BIOGEN IDEC INC. Form 10-Q May 03, 2007

# 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 March 31, 2007

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**

(State or other jurisdiction of incorporation or organization)

## 33-0112644

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large Accelerated Filer b Accelerated Filer o Non-Accelerated Filer 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 registrant s Common Stock, \$0.0005 par value, outstanding as of April 25, 2007, was 342,161,653 shares.

# BIOGEN IDEC INC.

# FORM 10-Q Quarterly Report For the Quarterly Period Ended March 31, 2007

# TABLE OF CONTENTS

	Financial Statements (unaudited)	
	Consolidated Statements of Income Three Months Ended March 31, 2007 and 2006	3
	Consolidated Balance Sheets March 31, 2007 and December 31, 2006	4
	Consolidated Statements of Cash Flows Three Months Ended March 31, 2007 and	
	<u>2006</u>	5
	Notes to Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	38
<u>Item 4.</u>	Controls and Procedures	38
PART II OTHER	<u>R INFORMATIO</u> N	
Item 1.	<u>Legal Proceedings</u>	39
Item 1A.	Risk Factors	39
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
Item 6.	<u>Exhibits</u>	49
<u>Signatures</u>		50
	ted April 4, 2006, to 2005 Omnibus Equity Plan	
	ted February 12, 2007, to 2005 Omnibus Equity Plan	
Ex-31.1 Section 302 Cer Ex-31.2 Section 302 Cer		

2

# PART I FINANCIAL INFORMATION

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# CONSOLIDATED STATEMENTS OF INCOME (In thousands, except per share amounts) (Unaudited)

	Three Months Ende March 31,		
	2007	2006	
Revenues:			
Product	\$ 484,388	\$ 406,519	
Unconsolidated joint business	207,164	183,380	
Other	24,358	21,276	
Total revenues	715,910	611,175	
Costs and expenses:			
Cost of sales, excluding amortization of acquired intangible assets	81,950	67,494	
Research and development	191,449	145,892	
Selling, general and administrative	188,061	154,391	
Collaboration profit (loss) sharing	(5,567)		
Amortization of acquired intangible assets	59,920	70,707	
Acquired in-process research and development	18,405		
Gain on sale of long-lived assets		(298)	
Total costs and expenses	534,218	438,186	
Income from operations	181,692	172,989	
Other income (expense), net	21,702	18,665	
Income before income tax expense and cumulative effect of accounting change	203,394	191,654	
Income tax expense	71,893	72,464	
Income before cumulative effect of accounting change	131,501	119,190	
Cumulative effect of accounting change, net of income tax	131,301	3,779	
Net income	\$ 131,501	\$ 122,969	
Basic earnings per share:			
Income before cumulative effect of accounting change Cumulative effect of accounting change, net of income tax	\$ 0.39	\$ 0.35 0.01	
Basic earnings per share	\$ 0.39	\$ 0.36	
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Diluted earnings per share: Income before cumulative effect of accounting change Cumulative effect of accounting change, net of income tax	\$	0.38	\$	0.35 0.01
Diluted earnings per share	\$	0.38	\$	0.36
Shares used in calculating: Basic earnings per share	3	40,310	3	339,653
Diluted earnings per share	3	44,058	3	345,815

See accompanying notes to the consolidated financial statements.

3

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# CONSOLIDATED BALANCE SHEETS (In thousands, except per share amounts) (Unaudited)

	March 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 780,940	\$ 661,377
Marketable securities	346,639	241,314
Accounts receivable, net	324,569	317,353
Due from unconsolidated joint business	151,754	168,708
Inventory	186,220	169,102
Other current assets	151,219	154,713
Total current assets	1,941,341	1,712,567
Marketable securities	1,385,666	1,412,238
Property, plant and equipment, net	1,291,041	1,280,385
Intangible assets, net	2,688,090	2,747,241
Goodwill	1,135,745	1,154,757
Investments and other assets	267,697	245,620
Total assets	\$ 8,709,580	\$ 8,552,808
LIABILITIES AND SHAREHOLDERS	EOUITY	
Current liabilities:		
Accounts payable	\$ 102,183	\$ 100,457
Taxes payable	76,922	145,529
Accrued expenses and other	312,195	336,869
Current portion of notes payable	9,148	
Total current liabilities	500,448	582,855
Notes payable	52,043	96,694
Long-term deferred tax liability	614,586	643,645
Other long-term liabilities	195,337	79,836
Total liabilities	1,362,414	1,403,030
Commitments and contingencies (Notes 8, 11 and 15)		
Shareholders equity:		
Preferred stock, par value \$0.001 per share		
Common stock, par value \$0.0005 per share	173	173

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Additional paid-in capital	8,286,744	8,308,232
Accumulated other comprehensive income	31,658	21,855
Accumulated deficit	(821,215)	(860,827)
Treasury stock, at cost	(150,194)	(319,655)
Total shareholders equity	7,347,166	7,149,778
Total liabilities and shareholders equity	\$ 8,709,580 \$	8,552,808

See accompanying notes to the consolidated financial statements.

4

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

# (Unaudited)

		Three Mon	31,		
		2007		2006	
Cash flows from operating activities:					
Cash flows from operating activities: Net income	\$	131,501	\$	122,969	
Adjustments to reconcile net income to net cash flows from operating activities	φ	131,301	Ψ	122,909	
Depreciation and amortization of fixed and intangible assets		88,815		123,230	
Acquired in-process research and development		18,405		123,230	
Stock-based compensation		29,560		23,620	
Non-cash interest expense and amortization of investment premium		437		(108)	
Deferred income taxes		5,015		(26,532)	
Realized loss on sale of marketable securities		245		804	
Write-down of inventory to net realizable value		6,717		3,298	
Gain on sale of long-lived assets		0,717		(298)	
Impairment of investments and other assets		2,460		2,107	
Excess tax benefit from stock options		(5,193)		(15,195)	
Changes in assets and liabilities, net:		(3,193)		(13,193)	
Accounts receivable		(6,642)		(9,485)	
Due from unconsolidated joint business		16,954		(9,483)	
Inventory		(23,191)		(11,505)	
Other assets				(3,880)	
		(18,835)			
Accrued expenses and other current liabilities Other liabilities		13,494		(56,461)	
Other habilities		2,587		3,605	
Net cash flows provided by operating activities		262,329		156,253	
Cash flows from investing activities:					
Purchases of marketable securities		(878,550)		(596,216)	
Proceeds from sales and maturities of marketable securities		803,675		357,877	
Acquisition of Syntonix, net of cash acquired		(42,289)		201,011	
Purchases of property, plant and equipment		(37,402)		(65,630)	
Proceeds from sale of property, plant and equipment		70		33,851	
Purchases of other investments		(12,886)		(2,094)	
		(		( ) ,	
Net cash flows used in investing activities		(167,382)		(272,212)	
Cash flows from financing activities:					
Proceeds from issuance of stock for share-based payment arrangements		22,908		56,356	

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Change in cash overdrafts	3	7,664
Excess tax benefit from stock options	5,193	15,195
Proceeds of loan from joint venture partner		4,441
Repayments of loan to joint venture partner	(3,703)	
Net cash flow provided by financing activities	24,401	83,656
Net increase (decrease) in cash and cash equivalents	119,348	(32,303)
Effect of exchange rate changes on cash and cash equivalents	215	
Cash and cash equivalents, beginning of the period	661,377	568,168
Cash and cash equivalents, end of the period	\$ 780,940	\$ 535,865

Non-cash financing transaction:

See Note 13 Notes Payable for a discussion of non-cash financing transactions that occurred during the period.

See accompanying notes to the consolidated financial statements.

5

#### BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

## 1. Business Overview and Summary of Significant Accounting Policies

#### **Overview**

Biogen Idec Inc. is an international biotechnology company that creates new standards of care in oncology, neurology, immunology and other specialty areas of unmet medical need. We currently have five products: AVONEX®, RITUXAN®, TYSABRI®, FUMADERM®, and ZEVALIN®.

# 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, 2006. Our accounting policies are described in the Notes to the Consolidated Financial Statements in our 2006 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 this Form 10-Q does not contain all disclosures required by accounting principles generally accepted in the U.S. The results of operations for the three months ended March 31, 2007 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

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

#### Principles of Consolidation

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

#### 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 inventory are as follows (in thousands):

March 31, December 31, 2007 2006

Raw materials Work in process Finished goods		\$ 50,061 111,382 24,777	\$ 45,691 105,291 18,120
Total inventory		\$ 186,220	\$ 169,102
	6		

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in product we have on hand is TYSABRI inventory that was written-off in 2005, due to uncertainties surrounding the TYSABRI suspension, but which is available to fill future orders. The approximate value of this product, based on its cost of manufacture, is \$18.1 million.

Valuation of Inventory

During the three months ended March 31, 2007 and 2006, we wrote-down \$6.7 million and \$3.3 million, respectively, in unmarketable inventory, which was charged to cost of sales.

## 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; collectibility is reasonably assured; and title and the risks and rewards of ownership have transferred to the buyer.

Except for revenues from sales of TYSABRI in the U.S., revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Sales of TYSABRI in the U.S. are recognized on the sell-through model, that is, upon shipment of the product by our collaboration partner, Elan, to the customer. The timing of distributor orders and shipments for all sales can cause variability in earnings.

Revenues are recorded net of applicable allowances for returns, trade term discounts, wholesaler incentives, Medicaid rebates, Veteran s Administration rebates, managed care discounts and other applicable allowances.

# Reserves for Discounts and Allowances

We establish reserves for discounts (which include trade term discounts and wholesaler incentives), contractual adjustments (which include Medicaid rebates, Veteran s Administration, or VA, rebates and managed care) and returns (which include returns made by wholesalers). Such reserves are classified as reductions of accounts receivable (if the amount is payable to a customer) or a liability (if the amount is payable to a party other than a customer).

During the three months ended March 31, 2007, we changed the manner in which we administer our patient assistance and patient replacement goods programs. Prior to January 1, 2007, AVONEX product shipped to administer these programs was invoiced and recorded as gross product revenue. In addition, an offsetting provision for discount and returns was reflected for expected credit requests from the distributor that administers these programs on our behalf. On January 1, 2007, we established a consignment model. Under the new arrangement, no gross revenue is recorded for product shipped to satisfy these programs.

7

#### BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Dis	counts	tractual istments	Re	eturns	Т	otal
Beginning balance, January 1, 2007	\$	12.7	\$ 30.5	\$	17.8	\$	61.0
Current provisions relating to sales in current period		10.5	23.3		4.3		38.1
Adjustments relating to prior periods			(0.5)				(0.5)
Payments/returns relating to sales in current period		(5.5)	(6.5)				(12.0)
Payments/returns relating to sales in prior periods		(12.6)	(16.5)		(8.7)		(37.8)
Ending balance, March 31, 2007	\$	5.1	\$ 30.3	\$	13.4	\$	48.8

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

	March 31, 2007			December 31, 2006		
Reduction of accounts receivable Current liability	\$	20.6 28.2	\$	30.2 30.8		
Total reserves	\$	48.8	\$	61.0		

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

#### Accounting for Uncertainty In Income Taxes

Effective January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of each tax position taken or expected to be taken in a tax return. As a result of the adoption of FIN 48, we recognized a reduction in the liability for unrecognized tax benefits of \$14.2 million, which was recorded as a \$1.8 million reduction to the January 1, 2007 balance of our accumulated deficit, a \$9.1 million reduction in goodwill and a \$3.3 million increase in our deferred tax liability.

In connection with the adoption of FIN 48, we reclassified approximately \$113 million in reserves for uncertain tax positions from current taxes payable to long-term liabilities.

See Note 8, Income Taxes, for a discussion of our accounting for uncertain tax positions.

