

GENZYME CORP
Form 10-Q
May 11, 2009

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark
One)

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

For the quarterly period ended March 31, 2009

Or

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

For the transition period from _____ to _____
Commission File No. 0-14680

GENZYME CORPORATION

(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction of
incorporation or organization)

06-1047163
(I.R.S. Employer Identification No.)

500 Kendall Street
Cambridge, Massachusetts
(Address of principal executive offices)

02142
(Zip Code)

(617) 252-7500
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2

Edgar Filing: GENZYME CORP - Form 10-Q

of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>
---	---	--	---

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

Number of shares of Genzyme Stock outstanding as of April 30, 2009: 269,764,111

Table of Contents

NOTE REGARDING REFERENCES TO GENZYME

Throughout this Form 10-Q, the words "we," "us," "our" and "Genzyme" refer to Genzyme Corporation as a whole, and "our board of directors" refers to the board of directors of Genzyme Corporation.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements. These forward-looking statements include, among others, statements regarding:

our regulatory plans and expectations for approval of alglucosidase alpha produced at the 2000 liter and 4000 liter bioreactor, or 2000L and 4000L, scales by the United States Food and Drug Administration, or FDA, and the timing thereof, and our expectations regarding sales of Myozyme in Europe and the addition of Myozyme manufacturing capacity at our facility in Belgium;

our expectations regarding regulatory action with respect to several marketing applications, including for Renvela and Mozobil in Europe and label expansions for Renvela and clofarabine in the United States;

our expectations for sales of Renagel/Renvela and Hectorol and the anticipated drivers for the future growth of these products;

our expected timing for closing our transaction with Bayer Schering Pharma AG, or Bayer;

our assessment of competitors and potential competitors and the anticipated impact of potentially competitive products and services on our revenues;

Cerezyme's future contribution to our revenues and our expectations regarding its current growth trends;

our assessment of the financial impact of legal proceedings and claims on our financial position and results of operations;

the sufficiency of our cash, investments and cash flows from operations and our expected uses of cash;

our provision for potential tax audit exposures and our expectations regarding settlement of our 2006 to 2007 IRS audit;

the protection afforded by our patent rights;

our expectations regarding the impact of changes in foreign exchange rates on our revenues;

our estimates of the cost to complete and estimated commercialization dates for our in-process research and development, or IPR&D, programs;

our assessment of the deductibility of amounts allocated to goodwill; and

Edgar Filing: GENZYME CORP - Form 10-Q

our expectations regarding the amortization of intangible assets related to our expected future contingent payments due to Synpac (North Carolina), Inc. and Wyeth.

These statements are subject to risks and uncertainties, and our actual results may differ materially from those that are described in this report. These risks and uncertainties include:

the ability of us and our collaboration partners to successfully complete preclinical and clinical development of new products and services;

Table of Contents

our ability to expand the use of current and next generation products in existing and new indications;

our ability to obtain and maintain regulatory approvals for our products, services and manufacturing facilities and processes, and to do so in the anticipated timeframes, including our ability to obtain regulatory approvals for an expanded Renvela label and for alglucosidase alfa produced at the 2000L and 4000L scale in the United States and the timing of receipt of such approvals;

regulatory authority views regarding the safety, efficacy and risk-benefit profiles of our products;

the content and timing of submissions to and decisions made by the FDA, the European Agency for the Evaluation of Medicinal Products, or EMEA, and other regulatory agencies related to our products and services and the facilities and processes used to manufacture our products, including the timing and outcome of the FDA's re-inspection of our Allston, Massachusetts facility;

our ability to accurately forecast the impact of regulatory delays on our financial position and results of operations;

our ability to manufacture sufficient amounts of our products for development and commercialization activities and to do so in a timely and cost-effective manner;

potential future write-offs of inventory or product recalls;

our ability to satisfy the post-marketing commitments made to regulatory agencies as a condition of the marketing approvals of Fabrazyme, Aldurazyme, Myozyme, Clolar and Mozobil;

our ability to obtain and maintain adequate patent and other proprietary rights protection for our products and services and successfully enforce these proprietary rights;

our reliance on third parties to provide us with materials and services in connection with the manufacture of our products;

the accuracy of our estimates of the size and characteristics of the markets to be addressed by our products and services, including growth projections;

market acceptance of our products and services in expanded areas of use and new markets;

our ability to successfully identify and market our products and services to new patients;

our ability to increase market penetration of our products and services both outside and within the United States;

the accuracy of our information regarding the products and resources of our competitors and potential competitors;

competition from lower cost generic or biosimilar products;

Edgar Filing: GENZYME CORP - Form 10-Q

the availability of reimbursement for our products and services from third party payors, the extent of such coverage and the accuracy of our estimates of the payor mix for our products;

our ability to effectively manage wholesaler inventories of our products and the levels of their compliance with our inventory management programs;

our ability to continue to generate cash from operations and to effectively use our cash resources to grow our business;

Table of Contents

our ability to establish and maintain strategic license, collaboration and distribution arrangements and to successfully manage our relationships with licensors, collaborators, distributors and partners;

the impact of changes in the exchange rates for foreign currencies on our product and service revenues in future periods;

the resolution of our dispute with our insurance carriers regarding our claim for coverage under a director and officer liability insurance program;

the outcome of legal proceedings by or against us;

the impact of our recent and future merger and acquisition activity;

the receipt of regulatory approvals for our transaction with Bayer and our ability to successfully integrate the products and development programs that we would acquire from Bayer;

the outcome of our IRS and foreign tax audits;

general economic conditions; and

the possible disruption of our operations due to terrorist activities, armed conflict, severe climate change or outbreak of diseases, including as a result of the disruption of operations of regulatory authorities, our subsidiaries, manufacturing facilities, customers, suppliers, distributors, couriers, collaborative partners, licensees or clinical trial sites.

We refer to more detailed descriptions of these and other risks and uncertainties under the heading "Risk Factors" in Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations in Part I, Item 2 of this Form 10-Q. We encourage you to read those descriptions carefully. We caution investors not to place substantial reliance on the forward-looking statements contained in this Form 10-Q. These statements, like all statements in this Form 10-Q, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise the statements in light of future developments.

NOTE REGARDING INCORPORATION BY REFERENCE

The United States Securities and Exchange Commission, commonly referred to as the SEC, allows us to disclose important information to you by referring you to other documents we have filed with them. The information that we refer you to is "incorporated by reference" into this Form 10-Q. Please read that information.

NOTE REGARDING TRADEMARKS

Genzyme®, Cerezyme®, Ceredase®, Fabrazyme®, Thyrogen®, Myozyme®, Renagel®, Renvela®, Campath®, Clolar®, Mozobil®, Thymoglobulin®, Synvisc®, Septrafilm®, Carticel®, Epicel®, MACI®, and Hectorol® are registered trademarks, and Cholestagel®, Evoltra®, Lumizyme®, and Synvisc-One® are trademarks, of Genzyme or its subsidiaries. WelChol® is a registered trademark of Sankyo Pharma, Inc. Aldurazyme® is a registered trademark of BioMarin/Genzyme LLC. Elaprase® is a registered trademark of Shire Human Genetic Therapies, Inc. Prochymal® and Chondrogen® are registered trademarks of Osiris Therapeutics, Inc. Fludara® and Leukine® are registered trademarks of Bayer Schering Pharma AG. All rights reserved.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

FORM 10-Q, MARCH 31, 2009

TABLE OF CONTENTS

	PAGE NO.
<u>PART I. FINANCIAL INFORMATION</u>	<u>6</u>
<u>ITEM 1. Financial Statements</u>	<u>6</u>
<u>Unaudited, Consolidated Statements of Operations for the Three Months Ended March 31, 2009 and 2008</u>	<u>6</u>
<u>Unaudited, Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008</u>	<u>7</u>
<u>Unaudited, Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2009 and 2008</u>	<u>8</u>
<u>Notes to Unaudited, Consolidated Financial Statements</u>	<u>9</u>
<u>ITEM 2. Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations</u>	<u>29</u>
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>69</u>
<u>ITEM 4. Controls and Procedures</u>	<u>70</u>
<u>PART II. OTHER INFORMATION</u>	<u>70</u>
<u>ITEM 1. Legal Proceedings</u>	<u>70</u>
<u>ITEM 1A. Risk Factors</u>	<u>70</u>
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>71</u>
<u>ITEM 6. Exhibits</u>	<u>71</u>
<u>Signatures</u>	<u>72</u>

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****GENZYME CORPORATION AND SUBSIDIARIES****Consolidated Statements of Operations****(Unaudited, amounts in thousands, except per share amounts)**

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Net product sales	\$ 1,037,244	\$ 1,006,268
Net service sales	101,499	85,864
Research and development revenue	10,128	7,929
Total revenues	1,148,871	1,100,061
Operating costs and expenses:		
Cost of products sold	235,562	216,739
Cost of services sold	60,250	55,574
Selling, general and administrative	317,961	318,386
Research and development	206,925	262,797
Amortization of intangibles	57,598	55,658
Total operating costs and expenses	878,296	909,154
Operating income	270,575	190,907
Other income (expenses):		
Gains (losses) on investments in equity securities, net	(576)	775
Other	(979)	491
Investment income	5,350	14,870
Interest expense		(1,655)
Total other income	3,795	14,481
Income before income taxes	274,370	205,388
Provision for income taxes	(78,884)	(60,117)
Net income	\$ 195,486	\$ 145,271
Net income per share:		
Basic	\$ 0.72	\$ 0.54
Diluted	\$ 0.70	\$ 0.52
Weighted average shares outstanding:		
Basic	270,854	267,276
Diluted	277,628	285,208

The accompanying notes are an integral part of these unaudited, consolidated financial statements.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Consolidated Balance Sheets****(Unaudited, amounts in thousands, except par value amounts)**

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 643,438	\$ 572,106
Short-term investments	58,808	57,507
Accounts receivable, net	1,055,896	1,036,940
Inventories	438,905	453,437
Prepaid expenses and other current assets	150,709	208,040
Deferred tax assets	187,101	188,105
Total current assets	2,534,857	2,516,135
Property, plant and equipment, net	2,354,299	2,306,567
Long-term investments	279,524	344,078
Goodwill	1,400,625	1,401,074
Other intangible assets, net	1,597,925	1,654,698
Deferred tax assets noncurrent	304,620	269,237
Investments in equity securities	53,413	83,325
Other noncurrent assets	94,643	96,162
Total assets	\$8,619,906	\$ 8,671,276
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 126,850	\$ 127,869
Accrued expenses	682,645	765,386
Deferred revenue	18,035	13,462
Current portion of long-term debt and capital lease obligations	7,792	7,566
Total current liabilities	835,322	914,283
Long-term debt and capital lease obligations	121,508	124,341
Deferred revenue noncurrent	12,704	13,175
Other noncurrent liabilities	310,131	313,484
Total liabilities	1,279,665	1,365,283
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value		
Common stock, \$0.01 par value	2,696	2,707
Additional paid-in capital	5,759,004	5,779,279
Accumulated earnings	1,443,282	1,247,796
Accumulated other comprehensive income	135,259	276,211
Total stockholders' equity	7,340,241	7,305,993
Total liabilities and stockholders' equity	\$8,619,906	\$ 8,671,276

The accompanying notes are an integral part of these unaudited, consolidated financial statements.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Consolidated Statements of Cash Flows****(Unaudited, amounts in thousands)**

	Three Months Ended March 31,	
	2009	2008
Cash Flows from Operating Activities:		
Net income	\$ 195,486	\$ 145,271
Reconciliation of net income to cash flows from operating activities:		
Depreciation and amortization	98,958	91,039
Stock-based compensation	44,560	42,346
Provision for bad debts	5,762	2,862
Equity in income of equity method investments		(188)
(Gains) losses on investments in equity securities, net	576	(775)
Deferred income tax benefit	(24,376)	(24,712)
Tax benefit from employee stock-based compensation	6,549	17,599
Excess tax benefits from stock-based compensation	(3,492)	(5,790)
Other	2,238	1,770
Increase (decrease) in cash from working capital changes (excluding impact of acquired assets and assumed liabilities):		
Accounts receivable	(59,210)	(57,928)
Inventories	818	(1,239)
Prepaid expenses and other current assets	(22,659)	(6,326)
Income taxes payable	85,792	9,229
Accounts payable, accrued expenses and deferred revenue	(73,227)	(53,625)
Cash flows from operating activities	257,775	159,533
Cash Flows from Investing Activities:		
Purchases of investments	(13,292)	(146,862)
Sales and maturities of investments	75,058	180,037
Purchases of equity securities	(4,870)	(80,699)
Proceeds from sales of investments in equity securities	1,264	1,148
Purchases of property, plant and equipment	(161,561)	(121,967)
Distributions from equity method investments		6,595
Purchases of other intangible assets	(8,056)	(7,046)
Other	(47)	3,107
Cash flows from investing activities	(111,504)	(165,687)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	34,526	90,243
Repurchases of our common stock	(107,134)	(73,218)
Excess tax benefits from stock-based compensation	3,492	5,790
Payments of debt and capital lease obligations	(2,653)	(2,554)
Increase (decrease) in bank overdrafts	(3,392)	18,549
Other	1,995	959
Cash flows from financing activities	(73,166)	39,769
Effect of exchange rate changes on cash	(1,773)	(17,829)
Increase in cash and cash equivalents	71,332	15,786
Cash and cash equivalents at beginning of period	572,106	867,012
Cash and cash equivalents at end of period	\$ 643,438	\$ 882,798

The accompanying notes are an integral part of these unaudited, consolidated financial statements.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements

1. Description of Business

We are a global biotechnology company dedicated to making a major impact on the lives of people with serious diseases. Our broad product and service portfolio is focused on rare disorders, renal disease, orthopaedics, cancer, transplant and immune disease, and diagnostic and predictive testing.

In the fourth quarter of 2008, we changed our segment reporting structure to better reflect the way we manage and measure the performance of our businesses. Under the new reporting structure, we are organized into four financial reporting units, which we also consider to be our reporting segments:

Genetic Diseases, which develops, manufactures and distributes therapeutic products, with an expanding focus on products to treat patients suffering from genetic diseases and other chronic debilitating diseases, including a family of diseases known as lysosomal storage disorders, or LSDs. The unit derives substantially all of its revenue from sales of Cerezyme, Fabrazyme, Myozyme and Aldurazyme;

Cardiometabolic and Renal, which develops, manufactures and distributes products that treat patients suffering from renal diseases, including chronic renal failure, and endocrine and cardiovascular diseases. The unit derives substantially all of its revenue from sales of Renagel/Renvela (including sales of bulk sevelamer), Hectorol and Thyrogen;

Biosurgery, which develops, manufactures and distributes biotherapeutics and biomaterial-based products, with an emphasis on products that meet medical needs in the orthopaedics and broader surgical areas. The unit derives substantially all of its revenue from sales of Synvisc/Synvisc-One, the Septra line of products, Carticel and Matrix-induced Autologous Chondrocyte Implantation, or MACI; and

Hematologic Oncology, which develops, manufactures and distributes products for the treatment of cancer. The unit derives substantially all of its revenue from sales and royalties received on sales of Campath and clofarabine. Clofarabine is marketed under the names Clolar and Evoltra. This unit also includes Mozobil, which received marketing approval in the United States in December 2008.

Our transplant business unit, which develops, manufactures and distributes therapeutic products that address pre-transplantation, prevention and treatment of graft rejection in organ transplantation and other hematologic and auto-immune disorders, and our genetics business unit, which provides testing services for the oncology, prenatal and reproductive markets, were formerly reported as separate reporting segments. Effective as of the fourth quarter of 2008, we include our transplant and genetics business units under the caption "Other." We also report the activities of our diagnostic products, bulk pharmaceuticals and immune mediated disease business units under the caption "Other." These operating segments did not meet the quantitative threshold for separate segment reporting. We have revised our 2008 segment disclosures to conform to our 2009 presentation.

We report our corporate, general and administrative operations and corporate science activities under the caption "Corporate."

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

Our unaudited, consolidated financial statements for each period include the statements of operations, balance sheets and statements of cash flows for our operations taken as a whole. We have eliminated all intercompany items and transactions in consolidation. We prepare our unaudited, consolidated financial statements following the requirements of the SEC for interim reporting. As

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****2. Basis of Presentation and Significant Accounting Policies (Continued)**

permitted under these rules, we condense or omit certain footnotes and other financial information that are normally required by accounting principles generally accepted in the United States.

These financial statements include all normal and recurring adjustments that we consider necessary for the fair presentation of our financial position and results of operations. Since these are interim financial statements, you should also read our audited, consolidated financial statements and notes included in our 2008 Form 10-K. Revenues, expenses, assets and liabilities can vary from quarter to quarter. Therefore, the results and trends in these interim financial statements may not be indicative of results for future periods.

