assets:					
Cash and cash equivalents	\$	585.8	\$	622.4	(5.9)%
Marketable securities current		821.9		749.0	9.7%
Marketable securities non-current		1,497.4		891.4	68.0%
Total financial assets	\$	2,905.1	\$	2,262.8	28.4%
Borrowings:					
Current portion of notes payable and line of credit	\$	15.5	\$	27.7	(44.2)%
Notes payable		1,085.8		1,085.4	0.0%
Total borrowings	\$	1,101.3	\$	1,113.1	(1.1)%
Working capital	\$	1,850.9	\$	1,534.8	20.6%

During the first nine months of 2009, certain significant cash flows were as follows:

\$792.7 million of cash flows generated from operations, inclusive of the \$110.0 million upfront payment made to Acorda on July 1, 2009;

\$667.1 million used for net purchases of marketable securities;

\$110.1 million used for purchases of property, plant and equipment; and

\$57.6 million used for share repurchases.

We discuss our cash flows in more detail below.

We have financed our operating and capital expenditures principally through cash flows from our operations. We expect to finance our current and planned operating requirements principally through cash from operations, as well as existing cash resources. We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our operating, working capital, strategic alliance and acquisition, milestone payment, capital expenditure and debt service requirements for the foreseeable future. In addition, we plan to opportunistically pursue our stock repurchase program and other business initiatives, including acquisition and licensing activities. However, we may, from time to time, seek

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additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources.

Refer to Part II, Item 7A Quantitative and Qualitative Disclosures About Market Risk in our 2008 annual report on Form 10-K and Part II, Item 1A: Risk Factors of this Form 10-Q for discussion of risks that could negatively impact our cash position and ability to fund future operations.

## 2009 Share Repurchase Program

On October 19, 2009, our Board of Directors authorized the repurchase of our common stock in an amount of up to \$1.0 billion. This is in addition to the 6.0 million shares remaining from our previous share repurchase authorization. While we have used the prior share repurchase program principally for share stabilization, this new \$1.0 billion authorization is intended to reduce our shares outstanding, with the objective of returning excess cash to shareholders. The Company intends to retire these shares following repurchase on the open market. This repurchase program does not have an expiration date.

### Facet Biotech Tender Offer

On September 21, 2009, we commenced a tender offer to acquire all of the outstanding shares of Facet for approximately \$356.0 million or \$14.50 per share in cash. On October 16, 2009, we extended the offer to December 16, 2009 at the same offering price of \$14.50 per share. Our all-cash proposal is not subject to any financing contingency or approval by Biogen Idec shareholders. We may incur additional costs to complete this transaction in the event that this tender offer is successfully completed. We do not expect these additional transaction costs to be material to our financial position or results of operations.

We do not expect that external financing will be required to close this transaction or to fund any other costs that may be associated with the completion of this transaction.

#### Cash, Cash Equivalents and Marketable Securities

Until required for use in the business, we invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments and other interest bearing marketable debt instruments in accordance with our investment policy. We mitigate credit risk in our cash reserves and marketable securities by maintaining a well diversified portfolio that limits the amount of investment exposure as to institution, maturity, and investment type. However, the value of these securities may be adversely affected by instability in the global financial markets which could adversely impact our financial position and our overall liquidity.

The increase in cash and marketable securities from December 31, 2008 is primarily due to an increase in cash from operations and proceeds from the issuance related to share-based compensation arrangements partially offset by purchases of property, plant and equipment, share repurchases and purchases of strategic investments.

#### **Borrowings**

There has been no significant change in our borrowings since December 31, 2008. Refer to Note 5, *Fair Value Measurements*, in Notes to Consolidated Financial Statements for a summary of the fair and carrying value of outstanding borrowings as of September 30, 2009 and December 31, 2008.

We have a \$360.0 million senior unsecured revolving credit facility, which we may use for future working capital and general corporate purposes which terminates in June 2012. As of September 30, 2009 and December 31, 2008, there

were no borrowings under this credit facility and we were in compliance with applicable covenants.