# 2. Acquisition of Syntonix Pharmaceuticals, Inc.

In January 2007, we acquired 100% of the stock of Syntonix Pharmaceuticals, Inc., or Syntonix, a privately held biopharmaceutical company based in Waltham, Massachusetts. Syntonix focuses on discovering and developing long-acting therapeutic products to improve treatment regimens for chronic diseases, and is engaged in multiple pre-clinical programs in hemophilia. The purchase price was \$44.4 million, including transaction costs, and is subject to increase to as much as \$124.4 million if certain development milestones with respect to Syntonix s lead product, FIX:Fc, a proprietary long-acting factor IX product for the treatment

8

#### BIOGEN IDEC INC. AND SUBSIDIARIES

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

of hemophilia B, are achieved. The purpose of the acquisition was to enhance our pipeline and to expand into additional specialized markets.

The acquisition was funded from our existing cash on hand and was accounted for as an asset acquisition as Syntonix is a development-stage company. As a result of the acquisition we obtained the rights to the in-process technology of the Fc-fusion technology platform. Syntonix has two programs in development using the Fc-fusion platform, FIX:Fc and FVIII:Fc. Syntonix s lead product, FIX:Fc, is a proprietary long-acting factor IX product for the treatment of hemophilia B. Syntonix is expected to file an investigational new drug application with the Food and Drug Administration, or FDA, for FIX:Fc in 2007. FVIII:Fc is a long-acting Factor VIII product for the treatment of hemophilia A and is approximately two years from filing of the investigational new drug application with the FDA.

The results of operations of Syntonix are included in our consolidated results of operations from the date of acquisition. We have completed our purchase price allocation for the acquisition as set out below (in millions):

Current assets	\$ 0.3
Fixed assets	0.2
Deferred tax asset	27.8
Assembled workforce	0.7
In-process research and development	18.4
Current liabilities	(3.0)
	\$ 44.4

The purchase price included \$2.0 million in loan forgiveness and \$0.7 million in transaction fees. In addition, \$0.3 million of severance charges were accrued in the three months ended March 31, 2007, as a result of the acquisition.

The amount allocated to in-process research and development, or IPR&D, relates to the development of FIX:Fc and FVIII:Fc, which are in a development stage. We expect to incur an additional \$43.3 million to complete FIX:Fc and an additional \$67.1 million to complete FVIII:Fc. The estimated revenues from FIX:Fc and FVIII:Fc are expected to be recognized beginning in 2012 and 2014, respectively. A discount rate of 13% was used to value these projects which we believe to be commensurate with the stage of development and the uncertainties in the economic estimates described above. At the date of acquisition, these compounds had not reached technological feasibility and had no alternative future use. Accordingly, \$18.4 million in IPR&D was expensed upon acquisition.

Upon acquisition, we recognized a deferred tax asset of \$27.8 million relating, principally, to U.S. federal net operating loss carryforwards that we obtained with the acquisition of Syntonix. The deferred tax asset included approximately \$12.8 million of net operating loss and research credit carryovers that will be utilized prior to applicable expiration dates, as well as approximately \$15.3 million of other deferred tax assets primarily related to start-up and research expenditures that have been capitalized for tax purposes and will be amortized over the next several years.

Future contingent consideration payments, if ultimately payable, will be expensed as research and development.

The total revenue, operating income (loss) and net income (loss) impacts of the acquisition for the three months ended March 31, 2007 and 2006 were not material.

9

#### BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# 3. Intangible Assets and Goodwill

As of March 31, 2007 and December 31, 2006, intangible assets and goodwill, net of accumulated amortization, impairment charges and adjustments, are as follows (in thousands):

				Accumulated	
March 31, 2007:	Estimated Life	Cost	Adjustments	Amortization	Net
Out-licensed patents	12 years	\$ 578,000	\$	\$ (162,964)	\$ 415,036
Core/developed technology	15-20 years	3,001,614		(807,988)	2,193,626
Trademarks & tradenames	Indefinite	64,000			64,000
In-licensed patents	14 years	3,000		(523)	2,477
Assembled workforce	4 years	2,075		(320)	1,755
Distribution rights	2 years	11,196			11,196
Total		\$ 3,659,885	\$	\$ (971,795)	\$ 2,688,090
Goodwill	Indefinite	\$ 1,154,844	\$ (19,099)	\$	\$ 1,135,745

	T 4: 4 1	Accumulated							
December 31, 2006:	Estimated Life	Cost	Amortization		Net				
Out-licensed patents	12 years	\$ 578,000	\$	(150,922)	\$	427,078			
Core/developed technology	15-20 years	3,001,516		(760,224)		2,241,292			
Trademarks & tradenames	Indefinite	64,000				64,000			
In-licensed patents	14 years	3,000		(467)		2,533			
Assembled workforce	4 years	1,400		(205)		1,195			
Distribution rights	2 years	11,143				11,143			
Total		\$ 3,659,059	\$	(911,818)	\$	2,747,241			
Goodwill	Indefinite	\$ 1,154,757	\$		\$	1,154,757			

During the three months ended March 31, 2007, goodwill decreased by \$19.1 million as a result of certain tax adjustments. Approximately \$9.1 million of the adjustments related to the adoption of FIN 48. (See Note 8 for discussion on income taxes). Assembled workforce increased by \$0.7 million as a result of the acquisition of Syntonix.

Amortization expense was \$59.9 million and \$70.7 million for the three months ended March 31, 2007 and 2006, respectively.

10

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# 4. Financial Instruments

# Marketable Securities, including Strategic Investments

The following is a summary of marketable securities (in thousands):

March 31, 2007:		Fair Value		Gross realized Gains	Un	Gross realized Losses	Amortized Cost	
Available-for-sale								
Corporate debt securities								
Current	\$	250,607	\$	57	\$	(280)	\$	250,830
Non-current		390,777		618		(1,213)		391,372
U.S. Government securities								
Current		85,261		7		(315)		85,569
Non-current		284,090		450		(587)		284,227
Other interest bearing securities								
Current		10,771				(50)		10,821
Non-current		710,799		2,580		(1,076)		709,295
Total available-for-sale securities	\$	1,732,305	\$	3,712	\$	(3,521)	\$	1,732,114
Other Investments Other marketable securities, non-current	\$	119,061	\$	10,617	\$	(103)	\$	108,547

December 31, 2006:	Fair Value	Unr	Fross ealized Fains	Un	Gross Unrealized Losses		mortized Cost
Available-for-sale							
Corporate debt securities							
Current	\$ 197,088	\$	44	\$	(750)	\$	197,794
Non-current	439,427		368		(3,194)		442,253
U.S. Government securities							
Current	40,063		5		(207)		40,265
Non-current	270,291		254		(1,454)		271,491
Other interest bearing securities							
Current	4,163				(78)		4,241
Non-current	702,520		1,626		(2,713)		703,607

Total available-for-sale securities	\$ 1,653,552	\$ 2,297	\$ (8,396)	\$ 1,659,651
Other Investments Other marketable securities, non-current	\$ 116,949	\$ 8,652	\$ (23)	\$ 108,320

Proceeds from maturities and other sales of marketable securities during the three months ended March 31, 2007 and 2006, which were primarily reinvested, were approximately \$0.8 billion and \$0.4 billion, respectively. Realized losses on these sales for the three months ended March 31, 2007 and 2006, were approximately \$0.4 million and \$1.0 million, respectively. Realized gains on these sales for the three months ended March 31, 2007 and 2006, were approximately \$0.5 million and \$0.2 million, respectively.

11

#### BIOGEN IDEC INC. AND SUBSIDIARIES

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The amortized cost and estimated fair value of securities available-for-sale at March 31, 2007 by contractual maturity are as follows (in thousands):

	Es Fa	A	Amortized Cost		
Due in one year or less Due after one year through five years Mortgage and other asset backed securities	\$	322,872 682,873 726,560	\$	323,409 683,599 725,106	
Total	\$	1,732,305	\$	1,732,114	

The average maturity of our marketable securities as of March 31, 2007 and December 31, 2006, was 16 months and 18 months, respectively.

In the three months ended March 31, 2007 we recognized \$2.5 million in charges for the impairment of available-for-sale securities that were determined to be other-than-temporary following a decline in value. In the three months ended March 31, 2006 we recognized no charges for the impairment of available-for-sale securities. Unrealized losses on available-for-sale securities at March 31, 2007 consist of the following (in thousands):

	I	Less than f Fair Value	Uni	onths realized osses	1	2 Months Fair Value	Un	Greater crealized Losses	To Fair Value	 realized Losses
Corporate debt securities U.S. Government securities Other interest bearing securities	\$	123,960 66,642 5,197	\$	(280) (316) (50)	\$	167,820 162,466 222,586	\$	(1,213) (586) (1,076)	\$ 291,780 229,108 227,783	\$ (1,493) (902) (1,126)
Subtotal		195,799		(646)		552,872		(2,875)	748,671	(3,521)
Other marketable securities, noncurrent		13,435		(103)					13,435	(103)
Total	\$	209,234	\$	(749)	\$	552,872	\$	(2,875)	\$ 762,106	\$ (3,624)

Unrealized losses relate to various debt securities, including U.S. Government issues, corporate bonds and asset-backed securities. The unrealized losses on these securities were primarily caused by a rise in interest rates subsequent to purchase. We believe that these unrealized losses are temporary, and we have the intent and ability to hold these securities to recovery, which may be at maturity.

# Non-Marketable Securities

We hold other investments in equity securities of certain privately held biotechnology companies or biotechnology oriented venture capital funds. The carrying value of these strategic investments at March 31, 2007, and December 31, 2006, was \$44.8 million and \$32.6 million, respectively.

In the three months ended March 31, 2007 and 2006, we recorded \$0.4 million and \$2.1 million, respectively, in charges for the impairment of investments that were determined to be other-than-temporary.

#### **Forward Contracts**

We have foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies. All foreign currency forward contracts in effect at March 31, 2007 have durations of three to nine months. These contracts have been designated as cash flow hedges and accordingly, to the extent effective, any unrealized gains or losses on these foreign currency forward contracts are reported in other comprehensive income. Realized gains and losses for the effective portion are recognized with the completion

12

#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of the underlying hedge transaction. To the extent ineffective, hedge transaction gains and losses are reported in other income (expense).

The notional settlement amount of the foreign currency forward contracts outstanding at March 31, 2007 was approximately \$227.4 million. These contracts had an aggregate fair value of \$2.1 million, representing an unrealized loss, and were included in other current liabilities at March 31, 2007. The notional settlement amount of the foreign currency forward contracts outstanding at December 31, 2006 was approximately \$293.2 million. These contracts had an aggregate fair value of \$0.2 million, representing an unrealized loss, and were included in other current liabilities at December 31, 2006.

For the three months ended March 31, 2007, there was \$0.6 million recognized in earnings as a loss due to hedge ineffectiveness. For the three months ended March 31, 2006, we recognized \$0.7 million of losses in earnings due to hedge ineffectiveness. Minimal amounts were recognized in product revenue for the settlement of certain effective cash flow hedge instruments for the three months ended March 31, 2007, as compared to approximately \$0.9 million of losses for the three months ended March 31, 2006. These settlements were recorded in the same period as the related forecasted transactions affecting earnings.