Our unaudited, consolidated financial statements for each period include the accounts of our wholly owned and majority owned subsidiaries. As a result of our adoption of Financial Accounting Standards Board, or FASB, Interpretation No., or FIN, 46R, "Consolidation of Variable Interest Entities," we also consolidate certain variable interest entities for which we are the primary beneficiary. For consolidated subsidiaries in which we have less than a 100% ownership interest, we record the minority interest in our consolidated statements of operations for the ownership interest of the minority owner which was immaterial for all periods presented. We use the equity method of accounting to account for our investments in entities in which we have a substantial ownership interest (20% to 50%) which do not fall in the scope of FIN 46R, or over which we exercise significant influence. Our consolidated net income includes our share of the earnings or losses of these entities.

Recent Accounting Pronouncements

Periodically, accounting pronouncements and related information on the adoption, interpretation and application of accounting principles generally accepted in the United States are issued or amended by the various U.S. financial accounting regulatory groups. The following table provides a description of the types of accounting pronouncements that are frequently issued or amended:

Accounting Regulatory Group	Type of Pronouncement Issued or Amended
Accounting Principles Board	APB Opinion No., or APB
FASB	FASB Statement of Financial Accounting Standards No., or FAS
	FASB Statement of Position No., or FSP
	Emerging Issues Task Force Issue No., or EITF

The following table shows recently issued accounting pronouncements and our position for adoption:

Pronouncements	Relevant Requirements	Issued Date/ Our Effective Dates	Status
<i>EITF 07-1, "Accounting for Collaborative Arrangements."</i>	Defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties, including the appropriate income statement presentation and classification of, and the required disclosures related to, these arrangements.	Issued November 2007. Effective January 1, 2009, to be applied retrospectively for collaborative arrangements existing as of the effective date.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the periods presented.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

2. Basis of Presentation and Significant Accounting Policies (Continued)

Pronouncements	Relevant Requirements	Issued Date/ Our Effective Dates	Status
<i>FAS 141R, "Business Combinations."</i>	Modifies and prescribes new requirements for accounting for business combinations. Among other things, acquisition costs will be expensed as incurred; restructuring costs will be expensed subsequent to the acquisition date; non-controlling interests will be valued at fair value; IPR&D will be recorded at fair value as an indefinite lived intangible asset; contingent purchase price payments will be measured at the acquisition date and re-measured in subsequent periods with an adjustment to earnings; and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition will affect income tax expense.	Issued December 2007. Effective January 1, 2009, to be applied prospectively for all business combinations for which the acquisition date is on or after January 1, 2009.	This pronouncement will significantly change our accounting and reporting for business combination transactions completed on or after January 1, 2009. The adoption of this pronouncement did not have an impact on our consolidated financial statements for the three months ended March 31, 2009, because we did not complete any business combination transactions during this period but it will impact our consolidated financial statements if such transactions occur in future periods.
<i>FAS 160, "Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51."</i>	Requires ownership interests in subsidiaries, not held by the parent, to be clearly identified in the consolidated statement of financial position within equity, but separate from the parent's equity, and the minority interest in net income needs to be identified on the consolidated statement of income. Additional disclosures are required.	Issued December 2007. Effective January 1, 2009, prospectively. Disclosure requirements to be applied retrospectively.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the periods' presented.
<i>FAS 161, "Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133."</i>	Requires enhanced disclosures about an entity's derivative instruments and hedging activities to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows.	Issued March 2008. Effective January 1, 2009, prospectively. Comparative disclosures for earlier periods are encouraged, but not required, at initial adoption.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the three months ended March 31, 2009.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

2. Basis of Presentation and Significant Accounting Policies (Continued)

Pronouncements	Relevant Requirements	Issued Date/ Our Effective Dates	Status
<i>FAS 162, "The Hierarchy of Generally Accepted Accounting Principles."</i>	Identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (GAAP) in the United States (the GAAP hierarchy).	Issued in May 2008. Effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles."	We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
FSP FAS 107-1 and APB, 28-1, "Interim Disclosures about Fair Value of Financial Instruments."	Amends guidance on disclosures about fair value and interim financial reporting to require disclosure about fair value of financial instruments whenever summarized financial information is issued for interim reporting periods.	Issued April 2009. Effective for periods ending after June 15, 2009.	We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.
FSP FAS 115-2, FAS 124-2, and EITF 99-20-2, "Recognition and Presentation of Other-Than-Temporary Impairments."	Amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments in the financial statements.	Issued April 2009. Effective for periods ending after June 15, 2009.	We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.
FSP FAS 157-2, "Effective Date of FASB Statement 157."	Provides a one year deferral of the effective date of FAS 157, "Fair Value Measurements," or FAS 157, for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed in financial statements at fair value on a recurring basis (at least annually).	Issued February 2008. Effective January 1, 2009, prospectively.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the three months ended March 31, 2009.
FSP FAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly."	Provides guidelines for making fair value measurements more consistent with the principles presented in FAS 157, as well as additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed. Applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures.	Issued April 2009. Effective for periods ending after June 15, 2009.	We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements

A significant number of our financial instruments are carried at fair value. These assets and liabilities include:

fixed income investments;

derivatives; and

investments in publicly-traded equity securities.

Fair Value Measurement Definition and Hierarchy

FAS 157 provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. FAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. In determining fair value, FAS 157 permits the use of various valuation approaches, including market, income and cost approaches. FAS 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

The fair value hierarchy is broken down into three levels based on the reliability of inputs. We have categorized our fixed income, derivatives and equity securities within the hierarchy as follows:

Level 1 These valuations are based on a "market approach" using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs include money market funds, U.S. government securities, bank deposits and exchange-traded equity securities;

Level 2 These valuations are based primarily on a "market approach" using quoted prices in markets that are not very active, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Fixed income assets utilizing Level 2 inputs include U.S. agency securities, including direct issuance bonds and mortgage-backed securities, asset-backed securities, corporate bonds and commercial paper. Derivative securities utilizing Level 2 inputs include forward foreign-exchange contracts; and

Level 3 These valuations are based on various approaches using inputs that are unobservable and significant to the overall fair value measurement. Certain assets are classified within Level 3 of the fair value hierarchy because they trade infrequently and, therefore, have little or no transparency. We currently have no assets or liabilities that are valued with Level 3 inputs.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****3. Fair Value Measurements (Continued)**

The following tables set forth our financial assets and liabilities that were accounted for at fair value on a recurring basis as of March 31, 2009 and December 31, 2008 (amounts in thousands):

Description		Balance as of March 31, 2009	Level 1	Level 2	Level 3
Fixed income investments(1):	Money market funds/other	\$ 374,771	\$374,771	\$	\$
	Short-term investments:				
	U.S. Treasury notes	7,508	7,508		
	U.S. agency notes	7,081		7,081	
	Corporate notes global	44,219		44,219	
	Total	58,808	7,508	51,300	
	Long-term investments:				
	U.S. Treasury notes	55,493	55,493		
	Non U.S. Governmental notes	7,290		7,290	
	U.S. agency notes	108,039		108,039	
	Corporate notes global	108,702		108,702	
	Total	279,524	55,493	224,031	
	Total fixed income investments	713,103	437,772	275,331	
Derivatives:	Foreign exchange forward contracts(2)	2,237		2,237	
Equity holdings(1):	Publicly-traded equity securities	27,619	27,619		
Total assets (liabilities) at fair value		\$ 742,959	\$465,391	\$277,568	\$

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements (Continued)

Description			Balance as of December 31, 2008	Level 1	Level 2	Level 3
Fixed income investments(1):	Cash equivalents:	Money market funds/other	\$ 357,680	\$357,680	\$	\$
	Short-term investments:	U.S. Treasury notes	7,505	7,505		
		U.S. agency notes	10,328		10,328	
		Corporate notes global	39,674		39,674	
		Total	57,507	7,505	50,002	
	Long-term investments:	U.S. Treasury notes	75,040	75,040		
		Non U.S. Governmental notes	7,322		7,322	
		U.S. agency notes	121,707		121,707	
		Corporate notes global	140,009		140,009	
		Total	344,078	75,040	269,038	
		Total fixed income investments	759,265	440,225	319,040	
Derivatives:	Foreign exchange forward contracts(2)		(1,434)		(1,434)	
Equity holdings(1):	Publicly-traded equity securities		56,596	56,596		
Total assets (liabilities) at fair value			\$ 814,427	\$496,821	\$317,606	\$

(1)

Changes in the fair value of our fixed income investments and investments in publicly-traded equity securities are recorded in accumulated other comprehensive income (loss), a component of stockholders' equity, in our consolidated balance sheets.

(2)

The aggregate fair value of our foreign exchange forward contracts was an unrealized gain of \$2.2 million as of March 31, 2009, which we recorded as an increase to prepaid expenses and other current assets in our consolidated balance sheets as of that date, and an unrealized loss of \$(1.4) million as of December 31, 2008, which we recorded as an increase to accrued expenses as of that date. Changes in the fair value of our foreign exchange forward contracts are recorded in unrealized foreign exchange gains and losses, a component of selling, general and administrative expenses, or SG&A, in our consolidated statements of operations.

The carrying amounts reflected in our consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Derivative Instruments

Edgar Filing: GENZYME CORP - Form 10-Q

As a result of our worldwide operations, we may face exposure to potential adverse movements in foreign currency exchange rates. Exposures to currency fluctuations that result from sales of our products in foreign markets are partially offset by the impact of currency fluctuations on our international expenses. We may also use derivatives, primarily foreign exchange forward contracts for which we do not seek hedge accounting treatment under FAS 133, "Accounting for Derivative Instruments and Hedging Activities," or FAS 133, to further reduce our exposure to changes in

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements (Continued)

exchange rates, primarily to offset the earnings effect from short-term foreign currency assets and liabilities. We account for such derivatives at market value with the resulting gains and losses reflected in our consolidated statements of operations. We do not have any derivatives designated as hedging instruments under FAS 133 and we do not use derivative instruments for trading or speculative purposes.

Foreign Exchange Forward Contracts

Generally, we enter into foreign exchange forward contracts with maturities of not more than 15 months. All foreign exchange forward contracts in effect as of March 31, 2009 and December 31, 2008 had maturities of 1 to 2 months. We report these contracts on a net basis. Net asset derivatives are included in prepaid expenses and other current assets and net liability derivatives are included in accrued expenses in our consolidated balance sheets.

In accordance with the provisions of FAS 161, the following table summarizes the balance sheet location of the fair value of these derivatives on both a gross and a net basis as of March 31, 2009 and December 31, 2008 (amounts in thousands):

Period	Foreign Exchange Forward Contracts			
	Gross		As Reported	
	Asset	Liability	Asset	Liability
	Derivatives Prepaid expenses and other current assets	Derivatives Accrued expenses	Derivatives Prepaid expenses and other current assets	Derivatives Accrued expenses
March 31, 2009	\$ 2,657	\$ 420	\$ 2,237	\$
December 31, 2008	\$ 2,758	\$ 4,192	\$	\$ 1,434

Total foreign exchange (gains) and losses included in SG&A in our consolidated statements of operations includes unrealized and realized (gains) and losses related to both our foreign exchange forward contracts and our foreign currency assets and liabilities. The net impact of our overall unrealized and realized foreign exchange (gains) and losses for both the three months ended March 31, 2009 and 2008 was not significant.

In accordance with the provisions of FAS 161, the following table summarizes only the effect of the unrealized and realized (gains) and losses related to our foreign exchange forward contracts on our consolidated statements of operations for the three months ended March 31, 2009 and 2008 (amounts in thousands):

Derivative Instrument	Three Months Ended March 31,			
	2009		2008	
	Statement of Operations Location	Net (Gains) Losses Recorded	Statement of Operations Location	Net (Gains) Losses Recorded
Foreign exchange forward contracts	SG&A	\$ (10,830)	SG&A	\$ 35,897

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

4. Net Income Per Share

The following table sets forth our computation of basic and diluted net income per common share (amounts in thousands, except per share amounts):

	Three Months Ended March 31,	
	2009	2008
Net income basic	\$ 195,486	\$ 145,271
Effect of dilutive securities:		
Interest expense and debt fee amortization, net of tax, related to our 1.25% convertible senior notes(1)		1,886
Net income diluted	\$ 195,486	\$ 147,157
Shares used in computing net income per common share basic	270,854	267,276
Effect of dilutive securities:		
Shares issuable upon the assumed conversion of our 1.25% convertible senior notes(1)		9,686
Stock options(2)	5,553	7,791
Restricted stock units	1,138	443
Other	83	12
Dilutive potential common shares	6,774	17,932
Shares used in computing net income per common share diluted(1,2)	277,628	285,208
Net income per common share:		
Basic	\$ 0.72	\$ 0.54
Diluted	\$ 0.70	\$ 0.52

(1)

Prior to January 1, 2009, in accordance with EITF 04-8, "The Effect of Contingently Convertible Debt on Diluted Earnings Per Share," the shares issuable upon conversion of our \$690.0 million in principal of 1.25% convertible senior notes were included in diluted weighted average shares outstanding for purposes of computing diluted earnings per share, unless the effect was anti-dilutive. Accordingly, for the three months ended March 31, 2008, interest and debt fees related to these notes of \$1.9 million, net of tax, have been added back to net income and approximately 9.7 million shares issuable upon conversion of these notes have been included in diluted weighted average shares outstanding. There are no similar adjustments to the computation of diluted earnings per share for the three months ended March 31, 2009, because we redeemed these notes, primarily for cash, on December 1, 2008.

(2)

We did not include the securities described in the following table in the computation of diluted earnings per share because these securities were anti-dilutive during both periods (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Shares issuable upon exercise of outstanding options	8,650	1,982

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

5. Comprehensive Income

The components of comprehensive income for the periods presented are as follows (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Comprehensive income, net of tax:		
Net income	\$ 195,486	\$ 145,271
Other comprehensive income (loss):		
Foreign currency translation adjustments	(120,148)	109,654
Pension liability adjustments, net of tax(1)		78
Unrealized gains (losses) on securities, net of tax:		
Unrealized gains (losses) arising during the period, net of tax	(20,607)	3,905
Reclassification adjustment for gains included in net income, net of tax	(197)	(270)
Unrealized gains (losses) on securities, net of tax(2)	(20,804)	3,635
Other comprehensive income (loss)	(140,952)	113,367
Comprehensive income	\$ 54,534	\$ 258,638

(1) Tax amounts for both periods were not significant.

(2) Net of \$11.9 million of tax for the three months ended March 31, 2009 and \$(2.0) million of tax for the three months ended March 31, 2008.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****6. Strategic Transactions**

We account for business combinations completed prior to January 1, 2009 in accordance with FAS 141 and business combinations completed on or after January 1, 2009 in accordance with FAS 141R. FAS 141R modifies the criteria that must be met to qualify as a business combination and prescribes new accounting requirements that differ significantly from FAS 141. Among various other requirements and differences, the following table illustrates how we account for specific elements of our business combinations under FAS 141 and FAS 141R:

Element	Prior to January 1, 2009, FAS 141	On or after January 1, 2009, FAS 141R
Transaction costs	Capitalized as cost of acquisition	Expensed as incurred
Exit costs	Capitalized as cost of acquisition if certain criteria were met	Expensed as incurred subsequent to acquisition date
Acquired in-process research and development programs	Measured at fair value and expensed on acquisition date, or capitalized as an intangible asset if certain criteria were met	Measured at fair value and capitalized as an intangible asset and tested for impairment until completion of program Amortized from date of completion over estimated useful life
Contingent consideration	Capitalized as cost of acquisition when contingency was resolved	Measured at fair value and recorded on acquisition date Re-measured in subsequent periods with an adjustment to earnings
Changes in deferred tax assets and valuation allowances	Recorded as adjustments to goodwill	Recorded as tax expense
Adjustments to acquisition accounting	Recorded in the current period financial statements	Recorded as adjustments to prior period financial statements

Pending Acquisition from Bayer

On March 30, 2009, we entered into an agreement with Bayer to exclusively in-license and acquire:

worldwide rights to commercialize alemtuzumab (Campath) for the treatment of multiple sclerosis, or MS;

worldwide rights to Campath for B-cell chronic lymphocytic leukemia, or B-CLL, and other indications, which we refer to as "Campath for oncology;"

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

Bayer's rights to the oncology products Fludara (fludarabine phosphate) and Leukine (sargramostim); and

a new Leukine manufacturing facility located in Lynnwood, Washington, contingent upon the facility receiving FDA approval, which is expected in 2010.