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#### Working Capital

	Sept	As of ember 30,	Dec	As of ember 31,			
(In millions, except percentages)			2008	Change %			
Current assets Current liabilities	\$ \$	2,572.3 (721.4)	\$ \$	2,458.0 (923.2)	4.6% (21.9)%		
Working capital	\$	1,850.9	\$	1,534.8	20.6%		

We define working capital as current assets less current liabilities. The increase in working capital primarily reflects the overall increase in balances attributable to accounts receivable and marketable securities included within current assets and the overall reduction of current liabilities by \$201.8 million. The reduction in current liabilities was primarily driven by a \$163.3 million reduction in balances attributable to taxes payable.

#### Cash Flows

The following table summarizes our cash flow activity:

	For the Nine Months Ended September 30,								
(In millions, except percentages)		2009	_	2008	Change %				
Net cash flows provided by operating activities	\$	792.7	\$	1,155.2	(31.4)%				
Net cash flows (used in) provided by investing activities	\$	(777.7)	\$	99.9	(878.6)%				
Net cash flows used in financing activities	\$	(54.6)	\$	(902.8)	(94.0)%				

## **Operating Activities**

Cash flows from operating activities represent the cash receipts and disbursements related to all activities of the Company other than investing and financing activities. Operating cash flow is derived by adjusting net income for:

Non-cash operating items such as depreciation and amortization, impairment charges and share-based compensation charges;

Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

Cash provided by operating activities is primarily driven by our earnings and changes in working capital. We expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures over the foreseeable future. The decrease in cash provided by operating activities for the nine months ended September 30, 2009, as compared to the prior year comparative period, was primarily driven by a \$169.4 million net reduction in our short and long term income taxes payable balances, the \$110.0 million upfront payment made to Acorda on July 1, 2009 and the payment of certain accrued expenses and other liabilities

# **Investing Activities**

The increase in cash used in investing activities is primarily due to an increase in net purchases of marketable securities during the nine months ended September 30, 2009, as compared to the same period in 2008, partially offset by a reduction in purchases of property, plant and equipment.

Proceeds from sales and maturities of marketable securities totaled \$2,334.1 million for the nine months ended September 30, 2009, as compared to purchases of marketable securities of \$3,001.2 million made during the same period.

Purchases of property, plant and equipment decreased from \$222.0 million for the nine months ended September 30, 2008 to \$110.1 million for the nine months ended September 30, 2009. This decrease is

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primarily attributed to reduced capital expenditures as our Hillerød, Denmark manufacturing facility and certain other manufacturing upgrades near completion.

#### Financing Activities

The decrease in cash used in financing activities is due, principally, to the repayment of our term loan facility of \$1.5 billion in 2008, partially offset by the issuance of our notes payable, and a reduction in the amounts of our common stock repurchased as compared to the same period in 2008.

In addition to recently announced share repurchase described above, in October 2006, our Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. We utilize this program to stabilize the number of common shares outstanding and will, from time to time, purchase shares on the open market. The following table summarizes our activity under the 2006 program:

	Mont	the Nine hs Ended mber 30,
(In millions)	2009	2008
Amount of stock repurchased	\$ 57.6	\$ 559.8
Shares of stock repurchased	1.2	9.0
Number of shares remaining for repurchase under this program	6.0	11.0

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

As of September 30, 2009, we have funding commitments of up to approximately \$27.0 million as part of our investment in biotechnology oriented venture capital investments.

Based on our development plans as of September 30, 2009, we have committed to make potential future milestone payments to third-parties of up to \$1,554.9 million 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, 2009, such contingencies have not been recorded in our financial statements. We anticipate that we may pay approximately \$40.0 million of additional milestone payments during the remainder of 2009, provided various developmental, regulatory or commercial milestones are achieved.

As of September 30, 2009, we have several clinical studies in various clinical trial stages. Our most significant clinical trial expenditures are to CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded \$37.5 million of accrued expenses on our consolidated balance sheet for work done by CROs as of September 30, 2009. We have approximately \$394.0 million in cancellable future commitments based on existing CRO contracts as of September 30, 2009.