# 5. Comprehensive Income

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

		nths Ended ch 31,
	2007	2006
Net income	\$ 131,501	\$ 122,969
Translation adjustments	5,629	4,796
Net unrealized gains on available-for-sale marketable securities, net of tax of \$(3,838)		
and \$(8,989), respectively	5,451	15,364
Net unrealized losses on foreign currency forward contracts, net of tax of \$686, and		
\$972, respectively	(1,277)	(1,655)
Total comprehensive income	\$ 141,304	\$ 141,474

13

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# 6. Earnings per Share

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

		onths Ended ech 31, 2006
	2007	2000
Numerator: Income before cumulative effect of accounting change Cumulative effect of accounting change	\$ 131,501	\$ 119,190 3,779
Net income Adjustment for net income allocable to preferred shares	131,501 (190)	122,969 (179)
Net income used in calculating basic and diluted earnings per share	\$ 131,311	\$ 122,790
Denominator:		
Weighted average number of common shares outstanding  Effect of dilutive securities:	340,310	339,653
Convertible promissory notes due 2019	465	3,048
Stock options	1,898	2,205
Restricted stock awards	633	747
Time-vested restricted stock units	511	89
Performance-based restricted stock units	168	
Convertible promissory notes due 2032	73	73
Dilutive potential common shares	3,748	6,162
Shares used in calculating diluted earnings per share	344,058	345,815

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

	Th	ree Mor Marc	nths Each 31,	nded
	2	007	2	006
Numerator: Net income allocable to preferred shares	\$	190	\$	179

Denominator	:

Stock options Time-vested restricted stock units Convertible preferred stock	13,753 907 493	18,119 493
Total	15,153	18,612

14

# **BIOGEN IDEC INC. AND SUBSIDIARIES**

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

# 7. Share-Based Payments

For the three months ended March 31, 2007 and 2006, share-based compensation expense reduced our results of operations as follows (in thousands, except for earnings per share):

	Thr	ee Months	<b>Three Months Ended March</b>					06
		Ended March 31,		Impact Before				
	2007  Effect on Net Income		Cu	ımulative Effect of		mulative Effect		
				ecounting Change		ccounting Change	Effect on Net Income	
Income before income taxes Tax effect	\$	(29,560) 9,228	\$	(29,194) 9,114	\$	5,574 (1,795)	\$	(23,620) 7,319
Net income	\$	(20,332)	\$	(20,080)	\$	3,779	\$	(16,301)
Basic earnings per share	\$	(0.06)	\$	(0.06)	\$	0.01	\$	(0.05)
Diluted earnings per share	\$	(0.06)	\$	(0.06)	\$	0.01	\$	(0.05)

Share-based compensation expense and cost for the three months ended March 31, 2007 and 2006 is as follows (in thousands):

	Three Months Ended March 31, 2007 Restricted Stock					Three Months Ended March 31, 2006 Restricted Stock						
	Stock Options & ESPP		and Restricted Stock Units		Total		Stock Options & ESPP		and Restricted Stock Units		Total	
Research and development Selling, general and	\$	3,038	\$	7,690	\$	10,728	\$	4,955	\$	6,403	\$	11,358
administrative		6,138		13,666		19,804		8,438		9,807		18,245
Total	\$	9,176	\$	21,356	\$	30,532	\$	13,393	\$	16,210	\$	29,603
Pre-tax cumulative effect catch-up												(5,574)

Pre-tax effect of		
share-based compensation	\$ 30,532	\$ 24,029
Capitalized		
share-based payment costs	(972)	(409)
COSIS	(312)	(407)
Share-based		
compensation expense	\$ 29,560	\$ 23,620

For the three months ended March 31, 2006, the expense is net of a cumulative pre-tax adjustment of \$5.6 million resulting from the application of an estimated forfeiture rate for prior period unvested restricted stock awards.

# Stock options

During the three months ended March 31, 2007 and 2006, we made our annual awards of stock options. Approximately one million stock options were awarded as part of the annual award in February 2007 and bore an exercise price of \$49.31 per share. Approximately 0.9 million stock options were awarded as part of the annual grant in February 2006 and bore an exercise price of \$44.24 per share.

15

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair value of the stock option grants awarded in the three months ended March 31, 2007 and 2006 were estimated as of the date of grant using a Black-Scholes option valuation model that uses the following weighted-average assumptions:

		Three Months Ended March 31,		
	2007	2006		
Expected dividend yield	0.0%	0.0%		
Expected stock price volatility	34.8%	34.8%		
Risk-free interest rate	4.46%	4.35%		
Expected option life in years	4.87	4.87		
Per share grant-date fair value	\$ 16.12	\$ 16.82		

For the three months ended March 31, 2007 and 2006, we recorded \$8.4 million and \$10.7 million, respectively, of stock compensation charges related to stock options.

#### Time-Vested Restricted Stock Units

During the three months ended March 31, 2007 and 2006, we made our annual awards of time-vested restricted stock units, or RSUs. Approximately 2.3 million RSUs were awarded as part of the annual grant in February 2007 at a grant date fair value of \$49.31 per share. Approximately 2.2 million RSUs were awarded as part of the annual grant in February 2006 at a grant date fair value of \$44.24 per share.

For the three months ended March 31, 2007 and 2006, we recorded \$16.0 million and \$3.7 million, respectively, of stock compensation charges related to time-vested RSUs.

# Performance-Based Restricted Stock Units

On March 14, 2007, 258,000 performance-based RSUs vested and were converted into shares of common stock. The shares had been earned by employees pursuant to the terms of the awards granted in September 2005. The amounts that vested represented 83% of the remaining 30% of the total shares issued under the program that had not already vested in September 2006.

In addition, in February 2007, 100,000 performance-based RSU s, granted to our CEO in February 2006, vested and were converted into shares of common stock.

In June 2006, we committed to grant 120,000 performance-based RSUs to an executive. These RSUs will be issued at a rate of 30,000 per year for four years. The first tranche of 30,000 RSUs was granted in January 2007. This tranche, and subsequent tranches, are subject to performance conditions established at the time of issuance. The total grant of 120,000 RSUs is being recognized as compensation expense over the requisite service period as if it were multiple awards, in accordance with FIN 28, Accounting for Stock Appreciation Rights and Other Variable Stock Options or

#### Award Plans.

In the three months ended March 31, 2007 and 2006, we recorded compensation charges of approximately \$1.7 million and \$10.1 million, respectively, related to performance-based restricted stock units.

# Restricted Stock Awards

For the three months ended March 31, 2007 and 2006, we recorded \$3.7 million and \$2.4 million, respectively, of stock compensation charges related to restricted stock awards.

# Employee Stock Purchase Plan

During the three months ended March 31, 2007, 0.2 million shares were issued under the employee stock purchase plan, or ESPP. During the three months ended March 31, 2006, 0.1 million shares were issued under

16

#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the ESPP. In the three months ended March 31, 2007 and 2006, we recorded compensation charges of approximately \$0.8 million and \$2.7 million, respectively.

#### 8. Income Taxes

#### Tax Rate

Our effective tax rate was 35.3% on pre-tax income for the three months ended March 31, 2007, compared to 37.8% for the comparable period in 2006.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the three months ended March 31, 2007 and 2006, respectively, is as follows:

		Three Months Ended March 31,		
	2007	2006		
Statutory rate	35.0%	35.0%		
State taxes	2.0	1.9		
Foreign taxes	(7.3)	(6.1)		
Credits and net operating loss utilization	(1.1)	(0.3)		
Other	1.3	0.5		
Fair value adjustment	2.9	6.4		
IPR&D	3.3			
Non-deductible items	(0.8)	0.4		
Effective tax rates	35.3%	37.8%		

#### **Contingency**

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

# Adoption of FASB Interpretation No. 48

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, on January 1, 2007. As a result of the adoption of FIN 48, we recognized a reduction in the liability for unrecognized tax benefits of \$14.2 million, which was recorded as a \$1.8 million reduction to the January 1, 2007 balance of our

accumulated deficit, a \$9.1 million reduction in goodwill and a \$3.3 million increase in our deferred tax liability.

17

#### BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in millions):

Balance at January 1, 2007	\$ 196.8
Additions based on tax positions related to the current period	7.0
Additions for tax positions of prior periods	48.2
Reductions for tax positions of prior periods	(36.7)
Settlements	(1.8)
Balance at March 31, 2007	\$ 213.5

Included in the balance at March 31, 2007 and January 1, 2007, are \$114.1 million and \$98.2 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in any future periods.

We recognize interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the three months ended March 31, 2007 and 2006, we recognized approximately \$6.2 million and \$3.4 million in interest. We accrued approximately \$26.5 million and \$20.3 million for the payment of interest at March 31, 2007 and January 1, 2007, respectively.

We file income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2001. The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2003 and 2004 in 2006. We expect the IRS to complete its examination by December 31, 2007. The final outcome of the examination is not yet determinable; however, we do not expect that any adjustments as a result of the examination would have a material effect on our financial position.

In connection with the adoption of FIN 48, we reclassified approximately \$113 million in reserves for uncertain tax positions from current taxes payable to long-term liabilities.

# 9. Other Income (Expense), Net

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

		Three Months Ended March 31,		
	2007	2006		
Interest income	\$ 29,141	\$ 23,557		
Interest expense	(406)	(293)		
Other expense, net	(7,033)	(4,599)		

Total other income (expense), net

\$ 21,702 \$ 18,665

For the three months ended March 31, 2007, the principal components of other expense, net, were minority interest expense (\$2.1 million), legal settlements (\$1.4 million), and net realized losses on sales of marketable securities (\$2.3 million). For the three months ended March 31, 2006, the principal components of other expense, net, were impairment charges on certain marketable securities (\$2.1 million), legal settlements (\$1.5 million), and our minority interest in joint ventures (\$2.0 million) offset by hedging gains (\$1.8 million).

18

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

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

#### 10. Unconsolidated Joint Business

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

		Three Months Ended March 31,		
	2007	2006		
Copromotion profits Reimbursement of selling and development expenses	\$ 136,548 14,099	\$ 124,057 15,928		
Royalty revenue on sales of RITUXAN outside the U.S.	56,517	43,395		
Total unconsolidated joint business revenue	\$ 207,164	\$ 183,380		

Our royalty revenue on sales of RITUXAN outside the U.S. is based on Roche s and Zenyaku s net sales to third-party customers and is recorded on a cash basis.

Under our collaboration agreement, we will receive lower royalty percentage of revenue from Genentech on sales by Roche and Zenyaku of any new anti-CD20 products, as compared to royalty percentage of revenue received on sales of RITUXAN. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis. For the majority of European countries, the first commercial sale of RITUXAN occurred in the second half of 1998.

#### 11. Litigation

On March 2, 2005, we, along with William H. Rastetter, our former Executive Chairman, and James C. Mullen, our Chief Executive Officer, were named as defendants in a purported class action lawsuit, captioned Brown v. Biogen Idec Inc., et al. ( Brown ), filed in the U.S. District Court for the District of Massachusetts (the Court ). The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The action is purportedly brought on behalf of all purchasers of our publicly-traded securities between February 18, 2004 and February 25, 2005. The plaintiff alleges that the defendants made materially false and misleading statements regarding potentially serious side effects of TYSABRI in order to gain accelerated approval from the FDA for the product s distribution and sale. The plaintiff alleges that these materially false and misleading statements harmed the purported class by artificially inflating our stock price during the purported class period and that company insiders benefited personally from the inflated price by selling our stock. The plaintiff seeks unspecified damages, as well as interest, costs and attorneys fees. Substantially similar actions, captioned Grill v. Biogen Idec Inc., et al. and Lobel v. Biogen Idec Inc., et al., were filed on March 10, 2005 and April 21, 2005, respectively, in the same court by other purported class representatives. Those actions have been consolidated with the Brown case. On October 13, 2006, the plaintiffs filed an amended consolidated complaint which, among other amendments to the allegations, adds as defendants Peter N. Kellogg, our Chief Financial Officer, William R. Rohn, our former Chief Operating Officer, Burt A. Adelman, our Executive Vice President, Portfolio Strategy, and Thomas J. Bucknum, our

former General Counsel. On November 15, 2006, we and all the other defendants who had been served as of that date filed a motion to dismiss the amended consolidated complaint. A hearing on the Motion to Dismiss was held on March 12, 2007. We believe that the actions are without merit and intend to contest them vigorously. At this early stage of litigation, we cannot make any estimate of a potential loss or range of loss.