The agreement also provides an opportunity to employ certain members of Bayer's commercial and manufacturing teams for all three products. Prior to this agreement, we shared with Bayer the development and certain commercial rights to alemtuzumab for the treatment of MS and Campath for oncology. Under the new agreement, prior to regulatory approval of alemtuzumab as a treatment for MS, we will have primary responsibility for its development while Bayer will continue to fund that development at current levels. We will have worldwide commercialization rights, with Bayer retaining an option to co-promote the product as a treatment for MS. Bayer is eligible to receive the following contingent purchase price payments:

up to \$1.25 billion based on a percentage of monthly revenues for alemtuzumab for the treatment of MS, subject to a time limit of ten years;

up to \$500.0 million based on a percentage of the monthly combined revenues of Campath for oncology, Fludara and Leukine, subject to a time limit of eight years;

sales-based milestone payments determined as a percentage of annual worldwide revenues of alemtuzumab for the treatment of MS beginning in 2021 if certain minimum annual revenue targets are achieved, provided that we do not exercise our right to buyout such potential future milestones in 2020 for a one-time payment of up to \$900.0 million;

up to \$150.0 million if certain annual combined revenues of Campath for oncology, Fludara and Leukine are reached beginning in 2011; and

from \$75.0 to \$100.0 million for the Leukine manufacturing facility, following the receipt of FDA approval of the facility.

The agreement also includes our purchase of certain transition services and commercial supply of Fludara and Leukine from Bayer. The transaction will be accounted for as a business combination under FAS 141R and is expected to close in the second quarter of 2009, after the satisfaction of closing conditions, including receipt of clearance from the U.S. Federal Trade Commission, or FTC, and Department of Justice, or DOJ. The transaction will be included in our results of operations beginning on the date of acquisition. The results for Campath for oncology, Fludara and Leukine will be included in our Hematologic Oncology reporting segment and the results of alemtuzumab for the treatment of MS will be included in our MS business unit, which is reported under the caption "Other."

Purchase of Intellectual Property from EXACT Sciences Corporation

On January 27, 2009, we purchased certain intellectual property in the fields of prenatal testing and reproductive health from EXACT Sciences Corporation, or EXACT Sciences, for our diagnostic testing services business and 3,000,000 shares of EXACT Sciences common stock. We paid EXACT Sciences total cash consideration of \$22.7 million. Of this amount, we allocated \$4.5 million to the acquired shares of EXACT Sciences common stock based on the fair value of the stock on the date of acquisition, which we recorded as an increase to other noncurrent assets in our consolidated balance sheet as of March 31, 2009. As the purchased assets did not qualify as a business combination under FAS 141R and have not reached technological feasibility nor have alternative future use, we allocated

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****6. Strategic Transactions (Continued)**

the remaining \$18.2 million to the acquired intellectual property, which we recorded as a charge to research and development expenses in our consolidated statement of operations for the three months ended March 31, 2009. We will pay EXACT Sciences an additional \$1.9 million by July 2010 contingent upon the non-occurrence of certain events.

Purchase of In-Process Research and Development

Prior to January 1, 2009, we expensed IPR&D acquired through a business combination which had not yet reached technological feasibility and had no alternative future use. In accordance with our adoption of FAS 141R, all IPR&D we acquire through business combinations on or after January 1, 2009 will be capitalized as an intangible asset on our consolidated balance sheets and periodically tested for impairment.

We did not complete any business combination acquisitions in the year ended December 31, 2008 or during the three months ended March 31, 2009. In connection with two business combinations we completed between January 1, 2006 and December 31, 2007, we acquired various IPR&D projects. The following table sets forth the significant IPR&D projects we acquired between January 1, 2006 and December 31, 2007 (amounts in millions):

Company/Assets Acquired	Purchase Price	IPR&D	Programs Acquired	Discount Rate Used in Estimating Cash Flows	Year of Expected Launch
Bioenvision (2007)	\$ 349.9	\$ 125.5	Evoltra (clofarabine)(1)	17%	2009-2013
AnorMED (2006)	\$ 589.2	\$ 526.8	Mozobil (stem cell transplant)(2)	15%	2009-2014
		26.1	AMD070 (HIV)(3)	15%	
		\$ 552.9			

- (1) Clofarabine, which is approved for the treatment of relapsed and refractory pediatric acute lymphoblastic leukemia, or ALL, is marketed under the names Clolar and Evoltra. The IPR&D projects for clofarabine are related to the development of the product for the treatment of other medical issues.
- (2) Mozobil received marketing approval in the United States in December 2008 and our marketing application in Europe is pending.
- (3) Year of expected launch is not provided for AMD070 at this time because we are assessing our future plans for this program.

7. Inventories

	March 31, 2009	December 31, 2008
	(Amounts in thousands)	
Raw materials	\$ 93,711	\$ 96,986
Work-in-process	156,807	141,094
Finished goods	188,387	215,357
Total	\$438,905	\$ 453,437

Edgar Filing: GENZYME CORP - Form 10-Q

We capitalize inventory produced for commercial sale, which may result in the capitalization of inventory prior to regulatory approval. If a product is not approved for sale, it would result in the write off of the inventory and a charge to earnings. Our total inventories at March 31, 2009, included

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****7. Inventories (Continued)**

\$3.3 million of Campath for oncology inventory, produced at our manufacturing facility in Belgium, that has not yet been approved for sale because the facility has not yet received approval to manufacture Campath.

8. Goodwill and Other Intangible Assets*Goodwill*

The following table contains the change in our goodwill during the three months ended March 31, 2009 (amounts in thousands):

	As of December 31, 2008	Adjustments	As of March 31, 2009
Genetic Diseases	\$ 339,563	\$	\$ 339,563
Cardiometabolic and Renal	319,882		319,882
Biosurgery	7,585		7,585
Hematologic Oncology	322,078		322,078
Other(1)	411,966	(449)	411,517
Goodwill	\$ 1,401,074	\$ (449)	\$ 1,400,625

(1)

The adjustments to Other primarily include foreign currency revaluation adjustments for goodwill denominated in foreign currency.

Other Intangible Assets

The following table contains information about our other intangible assets for the periods presented (amounts in thousands):

	As of March 31, 2009			As of December 31, 2008		
	Gross Other Intangible Assets	Accumulated Amortization	Net Other Intangible Assets	Gross Other Intangible Assets	Accumulated Amortization	Net Other Intangible Assets
Technology	\$ 1,918,793	\$ (731,369)	\$ 1,187,424	\$ 1,919,074	\$ (692,235)	\$ 1,226,839
Patents	194,560	(125,914)	68,646	194,560	(121,763)	72,797
Trademarks	60,544	(43,542)	17,002	60,556	(42,194)	18,362
License fees	98,136	(41,557)	56,579	98,123	(39,824)	58,299
Distribution rights(1)	406,447	(184,625)	221,822	399,768	(170,892)	228,876
Customer lists	82,810	(36,358)	46,452	83,729	(34,271)	49,458
Other	2,039	(2,039)		2,039	(1,972)	67
Total	\$ 2,763,329	\$ (1,165,404)	\$ 1,597,925	\$ 2,757,849	\$ (1,103,151)	\$ 1,654,698

(1)

Includes an additional \$7.9 million in the first quarter of 2009 for additional payments made or accrued in connection with the reacquisition of the Synvisc sales and marketing rights from Wyeth in January 2005. In addition, we will make a series of additional contingent royalty payments to Wyeth based on the volume of Synvisc sales in the covered territories. These

contingent royalty

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****8. Goodwill and Other Intangible Assets (Continued)**

payments could extend out to June 2012, or could total a maximum of \$293.7 million, whichever comes first. To date, \$253.5 million of the \$293.7 million has been paid.

All of our other intangible assets are amortized over their estimated useful lives. Total amortization expense for our other intangible assets was:

\$57.6 million for the three months ended March 31, 2009; and

\$55.7 million for the three months ended March 31, 2008.

The estimated future amortization expense for other intangible assets for the remainder of fiscal year 2009, the four succeeding fiscal years and thereafter is as follows (amounts in thousands):

Year Ended December 31,	Estimated Amortization Expense(1,2)
2009 (remaining nine months)	\$ 171,605
2010	242,519
2011	256,064
2012	195,694
2013	125,437
Thereafter	448,183

(1)

Includes estimated future amortization expense for the Synvisc distribution rights based on the forecasted respective future sales of Synvisc and the resulting future contingent payments we will be required to make to Wyeth, and for the Myozyme patent and technology rights pursuant to a license agreement with Synpac based on forecasted future sales of Myozyme and the milestone payments we will be required to make to Synpac. These contingent payments will be recorded as intangible assets when the payments are accrued. Estimated future amortization expense also includes estimated amortization for other arrangements involving contingent payments.

(2)

Excludes future amortization expense related to the \$240.2 million of technology recorded effective January 1, 2008, related to our consolidation of the results of BioMarin/Genzyme LLC, because such amortization is entirely offset by the corresponding amortization of a noncurrent liability related to the consolidation of BioMarin/Genzyme LLC.

9. Revolving Credit Facility

As of March 31, 2009, no amounts were outstanding under our five-year \$350.0 million senior unsecured revolving credit facility, which matures July 14, 2011. The terms of this credit facility include various covenants, including financial covenants, that require us to meet minimum interest coverage ratios and maximum leverage ratios. As of March 31, 2009, we were in compliance with these covenants.

10. Stockholders' Equity***Stock Repurchase***

In May 2007, our board of directors authorized a stock repurchase program to repurchase up to an aggregate maximum amount of \$1.5 billion or 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. The repurchases are being made from time to time and

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****10. Stockholders' Equity (Continued)**

can be effectuated through open market purchases, privately negotiated transactions, transactions structured through investment banking institutions, or by other means, subject to management's discretion and as permitted by securities laws and other legal requirements. The manner of the purchase, the amount that we spend and the number of shares we ultimately purchase will vary based on a range of factors, including share price. The program does not obligate us to acquire any particular amount of common stock and the program may be suspended at any time at our discretion.

During the three months ended March 31, 2009, we repurchased 2,000,000 shares of our common stock under this program for an average price of \$53.55 per share for a total of \$107.1 million in cash, including fees. Since June 2007, when we first began repurchasing shares of our common stock under this program, we have repurchased a cumulative total of 7,500,000 shares of our common stock at an average price of \$64.21 per share for a total of \$481.7 million in cash, including fees. We recorded the repurchases in our consolidated balance sheets as a reduction to our common stock account for the par value of the repurchased shares and as a reduction to our additional paid-in capital account.

Stock-Based Compensation Expense, Net of Estimated Forfeitures

We allocated pre-tax stock-based compensation expense, net of estimated forfeitures, based on the functional cost center of each employee as follows (amounts in thousands, except per share amounts):

	Three Months Ended March 31,	
	2009	2008
Pre-tax stock-based compensation expense, net of estimated forfeitures charged to:		
Cost of products and services sold(1)	\$ (7,234)	\$ (6,514)
Selling, general and administrative expense	(23,836)	(22,889)
Research and development expense	(13,536)	(12,585)
Total	(44,606)	(41,988)
Less: tax benefit from stock options	12,589	12,537
Total stock-based compensation expense, net of tax	\$(32,017)	\$(29,451)
Effect per common share:		
Basic	\$ (0.12)	\$ (0.12)
Diluted	\$ (0.12)	\$ (0.10)

(1)

We also capitalized the following amounts of stock-based compensation expense to inventory, all of which is attributable to participating employees that support our manufacturing operations (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Stock-based compensation expense capitalized to inventory	\$ 3,412	\$ 3,121

We amortize stock-based compensation expense capitalized to inventory based on inventory turns.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

10. Stockholders' Equity (Continued)

At March 31, 2009, there was \$211.9 million of pre-tax stock-based compensation expense, net of estimated forfeitures, related to unvested awards not yet recognized which is expected to be recognized over a weighted average period of 1.8 years.

11. Commitments and Contingencies

Legal Proceedings

In April 2005, Church & Dwight Co., Inc., or Church & Dwight, filed a suit in U.S. District Court for the District of New Jersey against Abbott Laboratories, or Abbott, claiming that certain over-the-counter pregnancy tests distributed by Abbott between 1999 and 2003 infringed upon patents owned by Church & Dwight. During part of this period, a portion of the test kits distributed by Abbott were manufactured by Wyntek Diagnostics, Inc., or Wyntek, which had agreed to indemnify Abbott for patent infringement related costs and damages for these products. In 2002, we acquired Wyntek and assumed the obligations under this agreement. In June 2008, the court issued a ruling awarding Church & Dwight approximately \$29 million in damages based on a jury finding of willful infringement by Abbott. This award has been entered as a final ruling and Abbott has filed an appeal. Because multiple parties, including Abbott, manufactured infringing product for Abbott during this period, any responsibility that we may have for indemnifying Abbott is only for a portion of its costs and damages related to this case. We currently are disputing with Abbott the percentage of infringing product that was supplied by us and may in the future assert additional claims that, if successful, would reduce or relieve us of any liability.

Through June 30, 2003, we had three outstanding series of common stock, which we referred to as tracking stocks: Genzyme General Stock (which we now refer to as Genzyme Stock); Biosurgery Stock; and Molecular Oncology Stock. On August 6, 2007, we reached an agreement in principle to settle for \$64.0 million the lawsuits related to our 2003 exchange of Genzyme Stock for Biosurgery Stock. We recorded a liability for the settlement payment of \$64.0 million as a charge to SG&A in our consolidated statement of operations for the quarterly period ended June 30, 2007. We paid the settlement in August 2007. The court approved the settlement in October 2007. We have submitted claims to our insurers for reimbursement of portions of the expenses incurred in connection with these cases; the insurer has purported to deny coverage, and, therefore, we have not recorded a receivable for any potential recovery from our insurer. We are vigorously pursuing our rights with respect to insurance coverage. To the extent we are successful, we will record the recovery in our consolidated statements of operations.

We periodically become subject to legal proceedings and claims arising in connection with our business. Although we cannot predict the outcome of these additional proceedings and claims, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our consolidated financial position or results of operations.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****12. Provision for Income Taxes**

	Three Months Ended March 31,	
	2009	2008
	(Amounts in thousands)	
Provision for income taxes	\$ 78,884	\$ 60,117
Effective tax rate	29%	29%

Our effective tax rate for both periods varies from the U.S. statutory tax rate as a result of:

income and expenses taxed at rates other than the U.S. statutory tax rate;

our provision for state income taxes;

the tax benefits from manufacturing activities;

benefits related to tax credits; and

non-deductible stock-based compensation expenses totaling \$9.7 million for the three months ended March 31, 2009 as compared to \$8.1 million for the three months ended March 31, 2008.

We are currently under IRS audit for tax years 2006 to 2007. We believe that we have provided sufficiently for all audit exposures. We expect to settle the 2006 to 2007 IRS audit within the next twelve months and do not expect that the settlement will have a material impact on our financial position or results of operations. Settlement of these audits or the expiration of the statute of limitations on the assessment of income taxes for any tax year may result in a reduction of future tax provisions. Any such benefit would be recorded upon final resolution of the audit or expiration of the applicable statute of limitations.

13. Segment Information

In accordance with FAS 131, "Disclosures about Segments of an Enterprise and Related Information," we present segment information in a manner consistent with the method we use to report this information to our management. Applying FAS 131, in the fourth quarter of 2008, we changed our segment reporting structure to better reflect the way we manage and measure the performance of our businesses. Under the new reporting structure, we are organized into four reporting segments as described above in Note 1., "Description of Business," to these consolidated financial statements. We have revised our 2008 segment disclosures to conform to our 2009 presentation.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****13. Segment Information (Continued)**

We have provided information concerning the operations of these reportable segments in the following tables (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Genetic Diseases	\$ 537,050	\$ 534,889
Cardiometabolic and Renal	242,962	231,838
Biosurgery	119,522	111,662
Hematologic Oncology	35,907	23,880
Other	212,976	197,409
Corporate	454	383
 Total	 1,148,871	 1,100,061
Income (loss) before income taxes:		
Genetic Diseases	351,974	356,721
Cardiometabolic and Renal(1)	102,218	28,831
Biosurgery	28,333	18,787
Hematologic Oncology	(13,642)	(25,961)
Other(2)	(6,922)	5,177
Corporate(3)	(187,591)	(178,167)
 Total	 \$ 274,370	 \$ 205,388

(1)

Includes a charge of \$69.9 million recorded to research and development expense in our consolidated statements of operations for a license fee we paid to Isis Pharmaceuticals, Inc., or Isis, in February 2008.

(2)

Includes a charge of \$18.2 million recorded to research and development expense in our consolidated statements of operations for the three months ended March 31, 2009, for intellectual property we acquired from EXACT Sciences in January 2009.

(3)

Loss before income taxes for Corporate includes our corporate, general and administrative and corporate science activities, all of the stock-based compensation expenses, as well as net gains on investments in equity securities, investment income, interest expense and other income and expense items that we do not specifically allocate to a particular reporting segment.