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. 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 the *Consolidation* Topic of the Codification if we are the primary beneficiary.

As of September 30, 2009, we have approximately \$138.5 million of long-term liabilities associated with uncertain tax positions.

# **Commitments**

## Weston Lease

In November 2008, we executed an agreement with a real estate developer for a fifteen year lease of a 356,000 square foot office building in Weston, Massachusetts, which will serve as the future location of our

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executive offices. Construction was begun in 2009 with a planned occupancy of this building during the third quarter of 2010.

The initial lease term is from 2010 through 2025 under which total minimum lease payments are \$258.6 million. The lease agreements contain various clauses for renewal at our option and, in certain cases, escalation clauses typically linked to rates of inflation.

## Hillerød Manufacturing Facility

During 2008, we completed the first phase of our large-scale biologic manufacturing facility in Hillerød, Denmark, which included partial completion of a bulk manufacturing component, a labeling and packaging component, construction of a warehouse 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. As of September 30, 2009, we had contractual commitments of approximately \$4.5 million related to the second phase. This project is expected to be ready for commercial production in 2011.

The timing of the completion and anticipated licensing of the bulk manufacturing facility is in part dependent upon the demand for our current and future products and the manufacturing capacity from our other facilities.

# **Legal Matters**

Refer to Note 15, *Litigation*, in Notes to Consolidated Financial Statements , for a discussion of legal matters as of September 30, 2009.

## **New Accounting Standards**

Refer to Note 17, *New Accounting Pronouncements*, in Notes to Consolidated Financial Statements , for a discussion of new accounting standards.

# **Critical Accounting Estimates**

The discussion and analysis of our financial position and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements in accordance with generally accepted accounting principles requires us to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and related allowances, marketable securities, derivatives and hedging activities, inventory, impairments of long-lived assets, including intangible assets, impairments of goodwill, income taxes including the valuation allowance for deferred tax assets, valuation of investments, research and development expenses, contingencies and litigation, and share-based payments. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Refer to Part II, 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, 2008 for a discussion of the Company s critical accounting estimates.

## Changes to Critical Accounting Estimates

In April 2009, we implemented newly issued accounting standards which provided guidance for recognition and presentation of other-than-temporary impairments. This newly issued guidance amended the other-than-temporary impairment model for debt securities. The impairment model for equity securities was not affected. The adoption of the guidance did not have a material impact on our financial position or results of operations.

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# Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended December 31, 2008. 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 2009 to our market risks or to our management of such risks.

#### Item 4. Controls and Procedures

# Disclosure Controls and Procedures and Internal Control over Financial Reporting

#### 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, 2009. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring 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 Securities and Exchange Commission 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

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Part II OTHER INFORMATION

## Item 1. Legal Proceedings

Refer to Note 15, *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 three principal products.

Our current and future revenues depend upon continued sales of our three principal products, AVONEX, RITUXAN and TYSABRI, which represented substantially all of our total revenues during the third quarter of 2009. Although we have developed and continue to develop additional products for commercial introduction, we expect to be

substantially dependent on sales from these three products for many years. Any negative developments relating to any of these products, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments may reduce our revenues and adversely affect our results of operations.

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#### Market acceptance and successful sales growth of TYSABRI are important to our success.

TYSABRI is expected to drive additional revenue growth over the next several years. 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. Since the reintroduction of TYSABRI to the market in July 2006, we have disclosed cases of progressive multifocal leukoencephalopathy, or PML, a known side effect, in patients taking TYSABRI. If the incidence of PML exceeds the rate implied by the TYSABRI label, it could harm acceptance, limit sales or result in a withdrawal of TYSABRI from the market. We currently believe that the risk of developing PML increases with the number of TYSABRI infusions received and we are currently discussing with regulatory authorities a potential TYSABRI label change. Additional regulatory restrictions on the use of TYSABRI and safety-related labeling changes, whether as a result of additional cases of PML or otherwise, may significantly reduce expected revenues and require significant expense and management time to address the associated legal and regulatory issues, including enhanced risk management programs. In addition, as a relatively new entrant to a maturing 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. Failure to grow sales of TYSABRI would materially and adversely affect our growth and plans for the future.