On June 9, 2005, we, along with numerous other companies, received a request for information from the U.S. Senate Committee on Finance regarding our practices relating to educational and other grants. On January 9, 2006, we, along with numerous other companies, received a further request for information from the Committee. We filed a timely response to the request on March 6, 2006 and have cooperated fully with the Committee s information requests. The Committee issued a report in April 2007 and stated that it may

19

## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

request more information. We are unable to predict the outcome of this review or the timing of its resolution at this time.

On October 4, 2004, Genentech, Inc. received a subpoena from the U.S. Department of Justice requesting documents related to the promotion of RITUXAN. We market RITUXAN in the U.S. in collaboration with Genentech. Genentech has disclosed that it is cooperating with the associated investigation which they disclosed that they have been advised is both civil and criminal in nature. Genentech has reported further that the government has called and is expected to call former and current Genentech employees to appear before a grand jury in connection with this investigation. 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.

Along with several other major pharmaceutical and biotechnology companies, Biogen, Inc. (now Biogen Idec MA, Inc., one of our wholly-owned subsidiaries) or, in certain cases, Biogen Idec Inc., was named as a defendant in lawsuits filed by the City of New York and numerous Counties of the State of New York. All of the cases except for cases filed by the County of Erie, County of Nassau, County of Oswego and County of Schenectady are the subject of a Consolidated Complaint (Consolidated Complaint), which was filed on June 15, 2005, in the U.S. District Court for the District of Massachusetts in Multi-District Litigation No. 1456 (the MDL proceedings). The County of Nassau filed a second amended complaint on January 6, 2006, also in the MDL proceedings. The County of Erie, County of Oswego and County of Schenectady cases have been removed and transferred to the MDL proceedings, and are currently subject to motions to remand these cases to state court.

All of the complaints in these cases allege that the defendants (i) fraudulently reported the Average Wholesale Price for certain drugs for which Medicaid provides reimbursement ( Covered Drugs ); (ii) marketed and promoted the sale of Covered Drugs to providers based on the providers ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; (iii) provided financial 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 Consolidated Complaint and County of Nassau complaint allege that the defendants failed to accurately report the best price on the Covered Drugs to the Secretary of Health and Human Services pursuant to rebate agreements, and excluded from their reporting certain discounts and other rebates that would have reduced the best price. The County of Nassau complaint also alleged a violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO) statute.

On April 2, 2007, the defendants joint motion to dismiss the Consolidated Complaint and the County of Nassau complaint was granted in part, but certain claims against us remained. Our individual motion to dismiss these complaints remains pending. On September 7, 2006, a New York State court granted in part and denied in part our motion to dismiss the County of Erie complaint. We subsequently answered the complaints filed by the Counties of Erie, Oswego and Schenectady. We intend to defend ourselves vigorously against all of the allegations and claims in these lawsuits. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

Along with several other major pharmaceutical and biotechnology companies, we were also named as a defendant in a lawsuit filed by the Attorney General of Arizona. The lawsuit was filed in the Superior Court of the State of Arizona and transferred to the MDL proceedings. The complaint, as amended on March 13, 2007, is brought on behalf of Arizona consumers and other payors for drugs, and alleges that the defendants violated the state consumer fraud

statute by fraudulently reporting the Average Wholesale Price for certain drugs covered by various private and public insurance mechanisms and by marketing these drugs to providers based on the providers ability to collect inflated payments from third-party payors. Motions to dismiss the complaint have not yet been filed and briefed. We intend to defend ourselves vigorously against all of the

20

## BIOGEN IDEC INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

allegations and claims in this lawsuit. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On January 6, 2006, we were served with a lawsuit, captioned United States of America ex rel. Paul P. McDermott v. Genentech, Inc. and Biogen Idec, Inc., filed in the United States District Court of the District of Maine (Court), The lawsuit was filed under seal on July 29, 2005 by a former employee of our co-defendant Genentech pursuant to the False Claims Act, 31 U.S.C. section 3729 et. seq. On December 20, 2005, the U.S. government elected not to intervene, and the complaint was subsequently unsealed and served. On April 4, 2006, the plaintiff filed his first amended complaint alleging, among other things, that we directly solicited physicians and their staff members to illegally market off-label uses of RITUXAN for treating rheumatoid arthritis, provided illegal kickbacks to physicians to promote off-label uses, trained our employees in methods of avoiding the detection of these off-label sales and marketing activities, formed a network of employees whose assigned duties involved off-label promotion of RITUXAN, intended and caused the off-label promotion of RITUXAN to result in the submission of false claims to the government, and conspired with Genentech to defraud the government. The plaintiff seeks entry of judgment on behalf of the United States of America against the defendants, an award to the plaintiff as relator, and all costs, expenses, attorneys fees, interest and other appropriate relief. On May 4, 2006, we filed a motion to dismiss the first amended complaint on the grounds that the Court lacks subject matter jurisdiction, the complaint fails to state a claim and the claims were not pleaded with particularity. On December 14, 2006, the Magistrate Judge recommended that the Court dismiss the case based on our and Genentech s Motion to Dismiss. The Plaintiff filed objections to this recommendation and the matter awaits decision by the District Court Judge. At this stage of the litigation, we cannot make any estimate of a potential loss or range of loss.

On June 17, 2006, we filed a Demand for Arbitration against Genentech, Inc. with the American Arbitration Association ( AAA ). In the Demand for Arbitration, we alleged that Genentech breached the parties Amended and Restated Collaboration Agreement dated June 19, 2003 (the Collaboration Agreement ), by failing to honor our contractual right to participate in strategic decisions affecting the parties joint development and commercialization of certain pharmaceutical products, including humanized anti-CD20 antibodies. The original Demand for Arbitration we filed focused primarily on Genentech s unilateral development of an anti-CD20 product known as a second generation anti-CD20 molecule to treat Neuromyelitis Optica ( NMO ), a relatively rare disorder of the central nervous system. Genentech filed an Answering Statement in response to our Demand in which Genentech denied that it had breached the Collaboration Agreement and alleged that we had breached the Collaboration Agreement. Genentech also asserted for the first time that the November 2003 transaction in which Idec acquired Biogen and became Biogen Idec was a change of control of our company under the Collaboration Agreement, a position with which we disagree strongly. It is our position that the Biogen Idec merger did not constitute a change of control under the Collaboration Agreement and that, even if it did, Genentech s rights under the change of control provision, which must be asserted within ninety (90) days of the change of control event, have long since expired. We intend to vigorously assert that position if Genentech persists in making this claim. On December 5, 2006, we filed an Amended Demand for Arbitration with the AAA to make clear that the parties dispute also includes a disagreement over Genentech s unilateral development of another collaboration product a third generation anti-CD20 molecule to treat certain oncology indications. A three-member arbitration panel has been selected to decide this matter. The arbitration is in a very early stage and we cannot make a determination as to the likely outcome.

On August 10, 2004, Classen Immunotherapies, Inc. filed suit against us, GlaxoSmithKline, Chiron Corporation, Merck & Co., Inc., and Kaiser-Permanente, Inc. in the U.S. District Court for the District of Maryland contending that we induced infringement of U.S. Patent Nos, 6,420,139, 6,638,739, 5,728,383, and 5,723,283, all of which are

directed to various methods of immunization or determination of immunization schedules. All Counts asserted against us by Classen were dismissed by the Court upon various motions filed by the Parties. In early December 2006, Classen filed its initial appeal brief with the United States Court of

21

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

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

Appeals for the Federal Circuit. In that brief, Classen argues for the first time that we have no reporting duties and no activities related to FDA reporting regarding Hepatitis B vaccines and hence can have no claim to a safe harbor protection under Section 271(e)1. Classen asserts, however, that we are inducing infringement by having users consider risk prior to choosing an immunization schedule. We have opposed the appeal on the basis that Classen has waived this argument by not raising it in the district court and, moreover, that the argument lacks merit because we cannot induce infringement if there has been no actual infringement. We are unable, however, to predict the outcome of this appeal.

On January, 30, 2007, the Estate of Thaddeus Leoniak commenced a civil lawsuit in the Court of Common Pleas, Philadelphia County, Pennsylvania, against us, the Fox Chase Cancer Center and three physicians. The Complaint alleges that Thaddeus Leoniak died as a result of taking the drug ZEVALIN, and seeks to hold us strictly liable for placing an allegedly unreasonably dangerous product in the stream of commerce without proper warnings. The Complaint also seeks to hold us liable for alleged negligence in the design, manufacture, advertising, marketing, promoting, distributing, supplying and selling of ZEVALIN. The lawsuit seeks damages for pecuniary losses suffered by the decedent s survivors and for compensatory damages for decedent s pain and suffering, loss of earnings and deprivation of normal activities, all in an amount in excess of \$50,000. On January 31, 2007, the Plaintiff s counsel demanded \$7.0 million to settle the lawsuit. We believe that we have good and valid defenses to the Complaint and intend to vigorously defend the case. At this stage of the litigation, we cannot make any estimate of a potential loss, if any.

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 condition.

## 12. 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 our operations as a single operating segment.

## 13. Notes Payable

Notes payable consists of the following (in thousands):

		rch 31, 2007	December 31, 2006
Current portion: 30-year senior convertible promissory notes, due 2032 at 1.75% 20-year subordinated convertible promissory notes, due 2019 at 5.5%	\$	6,570 2,578	\$
	\$	9,148	\$

Non-current portion:			
30-year senior convertible promissory notes, due 2032 at 1.75%	\$	\$	6,541
20-year subordinated convertible promissory notes, due 2019 at 5	.5%		39,081
Credit line from Dompé		12,035	11,876
Note payable to Fumedica		40,008	39,196
	\$	52,043 \$	96,694
22			
22			

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

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

In January 2007, we issued 2.8 million shares of common stock for \$70.5 million in face value and \$36.6 million in carrying value of our 2019 subordinated notes that the holders had elected to convert into common stock.

On May 1, 2007, we paid \$6.6 million to note holders of the 2032 senior notes that had exercised their right to put the notes back to us. These notes had a face value of \$10.1 million.

## 14. New Accounting Pronouncements

On February 15, 2007, FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, or SFAS 159, was issued. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this standard would have on our financial statements.

On September 6, 2006, FASB Statement No. 157 *Fair Value Measurement*, or SFAS 157, was issued. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. The Statement will be effective for financial statements for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact this standard would have on our financial statements.

## 15. Contingency

In connection with the relocation from leased facilities to our research and corporate campus in San Diego, California, we entered into a lease assignment, in January 2005, with Tanox West, Inc., or Tanox, for a manufacturing facility in San Diego for which we have outstanding lease obligations through September 2008. Under the lease assignment, Tanox was assigned all of our rights, title, and interest in the amended lease and assumed all of the terms, covenants, conditions and obligations required to be kept, performed and fulfilled under the amended lease, including the making of all payments under the amended lease. However, if Tanox were to fail to perform under the lease assignment we would be responsible for all obligations under the amended lease through September 2008. At March 31, 2007, our estimate of the maximum potential of future payments under the amended lease through September 2008 is \$7.3 million. Under the lease assignment, Tanox has agreed to indemnify and hold us harmless from and against any and all claims, proceedings and demands and all costs, expenses and liabilities arising out of their performance or failure to perform under the lease assignment.