Table of Contents**GENZYME CORPORATION AND SUBSIDIARIES****Notes to Unaudited, Consolidated Financial Statements (Continued)****13. Segment Information (Continued)****Segment Assets**

We provide information concerning the assets of our reportable segments in the following table (amounts in thousands):

	March 31, 2009	December 31, 2008
Segment Assets(1):		
Genetic Diseases	\$ 1,632,942	\$ 1,520,586
Cardiometabolic and Renal	1,307,437	1,366,970
Biosurgery	491,390	497,813
Hematologic Oncology	669,892	700,563
Other	1,131,758	1,097,169
Corporate(2)	3,386,487	3,488,175
 Total	 \$8,619,906	 \$ 8,671,276

(1)

Assets for our four reporting segments and Other include primarily accounts receivable, inventory and certain fixed and intangible assets, including goodwill.

(2)

Includes the assets related to our corporate, general and administrative operations, and corporate science activities that we do not allocate to a particular segment. Segment assets for Corporate consist of the following (amounts in thousands):

	March 31, 2009	December 31, 2008
Cash, cash equivalents, short- and long-term investments in debt securities	\$ 981,770	\$ 973,691
Deferred tax assets, net	491,720	457,342
Property, plant & equipment, net	1,484,134	1,524,442
Investments in equity securities	53,413	83,325
Other	375,450	449,375
 Total	 \$3,386,487	 \$ 3,488,175

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF GENZYME CORPORATION AND SUBSIDIARIES' FINANCIAL CONDITION AND RESULTS OF OPERATIONS

When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described under the heading "Risk Factors" below. These risks and uncertainties could cause actual results to differ materially from those forecasted in forward-looking statements or implied by past results and trends. Forward-looking statements are statements that attempt to project or anticipate future developments in our business; we encourage you to review the examples of forward-looking statements under "Note Regarding Forward-Looking Statements" at the beginning of this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise the statements in light of future developments.

INTRODUCTION

We are a global biotechnology company dedicated to making a major impact on the lives of people with serious diseases. Our broad product and service portfolio is focused on rare disorders, renal disease, orthopaedics, cancer, transplant and immune disease, and diagnostic and predictive testing.

In the fourth quarter of 2008, we changed our segment reporting structure to better reflect the way we manage and measure the performance of our businesses. Under the new reporting structure, we are organized into four financial reporting units, which we also consider to be our reporting segments:

Genetic Diseases, which develops, manufactures and distributes therapeutic products, with an expanding focus on products to treat patients suffering from genetic diseases and other chronic debilitating diseases, including a family of diseases known as LSDs. The unit derives substantially all of its revenue from sales of Cerezyme, Fabrazyme, Myozyme and Aldurazyme;

Cardiometabolic and Renal, which develops, manufactures and distributes products that treat patients suffering from renal diseases, including chronic renal failure, and endocrine and cardiovascular diseases. The unit derives substantially all of its revenue from sales of Renagel/Renvela (including sales of bulk sevelamer), Hectorol and Thyrogen;

Biosurgery, which develops, manufactures and distributes biotherapeutics and biomaterial-based products, with an emphasis on products that meet medical needs in the orthopaedics and broader surgical areas. The unit derives substantially all of its revenue from sales of Synvisc/Synvisc-One, the Sepra line of products, Carticel and MACI; and

Hematologic Oncology, which develops, manufactures and distributes products for the treatment of cancer. The unit derives substantially all of its revenue from sales and royalties received on sales of Campath and clofarabine. Clofarabine is marketed under the names Clolar and Evoltra. This unit also includes Mozobil, which received marketing approval in the United States in December 2008.

Our transplant business unit, which develops, manufactures and distributes therapeutic products that address pre-transplantation, prevention and treatment of graft rejection in organ transplantation and other hematologic and auto-immune disorders, and our genetics business unit, which provides testing services for the oncology, prenatal and reproductive markets, were formerly reported as separate reporting segments. Effective as of the fourth quarter of 2008, we include our transplant and genetics business units under the caption "Other." We also report the activities of our diagnostic products, bulk pharmaceuticals and immune mediated disease business units under the caption "Other." These operating segments did not meet the quantitative threshold for separate segment reporting. We have revised our 2008 segment disclosures to conform to our 2009 presentation.

Table of Contents

We report our corporate, general and administrative operations and corporate science activities under the caption "Corporate."

STRATEGIC TRANSACTIONS

Pending Acquisition from Bayer

On March 30, 2009, we entered into an agreement with Bayer to exclusively in-license and acquire:

worldwide rights to commercialize alemtuzumab (Campath) for the treatment of MS;

worldwide rights to Campath for oncology;

Bayer's rights to the oncology products Fludara (fludarabine phosphate) and Leukine (sargramostim); and

a new Leukine manufacturing facility located in Lynnwood, Washington, contingent upon the facility receiving FDA approval, which is expected in 2010.

The agreement also provides an opportunity to employ certain members of Bayer's commercial and manufacturing teams for all three products. Prior to this agreement, we shared with Bayer the development and certain commercial rights to alemtuzumab for the treatment of MS and Campath for oncology. Under the new agreement, prior to regulatory approval of alemtuzumab as a treatment for MS, we will have primary responsibility for its development while Bayer will continue to fund that development at current levels. We will have worldwide commercialization rights, with Bayer retaining an option to co-promote the product as a treatment for MS. Bayer is eligible to receive the following contingent purchase price payments:

up to \$1.25 billion based on a percentage of monthly revenues for alemtuzumab for the treatment of MS, subject to a time limit of ten years;

up to \$500.0 million based on a percentage of the monthly combined revenues of Campath for oncology, Fludara and Leukine, subject to a time limit of eight years;

sales-based milestone payments determined as a percentage of annual worldwide revenues of alemtuzumab for the treatment of MS beginning in 2021 if certain minimum annual revenue targets are achieved, provided that we do not exercise our right to buyout such potential future milestones in 2020 for a one-time payment of up to \$900.0 million;

up to \$150.0 million if certain annual combined revenues of Campath for oncology, Fludara and Leukine are reached beginning in 2011; and

from \$75.0 to \$100.0 million for the Leukine manufacturing facility, following the receipt of FDA approval of the facility.

The agreement also includes our purchase of certain transition services and commercial supply of Fludara and Leukine from Bayer. The transaction will be accounted for as a business combination under FAS 141R and is expected to close in the second quarter of 2009, after the satisfaction of closing conditions, including receipt of clearance from the FTC and DOJ. The transaction will be included in our results of operations beginning on the date of acquisition. The results for Campath for oncology, Fludara and Leukine will be included in our Hematologic Oncology reporting segment and the results for alemtuzumab for the treatment of MS will be included in our MS business unit, which is reported under the caption "Other."

Purchase of Intellectual Property from EXACT Sciences

On January 27, 2009, we purchased certain intellectual property in the fields of prenatal testing and reproductive health from EXACT Sciences for our diagnostic testing services business and

Table of Contents

3,000,000 shares of EXACT Sciences common stock. We paid EXACT Sciences total cash consideration of \$22.7 million. Of this amount, we allocated \$4.5 million to the acquired shares of EXACT Sciences common stock based on the fair value of the stock on the date of acquisition, which we recorded as an increase to other noncurrent assets in our consolidated balance sheet as of March 31, 2009. As the purchased assets did not qualify as a business combination under FAS 141R and have not reached technological feasibility nor have alternative future use, we allocated the remaining \$18.2 million to the acquired intellectual property, which we recorded as a charge to research and development expenses in our consolidated statement of operations for the three months ended March 31, 2009. We will pay EXACT Sciences an additional \$1.9 million by July 2010 contingent upon the non-occurrence of certain events.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our critical accounting policies and significant judgments and estimates are set forth under the heading "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates" in Exhibit 13 to our 2008 Form 10-K. There have been no significant changes to our critical accounting policies or significant judgments and estimates since December 31, 2008. Additional information regarding our provisions and estimates for our product sales allowances, sales allowance reserves and accruals, and distributor fees and IPR&D are included below.

Revenue Recognition

Product Sales Allowances

Sales of many biotechnology products in the United States are subject to increased pricing pressure from managed care groups, institutions, government agencies and other groups seeking discounts. We and other biotechnology companies in the U.S. market are also required to provide statutorily defined rebates and discounts to various U.S. government agencies in order to participate in the Medicaid program and other government-funded programs. In most international markets, we operate in an environment where governments may and have mandated cost-containment programs, placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and enacted across-the-board price cuts as methods to control costs. The sensitivity of our estimates can vary by program, type of customer and geographic location. Estimates associated with Medicaid and other government allowances may become subject to adjustment in a subsequent period.

We record product sales net of the following significant categories of product sales allowances:

Contractual adjustments We offer chargebacks and contractual discounts and rebates, which we collectively refer to as contractual adjustments, to certain private institutions and various government agencies in both the United States and international markets. We record chargebacks and contractual discounts as allowances against accounts receivable in our consolidated balance sheets. We account for rebates by establishing an accrual for the amounts payable by us to these agencies and institutions, which is included in accrued liabilities in our consolidated balance sheets. We estimate the allowances and accruals for our contractual adjustments based on historical experience and current contract prices, using both internal data as well as information obtained from external sources, such as independent market research agencies and data from wholesalers. We continually monitor the adequacy of these estimates and adjust the allowances and accruals periodically throughout each quarter to reflect our actual experience. In evaluating these allowances and accruals, we consider several factors, including significant changes in the sales performance of our products subject to contractual adjustments, inventory in the distribution channel, changes in U.S. and foreign healthcare legislation impacting rebate or allowance rates, changes in contractual discount rates and the estimated lag time between a sale and payment of the corresponding rebate;

Table of Contents

Discounts In some countries, we offer cash discounts for certain products as an incentive for prompt payment, which are generally a stated percentage off the sales price. We account for cash discounts by reducing accounts receivable by the full amounts of the discounts. We consider payment performance and adjust the accrual to reflect actual experience; and

Sales returns We record allowances for product returns at the time product sales are recorded. The product returns reserve is estimated based on the returns policies for our individual products and our experience of returns for each of our products. If the price of a product changes or if the history of product returns changes, the reserve is adjusted accordingly. We determine our estimates of the sales return accrual for new products primarily based on the historical sales returns experience of similar products, or those within the same or similar therapeutic category (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Product sales allowances:			
Contractual adjustments	\$ 136,180	\$ 102,002	34%
Discounts	6,275	5,505	14%
Sales returns	6,523	6,751	(3)%
Total product sales allowances	\$ 148,978	\$ 114,258	30%
 Total gross product sales	 \$ 1,186,222	 \$ 1,120,525	 6%
 Total product sales allowances as a percent of total gross product sales	 13%	 10%	

Total product sales allowances increased \$34.7 million, or 30%, in 2009, as compared to 2008, primarily due to the impact of price increases implemented after the first quarter of 2008, primarily for our Cardiometabolic and Renal reporting segment, and changes in our overall product mix.

Total estimated product sales allowance reserves and accruals in our consolidated balance sheets increased 4% to approximately \$219 million as of March 31, 2009, as compared to approximately \$210 million as of December 31, 2008, primarily due to changes in the timing of certain payments. Our actual results have not differed materially from amounts recorded. The annual variation has been less than 0.5% of total product sales for each of the last three years.

Distributor Fees

EITF 01-9, "Accounting for Consideration given by a Vendor to a Customer (including a Reseller of a Vendor's Products)" specifies that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue. We include such fees in contractual adjustments, which are recorded as a reduction to product sales. That presumption is overcome and the consideration should be characterized as a cost incurred if, and to the extent that, both of the following conditions are met:

the vendor receives, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and

the vendor can reasonably estimate the fair value of the benefit received.

Table of Contents

We record service fees paid to our distributors as a charge to SG&A, a component of operating expenses, only if the criteria set forth above are met. The following table sets forth the distributor fees recorded as a reduction to product sales and charged to SG&A (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Distributor fees:		
Included in contractual adjustments and recorded as a reduction to product sales	\$ 3,479	\$ 4,696
Charged to SG&A	3,547	2,951
Total distributor fees	\$ 7,026	\$ 7,647

In-Process Research and Development

IPR&D represents the fair value assigned to incomplete technologies that we acquire, which at the time of acquisition have not reached technological feasibility and have no alternative future use. A technology is considered to have an alternative future use if it is probable that the acquirer will use the asset in its incomplete state as it exists at the acquisition date, in another research and development project that has not yet commenced, and economic benefit is anticipated from that use.

Substantial additional research and development will be required before any of our acquired programs reach technological feasibility. In addition, once research is completed, each underlying product candidate will need to complete a series of clinical trials and receive regulatory approvals prior to commercialization. Management assumes responsibility for determining the valuation of the acquired IPR&D programs. The fair value assigned to IPR&D for each acquisition is estimated by discounting, to present value, the future cash flows expected from the programs since the date of our acquisition. Accordingly, such cash flows reflect our estimates of revenues, costs of sales, operating expenses and income taxes from the acquired IPR&D programs based on the following factors:

relevant market sizes and market growth factors;

current and expected trends in technology and product life cycles;

the time and investment that will be required to develop products and technologies;

the ability to obtain marketing authorization and regulatory approvals;

the ability to manufacture and commercialize the products;

the extent and timing of potential new product introductions by our competitors that may be deemed more efficacious, more convenient to use, or more cost effective;

the amount of revenues that could be derived from the products; and

the appropriate discount rates to use in the analysis.

The discount rates used are commensurate with the uncertainties associated with the economic estimates described above. The resulting discounted future cash flows are then probability-adjusted to reflect the different stages of development, the time and resources needed to complete the development of the product and the risks of advancement through the product approval process. In estimating the future cash flows, we also consider the tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D programs and adjust future cash flows for a charge reflecting the contribution to value of these assets. Such contributory tangible and intangible assets may include, but are not limited to, working capital, fixed assets, assembled workforce, customer relationships, patents, trademarks, and core technology.

Table of Contents

Use of different estimates and judgments could yield materially different results in our analysis and could result in materially different asset values or expense. There can be no assurance that we will be able to successfully develop and complete the acquired IPR&D programs and profitably commercialize the underlying product candidates at all or before our competitors develop and commercialize products for the same indications. Moreover, if certain of the acquired IPR&D programs fail, are abandoned during development, or do not receive regulatory approval, then we may not realize the value we have estimated and recorded in our financial statements on the acquisition date, and we may also not recover the research and development investment made since the acquisition to further develop that program. If such circumstances were to occur, our future operating results could be materially adversely impacted.

Prior to January 1, 2009, IPR&D acquired through a business combination was expensed. In accordance with the adoption of FAS 141R, IPR&D acquired through business combinations on or after January 1, 2009 will be capitalized as an intangible asset on the balance sheet and periodically tested for impairment. Amortization of such capitalized IPR&D will commence upon the successful completion of the program and continue for the estimated useful life of the asset.

None of the incomplete technology programs we have acquired through our business combinations prior to January 1, 2009 have reached technological feasibility nor had an alternative future use and, therefore, the fair value of those programs was expensed on the acquisition date and classified in our consolidated statements of operations within the line item Purchase of In-Process Research and Development. We did not complete any business combinations on or after January 1, 2009 and therefore did not capitalize any IPR&D during the three months ended March 31, 2009.

FAS 141R has no impact on the accounting and classification for incomplete technology programs acquired outside of a business combination. As such, nonrefundable fees paid for the acquisition or licensing of products that have not received regulatory approval and have no future alternative use are classified in our consolidated statements of operations within the line item Research and Development. However, if a technology acquired outside of a business combination is determined to have an alternative future use, then the fair value of the program would be recorded as an intangible asset on our consolidated balance sheet.

RESULTS OF OPERATIONS

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

REVENUES

The components of our total revenues are described in the following table (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Product revenue	\$ 1,037,244	\$ 1,006,268	3%
Service revenue	101,499	85,864	18%
Total product and service revenue	1,138,743	1,092,132	4%
Research and development revenue	10,128	7,929	28%
Total revenues	\$ 1,148,871	\$ 1,100,061	4%

Table of Contents

Product Revenue

We derive product revenue from sales of:

Genetic Diseases products, including Cerezyme for the treatment of Gaucher disease, Fabrazyme for the treatment of Fabry disease, Myozyme for the treatment of Pompe disease, Aldurazyme for the treatment of MPS I and Elaprase for the treatment of Hunter Syndrome;

Cardiometabolic and Renal products, including Renagel/Renvela for the reduction of elevated serum phosphorus levels in end-stage renal disease patients on hemodialysis, Hectorol for the treatment of secondary hyperparathyroidism in patients on dialysis and those with chronic kidney disease, or CKD, bulk sevelamer, and Thyrogen, which is an adjunctive diagnostic agent used in the follow-up treatment of patients with well-differentiated thyroid cancer and an adjunctive therapy in the ablation of remnant thyroid tissue;

Biosurgery products, including orthopaedic products, such as Synvisc/Synvisc-One, and the Septra line of products, such as Septrafilm;

Hematologic Oncology products, including Campath for the treatment of B-CLL, Clolar/Evoltra for the treatment of ALL after at least two prior regimens and Mozobil; and

Other products, including:

transplant products for the treatment of immune-mediated diseases, primarily Thymoglobulin, which induces immunosuppression of certain types of cells responsible for organ rejection in transplant patients;

diagnostic products, including infectious disease and cholesterol testing products; and

bulk pharmaceuticals, including WelChol, which is a therapy for the reduction of LDL cholesterol in patients with primary hypercholesterolemia.