# Our long-term success depends upon the successful development and commercialization of other product candidates.

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, regulatory authorities may disagree with our view of the data or require 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 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 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.

Our product pipeline includes several small molecule drug candidates. Our small-molecule drug discovery platform is not as well developed as our biologics platform and we will have to make a significant investment of time and resources to expand our capabilities in this area. Currently, third party manufacturers supply substantially all of our clinical requirements for small molecules. If these manufacturers fail to deliver sufficient quantities of such drug candidates in a timely and cost-effective manner, it could adversely affect our small molecule drug discovery efforts. If we decide to manufacture clinical or commercial supplies of any small molecule drugs in our own facilities, we will need to invest substantial additional funds and recruit qualified personnel to develop our small molecule manufacturing capabilities.

Adverse safety events can negatively affect our business and stock price.

Even after we receive marketing approval for a product, adverse event reports may have a negative impact on our commercialization efforts. 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

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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 and in the product pipeline, greater financial and other resources and other technological or competitive advantages. One or more of our competitors may receive patent protection that dominates, blocks or adversely affects our product development or business, may benefit from significantly greater sales and marketing capabilities, and may develop products that are accepted more widely than ours. The introduction of more efficacious, safer, cheaper, or more convenient alternatives to our products could reduce our revenues and the value of our product development efforts. 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.

We depend, to a significant extent, on reimbursement from third party payors and a reduction in the extent of reimbursement could reduce 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. Changes in government regulations or private third-party payors reimbursement policies may reduce reimbursement for our products and adversely affect our future results.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. Congress is considering legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for our products, it may also include changes that adversely affect reimbursement for our products. Congress is also considering legislation to change the Medicare reimbursement system for outpatient drugs, increase the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs and to facilitate the importation of lower-cost prescription drugs that are marketed outside the United States. Some states are considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. 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.

We encounter similar regulatory and legislative issues in most other countries. In the E.U. 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 system of price regulations may lead to inconsistent prices. Within the E.U. and in

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other countries, the availability of our products in some markets at lower prices undermines our sales in some markets with higher prices. Additionally, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our 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 third party cross border trade or influence our decision to sell or 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.

# 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 are subject to several risks:

we are not fully in control of the royalty or profit sharing revenues we receive from collaborators, which may be adversely affected by 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 adverse impact on product sales by our collaborators and partners, and could adversely affect the clinical development of products or programs under joint control.

In addition, under our collaboration agreement with Genentech, the successful development and commercialization of the first anti-CD20 product acquired or developed by Genentech will decrease our percentage of the collaboration s co-promotion profits.

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

We anticipate growing through internal development projects as well as external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. 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, from time to time, may not be available to us on favorable terms, if at all. 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. In addition, third parties may be more reluctant to partner with us due to the uncertainty created by the presence on our Board of Directors of two individuals nominated by certain entities affiliated with Carl Icahn that have advocated for a sale or break-up of the company. 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.

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

Our activities, and the activities of our collaborators and third party providers, are subject to extensive government regulation and oversight both in the United States and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of health care companies. In addition, 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, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, antitrust violations, or 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, including Medicare and Medicaid. 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.

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. In addition, the FDA must approve any significant changes to our suppliers or manufacturing methods. If we or our third party service providers cannot demonstrate ongoing cGMP compliance, we may be required 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. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions. This non-compliance could increase our costs, cause us to lose revenue or market share and damage our reputation.

## Changes in laws affecting the health care industry could adversely affect our revenues and profitability.

We and our collaborators and third party providers operate 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, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products;

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

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The enactment in the United States of health care reform, possible legislation which could ease the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future 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 an expanded clinical trials registry and clinical trials results database, and expanded authority for FDA to impose civil monetary penalties on companies that fail to meet certain commitments.