23

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

## **Forward-Looking Information**

In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those reflected in such forward-looking statements. You can identify these forward-looking statements by their use of words such as anticipate, believe. forecast, intend, plan, project, target, will and other words and terms of similar meani can identify them by the fact that they do not relate strictly to historical or current facts. Reference is made in particular to forward-looking statements regarding the anticipated level of future product sales, royalty revenues, expenses and profits, regulatory approvals, our long-term growth, the development and marketing of additional products, the impact of competitive products, the anticipated outcome of pending or anticipated litigation and patent-related proceedings, our ability to meet our manufacturing needs, the value of investments in certain marketable securities, and our plans to spend additional capital on external business development and research opportunities. Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed in the section entitled Risk Factors in Part II of this report and elsewhere in this report. 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 appearing elsewhere in this Report on Form 10-Q, beginning on page 3.

#### Overview

Biogen Idec Inc. is an international biotechnology company that creates new standards of care in oncology, neurology, immunology and other speciality areas of unmet medical need.

We currently have five products:

AVONEX® (interferon beta-1a);

RITUXAN® (rituximab);

TYSABRI® (natalizumab);

FUMADERM® (dimethylfumarate and monoethylfumarate salts); and,

ZEVALIN® (ibritumomab tiuxetan). During the third quarter of 2006, we began executing a plan to divest our ZEVALIN product line.

Additionally, through April 2006, we recorded product revenues from sales of AMEVIVE® (alefacept). In April 2006, we sold the worldwide rights to this product to Astellas Pharma US, Inc., or Astellas. We will continue to manufacture and supply this product to Astellas for a period of up to 11 years.

## **Significant Event**

During the three months ended March 31, 2007, we completed the acquisition of 100% of the stock of Syntonix Pharmaceuticals, Inc. for total consideration of \$44.4 million. The most significant financial statement impact resulting from the purchase was the recognition of a charge for acquired in-process research and development, or IPR&D, of approximately \$18.4 million.

24

# **Results of Operations**

# **Revenues (in thousands)**

	Three Months Ended March 31, 2007 2006				
Product Revenues U.S.	\$ 291,199	41%	\$ 240,067	39%	
Rest of world	193,189	27%	166,452	28%	
Total product revenues Unconsolidated joint business Other Revenue	484,388 207,164	68% 29%	406,519 183,380	67% 30%	
Royalties	22,987	3%	20,561	3%	
Corporate partner  Total other revenue	1,371 24,358	0% 3%	715 21,276	0% 3%	
Total revenues	\$ 715,910	100%	\$ 611,175	100%	

# **Product Revenues (in thousands)**

	Three Months Ended March 31,				
	2007 200				
AVONEX	\$ 448,809	93%	\$ 393,427	97%	
TYSABRI	29,760	6%	(196)	0%	
AMEVIVE	216	0%	8,278	2%	
ZEVALIN	5,603	1%	5,010	1%	
Total product revenues	\$ 484,388	100%	\$ 406,519	100%	

## **AVONEX**

Revenues from AVONEX for the three months ended March 31, 2007 and 2006 were as follows (in thousands):

	Three Months Ended March 31,					
	2007			2006		
AVONEX						
U.S.	\$	270,004	60%	\$	232,052	59%
Rest of World		178,805	40%		161,375	41%

Total AVONEX revenues \$ 448,809 100% \$ 393,427 100%

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, U.S. sales of AVONEX increased \$38.0 million, or 16.4%, due, principally, to the impact of price increases.

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, international sales of AVONEX increased \$17.4 million, or 10.8%, due to the impact of exchange rates (9.1%) and slightly higher volume.

We expect to face increasing competition in the MS marketplace in and outside the U.S. from existing and new MS treatments, including TYSABRI, which may impact sales of AVONEX. We expect future sales of AVONEX to be dependent to a large extent on our ability to compete successfully with the products of our competitors.

25

## **TYSABRI**

Revenues from TYSABRI for the three months ended March 31, 2007 and 2006 were as follows (in thousands):

		nree Months Er 2007	nded March 31, 2006	
TYSABRI U.S. Rest of World	\$ 17,04 12,7		\$ (196) 1009	%
Total TYSABRI revenues	\$ 29,70	60 100%	\$ (196) 1009	%

In July 2006, we began to ship TYSABRI in both the U.S. and Europe. The revenue for such shipments in the three months ended March 31, 2007 was \$17.0 million and \$12.7 million in the U.S. and Europe, respectively.

For the three months ended March 31, 2006, no sales were made but certain amounts were recognized related to the amortization of intangible assets, giving rise to negative revenue of \$196,000.

#### **ZEVALIN**

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, sales of ZEVALIN increased \$0.6 million, or 11.8%, due, principally to an increase in international sales.

## **FUMADERM**

We began recognizing revenue on sales of FUMADERM upon completion of our acquisition of Fumapharm in June 2006.

In December 2006, we acquired from Fumedica the right to distribute FUMADERM in Germany effective May 2007. In connection with the acquisition we committed to the repurchase of inventory not sold by May 2007. As a result of this provision, we are currently deferring the recognition of revenue on shipments made to Fumedica and, accordingly, no revenue has been recognized on sales of FUMADERM in the three months ended March 31, 2007. Revenue previously deferred will be recognized in the three months ended June 30, 2007, to the extent the inventory was shipped to customers.

We commence shipments of FUMADERM directly to customers in May 2007.

## **Provisions for Discounts and Allowances**

Revenues from product sales are recognized when product is shipped and title and risk of loss has passed to the customer, typically upon delivery. Revenues are recorded net of applicable allowances for trade term discounts, wholesaler incentives, Medicaid rebates, Veteran s Administration, or VA, rebates, managed care, product returns and other applicable allowances and the estimates we make with respect to these allowances represent significant judgments that we make with regard to revenue recognition.

Reserves for discounts and allowances reduced gross product revenues as follows (in millions):

	Th	Three Months Ended March 31,			
	20	007	,	2006	
Discounts Contractual adjustments Returns	\$	10.5 22.8 4.3	\$	22.8 28.7 7.3	
Total allowances	\$	37.6	\$	58.8	
Gross product revenues Percent of gross product revenues	\$ :	522.0 7.2%	\$	465.3 12.6%	

Product revenue allowances are categorized as follows: discounts, contractual adjustments and returns.

Discount reserves include trade term discounts and wholesaler incentives. During the three months ended March 31, 2007, we changed the manner in which we administer our patient assistance and patient replacement goods programs. Prior to January 1, 2007, AVONEX product shipped to administer these programs was invoiced and recorded as gross product revenue. In addition, an offsetting provision for discount and returns was reflected for expected credit requests from the distributor that administers these programs on our behalf. On January 1, 2007, we established a consignment model. Under the new arrangement, no gross revenue is recorded for product shipped to satisfy these programs. For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, discounts expense decreased as a result of the change in the manner in which patient assistance is now administered (\$15.1 million), offset by higher discounts and incentives related to higher pricing levels.

Contractual adjustments relate to Medicaid rebates, VA rebates and managed care. For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, contractual adjustments decreased due, principally, to lower Medicaid rebates as a result of the introduction of Medicare Part D in 2006.

Allowances for returns are established for returns made by wholesalers. In accordance with contractual terms, wholesalers are permitted to return product for reasons such as damaged or expired product. For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, returns decreased by \$3.0 million, primarily as a result of the change in the manner in which we administer the patient replacement goods program (\$4.2 million), offset by slightly higher return levels.

## **Unconsolidated Joint Business Revenue**

Copromotion profits consist of the following (in thousands):

Three Months Ended March 31, 2007 2006

Product revenues, net Costs and expenses	\$ 534,792 180,922	\$ 476,978 154,334
Copromotion profits	\$ 353,870	\$ 322,644
Biogen Idec s share of copromotion profits	\$ 136,548	\$ 124,057

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, our share of copromotion profits increased \$12.5 million, or 10.1%, due, principally, to higher sales of RITUXAN, as well as the approval of RITUXAN for treatment of rheumatoid arthritis, or RA, in February 2006.

27

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

	Three Mon Marc	
	2007	2006
Copromotion profits Reimbursement of selling and development expenses	\$ 136,548 14,099	\$ 124,057 15,928
Royalty revenue on sales of RITUXAN outside the U.S.  Total unconsolidated joint business revenue	56,517 \$ 207,164	43,395 \$ 183,380

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, royalty revenue on sales of RITUXAN outside the U.S. increased \$13.1 million, or 30.2%, due, principally to increased sales outside the U.S. reflecting greater market penetration.

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

	Biogen Idec s Share of Copromotion
Copromotion Operating Profits	Profits
First \$50 million	30%
Greater than \$50 million	40%

In 2007 and 2006, the 40% threshold was met during the first quarter. For each calendar year or portion thereof following the approval date of the first new anti-CD20 product, the pretax copromotion profit-sharing formula for RITUXAN and other anti-CD20 products sold by us and Genentech will change to the following:

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

Table of Contents 52

30%

After such sales exceed \$350 million in any calendar year(4)

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

28

(4) if \$350 million in new product sales is achieved in the same calendar year that \$150 million in new product sales is achieved, then the 30% copromotion profit-sharing rate will not be effective until January 1 of the following calendar year (or January 1 of the second following calendar year if the first new anti-CD20 product receives approval and, in the same calendar year, the \$150 million and \$350 million new product sales levels are achieved). Once the \$350 million new product sales level is achieved then our share of copromotion profits for the balance of the year and all subsequent years will be 30%.

Currently, we record our share of expenses incurred for the development of new anti-CD20 products in research and development expense until such time as a new product is approved, at which time we will record our share of pretax copromotion profits related to the new product in revenues from unconsolidated joint business. We record our royalty revenue on sales of RITUXAN outside the U.S. on a cash basis.

Under the amended and restated collaboration agreement, we will receive a lower royalty percentage of revenue from Genentech on sales by Roche and Zenyaku of new anti-CD20 products, as compared to the royalty percentage of revenue on sales of RITUXAN. The royalty period with respect to all products is 11 years from the first commercial sale of such product on a country-by-country basis. For the majority of European countries, the first commercial sale of RITUXAN occurred in the second half of 1998.

Total unconsolidated joint business revenue represented 28.9% of our total revenues for the three months ended March 31, 2007, as compared to 30.0% for the comparable period in 2006.

#### Other Revenue

Other revenue for the three months ended March 31, 2007 and 2006 were as follows (in thousands):

	Three Months Ended March 31,						
	2007		2006				
Royalties	\$ 22,987	94%	\$ 20,561	97%			
Corporate partner	1,371	6%	715	3%			
Other revenue	\$ 24,358	100%	\$ 21,276	100%			

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, royalties increased \$2.4 million, or 11.8%, due, principally, to higher royalties on sales of product licensed by The Medicines Company, offset by lower royalties on sales of product licensed by Schering-Plough Corporation.

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

Corporate partner revenues consist of contract revenues and license fees.

## Cost of Sales, excluding Amortization of Intangibles

Cost of sales, excluding amortization of intangibles, includes the following (in thousands):

		Three Months Ended March 31, 2007 2006						
Cost of product revenues Cost of royalty revenues	\$	80,779 1,171	99% 1%	\$	66,428 1,066	98% 2%		
Cost of sales, excluding amortization of intangibles	\$	81,950	100%	\$	67,494	100%		
	29							

## **Table of Contents**

Cost of product revenues, included in cost of sales, by product, are as follows (in thousands):

	Three Months Ended March 31,					
Product	2007	2006				
AVONEX	\$ 67,118	\$ 55,624				
AMEVIVE	572	7,792				
ZEVALIN	4,625	2,161				
TYSABRI	781	851				
FUMADERM	32					
OTHER	7,651					
Cost of product revenue, excluding amortization of intangibles	\$ 80,779	\$ 66,428				

#### **AVONEX**

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, the cost of product revenue for AVONEX increased \$11.5 million, or 20.7%, due, principally, to increased write-offs of unmarketable inventory (\$3.4 million), and increased expenses (\$5.5 million) related to inventory that has been scrapped.