Table of Contents

The following table sets forth our product revenue on a reporting segment basis (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Genetic Diseases:			
Cerezyme	\$ 295,970	\$ 304,303	(3)%
Fabrazyme	122,201	116,475	5%
Myozyme	67,392	67,324	
Aldurazyme	36,837	36,839	
Other Genetic Diseases	14,625	9,772	50%
Total Genetic Diseases	537,025	534,713	
Cardiometabolic and Renal:			
Renegel/Renvela (including sales of bulk sevelamer)	170,599	168,694	1%
Hectorol	33,030	29,076	14%
Thyrogen	38,826	33,785	15%
Other Cardiometabolic and Renal	482	237	>100%
Total Cardiometabolic and Renal	242,937	231,792	5%
Biosurgery:			
Synvisc/Synvisc-One	63,171	56,142	13%
Sepra products	34,304	30,604	12%
Other Biosurgery	11,653	13,581	(14)%
Total Biosurgery	109,128	100,327	9%
Hematologic Oncology	33,978	22,281	52%
Other product revenue	114,176	117,155	(3)%
Total product revenue	\$1,037,244	\$1,006,268	3%

Genetic Diseases

Genetic Diseases product revenue remained substantially unchanged for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to unfavorable exchange rate fluctuations, which offset continued growth in sales volume for Cerezyme, Fabrazyme, Myozyme, Aldurazyme and Elaprase. Elaprase was developed by Shire Human Genetic Therapies Inc., or Shire. We have the rights to commercialize the product in Japan and other Asia Pacific countries under an agreement with Shire. We launched Elaprase in Japan in the fourth quarter of 2007. Sales of Elaprase are included in Other Genetic Diseases product revenue.

The 3% decrease in Cerezyme revenue to \$296.0 million for the three months ended March 31, 2009, as compared to the same period of 2008, is primarily due to the weakening of foreign currencies against the U.S. dollar, which adversely impacted revenue by \$22.6 million for the three months ended March 31, 2009, as compared to the same period of 2008. This decrease was offset, in part, by increases in sales volume due to continued identification of Gaucher disease patients, particularly in international markets. Although we expect Cerezyme to continue to be a substantial contributor to revenues in the future, it is a mature product and, as a result, we expect that the current new patient growth trend will continue at a modest pace going forward.

Our results of operations are dependent on sales of Cerezyme and a reduction in revenue from sales of this product would adversely affect our results of operations. Sales of Cerezyme were

Table of Contents

approximately 26% of our total revenue for the three months ended March 31, 2009, as compared to 28% for the same period in 2008. Revenue from Cerezyme would be impacted negatively if competitors developed alternative treatments for Gaucher disease which gained commercial acceptance, if our marketing activities are restricted, or if coverage, pricing or reimbursement is limited.

The 5% increase in Fabrazyme revenue to \$122.2 million for the three months ended March 31, 2009, as compared to the same period of 2008, is primarily attributable to increased patient identification worldwide as Fabrazyme is introduced into new markets. The increase in the sales volume of Fabrazyme was offset, in part, by decreases of \$6.8 million attributable to the weakening of foreign currencies against the U.S. dollar.

Sales of Myozyme were virtually the same for the three months ended March 31, 2009, as compared to the same period of 2008. Although sales of Myozyme increased for the three months ended March 31, 2009, due to the identification of new patients following European approval of product produced at the 4000L scale in February 2009, the growth in sales of Myozyme was adversely affected by the product not yet being approved for promotion in the U.S. market and by a global supply management program under which adult Pompe disease patients temporarily adjusted their infusion schedules in order to preserve constrained product supply for infants and children. Sales of Myozyme were also adversely impacted for the three months ended March 31, 2009, as compared to the same period of 2008, by decreases of \$8.8 million attributable to the weakening of foreign currencies against the U.S. dollar.

We currently manufacture Myozyme (alglucosidase alfa) in the United States using a 160L scale process at our manufacturing facility in Framingham, Massachusetts and using the 2000L scale process at our manufacturing facility in Allston, Massachusetts. We have approval to sell Myozyme manufactured using the 160L scale process in the United States and Canada. Myozyme produced using the 2000L scale process has been approved for sale in more than 40 countries outside of the United States. The product produced using the 160L scale process is reserved for infants and children because the smaller scale produces a limited supply of FDA-approved product for the U.S. market.

In October 2007, we submitted a supplemental biologics license application, or BLA, to the FDA seeking approval of alglucosidase alfa produced using the 2000L scale process to help meet the demand for the product in the U.S. market. In April 2008, the FDA concluded that alglucosidase alfa produced using the 160L scale process and using the 2000L scale process should be classified as two different products because of analytical differences observed as part of the comparability efforts supporting the manufacturing change. As a result, the FDA required us to submit a separate BLA to gain U.S. approval for alglucosidase alfa produced using the 2000L scale process, which we submitted in May 2008. In October 2008, the Endocrinologic and Metabolic Drugs Advisory Committee affirmed by a vote of 16 to 1 that our Late Onset Treatment Study established the clinical effectiveness of alglucosidase alfa produced using the 2000L scale process for the treatment of patients with late-onset Pompe disease. After the product is approved, it will be marketed as Lumizyme in the United States, while the currently FDA-approved product produced using the 160L scale process will continue to be marketed as Myozyme.

In September and October 2008, FDA officials conducted a Good Manufacturing Practices, or GMP, inspection of licensed therapeutic drug products, bulk drug substances and drug components manufactured at our Allston, Massachusetts facility. We manufacture Cerezyme, Fabrazyme and Myozyme and perform fill/finish for Aldurazyme and Thyrogen at this facility. After this inspection, the FDA officials issued a list of inspection observations known as a Form FDA 483, or 483, which detailed observations considered by the FDA to be significant deviations from GMP compliance, including observations relating to our procedures designed to prevent microbiological contamination of sterile drug products; controls for in-process monitoring during bulk drug substance manufacturing, including our controls for bioburden monitoring; and maintenance of equipment and computer systems

Table of Contents

validation. We responded to the 483 on October 31, 2008 with a plan and timeline to address the inspectional observations. We also provided a progress update to the FDA on February 23, 2009. On February 27, 2009, we received a warning letter from the FDA that requested supplemental information in order to fully evaluate the adequacy of our corrective actions with respect to nine of the FDA's sixteen observations in the 483. We submitted an initial response to the FDA on March 6, 2009 with a plan and timeline for providing this supplemental information and have been providing regular updates to the FDA on our progress against this plan. We believe that we have addressed all the measures required to respond to the FDA warning letter. We are awaiting the FDA's re-inspection of the Allston facility. Failure to correct the deviations cited in an FDA warning letter can result in further regulatory action, including suspension of our license to manufacture products at this facility, or lead to a delay in the approval of new products.

Also on February 27, 2009, we received a complete response letter, or CR Letter, from the FDA regarding our 2000L application. In the CR Letter, the FDA outlined items that need to be addressed before our application could be approved. These items included finalizing agreement with the FDA on the design of a post-approval verification study to demonstrate the clinical benefit of Lumizyme, as required under the FDA's accelerated approval process, as well as a Risk Evaluation and Mitigation Strategy, or REMS, for the product; finalizing label discussions with the FDA; and providing the FDA with information regarding specific chemistry, manufacturing and controls questions and with a safety update. In addition, the FDA's CR Letter stated that before the FDA would approve Lumizyme, we would need to resolve issues identified in the warning letter related to our Allston manufacturing facility. We have received final comments from the agency regarding the REMS for the product, the verification study, and the label.

The FDA has informed us that we can submit our response to the CR Letter before the re-inspection of our Allston facility in connection with the warning letter. In addition, the FDA has agreed that we can compile and submit existing registry data as part of our response to the CR Letter instead of conducting a separate post-marketing verification study. We are preparing the requested registry data and expect to submit our response to the CR Letter by the middle of May 2009. Because our submission will include clinical data, we believe that the FDA will classify our response as a Class 2 resubmission with a six-month review period under the Prescription Drug User Fee Act, or PDUFA. However, given our ongoing dialogue with the FDA, we believe that we could receive approval before the PDUFA date.

We are also in discussion with the FDA regarding the submission of a supplemental BLA for the 4000L scale product. We have met with the FDA to review comparability data and are working collaboratively to determine the most expeditious path toward approval.

In February 2009, we received approval from the European Commission to market Myozyme produced at our manufacturing facility in Belgium using a 4000L scale process. During January and February 2009, there was widespread adult patient compliance with our request to adjust infusion schedules to preserve product supply for infants and children. With the approval of Myozyme produced using the 4000L scale process, adult patients who adjusted their infusion schedules were able to resume their regular schedules and new patients will be able to initiate therapy outside of the United States. We expect Myozyme sales in Europe to accelerate starting in the second quarter of 2009 and to continue to increase throughout the second half of 2009. During the second half of 2009, we also plan to begin preparing to add a third 4000L bioreactor to our Belgium facility to help support Myozyme's growth over the longer term. We anticipate that this bioreactor will be approved for commercial production in the middle of 2011.

Aldurazyme revenue remained substantially unchanged for the three months ended March 31, 2009, as compared to the same period of 2008. Aldurazyme revenue increased for the three months ended March 31, 2009, as compared to the same period of 2008, due to increased patient identification

Table of Contents

worldwide as Aldurazyme was introduced into new markets. The weakening of foreign currencies against the U.S. dollar, adversely impacted Aldurazyme revenue by \$3.6 million for the three months ended March 31, 2009, as compared to the same period of 2008.

Other Genetic Diseases product revenue increased for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to increased sales of Elaprase, driven by the identification of new patients and the strengthening of the Japanese yen against the U.S. dollar, which favorably impacted revenue by \$1.1 million.

Cardiometabolic and Renal

In October 2007, the FDA granted marketing approval for Renvela, a second generation buffered form of Renagel. In March 2008, we launched Renvela for dialysis patients in the United States. We are currently pursuing regulatory approvals for Renvela in Europe, Latin America and other international markets.

Sales of Renagel/Renvela, including sales of bulk sevelamer, increased 1% to \$170.6 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to Renagel price increases in the United States after the first quarter of 2008, offset in part by decreases outside of the United States which adversely impacted revenue. The weakening of foreign currencies against the U.S. dollar adversely impacted Renagel revenue by \$12.9 million and had no impact on sales of Renvela. Sales of Renagel/Renvela, including sales of bulk sevelamer, were 15% of our total revenues for both the three months ended March 31, 2009 and 2008.

In October 2007, an FDA advisory committee voted to recommend that the agency extend the indications for phosphate binders to include patients with hyperphosphatemia who have not progressed to dialysis. In June 2008, we and two other companies submitted a position paper to the FDA regarding the expanded use of phosphate binders. We received written responses from the FDA and we are in the process of responding to the agency. There is no PDUFA date associated with this expanded label process; however, we anticipate that this indication could be added to Renvela's label in the United States by the middle of 2009. In March 2009, the European Medicines Agency's Committee for Human Medicinal Products, or CHMP, adopted a positive opinion for the marketing authorization of Renvela for use in patients with CKD, including patients not on dialysis. Our filing in Europe includes both powder and tablet formulations of Renvela. The European Commission generally follows the advice of the CHMP, but is not obligated to do so. A decision from the European Commission is expected at the end of May 2009. In addition, we have filed for FDA approval of a powder form of Renvela. While Renagel will remain available for a period of time, our goal is to transition patients in the United States to Renvela by the fourth quarter of 2009.

Sales of Hectorol increased 14% to \$33.0 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to Hectorol price increases in the second and fourth quarters of 2008.

We expect sales of Renagel/Renvela and Hectorol to continue to increase. Adoption rates for Renagel/Renvela are expected to trend favorably as a result of the introduction of Renvela globally, the potential label expansion to include hyperphosphatemic patients who are not on dialysis, and the introduction of a powder formulation expected in the first half of 2009. Adoption rates for Hectorol are expected to trend favorably as a result of growth in the CKD market and the launch of a 1mg capsule form of Hectorol in the second half of 2009.

Renagel/Renvela and Hectorol compete with several other marketed products and our future sales may be impacted negatively by these products. Renagel, Renvela and Hectorol are also subjects of Abbreviated New Drug Applications, or ANDAs, containing "Paragraph IV certifications," which is the filing a generic drug manufacturer uses to challenge the applicability of one or more Orange

Table of Contents

Book-listed patents in order to seek U.S. regulatory approval to market a generic version of a drug prior to the expiration date of those patents. See "*Some of our products may face competition from lower cost generic or follow-on products*" under the heading "Risk Factors" below. If any of the ANDA filers or any other generic drug manufacturer were to receive approval to sell a generic version of Renegel/Renvela or Hectorol, our revenues from those products would be adversely affected.

In addition, our ability to continue to increase sales of Renegel/Renvela and Hectorol will depend on many other factors, including our ability to optimize dosing and improve patient compliance, the availability of reimbursement from third-party payors and the extent of coverage, including under the Medicare Part D program. Also, the accuracy of our estimates of fluctuations in the payor mix and our ability to effectively manage wholesaler inventories and the levels of compliance with the inventory management programs we implemented for Renegel/Renvela and Hectorol with our wholesalers could impact the revenue from our Cardiometabolic and Renal reporting segment that we record from period to period.

Sales of Thyrogen increased 15% to \$38.8 million for the three months ended March 31, 2009, as compared to the same period of 2008 primarily due to a 15% price increase for Thyrogen, which we implemented in the United States in April 2008. In addition, worldwide volume growth, driven by a significant increase in the use of the product in thyroid remnant ablation procedures, positively impacted Thyrogen revenue. The weakening of foreign currencies against the U.S. dollar adversely impacted Thyrogen revenue by \$2.4 million for the three months ended March 31, 2009, as compared to the same period of 2008.

Biosurgery

Biosurgery product revenue increased 9% to \$109.1 million for the three months ended March 31, 2009, as compared to the same period of 2008. The combined revenues of Synvisc/Synvisc-One increased 13% to \$63.2 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to an expanded sales and marketing investment and the initiation of direct sales of the products in Latin America and the addition of Synvisc-One sales in the United States. We received approval to market Synvisc-One, a single injection regimen, in the European Union in December 2007. In February 2009, we received marketing approval for Synvisc-One in the United States.

Seprafilm revenue increased \$4.9 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to greater penetration of the product into the United States, Japan and Europe and the expanded use of Seprafilm in C-sections and gynecological procedures.

The weakening of foreign currencies against the U.S. dollar adversely impacted Biosurgery product revenue by \$1.3 million for the three months ended March 31, 2009, as compared to the same period of 2008.

Other Biosurgery product revenue decreased 14% to \$11.7 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to a decrease in milestone revenue associated with the development and commercialization of dermal filler products with Mentor Corporation.

Hematologic Oncology

Hematologic Oncology product revenue increased 52% to \$34.0 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to the addition of sales of Mozobil in the United States and increased demand for Clolar in the United States.

We are developing the intravenous formulation of clofarabine for new indications, including first-line and relapsed or refractory adult acute myeloid leukemia, or AML. In November 2008, we filed

Table of Contents

a supplemental New Drug Application, or NDA, with the FDA for the use of Clolar to treat previously untreated adults age 60 years or older with AML who have at least one unfavorable prognostic factor. FDA action is expected in the second half of 2009. We have discussed our adult AML development plans with the CHMP in Europe, and based on the CHMP's feedback, await the availability of additional data before seeking approval for this indication in Europe. We are also developing an oral formulation of clofarabine and have initiated clinical trials for the treatment of myelodysplastic syndrome, or MDS. Clofarabine has been granted orphan drug status for the treatment of ALL and AML in both the United States and the European Union.

Mozobil was approved by the FDA in December 2008 to prepare patients with non-Hodgkin's lymphoma and multiple myeloma for autologous stem cell transplants. We have also filed for approval for Mozobil in Europe and expect approval in the second half of 2009.

Other Product Revenue

Other product revenue decreased 3% to \$114.2 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to decreased demand for diagnostic products, WelChol and liquid crystals.

The decreases in Other product revenue were offset by a 15% increase in sales of transplant products to \$52.7 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to an increase in Thymoglobulin sales for the three months ended March 31, 2009, as compared to the same period of 2008, due to a shortage in supply in the first quarter of 2008. Sales of Thymoglobulin increased \$7.3 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to an increase in sales volume resulting from increased utilization of Thymoglobulin in transplant procedures worldwide. The weakening of foreign currencies against the U.S. dollar adversely impacted Thymoglobulin product revenue by \$2.3 million for the three months ended March 31, 2009, as compared to the same period of 2008.