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, resulting in product defects or contamination, shipment delays and recalls. Biologics manufacturing is extremely susceptible to product loss due to contamination, equipment failure, or vendor or operator error. In addition, microbial or viral contamination may cause the closure of a manufacturing facility for an extended period of time. Any of these events 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.

We rely solely on our manufacturing facility in Research Triangle Park, North Carolina, or RTP, for the production of TYSABRI. Our global supply of TYSABRI depends on the uninterrupted and efficient operation of this facility, which could be adversely affected by equipment failures, labor shortages (whether as a result of pandemic flu outbreak or otherwise), natural disasters, power failures and numerous other factors. If we are unable to meet demand for TYSABRI for any reason, we would need to rely on a limited number of qualified third party contract manufacturers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers or that the FDA would approve our use of such manufacturers on a timely basis, if at all. Moreover, the transition of our manufacturing process to a third party could take a significant amount of time. Conversely, 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 and charges for excess and obsolete inventory.

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.

We rely on third parties to provide services in connection with the manufacture of our products and, in some instances, manufacture 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. Any third party we use to fill-finish, package or store our products to be sold in the United States must be

licensed by the FDA. As a result, alternative third party providers may not be readily available on a timely basis. The manufacture of 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

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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.

Due to the unique manner in which our products are manufactured, we rely on single source providers of several 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.

# Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions 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 experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. In addition, unfavorable results of audits of our tax filings, our inability to secure or sustain arrangements with tax authorities, and previously enacted and future changes in tax laws in jurisdictions in which we operate, among other things, may cause us to be obligated to accrue for future tax payments in excess of amounts accrued in our financial statements.

The Obama administration recently announced several proposals to reform United States tax rules, including proposals that may reduce or eliminate the deferral of United States income tax on our unrepatriated earnings, potentially requiring those earnings to be taxed at the United States federal income tax rate, reduce or eliminate our ability to claim foreign tax credits, and eliminate various tax deductions until foreign earnings are repatriated to the United States. Our future reported financial results may be adversely affected by tax rule changes which restrict or eliminate our ability to claim foreign tax credits or deduct expenses attributable to foreign earnings, or otherwise affect the treatment of our unrepatriated earnings.

# We have made a significant investment in constructing a manufacturing facility, the success of which depends upon completion and licensing of the facility.

We have already made a significant investment in, and are in the final stages of completing, a large-scale biologic manufacturing facility in Hillerød, Denmark. Although the facility may be completed in 2011, we could experience delays in the completion or licensing of the facility and may incur substantial additional costs to make the facility ready for production.

# The growth of our business depends on our ability to attract and retain qualified personnel and key relationships.

The achievement of our commercial, research and development and external growth objectives depends upon our ability to attract and retain qualified scientific, manufacturing, sales and marketing and executive personnel and develop and maintain relationships with qualified clinical researchers and key distributors. Competition for these people and relationships is intense and comes from a variety of sources, including pharmaceutical and biotechnology companies, universities and non-profit research organizations. In addition, it may be more difficult for us to attract and retain these people and relationships due to the uncertainty created by the presence on our Board of Directors of two individuals nominated by certain entities affiliated with Carl Icahn that have advocated for a sale or break-up of the

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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 health care payment systems;

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.

In addition, our international operations are subject to regulation under U.S. law. For example, 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 health care professionals we regularly interact with may meet the definition of a foreign official for purposes of the FCPA. 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.

The recent election of two directors nominated by an activist shareholder, and the possibility that additional shareholder-nominated directors could be elected in the future, could cause uncertainty about the direction of our business.

During 2008 and 2009, proxy contests commenced by entities affiliated with Carl Icahn resulted in the 2009 election of two of the Icahn nominees to our Board of Directors. In the 2009 proxy contest, the Icahn entities proposed a strategic direction that is inconsistent with our strategic plan. If there is dissension among our directors about the direction of our business, it could impair our ability to effectively execute our strategic plan. In addition, 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.