#### **TYSABRI**

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, the cost of product revenue for TYSABRI decreased \$0.1 million, or 8.2%, due, principally to lower write-offs of inventory offset by cost of sales related to shipments made.

We have product on hand that was previously written down due to uncertainties surrounding the TYSABRI suspension in 2005, but which is available to fill future orders. As we sell TYSABRI inventory that was previously written down, we are realizing lower cost of sales and, therefore, higher margins. For the three months ended March 31, 2007, cost of sales was lower by approximately \$2.5 million due to previous write-downs. As of March 31, 2007, the approximate value of this product, based on its original cost of manufacture, is \$18.1 million.

#### **AMEVIVE**

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, the cost of product revenue for AMEVIVE decreased substantially due to the disposition of our worldwide rights in April 2006.

## **ZEVALIN**

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, the cost of product revenue for ZEVALIN increased \$2.5 million, or 114.0%, due, principally, to the increased write-off of unmarketable inventory.

#### **FUMADERM**

The cost of sales recognized in the three months ended March 31, 2007 is due, principally, to the write-off of unmarketable inventory.

## Cost of Royalty Revenue

For the three months ended March 31, 2007, compared to the three months ended March 31, 2006, the cost of royalty revenue increased \$0.1 million, or 9.8%, due, principally, to the increase in royalty revenues.

30

## Valuation of Inventory

We wrote-down the following unmarketable inventory, which was charged to cost of sales in the respective periods (in thousands):

		Months March 31,
	2007	2006
AVONEX AMEVIVE	\$ 3,671	\$ 254 2,433
FUMADERM	68	
ZEVALIN	2,580	
TYSABRI	398	611
	\$ 6,717	\$ 3,298

The write-downs for the three months ended March 31, 2007 and 2006, respectively, were the result of the following (in thousands):

	Ende	ee Months d March 31,
	2007	2006
Failed quality specifications Excess and/or obsolescence	\$ 2,81 3,90	
	\$ 6,71	7 \$ 3,298

## **Research and Development Expenses**

Research and development expenses totaled \$191.4 million and \$145.9 million in the three months ended March 31, 2007 and 2006, respectively, an increase of \$45.5 million, or 31.2%. The increase reflects, principally, a \$25.3 million increase in expenses related to clinical trials (primarily related to new trials for BG-12, anti-CD23, and anti-CD80) and new projects (primarily related to technology arising from our acquisition of Conforma), and a \$16.4 million increase in salary and benefit expense arising from increased headcount in 2007 as compared to the comparable period in 2006.

We anticipate that research and development expenses in 2007 will continue to be higher than 2006.

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

During the three months ended March 31, 2007, we recorded expense related to acquired IPR&D of \$18.4 million related to the acquisition of Syntonix. See Note 2 of the consolidated financial statements, Acquisition of Syntonix Pharmaceuticals, Inc., for details on future expenditures with respect to the IPR&D. Future expenditures related to in-process research and development projects acquired in the prior year are \$141.2 million for Fumapharm and

## \$113.6 million for Conforma.

Since completing the acquisition in January of 2007, we have spent approximately \$2.6 million related to the in-process technology of Syntonix. Those expenses are included in research and development expenses in the accompanying consolidated statement of income.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses totaled \$188.1 million and \$154.4 million in the three months ended March 31, 2007 and 2006, respectively, an increase of \$33.7 million, or 21.8%. The increase reflects, principally, a \$20.1 million increase in sales and marketing activities for TYSABRI, and a \$13.2 million increase in salaries and benefits related to increased headcount in sales, marketing, and general and administrative personnel. These increases were offset by a \$6.1 million decrease in sales and marketing activities related to ZEVALIN and AMEVIVE and a \$2.3 million increase in reimbursable amounts related, principally, to the domestic collaboration with Elan for TYSABRI.

31

#### **Table of Contents**

We anticipate that total selling, general, and administrative expenses in 2007 will continue to be higher than 2006 due to sales and marketing and other general and administrative expenses to support AVONEX and TYSABRI growth.

## **Amortization of Intangible Assets**

Amortization of intangible assets totaled \$59.9 million for the three months ended March 31, 2007 compared to \$70.7 million in the comparable period in 2006, a decrease of \$10.8 million, or 15.3%. The decrease is due, principally, to a change in estimated economic consumption. The amount of amortization recorded for core technology in the three months ended March 31, 2007 was \$47.8 million as compared to the \$58.7 million that was recognized in the three months ended March 31, 2006.

## Other Income (Expense), Net

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

		nths Ended ch 31,
	2007	2006
Interest income Interest expense Other expense, net	\$ 29,141 (406) (7,033)	\$ 23,557 (293) (4,599)
Total other income (expense), net	\$ 21,702	\$ 18,665

Interest income totaled \$29.1 million and \$23.6 million in the three months ended March 31, 2007 and 2006, respectively, an increase of \$5.6 million, or 23.7%. The increase in interest income is due, principally, to higher yields on our marketable securities portfolio as well as higher average cash balances. Interest income levels that may be achieved in the future are, in part, dependent upon market conditions.

Other expense, net, totaled \$7.0 and \$4.6 million in the three months ended March 31, 2007 and 2006, respectively, an increase of \$2.4 million, or 52.9%. The increase reflects, principally, a \$1.9 million decrease in losses on strategic investments, offset by a \$1.9 million decrease in gains on foreign currency transaction adjustments, a \$0.5 million increase in sales and use tax, and a \$1.5 million increase in losses on security sales.

## **Share-Based Payments**

Our share-based compensation programs consist of share-based awards granted to employees including stock options, restricted stock, performance share units and restricted stock units, or RSUs, as well as our employee stock purchase plan, or ESPP.

For the three months ended March 31, 2007 and 2006, share-based compensation expense reduced our results of operations as follows (in thousands except for earnings per share):

Three Months Three Months Ended March 31, 2006

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		Ended farch 31, 2007	Impact Before Cumulative Effect of		Cumulative Effect			
		Effect on Net Income		ccounting Change	of Accounting Change			ect on Net Income
Income before income taxes Tax effect	\$	(29,560) 9,228	\$	(29,194) 9,114	\$	5,574 (1,795)	\$	(23,620) 7,319
Net income	\$	(20,332)	\$	(20,080)	\$	3,779	\$	(16,301)
Basic earnings per share: Diluted earnings per share	\$ \$	(0.06) (0.06)	\$ \$	(0.06) (0.06)	\$ \$	0.01 0.01	\$ \$	(0.05) (0.05)
		32	2					

#### **Table of Contents**

For the three months ended March 31, 2006, the expense is net of a cumulative pre-tax adjustment of \$5.6 million resulting from the application of an estimated forfeiture rate for prior period unvested restricted stock awards.

#### **Income Tax Provision**

## Tax Rate

Our effective tax rate was 35.3% on pre-tax income for the three months ended March 31, 2007, compared to 37.8% for the comparable period in 2006.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the three months ended March 31, 2007, and 2006, respectively, is as follows:

		Three Months Ended March 31,		
	2007	2006		
Statutory rate	35.0%	35.0%		
State taxes	2.0	1.9		
Foreign taxes	(7.3)	(6.1)		
Credits and net operating loss utilization	(1.1)	(0.3)		
Other	1.3	0.5		
Fair value adjustment	2.9	6.4		
IPR&D	3.3			
Non-deductible items	(0.8)	0.4		
Effective tax rates	35.3%	37.8%		

We have net operating loss carry forwards and tax credit carry forwards for federal and state income tax purposes available to offset future taxable income. The utilization of our net operating loss carry forwards and tax credits may be subject to an annual limitation under the Internal Revenue Code due to a cumulative change of ownership of more than 50% in prior years. However, other than for tax attributes acquired as part of the Conforma transaction, we anticipate that the annual limitation will result only in a modest delay in the utilization of such net operating loss and tax credits.

## **Contingency**

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

## Adoption of FASB Interpretation No. 48

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, on January 1, 2007. As a result of the adoption of FIN 48, we recognized a reduction in the liability for unrecognized tax benefits of \$14.2 million, which was recorded as a \$1.8 million reduction to the January 1, 2007 balance of our accumulated deficit, a \$9.1 million reduction in goodwill and a \$3.3 million increase in our deferred tax liability.

33

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in millions):

Balance at January 1, 2007	\$ 196.8
Additions based on tax positions related to the current period	7.0
Additions for tax positions of prior periods	48.2
Reductions for tax positions of prior periods	(36.7)
Settlements	(1.8)
Balance at March 31, 2007	\$ 213.5

Included in the balance at March 31, 2007 and January 1, 2007, are \$114.1 million and \$98.2 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in any future periods.

We recognize interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the three months ended March 31, 2007 and 2006, we recognized approximately \$6.2 million and \$3.4 million in interest. We accrued approximately \$26.5 million and \$20.3 million for the payment of interest at March 31, 2007 and January 1, 2007, respectively.

We file income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2001. The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2003 and 2004 in 2006. We expect the IRS to complete its examination by December 31, 2007. The final outcome of the examination is not yet determinable; however, we do not expect that any adjustments as a result of the examination would have a material effect on our financial position.

In connection with the adoption of FIN 48, we reclassified approximately \$113 million in reserves for uncertain tax positions from current taxes payable to long-term liabilities.

## **Liquidity and Capital Resources**

## Financial Condition

Our financial condition is summarized as follows (in thousands);

	March 31, 2007			December 31, 2006		
Cash and cash equivalents  Marketable securities short term  Marketable securities long term	\$	780,940 346,639 1,385,666	\$	661,377 241,314 1,412,238		
Total cash, cash equivalents and marketable securities	\$	2,513,245	\$	2,314,929		
Working capital	\$	1,440,893	\$	1,129,712		

Outstanding borrowings	convertible notes	\$ 9,148	\$ 45,622
Outstanding borrowings	other	\$ 52,043	\$ 51,072

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

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 these funds will be sufficient to meet our operating requirements for the foreseeable future. However, we may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and

34

#### **Table of Contents**

debt financings or from other sources. Our working capital and capital requirements will depend upon numerous factors, including:

the continued commercial success of AVONEX and RITUXAN;

the commercial success of TYSABRI:

the timing and expense of obtaining regulatory approvals for products in development;

the cost of launching new products, and the success of those products;

funding and timing of payments related to several significant capital projects;

the progress of our preclinical and clinical testing;

fluctuating or increasing manufacturing requirements and research and development programs;

levels of resources that we need to devote to the development of manufacturing, sales and marketing capabilities, including resources devoted to the marketing of AVONEX, RITUXAN, FUMADERM, TYSABRI and future products;

technological advances;

status of products being developed by competitors;

our ability to establish collaborative arrangements with other organizations;

and working capital required to satisfy the options of holders of our senior notes and subordinated notes who may require us to repurchase their notes on specified terms or upon the occurrence of specified events.

We intend to commit significant additional capital to external research and development opportunities. To date, we have financed our external growth initiatives through existing cash resources. We expect to finance our future growth initiative requirements either through existing cash resources or a combination of existing cash resources and debt financings.