Service Revenue

We derive service revenues primarily from the following sources:

sales of MACI, a proprietary cell therapy product for cartilage repair, in Europe and Australia, Carticel for the treatment of cartilage damage in the United States, and Epicel for the treatment of severe burns, all of which are included in our Biosurgery reporting segment; and

reproductive/genetics and pathology/oncology diagnostic testing services, which are included in our Other service revenue.

Table of Contents

The following table sets forth our service revenue on a segment basis (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Genetic Diseases	\$ 25	\$ 176	(86)%
Cardiometabolic and Renal	12	14	(14)%
Biosurgery	9,832	10,732	(8)%
Hematologic Oncology	445	410	9%
Other	91,185	74,532	22%
Total service revenue	\$ 101,499	\$ 85,864	18%

Service revenue attributable to our Biosurgery reporting segment decreased 8% to \$9.8 million for the three months ended March 31, 2009, as compared to the same period of 2008. The decrease is primarily due to a decrease in the demand for MACI.

Other service revenue increased 22% to \$91.2 million for the three months ended March 31, 2009, as compared to the same period of 2008. The increase was primarily attributable to continued growth in sales of genetic testing and prenatal screening services as well as growth in the demand for certain testing services for patients diagnosed with cancer.

International Product and Service Revenue

A substantial portion of our revenue is generated outside of the United States. The following table provides information regarding the change in international product and service revenue as a percentage of total product and service revenue during the periods presented (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
International product and service revenue	\$ 551,111	\$ 564,127	(2)%
% of total product and service revenue	48%	52%	

The 2% decrease to \$551.1 million in international product and service revenue for the three months ended March 31, 2009, as compared to the same period of 2008, is primarily due to the weakening of foreign currencies against the U.S. dollar, which adversely impacted total product and service revenue by \$65.7 million for the three months ended March 31, 2009, as compared to the same period of 2008. This decrease was offset in part by growth in the international sales volume of Renagel, Cerezyme, Fabrazyme, Myozyme, Aldurazyme, Elaprase, Synvisc, Campath, Evoltra and Thymoglobulin.

Table of Contents**Research and Development Revenue**

The following table sets forth our research and development revenue on a segment basis (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Cardiometabolic and Renal	\$ 13	\$ 32	(59)%
Biosurgery	562	603	(7)%
Hematologic Oncology	1,484	1,189	25%
Other	7,573	5,722	32%
Corporate	496	383	30%
Total research and development revenue	\$ 10,128	\$ 7,929	28%

Total research and development revenue increased \$2.2 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to increases in revenue recognized by our Hematologic Oncology reporting segment and Other research and development revenue. Other research and development revenue increased primarily due to our increase in spending for the development of alemtuzumab under our collaboration with Bayer, and Bayer's reimbursement of a portion of these development expenses, particularly in the MS development program. Effective as of the date our pending acquisition from Bayer closes, we will cease recognizing research and development revenue for Bayer's reimbursement of a portion of the development costs for alemtuzumab for the treatment of MS. In accordance with the provisions of FAS 141R, the fair value of the research and development costs to be reimbursed by Bayer will be accounted for as an offset to the consideration paid in the transaction.

GROSS PROFIT AND MARGINS

The components of our total margins are described in the following table (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Gross product profit	\$ 801,682	\$ 789,529	2%
Product margin	77%	78%	
Gross service profit	\$ 41,249	\$ 30,290	36%
Service margin	41%	35%	
Total gross product and service profit	\$ 842,931	\$ 819,819	3%
Total product and service margin	74%	75%	

Gross Product Profit and Product Margin

Our overall gross product profit increased \$12.2 million, or 2%, for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to:

increased sales volume for Cerezyme, Fabrazyme, Myozyme, Aldurazyme and Elaprase;

price increases for Renagel and Hectorol, the addition of sales of Renvela, which was launched for dialysis patients in the United States in March 2008, and increased sales volume for Thyrogen;

increased sales volume for Synvisc/Synvisc-One and Septrafilm;

Table of Contents

the addition of sales of Mozobil, which was launched in the United States in December 2008, and the increase in worldwide sales of Clolar/Evoltra; and

increased sales volume for Thymoglobulin.

Product margin decreased for the three months ended March 31, 2009, as compared to the three months ended March 31, 2008, primarily due to:

the increase in sales volume for Myozyme, Aldurazyme, and Elaprase, all of which have lower than average margins;

higher unit costs for Cerezyme and Fabrazyme; and

the \$9.2 million write off of Myozyme inventory costs related to incomplete production runs during the first quarter of 2009 at our Belgium facility.

For purposes of this discussion, the amortization of product related intangible assets is included in amortization expense and, as a result, is excluded from cost of products sold and the determination of product margins described above.

Gross Service Profit and Service Margin

Our overall gross service profit increased \$11.0 million, or 36%, for the three months ended March 31, 2009, as compared to the same period of 2008. The increase was primarily attributable to increases in revenue from our genetic testing and prenatal screening services due to the launch of our Spinal Muscular Atrophy test in February 2008.

Total service margin increased by 6% for the three months ended March 31, 2009, as compared to the same period of 2008, due to increases in Carticel revenue and genetic testing revenue.

OPERATING EXPENSES

Selling, General and Administrative Expenses

The following table provides information regarding the change in SG&A during the periods presented (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Selling, general and administrative expenses	\$317,961	\$318,386	(0)%
% of total revenue	28%	29%	

SG&A decreased slightly for the three months ended March 31, 2009, as compared to the same period of 2008, due to a decrease of \$15.0 million attributable to the weakening of foreign currencies against the U.S. dollar, offset in part by spending increases of:

\$3.3 million for Genetic Diseases, primarily due to increased market penetration;

\$3.7 million for Hematologic Oncology, primarily due to sales force expansion to support the launch of Mozobil in the United States and to increased selling and marketing expenses for Clolar in Europe;

\$4.8 million for Other, primarily due to personnel additions in our genetics business unit; and

\$2.5 million for Corporate.

Table of Contents**Research and Development Expenses**

The following table provides information regarding the change in research and development expenses during the periods presented (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Research and development expenses	\$206,925	\$262,797	(21)%
% of total revenue	18%	24%	

Research and development expenses decreased \$55.9 million, including decreases of \$4.9 million due to the weakening of foreign currencies against the U.S. dollar, for the three months ended March 31, 2009, as compared to the same period of 2008, as well as:

\$72.4 million decrease in spending on our Cardiometabolic and Renal research and development programs, primarily due to a charge of \$69.9 million recorded in February 2008 for a license fee paid to Isis for exclusive, worldwide rights to mipomersen, for which there was no comparable amount for the same period of 2009; and

spending decreases of \$4.2 million on Hematologic Oncology research and development programs primarily due to expenses related to the Mozobil NDA submission for the three months ended March 31, 2008, for which there were no comparable amounts for the same period of 2009.

These decreases were partially offset by spending increases for the three months ended March 31, 2009 of:

\$22.0 million on research and development programs included under the category "Other," due to a payment of \$18.2 million to EXACT Sciences for the purchase of intellectual property which was charged to research and development expense in our consolidated statements of operations in the first quarter of 2009; and

an increase in spending for the development of alemtuzumab for the treatment of MS under our collaboration with Bayer.

Amortization of Intangibles

The following table provides information regarding the change in amortization of intangibles expense during the periods presented (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
Amortization of intangibles	\$57,598	\$55,658	3%
% of total revenue	5%	5%	

Amortization of intangibles expense increased \$1.9 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily due to additional amortization expense for the Synvisc sales and marketing rights we reacquired from Wyeth.

As discussed in Note 8., "Goodwill and Other Intangible Assets," to our consolidated financial statements included in this report, we calculate amortization expense for the Synvisc sales and marketing rights we reacquired from Wyeth and the Myozyme patent and technology rights pursuant to a licensing agreement with Synpac by taking into account forecasted future sales of the products, and the resulting estimated future contingent payments we will be required to make. As a result, we expect amortization of intangibles expense to fluctuate over the next five years based on these future contingent payments.

Table of Contents**Purchase of In-Process Research and Development**

Prior to January 1, 2009, we expensed IPR&D acquired through a business combination which had not yet reached technological feasibility and had no alternative future use. In accordance with our adoption of FAS 141R, all IPR&D we acquire through business combinations on or after January 1, 2009 will be capitalized as an intangible asset on our consolidated balance sheets and periodically tested for impairment.

We did not complete any business combination acquisitions in the year ended December 31, 2008 or during the three months ended March 31, 2009. In connection with two business combinations we completed between January 1, 2006 and December 31, 2007, we acquired various IPR&D projects. The following table sets forth the significant IPR&D projects we acquired between January 1, 2006 and December 31, 2007 (amounts in millions):

Company/Assets Acquired	Purchase Price	IPR&D	Programs Acquired	Discount Rate Used in Estimating Cash Flows	Year of Expected Launch	Estimated Cost to Complete
Bioenvision (2007)	\$ 349.9	\$ 125.5	Evoltra (clofarabine)(1)	17%	2009-2013	\$ 49.4
AnorMED (2006)	\$ 589.2	\$ 526.8	Mozobil (stem cell transplant)(2)	15%	2009-2014	\$ 101.9
		26.1	AMD070 (HIV)(3)	15%		
		\$ 552.9				

-
- (1) The IPR&D projects for clofarabine are related to the development of the product for the treatment of other medical issues.
- (2) Mozobil received marketing approval in the United States in December 2008 and our marketing application in Europe is pending.
- (3) Year of expected launch and estimated cost to complete data is not provided for AMD070 at this time because we are assessing our future plans for this program.

OTHER INCOME AND EXPENSES

	Three Months Ended March 31,		Increase/ (Decrease) % Change
	2009	2008	
	(Amounts in thousands)		
Gains (losses) on investments in equity securities, net	\$ (576)	\$ 775	>(100)%
Other	(979)	491	>(100)%
Investment income	5,350	14,870	(64)%
Interest expense		(1,655)	100%
Total other income	\$ 3,795	\$ 14,481	(74)%

Investment Income

Our investment income decreased 64% to \$5.4 million for the three months ended March 31, 2009, as compared to \$14.9 million for the same period of 2008, primarily due to a decrease in our average portfolio yield and lower average cash and investment balances.

Table of Contents**Interest Expense**

Our interest expense decreased to zero for the three months ended March 31, 2009, as compared to \$1.7 million for the same period of 2008, primarily due to the redemption of our \$690.0 million of 1.25% convertible senior notes on December 1, 2008, offset by a decrease in capitalized interest.

Provision for Income Taxes

	Three Months Ended March 31,	
	2009	2008
	(Amounts in thousands)	
Provision for income taxes	\$ 78,884	\$ 60,117
Effective tax rate	29%	29%

Our effective tax rate for both periods varies from the U.S. statutory tax rate as a result of:

income and expenses taxed at rates other than the U.S. statutory tax rate;

our provision for state income taxes;

the tax benefits from manufacturing activities;

benefits related to tax credits; and

non-deductible stock-based compensation expenses of \$9.7 million for the three months ended March 31, 2009 and \$8.1 million for the three months ended March 31, 2008.

We are currently under IRS audit for tax years 2006 and 2007. We believe that we have provided sufficiently for all audit exposures. We expect to settle the 2006 to 2007 IRS audit within the next twelve months and do not expect that the settlement will have a material impact on our financial position or results of operations. Settlement of these audits or the expiration of the statute of limitations on the assessment of income taxes for any tax year may result in a reduction of future tax provisions. Any such benefit would be recorded upon final resolution of the audit or expiration of the applicable statute of limitations.

LIQUIDITY AND CAPITAL RESOURCES

We continue to generate cash from operations. We had cash, cash equivalents and short- and long-term investments of \$981.8 million at March 31, 2009 and \$973.7 million at December 31, 2008.

The following is a summary of our statements of cash flows for the three months ended March 31, 2009 and 2008:

Cash Flows from Operating Activities

Cash flows from operating activities are as follows (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities:		
Net income	\$ 195,486	\$ 145,271
Non-cash charges, net	130,775	124,151
Decrease in cash from working capital changes (excluding impact of acquired assets and assumed liabilities)	(68,486)	(109,889)
Cash flows from operating activities	\$ 257,775	\$ 159,533

Table of Contents

Cash provided by operating activities increased by \$98.2 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily driven by a \$50.2 million increase in net income as a result of a \$69.9 million charge to research and development expense for the license fee we paid to Isis in February 2008, compared to an \$18.2 million charge to research and development in 2009 for the intellectual property we acquired from EXACT Sciences in January 2009. Operating activities were also impacted by a \$41.4 million decrease in cash used for working capital, offset, in part, by an increase of \$6.6 million in non-cash charges, net. The increase in non-cash charges, net, for the three months ended March 31, 2009, as compared to the same period of 2008, is primarily attributable to a \$7.9 million increase in depreciation and amortization expenses.

Cash Flows from Investing Activities

Cash flows from investing activities are as follows (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Cash flows from investing activities:		
Net sales of investments, excluding investments in equity securities	\$ 61,766	\$ 33,175
Net purchases of investments in equity securities	(3,606)	(79,551)
Purchases of property, plant and equipment	(161,561)	(121,967)
Distributions from equity method investments		6,595
Purchases of other intangible assets	(8,056)	(7,046)
Other investing activities	(47)	3,107
 Cash flows from investing activities	 \$(111,504)	 \$(165,687)

For the three months ended March 31, 2009, net purchases of capital expenditures accounted for significant cash outlays for investing activities. During the three months ended March 31, 2009, we used \$161.6 million in cash to fund the purchase of property, plant and equipment, primarily related to the ongoing expansion of our manufacturing capacity in the Republic of Ireland and France, planned improvements at our facility in Allston, Massachusetts and capitalized costs of an internally developed enterprise software systems.

This cash outlay was partially offset by an increase in the net sale of investments and a decrease in the purchase of equity securities.

For the three months ended March 31, 2008, net purchases of investments in equity securities included \$80.1 million to purchase 5,000,000 shares of Isis common stock in February 2008.

Table of Contents**Cash Flows from Financing Activities**

Cash flows from financing activities are as follows (amounts in thousands):

	Three Months Ended March 31,	
	2009	2008
Cash flows from financing activities:		
Proceeds from issuance of common stock	\$ 34,526	\$ 90,243
Repurchases of common stock	(107,134)	(73,218)
Excess tax benefits from stock-based compensation	3,492	5,790
Payments of debt and capital lease obligations	(2,653)	(2,554)
Increase (decrease) in bank overdrafts	(3,392)	18,549
Other financing activities	1,995	959
Cash flows from financing activities	\$ (73,166)	\$ 39,769

Cash provided by financing activities decreased \$112.9 million for the three months ended March 31, 2009, as compared to the same period of 2008, primarily driven by a \$55.7 million decrease in proceeds from issuance of common stock due to fewer stock option exercises and a \$33.9 million increase in the repurchase of our common stock.

In May 2007, our board of directors authorized a stock repurchase program to repurchase up to an aggregate maximum amount of \$1.5 billion or 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. The repurchases are being made from time to time and can be effectuated through open market purchases, privately negotiated transactions, transactions structured through investment banking institutions, or by other means, subject to management's discretion and as permitted by securities laws and other legal requirements. During the three months ended March 31, 2009, we repurchased 2,000,000 shares of our common stock under this program at an average price of \$53.55 per share for a total of \$107.1 million in cash, including fees. Since June 2007, when we first began repurchasing shares of our common stock under this program, we have repurchased a cumulative total of 7,500,000 shares of our common stock at an average price of \$64.21 per share for a total of \$481.7 million in cash, including fees.

Revolving Credit Facility

As of March 31, 2009, no amounts were outstanding under our five-year \$350.0 million senior unsecured revolving credit facility, which matures July 14, 2011. The terms of this credit facility include various covenants, including financial covenants, that require us to meet minimum interest coverage ratios and maximum leverage ratios. As of March 31, 2009, we were in compliance with these covenants.

Contractual Obligations

The disclosure of payments we have committed to make under our contractual obligations is set forth under the heading "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations Liquidity and Capital Resources" in Exhibit 13 to our 2008 Form 10-K. As of March 31, 2009, there have been no material changes to our contractual obligations since December 31, 2008.