These proxy contests have also been disruptive to our operations and have caused us to incur substantial costs. The SEC has recently proposed to give shareholders the ability to include their director nominees and their proposals relating to a shareholder nomination process in company proxy materials, which would make it easier for activists to nominate directors to our Board of Directors. If the SEC implements its proxy access proposal, we may face an increase in the number of shareholder nominees for election to our Board of Directors. Future proxy contests and the presence of additional shareholder activist nominees on our Board of Directors could impair our ability to execute our strategic plan and be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees.

# 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:

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;

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

milestone payments under license and collaboration agreements;

payments in connection with acquisitions and other business development activity; and

the cost of restructurings.

Our revenues are also subject to foreign exchange rate fluctuations due to the global nature of our operations. We recognize foreign currency gains or losses arising from our operations in the period in which we incur those gains or losses. 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, currency fluctuations among our reporting currency, the U.S. dollar, and the currencies in which we do business will affect our operating results, often in unpredictable ways. 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 period do not necessarily suggest the anticipated results of future periods.

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 United States and various other countries seeking protection of the processes, products and other inventions originating from our research and development. 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 United States 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 and court decisions or patent office regulations that place additional restrictions on patent claims or that facilitate patent challenges could also reduce our ability to protect our intellectual property rights. If we cannot 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 pharmaceutical companies. To the extent that valid third party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services, and payments under them would reduce our profits from these products and services. 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 United States 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 United States 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 United States 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 non-infringement 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.

We are subject from time to time to lawsuits based on product liability and related claims. 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 if in excess of our insurance coverage. 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.

#### Credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of 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 Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could reduce our product sales and revenue.

We rely on third parties for several important aspects of our business, including portions of our product manufacturing, royalty revenue, clinical development of future collaboration products, conduct of clinical trials, and raw materials. Such third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business.

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Our portfolio of marketable securities is significant and subject to market, interest and credit risk that may reduce its value.

We maintain a significant portfolio of marketable securities. Changes in the value of this portfolio could adversely affect our earnings. In particular, the value of our investments may decline due to increases in interest rates, downgrades in the corporate bonds and other securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio, declines in the value of collateral underlying the mortgage and asset-backed securities included in our portfolio, and other factors. 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. Although we attempt to mitigate these risks by investing in high quality securities and continuously monitoring our portfolio s overall risk profile, the value of our investments may nevertheless decline.

Our level of indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business.

As of September 30, 2009, we had \$1,101.3 million of outstanding indebtedness, and we may incur additional debt in the future. Our level of indebtedness could adversely affect our business by, among other things:

increasing our vulnerability to general adverse economic and industry conditions;

requiring 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

limiting 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. 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. 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;

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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;

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. 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 royalty on net sales in the United States of any anti-CD20 product acquired or developed by Genentech or any anti-CD20 product that Genentech licenses from a third party that is 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

# **Issuer Purchases of Equity Securities**

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 2006 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, 2009.

On October 19, 2009, our Board of Directors authorized the repurchase of our common stock in an amount of up to \$1.0 billion. This is in addition to the 6.0 million shares remaining from our 2006 repurchase program. This new \$1.0 billion authorization is intended to reduce our shares outstanding, with the objective of returning excess cash to shareholders. The Company intends to retire these shares following repurchase on the open market. This repurchase program does not have an expiration date. We publicly announced the repurchase program in our press release dated October 20, 2009, which was furnished to the SEC as Exhibit 99.1 of our Current Report on Form 8-K filed on October 20, 2009. As of October 20, 2009, no shares have been repurchased under this program. The number of shares that may yet be purchased under this program is subject to price fluctuations of our common stock.

#### 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, 2009

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# **EXHIBIT INDEX**

Exhibit Number*	Description of Exhibit
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.
101++	The following materials from Biogen Idec Inc. s Quarterly Report on Form 10-Q for the quarter ended
	September 30, 2009, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated
	Statements of Income, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Cash
	Flows, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

- \* 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