## Operating activities

Cash provided by operations was \$262.3 million and \$156.3 million in the three months ended March 31, 2007 and 2006, respectively, an increase of \$106.0 million, or 67.8%. The increase is due to higher earnings and a lower investment in working capital. Specifically, cash used to finance movements in working capital asset and liability accounts gave rise to a use of funds in the current period of approximately \$15.6 million versus a use of funds of \$77.6 million in the prior year. The current year includes an increase in net income of approximately \$8.5 million as well as an increase in non-cash charges. The principal component of non-cash charges for the three months ended March 31, 2007 was acquired in-process research and development of \$18.4 million. Additionally, deferred income taxes represented a source of funds of \$5.0 million during the three months ended March 31, 2007 versus a use of funds of \$26.5 million in 2006. These increases were offset by a decrease in non-cash charges relating to depreciation and amortization which declined by \$34.4 million to \$88.8 million for the three months ended March 31, 2007 from \$123.2 million for the three months ended March 31, 2006.

## Investing activities

Cash used in investing activities was \$167.4 million and \$272.2 million in the three months ended March 31, 2007 and 2006, respectively. The reduction in the use of cash in investing activities reflects lower net purchases of marketable securities. For the three months ended March 31, 2007, net purchases were \$74.9 million as compared to \$238.3 million for the three months ended March 31, 2006. Purchases of property and equipment totaled \$37.4 million for the three months ended March 31, 2007 as compared to \$65.6 million for the three months ended March 31, 2006. These reductions in uses of cash were offset by the

35

#### **Table of Contents**

impact of payments made for the acquisition of Syntonix of \$42.3 million in 2007. In the prior year, proceeds from sales of property, plant and equipment was a source of cash of \$33.9 million.

## Financing activities

Cash provided by financing activities during the three months ended March 31, 2007 was \$24.4 million compared to cash provided of \$83.7 million in the three months ended March 31, 2006. The decrease was due, principally, to lower proceeds from the issuance of stock for share based payment arrangements in the three months ended March 31, 2007, as compared to the comparable period of 2006.

## **Borrowings**

As of March 31, 2007, our remaining indebtedness under our subordinated notes was approximately \$9.1 million with a face value of \$15.1 million. On May 1, 2007, we paid \$6.6 million to note holders of the 2032 senior notes that had exercised their right to put the notes back to us. These notes had a face value of \$10.1 million.

At March 31, 2007 we have a long term note payable of approximately \$40.0 million relating to the acquisition of distribution rights of FUMADERM. Additionally, one of our international joint ventures maintained a loan that had a carrying value of \$12.1 million as of March 31, 2007.

## Working capital

At March 31, 2007, our working capital was \$1,441 million, as compared to \$1,130 million at December 31, 2006, an increase of \$311 million. Approximately \$113 million of this increase related to the reclassification of certain tax reserves from current liabilities to long term liabilities in connection with the adoption of FIN 48.

## **Commitments**

In August 2004, we restarted construction of our large-scale biologic manufacturing facility in Hillerod, Denmark. In March 2005, after our voluntary suspension of TYSABRI, we reconsidered our construction plans and determined that we would proceed with the bulk-manufacturing component of our large-scale biologic manufacturing facility in Hillerod, Denmark. Additionally, we added a labeling and packaging component to the project. We also determined that we would no longer proceed with the fill-finish component of that facility. As of March 31, 2007, we had committed approximately \$274 million to the project, of which approximately \$270 million had been paid.

We are proceeding with the second phase of the project, a large-scale manufacturing facility. In October 2006, our Board of Directors approved this phase of the project, which is expected to cost an additional \$225.0 million. As of March 31, 2007, we had committed approximately \$116 million to the second phase, of which approximately \$9 million had been paid.

The second phase of the project is expected to be ready for commercial production in 2009.

The timing of the completion and anticipated licensing of the Hillerod facility is in part dependent upon market acceptance of TYSABRI. See Risk Factors Safety Issues with TYSABRI Could Significantly Affect our Growth. Now that TYSABRI has been approved we are in the process of evaluating our requirements for TYSABRI inventory and additional manufacturing capacity in light of the approved label and our judgment of the potential market acceptance of TYSABRI in MS, and the probability of obtaining marketing approval of TYSABRI in additional indications in the U.S., EU and other jurisdictions.

## Share Repurchase Program

We did not repurchase any shares of our common stock under our authorized share repurchase program in the three months ended March 31, 2007.

36

## **Off-Balance Sheet Arrangements**

We do not have any significant relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

## **Legal Matters**

Please refer to Note 11 of the consolidated financial statements in Part I of this report on Form 10-Q, Litigation, for a discussion of legal matters as of March 31, 2007.

## **New Accounting Standards**

Please refer to Note 14 of the consolidated financial statements in Part I of this report on Form 10-Q, New Accounting Pronouncements, for a discussion of new accounting standards.

## **Critical Accounting Estimates**

We incorporate by reference the section Management s Discussion and Analysis of Financial Condition and Results of Operation Critical Accounting Estimates of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Significant judgments and/or updates to the policies since December 31, 2006 are included below.

## Reserves for Discounts and Allowances

We establish reserves for trade term discounts, wholesaler incentives, Medicaid rebates, Veteran s Administration, or VA, rebates, managed care, patient assistance, product returns and other applicable allowances. Such reserves are classified as reductions of accounts receivable (if the amount is payable to a customer) or a liability (if the amount is payable to a party other than a customer).

During the three months ended March 31, 2007, we changed the manner in which we administer our patient assistance and patient replacement goods programs. Prior to January 1, 2007, AVONEX product shipped to administer these programs was invoiced and recorded as gross product revenue. In addition, an offsetting provision for discount and returns was reflected for expected credit requests from the distributor that administers these programs on our behalf. On January 1, 2007, we established a consignment model. Under the new arrangement, no gross revenue is recorded for product shipped to satisfy these programs.

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

	Dis	counts	tractual istments	Re	eturns	Т	otal
Beginning balance, January 1, 2007	\$	12.7	\$ 30.5	\$	17.8	\$	61.0
Current provisions relating to sales in current period		10.5	23.3		4.3		38.1
Adjustments relating to prior periods			(0.5)				(0.5)
Payments/returns relating to sales in current period		(5.5)	(6.5)				(12.0)
Payments/returns relating to sales in prior periods		(12.6)	(16.5)		(8.7)		(37.8)

Ending balance, March 31, 2007

\$ 5.1

\$

30.3

\$ 13.4

\$ 48.8

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

	March 31, 2007			
Reduction of accounts receivable Current liability	\$	20.6 28.2	\$	30.2 30.8
Total reserves	\$	48.8	\$	61.0

37

#### **Table of Contents**

## **Income Taxes**

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48, on January 1, 2007. As a result of the adoption of FIN 48, we recognized a reduction in the liability for unrecognized tax benefits of \$14.2 million, which was recorded as a \$1.8 million reduction to the January 1, 2007 balance of our accumulated deficit, a \$9.1 million reduction in goodwill and a \$3.3 million increase in our deferred tax liability.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in millions):

Balance at January 1, 2007	\$ 196.8
Additions based on tax positions related to the current period	7.0
Additions for tax positions of prior periods	48.2
Reductions for tax positions of prior periods	(36.7)
Settlements	(1.8)
Balance at March 31, 2007	\$ 213.5

Included in the balance at March 31, 2007 and January 1, 2007, are \$114.1 million and \$98.2 million (net of the federal benefit on state issues), respectively, of unrecognized tax benefits that, if recognized, would affect the effective income tax rate in any future periods.

We recognize interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the three months ended March 31, 2007 and 2006, we recognized approximately \$6.2 million and \$3.4 million in interest. We accrued approximately \$26.5 million and \$20.3 million for the payment of interest at March 31, 2007 and January 1, 2007, respectively.

We file income tax returns in the U.S. federal jurisdiction, and various states and foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2001. The Internal Revenue Service (IRS) commenced an examination of our U.S. income tax returns for 2003 and 2004 in 2006. We expect the IRS to complete its examination by December 31, 2007. The final outcome of the examination is not yet determinable; however, we do not expect that any adjustments as a result of the examination would have a material effect on our financial position.

In connection with the adoption of FIN 48, we reclassified approximately \$113 million in reserves for uncertain tax positions from current taxes payable to long-term liabilities.

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

Our market risks, and the ways we manage them, are summarized in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. There have been no material changes in the first three months of 2007 to such risks or our management of such risks.

## Item 4. Controls and Procedures

#### **Disclosure Controls and Procedures**

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act) as of March 31, 2007. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2007, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information is accumulated and communicated to our management, including

38

#### **Table of Contents**

our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

We have not made any changes in our internal control over financial reporting during the first quarter of 2007 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

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

#### Item 1A. Risk Factors

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

Our current and future revenues depend substantially upon continued sales of our two principal products, AVONEX and RITUXAN, which represented approximately 94% of our total revenues in 2006. Any significant negative developments relating to these two products, such as safety or efficacy issues, the introduction or greater acceptance of competing products (including greater than anticipated substitution of TYSABRI for AVONEX) or adverse regulatory or legislative developments, would have a material adverse effect on our results of operations. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from these two products for many years. A decline in sales from either of these two products would adversely affect our business.

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

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities. We, along with Genentech, continue to expand our development efforts related to additional uses for RITUXAN and follow on anti-CD20 product candidates, and we are independently expanding development efforts around other potential products in our pipeline. Product development and commercialization are very expensive and involve a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

If we are unable to introduce new products to the market successfully or are unable to expand the indicated uses of approved products such as RITUXAN and TYSABRI, our results of operations would be adversely affected.

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

Even after we receive marketing approval for a product, adverse event reports may have a negative impact on our commercialization efforts. Our voluntary withdrawal of TYSABRI from the market in February 2005

39

#### **Table of Contents**

following reports of cases of PML resulted in a significant reduction in expected revenues as well as significant expense and management time required to address the legal and regulatory issues arising from the withdrawal, including revised labeling and enhanced risk management programs. Later discovery of safety issues with our products that were not known at the time of their approval by the FDA could cause product liability events, additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market and the imposition of fines or criminal penalties. Any of these actions could result in, among other things, material write-offs of inventory and impairments of intangible assets, goodwill and fixed assets.

### Our near-term success depends on the market acceptance and successful launch of our third product TYSABRI

A substantial portion of our growth in the near-term is dependent on anticipated sales of TYSABRI. We received regulatory approval to market TYSABRI in the U.S. and the EU for relapsing forms of MS in June of 2006. We re-introduced TYSABRI in the U.S. and launched TYSABRI for the first time in Europe in the second half of 2006. TYSABRI is expected to meaningfully diversify our product offerings and revenues, and to drive additional revenue growth over the next several years. Failure to launch the drug successfully would result in a significant reduction in diversification and expected revenues, and adversely affect our business.

The success of the reintroduction of TYSABRI into the U.S. market and launch in the EU will depend upon its acceptance by the medical community and patients, which cannot be certain given the significant restrictions on use and the significant safety warnings in the label. Additional cases of the known side effect PML at a higher rate than indicated in the prescribing information, or the occurrence of other unexpected side effects could harm acceptance and limit TYSABRI sales. Any significant lack of acceptance of TYSABRI by the medical community or patients would materially and adversely affect our growth and our plans for the future.

As a new entrant to a relatively mature 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.

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

In addition to the expansion of our pipeline through spending on internal development projects, we plan to grow through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to complete or manage these external growth opportunities successfully, we will not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to identify suitable candidates or complete transactions on terms that are acceptable to us. In addition, even if we are able to successfully identify and complete acquisitions, we may not be able to integrate them or take full advantage of them and therefore may not realize the benefits that we expect. If we are unsuccessful in our external growth program, we may not be able to grow our business significantly and we may incur asset impairment charges as a result of acquisitions that are not successful.