Financial Position

We believe that our available cash, investments and cash flows from operations will be sufficient to fund our planned operations and capital requirements for the foreseeable future. Although we currently

Table of Contents

have substantial cash resources and positive cash flow, we have used or intend to use substantial portions of our available cash and may make additional borrowings for:

product development and marketing;

business combinations and strategic business initiatives;

the remaining \$1.02 billion available under our ongoing stock repurchase program;

upgrading our information technology systems;

expanding existing and constructing additional manufacturing facilities;

contingent payments under business combinations, license and other agreements, including payments related to our license of mipomersen from Isis, ataluren from PTC Therapeutics, Inc., or PTC, and Prochymal and Chondrogen from Osiris Therapeutics, Inc., or Osiris, including the additional \$55.0 million upfront license fee we are obligated to pay Osiris on July 1, 2009;

expanding staff; and

working capital and satisfaction of our obligations under capital and operating leases.

In addition, we have several outstanding legal proceedings. Involvement in investigations and litigation can be expensive and a court may ultimately require that we pay expenses and damages. As a result of legal proceedings, we also may be required to pay fees to a holder of proprietary rights in order to continue certain operations.

Recently, the general economic, global capital and credit market conditions in the United States and other parts of the world have deteriorated significantly and have adversely affected access to capital and increased the cost of capital. However, we continue to believe that our available cash, investments and cash flow from operations, together with our revolving credit facility and other available debt financing, will be adequate to meet our operating, investing and financing needs in the foreseeable future. We currently do not rely on short-term borrowing to fund our operations and, as a result, we do not believe that existing global capital and credit market conditions will have a significant impact on our near-term liquidity. We are closely monitoring our liquidity as well as the condition of these markets. If these conditions continue or become worse, our future cost of debt and equity capital and our future access to capital markets could be adversely affected. We cannot guarantee that we will be able to obtain any additional financing in the future or extend any existing financing arrangements on favorable terms, or at all.

Off-Balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing arrangements. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries. In addition, we have joint ventures and certain other arrangements that are focused on research, development, and the commercialization of products. Entities falling within the scope of FIN 46R are included in our consolidated statements of operations if we qualify as the primary beneficiary. Entities not subject to consolidation under FIN 46R are accounted for under the equity method of accounting if our ownership percent exceeds 20% or if we exercise significant influence over the entity. We account for our portion of the results of these entities in the line item "Equity in income of equity method investments" in our consolidated statements of operations. We also acquire companies in which we agree to pay contingent consideration based on attaining certain thresholds.

Table of Contents**Recent Accounting Pronouncements**

The following table shows recently issued accounting pronouncements and our position for adoption:

Pronouncements	Relevant Requirements of FASB Pronouncements	Issued Date/ Our Effective Dates	Status
<i>EITF 07-1, "Accounting for Collaborative Arrangements."</i>	Defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties, including the appropriate income statement presentation and classification of, and the required disclosures related to, these arrangements.	Issued November 2007. Effective January 1, 2009, to be applied retrospectively for collaborative arrangements existing as of the effective date.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the periods presented.
<i>FAS 141R, "Business Combinations."</i>	Modifies and prescribes new requirements for accounting for business combinations. Among other things, acquisition costs will be expensed as incurred; restructuring costs will be expensed subsequent to the acquisition date; non-controlling interests will be valued at fair value; IPR&D will be recorded at fair value as an indefinite lived intangible asset; contingent purchase price payments will be measured at the acquisition date and re-measured in subsequent periods with an adjustment to earnings; and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition will affect income tax expense.	Issued December 2007. Effective January 1, 2009, to be applied prospectively for all business combinations for which the acquisition date is on or after January 1, 2009.	This pronouncement will significantly change our accounting and reporting for business combination transactions completed on or after January 1, 2009. The adoption of this pronouncement did not have an impact on our consolidated financial statements for the three months ended March 31, 2009, because we did not complete any business combination transactions during this period but it will impact our consolidated financial statements if such transactions occur in future periods.
<i>FAS 160, "Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51."</i>	Requires ownership interests in subsidiaries, not held by the parent, to be clearly identified in the consolidated statement of financial position within equity, but separate from the parent's equity, and the minority interest in net income needs to be identified on the consolidated statement of income. Additional disclosures are required.	Issued December 2007. Effective January 1, 2009, prospectively. Disclosure requirements to be applied retrospectively.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the periods presented.

Table of Contents

Pronouncements	Relevant Requirements of FASB Pronouncements	Issued Date/ Our Effective Dates	Status
<i>FAS 161, "Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133."</i>	Requires enhanced disclosures about an entity's derivative instruments and hedging activities to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows.	Issued March 2008. Effective January 1, 2009, prospectively. Comparative disclosures for earlier periods are encouraged, but not required, at initial adoption.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the three months ended March 31, 2009.
<i>FAS 162, "The Hierarchy of Generally Accepted Accounting Principles."</i>	Identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States (the GAAP hierarchy).	Issued in May 2008. Effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles."	We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
<i>FSP FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments."</i>	Amends guidance on disclosures about fair value and interim financial reporting to require disclosure about fair value of financial instruments whenever summarized financial information is issued for interim reporting periods.	Issued April 2009. Effective for periods ending after June 15, 2009.	We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.
<i>FSP FAS 115-2, FAS 124-2, and EITF 99-20-2, "Recognition and Presentation of Other-Than-Temporary Impairments."</i>	Amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments in the financial statements.	Issued April 2009. Effective for periods ending after June 15, 2009.	We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.
<i>FSP FAS 157-2, "Effective Date of FASB Statement 157."</i>	Provides a one year deferral of the effective date of FAS 157 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed in financial statements at fair value on a recurring basis (at least annually).	Issued February 2008. Effective January 1, 2009, prospectively.	The adoption of this pronouncement did not have a material impact on our consolidated financial statements for the three months ended March 31, 2009.

Table of Contents

Pronouncements	Relevant Requirements of FASB Pronouncements	Issued Date/ Our Effective Dates	Status
<p>FSP FAS 157-4, "<i>Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly.</i>"</p>	<p>Provides guidelines for making fair value measurements more consistent with the principles presented in FAS 157, as well as additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed. Applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures.</p>	<p>Issued April 2009. Effective for periods ending after June 15, 2009.</p>	<p>We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.</p>

Table of Contents

RISK FACTORS

Our future operating results could differ materially from the results described in this report due to the risks and uncertainties related to our business, including those discussed below.

If we fail to increase sales of several existing products and services or to commercialize new products in our pipeline, we will not meet our financial goals.

Over the next few years, our success will depend substantially on our ability to increase revenue from our existing products and services. These products and services include Renagel/Renvela, Synvisc, Synvisc-One, Fabrazyme, Myozyme, Aldurazyme, Hectorol, Thymoglobulin, Thyrogen, Clolar/Evoltra, Campath, Mozobil and diagnostic testing services.

Our ability to increase sales will depend on a number of factors, including:

acceptance by the medical community of each product or service;

the availability of competing treatments that are deemed safer, more efficacious, more convenient to use, or more cost effective;

our ability, and the ability of our collaborators, to efficiently manufacture sufficient quantities of each product to meet demand and to do so in a timely and cost efficient manner;

compliance with regulation by the U.S. Food and Drug Administration, commonly referred to as the FDA, and the European Agency for the Evaluation of Medicinal Products, or EMEA, and other regulatory authorities of these products and services and the facilities and processes used to manufacture these products;

the scope of the labeling approved by regulatory authorities for each product and competitive products;

the effectiveness of our sales force;

the availability and extent of coverage, pricing and level of reimbursement from governmental agencies and third party payors; and

the size of the patient population for each product or service and our ability to identify new patients.

Part of our growth strategy involves conducting additional clinical trials to support approval of expanded uses of some of our products, including Clolar/Evoltra and alemtuzumab for multiple sclerosis, pursuing marketing approval for our products in new jurisdictions and developing next generation products, such as Genz-112638 and our advanced phosphate binder. The success of this component of our growth strategy will depend on the outcome of these additional clinical trials, the content and timing of our submissions to regulatory authorities and whether and when those authorities determine to grant approvals. Because the healthcare industry is extremely competitive and regulatory requirements are rigorous, we spend substantial funds marketing our products and attempting to expand approved uses for them. These expenditures depress near-term profitability with no assurance that the expenditures will generate future profits that justify the expenditures.

Our growth strategy also depends on developing new products, such as mipomersen, Prochymal and ataluren, through entry into strategic alliances and collaborations. If we are unable to manage these external growth opportunities successfully or if the product development process is unsuccessful, we will not be able to grow our business in the way that we currently expect.

Our future success will depend on our ability to effectively develop and market our products and services against those of our competitors.

Edgar Filing: GENZYME CORP - Form 10-Q

The human healthcare products and services industry is extremely competitive. Other organizations, including pharmaceutical, biotechnology, device and diagnostic testing companies, and

Table of Contents

generic and biosimilar manufacturers, have developed and are developing products and services to compete with our products, services, and product candidates. If healthcare providers, patients or payors prefer these competitive products or services or these competitive products or services have superior safety, efficacy, pricing or reimbursement characteristics, we will have difficulty maintaining or increasing the sales of our products and services.

Renagel/Renvela competes with several other products for the control of elevated phosphorus levels in patients with chronic kidney failure on hemodialysis. PhosLo®, a prescription calcium acetate preparation sold by Fresenius Medical Care, is marketed in the United States. Fosrenol®, a prescription lanthanum carbonate sold by Shire, is marketed in the United States, Europe, Canada and Latin America. A generic formulation of PhosLo was launched in the United States in October 2008. Renagel/Renvela also competes with over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium.

UCB S.A. has developed Zavesca®, a small molecule drug for the treatment of Gaucher disease, the disease addressed by Cerezyme. Zavesca, sold by Actelion Ltd., has been approved in the United States, European Union and Israel as an oral therapy for use in patients with mild to moderate Type 1 Gaucher disease for whom enzyme replacement therapy is unsuitable. In addition, Shire reported top-line data from a phase 1/2 clinical trial for its gene-activated glucocerebrosidase program to treat Gaucher disease and has completed enrollment in a phase 3 trial initiated in July 2007. Protalix Biotherapeutics Ltd. initiated a phase 3 trial for a plant-derived enzyme replacement therapy to treat Gaucher disease in the third quarter of 2007 and has completed enrollment in the trial. Amicus Therapeutics, Inc., or Amicus, is conducting a phase 2 trial for an oral chaperone medication to treat Gaucher disease and has completed enrollment. We are also aware of other development efforts aimed at treating Gaucher disease.

Outside the United States, Shire is marketing Replagal®, a competitive enzyme replacement therapy for Fabry disease which is the disease addressed by Fabrazyme. In addition, while Fabrazyme has received orphan drug designation, which provides us with seven years of market exclusivity for the product in the United States, other companies may seek to overcome our market exclusivity and, if successful, compete with Fabrazyme in the United States. Amicus has completed phase 2 trials for an oral chaperone medication to treat Fabry disease and is in discussions with the FDA regarding the conduct of a phase 3 clinical trial, which it plans to initiate in the second quarter of 2009. We are aware of other development efforts aimed at treating Fabry disease.

Myozyme has marketing exclusivity in the United States until 2013 and in the European Union until 2016 due to its orphan drug status, although companies may seek to overcome the associated marketing exclusivity. Amicus has completed two phase 1 clinical studies for a small molecule treatment for Pompe disease and initiated a phase 2 clinical trial in June 2008. In February 2009, Amicus announced that the company had suspended enrollment for its phase 2 clinical trial and that it had received verbal notice from the FDA that the trial is on clinical hold.

Current competition for Synvisc and Synvisc-One includes: Supartz®, a product manufactured by Seikagaku Corporation that is sold in the United States by Smith & Nephew Orthopaedics and in Japan by Kaken Pharmaceutical Co. under the name Artz®; Hyalgan®, produced by Fidia Farmaceutici S.p.A. and marketed in the United States by sanofi-aventis; Orthovisc®, produced by Anika Therapeutics, Inc., and marketed in the United States by Johnson & Johnson and marketed outside the United States through distributors; Anika's Monovisc, which is marketed in Europe; Euflexxa, a product manufactured and sold by Ferring Pharmaceuticals and marketed by Ferring in the United States and Europe; and Durolane®, manufactured by Q-Med AB and distributed outside the United States by Smith & Nephew Orthopedics. Durolane and Euflexxa are produced by bacterial fermentation, which may provide these products a competitive advantage over avian-sourced Synvisc and Synvisc-One. We are aware of various viscosupplementation products on the market or in development, but are unaware of any products that have physical properties of viscosity, elasticity or

Table of Contents

molecular weight comparable to those of Synvisc and Synvisc-One. Furthermore, several companies market products that are not viscosupplementation products but which are designed to relieve the pain associated with osteoarthritis. Synvisc and Synvisc-One will have difficulty competing with any of these products to the extent the competitive products have a similar safety profile and are considered more efficacious, less burdensome to administer or more cost-effective.

Competition for Campath for patients with relapsed or refractory B-CLL includes: single agent and combination chemotherapy regimens; rituximab, which is marketed as Rituxan® by Biogen Idec, Inc. and Genentech, Inc. in the United States and as MabThera® by Roche outside of the United States; and bendamustine, which is marketed as Treanda® by Cephalon, Inc. in the United States. There are also other therapies under clinical study for the treatment of B-CLL, including ofatumumab, lumiliximab and lenalidomide. Competition for Clolar/Evoltra for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory ALL after at least two prior regimens includes: cytarabine and mitoxantrone, which are available as generics with no significant commercial promotion; and Arranon® (nelarabine), which is marketed by GlaxoSmithKline and indicated for the treatment of patients with T-cell ALL whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. T-cell ALL is estimated to represent less than 20% of pediatric ALL patients. There are a limited number of anti-cancer agents in clinical trials for the treatment of relapsed pediatric ALL patients, including epratuzamab, which is being developed by Immunomedics, Inc.

The examples above are illustrative and not exhaustive. Almost all of our products and services face competition. Furthermore, the field of biotechnology is characterized by significant and rapid technological change. Discoveries by others may make our products or services obsolete. For example, competitors may develop approaches to treating LSDs that are more effective, convenient or less expensive than our products and product candidates. Because a significant portion of our revenue is derived from products that address this class of diseases and a substantial portion of our expenditures is devoted to developing new therapies for this class of diseases, such a development would have a material negative impact on our results of operations.

If we fail to obtain and maintain adequate levels of reimbursement for our products and services from third party payors, the commercial potential of our products and services will be significantly limited.

A substantial portion of our domestic and international revenue comes from payments by third party payors, including government health administration authorities and private health insurers. Governments and other third party payors may not provide adequate insurance coverage or reimbursement for our products and services, which could impair our financial results.

Third party payors are increasingly scrutinizing pharmaceutical budgets and healthcare expenses and are attempting to contain healthcare costs by:

challenging the prices charged for healthcare products and services;

limiting both the coverage and the amount of reimbursement for new therapeutic products;

reducing existing reimbursement rates for commercialized products and services;

limiting coverage for the treatment of a particular patient to a maximum dollar amount or specified period of time;

denying or limiting coverage for products that are approved by the FDA, EMEA or other governmental regulatory bodies but are considered experimental or investigational by third party payors; and

refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA, EMEA or other applicable marketing approval.

Table of Contents

Efforts by third party payors to reduce costs could decrease demand for our products and services. In addition, in certain countries, including countries in the European Union and Canada, the coverage of prescription drugs, pricing and levels of reimbursement are subject to governmental control. Therefore, we may be unable to negotiate coverage, pricing and/or reimbursement on terms that are favorable to us. Moreover, 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 maintain or obtain acceptable prices in existing and potential new markets. Government health administration authorities may also rely on analyses of the cost-effectiveness of certain therapeutic products in determining whether to provide reimbursement for such products. Our ability to obtain satisfactory pricing and reimbursement may depend in part on whether our products, the cost of some of which is high in comparison to other therapeutic products, are viewed as cost-effective.

Furthermore, governmental regulatory bodies, such as the Centers for Medicare and Medicaid Services (CMS), may from time-to-time make unilateral changes to reimbursement rates for our products and services. These changes could reduce our revenue by causing healthcare providers to be less willing to use our products and services. Although we actively seek to assure that any initiatives that are undertaken by regulatory agencies involving reimbursement for our products and services do not have an adverse impact on us, we may not always be successful in these efforts.

The development of new biotechnology products involves a lengthy and complex process, and we may be unable to commercialize any of the products we are currently developing.

We have numerous products under development and devote considerable resources to research and development, including clinical trials.

Before we can commercialize our product candidates, we will need to:

conduct substantial research and development;

undertake preclinical and clinical testing;

develop and scale-up manufacturing processes; and

pursue marketing approvals and, in some jurisdictions, pricing and reimbursement approvals.

This process involves a high degree of risk and takes many years. Our product development efforts with respect to a product candidate may fail for many reasons, including:

failure of the product candidate in preclinical studies;

difficulty enrolling patients in clinical trials, particularly for disease indications with small patient populations;

patients exhibiting adverse reactions to the product candidate or indications of other safety concerns;

insufficient clinical trial data to support the effectiveness or superiority of the product candidate;

our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner, if at all;

our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate; or

Edgar Filing: GENZYME CORP - Form 10-Q

changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer desirable.