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

The biotechnology industry is intensely competitive. We compete in the marketing and sale of our products, the development of new products and processes, the acquisition of rights to new products with commercial potential and the hiring and retention of personnel. We compete with biotechnology and pharmaceutical companies that have a greater number of products on the market, greater financial and other resources and other technological or competitive

advantages. We cannot be certain that one or more of our competitors will not receive patent protection that dominates, blocks or adversely affects our product development or business, will not benefit from significantly greater sales and marketing capabilities, or will not develop products that are accepted more widely than ours. The introduction of alternatives to our products

40

#### **Table of Contents**

that offer advantages in efficacy, safety or ease of use could negatively affect our revenues and reduce the value of our product development efforts. In addition, potential governmental action in the future could provide a means for competition from developers of follow-on biologics, which could compete on price and differentiation with products that we now or could in the future market.

In addition to competing directly with products that are marketed by substantial pharmaceutical competitors, both AVONEX and RITUXAN 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 on collaborators for both product and royalty revenue and the clinical development of future collaboration products, two important parts of our business outside of our full control

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

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

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

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

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

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

Sales of our products are dependent, in large part, on the availability and extent of reimbursement from government health administration authorities, private health insurers and other organizations. U.S. and foreign government regulations mandating price controls and limitations on patient access to our products impact our business and our future results could be adversely affected by changes in such regulations. In addition, states may more aggressively seek Medicaid rebates as a result of legislation enacted in 2006, which rebate activity could adversely affect our results of operations.

In the U.S., many of our products are subject to increasing pricing pressures. Such pressures may increase as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Managed care organizations as well as Medicaid and other government health administration authorities continue to seek price discounts. Government efforts to reduce Medicaid expenses may continue to increase the use of managed care organizations. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. In addition, some states have implemented and other states are considering price controls or patient-access

41

#### **Table of Contents**

constraints under the Medicaid program and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid eligible. Other matters also could be the subject of U.S. federal or state legislative or regulatory action that could adversely affect our business, including the importation of prescription drugs that are marketed outside the U.S. and sold at lower prices as a result of drug price regulations by the governments of various foreign countries.

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

When a new medical product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our product candidates.

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

Our business is in a highly regulated industry. As a result, governmental actions may adversely affect our business, operations or financial condition, including:

new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services;

changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

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

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

changes in the tax laws relating to our operations.

The enactment in the U.S. of the Medicare Prescription Drug Improvement and Modernization Act of 2003, possible legislation which could ease the entry of competing follow-on biologics in the marketplace, and importation of lower-cost competing drugs from other jurisdictions are examples of changes and possible changes in laws that could adversely affect our business.

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

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the U.S. Food, Drug and Cosmetic Act and other federal and state statutes and similar laws in foreign jurisdictions. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations and violations of the Prescription Drug Marketing Act, or other violations related to environmental matters. Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in government programs. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could

42

#### **Table of Contents**

increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

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

# Manufacturing problems could result in our inability to deliver products, inventory shortages, product recalls and increased costs

We manufacture and expect to continue to manufacture our own commercial requirements of bulk AVONEX and TYSABRI. Our products are difficult to manufacture and problems in our manufacturing processes can occur. Our inability to manufacture successfully bulk product and to maintain regulatory approvals of our manufacturing facilities would harm our ability to produce timely sufficient quantities of commercial supplies of AVONEX and TYSABRI to meet demand. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products, recall, or withdraw products previously shipped, or 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 currently manufacture TYSABRI at our manufacturing facility in Research Triangle Park, North Carolina, or RTP. Although we are proceeding with construction of the bulk manufacturing component of our large-scale biologic manufacturing facility in Hillerod, Denmark and have added a labeling and packaging component to the project, we currently rely exclusively on our RTP facility for the manufacture of TYSABRI.

If we cannot produce sufficient commercial requirements of bulk product to meet demand, we would need to rely on third party contract manufacturers, of which there are only a limited number capable of manufacturing bulk products of the type we require. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time. Our ability to supply products in sufficient capacity to meet demand is also dependent upon third party contractors to fill-finish, package and store such products. Any prolonged interruption in the operations of our existing manufacturing facilities could result in cancellations of shipments or loss of product in the process of being manufactured. Because our manufacturing processes are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all.

# We rely on third parties to provide services in connection with the manufacture of our products and, in some instances, the manufacture of the product itself

We rely on Genentech for all RITUXAN manufacturing. Genentech relies on a third party to manufacture certain bulk RITUXAN requirements. If Genentech or any third party upon which it relies does not manufacture or fill-finish RITUXAN in sufficient quantities and on a timely and cost-effective basis, or if Genentech or any third party does not obtain and maintain all required manufacturing approvals, our business could be harmed.

We also source all of our fill-finish and the majority of our final product storage operations, along with a substantial portion of our packaging operations of the components used with our products, to a concentrated group of third party contractors. The manufacture of products and product components, fill-finish, packaging

43

#### **Table of Contents**

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

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

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

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

# We are committing to a significant investment in the expansion of a manufacturing facility the success of which relies upon continued demand for our products

The first phase of our large-scale biologic manufacturing facility in Hillerod, Denmark, is almost complete. As of March 31, 2007, we had committed approximately \$274 million to this phase of the project, of which approximately \$270 million had been paid.

We are proceeding with the second phase of the facility and our Board of Directors has authorized an additional \$225 million to be spent on this phase of the project in addition to amounts spent for the first phase. As of March 31, 2007, we had committed approximately \$116 million to the second phase of the project, of which approximately \$9 million had been paid.

In the event that we fail to manage the projects, or other unforeseen events occur, we may incur additional costs to complete the project. Additionally, any costs incurred may not be recoverable in the event that projection of the demand for future manufacturing volumes, including the demand for TYSABRI, are not achieved.

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

Our success will depend, to a great extent, upon our ability to attract and retain qualified scientific, manufacturing, sales and marketing and executive personnel and our ability to develop and maintain relationships with qualified clinical researchers and key distributors. Competition for these people and relationships is intense and we compete

with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. Any inability we experience to continue to attract and retain qualified personnel or develop and maintain key relationships could have an adverse effect on our ability to accomplish our research, development and external growth objectives.

44

### Our operating results are subject to significant fluctuations

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

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

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;

the cost of restructurings.

Additionally, net income may fluctuate due to the impact of charges we may be required to take with respect to foreign currency hedge transactions. In particular, we may incur higher charges from hedge ineffectiveness than we expect or from the termination of a hedge relationship.

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

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

We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development, including a number of our processes and products. Patents have been issued on many of these applications. We have also obtained rights to various patents and patent applications under licenses with third parties, which provide for the payment of royalties by us. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. Our patents may not afford us substantial protection or commercial benefit. Similarly, our pending patent applications or patent applications licensed from third parties may not ultimately be granted as patents and we may not prevail if patents that have been issued to us are challenged in court. If we are unable to protect our intellectual property rights and prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect.

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

A substantial number of patents have already been issued to other biotechnology and biopharmaceutical companies. Competitors may have filed applications for, or have been issued patents and may obtain additional patents and proprietary rights that may relate to products or processes competitive with or similar to our products and processes. Moreover, the patent laws of the U.S. and foreign countries are distinct and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries. In general, we obtain licenses to third party patents that we deem necessary or desirable for the manufacture, use and sale of our products. We are currently unable to assess the extent to which we may wish or be required to acquire rights under such patents and the

availability and cost of acquiring such rights, or whether a license to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder our ability to market our products.

45

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

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

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

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

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

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

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

Our business and the business of several of our strategic partners, including Genentech and Elan, involve the controlled use of hazardous materials, chemicals, biologics and radioactive compounds. Biologics manufacturing is extremely susceptible to product loss due to microbial or viral contamination, material equipment failure, or vendor or operator error. Although we believe that our safety procedures for handling and disposing of such materials comply

with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, microbial or viral contamination may cause the closure of a manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. We currently store radioactive materials from our California operation on-site

46

#### **Table of Contents**

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.

### Our international sales and operations are subject to the risks of doing business abroad

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

economic problems that disrupt foreign healthcare 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.

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

A portion of our business is conducted in currencies other than our reporting currency, the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period in which we incur those gains or losses. As a result, currency fluctuations among the U.S. dollar and the currencies in which we do business have caused foreign currency transaction gains and losses in the past and will likely do so in the future. Because of the number of currencies involved, the variability of currency exposures and the potential volatility of currency exchange rates, we may suffer significant foreign currency transaction losses in the future due to the effect of exchange rate fluctuations.

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

We maintain a significant portfolio of investments in marketable securities. Our earnings may be adversely affected by changes in the value of this portfolio. In particular, the value of our investments may be adversely affected by increases in interest rates, downgrades in the corporate bonds included in the portfolio and by other than temporary

declines in value. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio.

47

### We may incur liabilities to tax authorities in excess of amounts that have been accrued

The preparation of our financial statements requires estimates of the amount of tax that will become payable in each of the jurisdictions in which we operate. Accordingly, we determine our estimated liability for Federal, state and local taxes (in the U.S.) and in connection with our tax liability in several overseas jurisdictions. We may be challenged by any of these taxing authorities and, in the event that we are not able to defend our position, we may incur liabilities with respect to the taxing authority and such amounts could be significant.

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

Several factors might discourage a takeover attempt that could be viewed as beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. For example:

we are subject to Section 203 of the Delaware General Corporation Law, which provides that we may not enter into a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203;

our stockholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors;

our board of directors has the authority to issue, without a vote or action of stockholders, up to 8,000,000 shares of preferred stock and to fix the price, rights, preferences and privileges of those shares, each of which could be superior to the rights of holders of common stock;

our amended and restated collaboration agreement with Genentech provides that, in the event we undergo a change of control, within ninety (90) days Genentech may present an offer to us to purchase our rights to RITUXAN. Recently, in an arbitration proceeding brought by Biogen Idec relating to the collaboration agreement, Genentech alleged for the first time that the November 2003 transaction in which Idec acquired Biogen and became Biogen Idec constituted such a change of control, an assertion with which we strongly disagree. It is our position that the Biogen Idec merger did not constitute a change of control under our agreement with Genentech and that, even if it did, Genentech s rights under the change of control provision have long since expired. We intend to vigorously assert our position if Genentech persists in making this claim. If the arbitrators decide this issue in favor of Genentech, or if a change of control were to occur in the future and Genentech were to present an offer for the RITUXAN rights, we must either accept Genentech s offer or purchase Genentech s rights to RITUXAN on the same terms as its offer. If Genentech presents such an offer, then they will be deemed concurrently to have exercised a right, in exchange for a share in the operating profits or net sales in the U.S. of any other anti CD-20 products developed under the agreement, to purchase our interest in each such product. The rights of Genentech described in this paragraph may limit our attractiveness to potential acquirers; 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 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 stock holders.

48

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

A summary of our stock repurchase activity for the three months ended March 31, 2007 is set forth in the table below:

### **Issuer Purchases of Equity Securities**

				Total Number of Shares Purchased as	Number of Shares
Period	Total Number of Shares Purchased (#)(a)	Average Price Paid  per Share (\$)		Part of Publicly Announced Program (#)(a)	that may yet be Purchased Under Our Program (#)
Three Months Ended March 31, 2007 Total	8,041(b) 8,041	\$ \$	44.99 44.99		20,000,000 20,000,000

- (a) On October 13, 2006 the Board of Directors authorized the repurchase of up to 20.0 million shares of our common stock. The repurchased stock will provide us with authorized shares for general corporate purposes, such as common stock to be issued under our employee equity and stock purchase plans. This repurchase program does not have an expiration date.
- (b) All of these shares are shares that were used by certain employees to pay the exercise price of their stock options in lieu of paying cash or utilizing our cashless option exercise program.

### Item 6. Exhibits

- 10.1 Amendment dated April 4, 2006, to 2005 Omnibus Equity Plan.
- 10.2 Amendment dated February 12, 2007, to 2005 Omnibus Equity Plan.
- 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.

49

## **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/ Peter N. Kellogg

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

May 3, 2007

50