Few research and development projects result in commercial products, and success in preclinical studies or early clinical trials often is not replicated in later studies. For example, in our phase 3 trial known as the Polymer Alternative for CDAD Treatment (PACT) study, tolevamer did not meet its

Table of Contents

primary endpoint. In our pivotal study of hylastan for treatment of patients with osteoarthritis of the knee, hylastan did not meet its primary endpoint. We may decide to abandon development of a product or service candidate at any time or we may be required to expend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs of development and delay any revenue from those programs.

Our efforts to expand the approved indications for our products, gain marketing approval in new jurisdictions and develop next generation products also may fail. These expansion efforts are subject to many of the risks associated with completely new products and, accordingly, we may fail to recoup the investments we make pursuing these strategies.

Our financial results are dependent on sales of Cerezyme.

Sales of Cerezyme, our enzyme-replacement product for patients with Gaucher disease, totaled \$296.0 million for the three months ended March 31, 2009, representing approximately 26% of our total revenue. Because our business is dependent on Cerezyme, negative trends in revenue from this product could have an adverse effect on our results of operations and cause the value of our common stock to decline. We will lose revenue if alternative treatments gain commercial acceptance, if our marketing activities are restricted, or if coverage, pricing or reimbursement is limited. In addition, the patient population with Gaucher disease is not large. Because a significant percentage of that population already uses Cerezyme, opportunities for future sales growth are constrained. Furthermore, changes in the methods for treating patients with Gaucher disease, including treatment protocols that combine Cerezyme with other therapeutic products or reduce the amount of Cerezyme prescribed, could limit growth, or result in a decline, in Cerezyme sales.

We may encounter substantial difficulties managing our growth.

Several risks are inherent to our plans to grow our business. Achieving our goals will require substantial investments in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our manufacturing facilities. We cannot assure you that these facilities will prove sufficient to meet demand for our products or that we will not have excess capacity at these facilities. In addition, building our facilities is expensive, and our ability to recover these costs will depend on increased revenue from the products produced at the facilities.

We produce relatively small amounts of material for research and development activities and pre-clinical trials. Even if a product candidate receives all necessary approvals for commercialization, we may not be able to successfully scale-up production of the product material at a reasonable cost or at all and we may not receive additional approvals in sufficient time to meet product demand. For example, the FDA has concluded that alglucosidase alfa produced in our 2000 liter bioreactors is a different product than alglucosidase alfa produced in our 160 liter bioreactors and therefore required us to submit a separate BLA for the 2000 liter product. This delay in receipt of FDA approval has had an adverse effect on our revenues and earnings and will continue to have an adverse effect until we receive regulatory approval.

If we are able to increase sales of our products, we may have difficulty managing inventory levels. Marketing new therapies is a complicated process, and gauging future demand is difficult. With Renagel, for example, we have encountered problems in the past managing inventory levels at wholesalers. Comparable problems may arise with any of our products, particularly during market introduction.

Table of Contents

Growth in our business may also contribute to fluctuations in our operating results, which may cause the price of our securities to decline. Our revenue may fluctuate due to many factors, including changes in:

- wholesaler buying patterns;
- reimbursement rates;
- physician prescribing habits;
- the availability or pricing of competitive products; and
- currency exchange rates.

We may also experience fluctuations in our quarterly results due to price changes and sales incentives. For example, purchasers of our products, particularly wholesalers, may increase purchase orders in anticipation of a price increase and reduce order levels following the price increase. We occasionally offer sales incentives and promotional discounts on some of our products and services that could have a similar impact. In addition, some of our products, including Synvisc, are subject to seasonal fluctuation in demand.

Our operating results and financial position may be negatively impacted when we attempt to grow through business combination transactions.

We may encounter problems assimilating operations acquired in business combination transactions. These transactions often entail the assumption of unknown liabilities, the loss of key employees, and the diversion of management attention. Furthermore, in any business combination there is a substantial risk that we will fail to realize the benefits we anticipated when we decided to undertake the transaction. We have in the past taken significant charges for impaired goodwill and for impaired assets acquired in business combination transactions. We may be required to take similar charges in the future. We enter into most such transactions with an expectation that an acquired business will enhance the long-term strength of our business. These transactions, however, often depress our earnings in the near-term and the expected long-term benefits may never be realized. Business combination transactions also either deplete cash resources, require us to issue substantial equity, and/or require us to incur significant debt.

Manufacturing problems may cause product launch delays, inventory shortages, recalls and unanticipated costs.

In order to generate revenue from our approved products, we must be able to produce sufficient quantities of the products to satisfy demand. Many of our products are difficult to manufacture. Our products that are biologics, for example, require product characterization steps that are more onerous than those required for most chemical pharmaceuticals. Accordingly, we employ multiple steps to attempt to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory. In the past, we have had to write down and incur other charges and expenses for products that failed to meet internal or external specifications, including Thymoglobulin, or for products that experience terminated production runs, including Myozyme produced at the 4000L scale. Similar charges could occur in the future.

Certain of the raw materials required in the commercial manufacturing and the formulation of our products are derived from biological sources, including mammalian sources and human plasma. Such raw materials may be difficult to procure and subject to contamination or recall. Also, some countries in which we market our products may restrict the use of certain biologically derived substances in the manufacture of drugs. A material shortage, contamination, recall, or restriction on the use of certain biologically derived substances in the manufacture of our products could adversely impact or disrupt our commercial manufacturing of our products or could result in a withdrawal of our products from

Table of Contents

markets. This too, in turn, could adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our operating results.

In addition, we may only be able to produce some of our products at a very limited number of facilities and, in some cases, we rely on third parties to formulate and manufacture our products. For example, we manufacture all of our Cerezyme and a portion of our Fabrazyme and Myozyme products at our facility in Allston, Massachusetts. A number of factors could cause production interruptions at our facilities or the facilities of our third party providers, including equipment malfunctions, labor problems, raw material shortages, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers.

Manufacturing is also subject to extensive government regulation. Regulatory authorities must approve the facilities in which human healthcare products are produced and those facilities are subject to ongoing inspections. For example, we received a warning letter from the FDA in September 2007 that addressed certain of our manufacturing procedures in our Thymoglobulin production facility in Lyon. The FDA has accepted our response to that warning letter. In February 2009, we received a warning letter from the FDA related to inspectional observations by the FDA at our Allston, Massachusetts facility considered to be significant deviations from compliance with "Good Manufacturing Practices." We submitted a response to the FDA's warning letter in March 2009. In addition, changes in manufacturing processes may require additional regulatory approvals. Obtaining and maintaining these regulatory approvals could cause us to incur significant additional costs and lose revenue. In addition, because our manufacturing processes are highly complex and are subject to lengthy regulatory approval processes, alternative qualified production capacity may not be available on a timely basis or at all if we cannot produce sufficient commercial requirements of bulk product to meet demand.

We rely on third parties to provide us with materials and services in connection with the manufacture of our products and the performance of our services.

Some materials necessary for commercial production of our products, including specialty chemicals and components necessary for manufacture, fill-finish and packaging, are provided by unaffiliated third party suppliers. In some cases, such materials are specifically cited in our marketing applications with regulatory authorities so that they must be obtained from that specific source unless and until the applicable authority approves another supplier. In addition, there may only be one available source for a particular chemical or component. For example, we acquire polyalylamine (PAA), used in the manufacture of Renagel, Renvela, Cholestagel and WelChol, from Cambrex Charles City, Inc., and N925, which is necessary to manufacture our LSD products, from Invitrogen Corporation. These suppliers are the only sources for these materials currently qualified in our FDA drug applications for these products. Our suppliers also may be subject to FDA regulations or the regulations of other governmental agencies outside the United States regarding manufacturing practices. We may be unable to manufacture our products or to perform our services in a timely manner or at all if these third party suppliers were to cease or interrupt production or otherwise fail to supply sufficient quantities of these materials or products to us for any reason, including due to regulatory requirements or actions, adverse financial developments at or affecting the supplier, labor shortages or disputes, or contamination of materials or equipment.

We also source some of our manufacturing, fill-finish, packaging and distribution operations to third party contractors. The manufacture of products, fill-finish, packaging and distribution of our products requires successful coordination among these third party providers and us. Our inability to coordinate these efforts, the inability of a third party contractor to secure sufficient source materials, the lack of capacity available at a third party contractor or any other problems with the operations of a third party contractor 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

Table of Contents

us to lose revenue or market share and damage our reputation. Furthermore, any third party we use to manufacture, fill-finish or package our products to be sold must also be licensed by the applicable regulatory authorities. As a result, alternative third party providers may not be readily available on a timely basis.

Our international sales and operating expenses are subject to fluctuations in currency exchange rates.

A significant 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 translation 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 translation losses in the future due to the effect of exchange rate fluctuations.

In 2008, the change in foreign exchange rates had a net favorable impact on our revenues; however, this trend changed during the fourth quarter of 2008 and adversely impacted our revenue during the first quarter of 2009. Although we cannot predict with certainty future changes in foreign exchange rates or their effect on our results, we do not expect the change in foreign exchange rates to have a positive impact on our revenues for the remainder of 2009.

Government regulation imposes significant costs and restrictions on the development and commercialization of our products and services.

Government agencies heavily regulate the production and sale of healthcare products and the provision of healthcare services. Our success will depend on our ability to satisfy regulatory requirements. In particular, the FDA, the EMEA and comparable regulatory agencies in foreign jurisdictions must approve human therapeutic and diagnostic products before they are marketed, as well as the facilities in which they are made. This approval process can involve lengthy and detailed laboratory and clinical testing, sampling activities and other costly and time-consuming procedures. We may not receive required regulatory approvals on a timely basis or at all.

Therapies that have received regulatory approval for commercial sale may continue to face regulatory difficulties. Failure to comply with applicable regulatory requirements results in regulatory authorities taking actions such as:

issuing warning letters;

issuing fines and other civil penalties;

suspending regulatory approvals;

refusing to approve pending applications or supplements to approved applications;

suspending product sales, imports and/or exports;

requiring us to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;

mandating product recalls; and

seizing products.

Furthermore, the FDA, the EMEA and comparable foreign regulatory agencies may require post-marketing clinical trials or patient outcome studies. We have agreed with the FDA, for example, to a number of post-marketing commitments as a condition to U.S. marketing approval for Fabrazyme, Aldurazyme, Myozyme, Clolar and Mozobil. In addition, regulatory agencies subject a

marketed therapy, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. The discovery of previously unknown problems with a therapy or the facility or process used to produce

Table of Contents

the therapy could prompt a regulatory authority to impose restrictions on us, or could cause us to voluntarily adopt such restrictions, including withdrawal of one or more of our products or services from the market.

If regulatory authorities fail to approve pending applications in a timely matter, our results of operations will suffer.

We expect regulatory action on several matters during the next 12 months. For example, we anticipate regulatory action on our marketing application for alglucosidase alfa produced at the 2000L scale in the United States; our marketing application for Mozobil in Europe; the expansion of labeling for clofarabine in the United States and Europe to include the treatment of adults with AML; our marketing application for Renvela in Europe and a label expansion of Renvela in the United States to include the treatment of CKD patients not on dialysis.

Regulatory authorities denying or delaying these approvals would adversely impact our projected revenue and income growth. A regulatory authority may deny or delay an approval because it was not satisfied with the structure or conduct of clinical trials or due to its assessment of the data we supply. A regulatory authority, for instance, may not believe that we have adequately established a product's risk-benefit profile or adequately addressed negative safety signals. Clinical data are subject to varied interpretations, and regulatory authorities may disagree with our assessments of our data. In any such case, a regulatory authority could insist that we provide additional data, which could substantially delay or even prevent commercialization efforts, particularly if we are required to conduct additional pre-approval clinical studies. In addition, the FDA has failed to act on pending marketing applications by the response dates prescribed in the Prescription Drug User Fee Act. We have encountered delays in marketing in the United States for alglucosidase alfa produced at the 2000L scale, which has adversely impacted our financial results and resulted in a very tight product supply, and we could face additional delays with this product or other products.

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

Sales of our products are dependent, in part, on the availability and extent of reimbursement from third party payers, including governments and private insurance plans. As a result of the current volatility in the financial markets, third-party payers may delay payment or be unable to satisfy their reimbursement obligations. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

In addition, we rely upon third parties for certain aspects of our business, including collaboration partners, wholesale distributors for our products, contract clinical trial providers, contract manufacturers, and third-party suppliers. Because of the recent tightening of global credit and the volatility in the financial markets, there may be a delay or disruption in the performance or satisfaction of commitments to us by these third parties, which could adversely affect our business.

We may incur substantial costs as a result of litigation or other proceedings.

A third party may sue us or one of our strategic collaborators for infringing the third party's patent or other intellectual property rights. Likewise, we or one of our strategic collaborators may sue to enforce intellectual property rights or to determine the scope and validity of third party proprietary rights. If we do not prevail in this type of litigation, we or our strategic collaborators may be required to:

pay monetary damages;

stop commercial activities relating to the affected products or services;

Table of Contents

obtain a license in order to continue manufacturing or marketing the affected products or services; or

compete in the market with a different product or service.

We are also currently involved in litigation matters and investigations that do not involve intellectual property claims and may be subject to additional actions in the future. For example, the federal government, state governments and private payors are investigating and have filed actions against numerous pharmaceutical and biotechnology companies, including Genzyme, alleging that the companies have overstated prices in order to inflate reimbursement rates. Domestic and international enforcement authorities also have instituted actions under healthcare "fraud and abuse" laws, including anti-kickback and false claims statutes. Moreover, individuals who use our products or services, including our diagnostic products and genetic testing services, sometimes bring product and professional liability claims against us or our subsidiaries.

Some of our products are prescribed by healthcare providers for uses not approved by the FDA, the EMEA or comparable regulatory agencies. Although healthcare providers may lawfully prescribe our products for off-label uses, any promotion by us of off-label uses would be unlawful. Some of our practices intended to make healthcare providers aware of off-label uses of our products without engaging in off-label promotion could nonetheless be construed as off-label promotion. Although we have policies and procedures in place designed to help assure ongoing compliance with regulatory requirements regarding off-label promotion, some non-compliant actions may nonetheless occur. Regulatory authorities could take enforcement action against us if they believe we are promoting, or have promoted, our products for off-label use.

We have only limited amounts of insurance, which may not provide coverage to offset a negative judgment or a settlement payment. We may be unable to obtain additional insurance in the future, or we may be unable to do so on favorable terms. Our insurers may dispute our claims for coverage. For example, we have submitted claims to our insurers for reimbursement of portions of the expenses incurred in connection with the litigation and settlement related to the consolidation of our tracking stock and are seeking coverage for the settlement. The insurers have purported to deny coverage. Any additional insurance we do obtain may not provide adequate coverage against any asserted claims.

Regardless of merit or eventual outcome, investigations and litigation can result in:

the diversion of management's time and attention;

the expenditure of large amounts of cash on legal fees, expenses, and payment of damages;

limitations on our ability to continue some of our operations;

decreased demand for our products and services; and

injury to our reputation.

Our international sales, clinical activities, manufacturing and other operations are subject to the economic, political, legal and business environments of the countries in which we do business, and our failure to operate successfully or adapt to changes in these environments could cause our international sales and operations to be limited or disrupted.

Our international operations accounted for approximately 48% of our consolidated product and service revenues for the three months ended March 31, 2009. We expect that international product and service sales will continue to account for a significant percentage of our revenues for the foreseeable future. In addition, we have direct investments in a number of subsidiaries outside of the United States.

Table of Contents

Our international sales and operations could be limited or disrupted, and the value of our direct investments may be diminished, by any of the following:

economic problems that disrupt foreign healthcare payment systems;

the imposition of governmental controls, including foreign exchange and currency restrictions;

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;

the inability to obtain third party reimbursement support for products;

product counterfeiting and intellectual property piracy;

parallel imports;

anti-competitive trade practices;

import and export license requirements;

political instability;

terrorist activities, armed conflict, or a pandemic;

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 countries in which we operate. In addition, the United States Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions generally prohibit companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business. We operate in many parts of the world that have experienced governmental corruption to some degree. Although we have policies and procedures designed to help ensure that we, our employees and our agents comply with the FCPA and other anti-bribery laws, there is no assurance that such policies and procedures will protect us against liability under the FCPA or other laws for actions taken by our employees, agents and intermediaries with respect to our business. Failure to comply with domestic or foreign laws could result in various adverse consequences, including possible delay in the 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.

We may fail to adequately protect our proprietary technology, which would allow competitors or others to take advantage of our research and development efforts.

Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection in the United States or abroad, we may not be able to prevent third parties from using our proprietary technologies. Our currently pending or future patent applications may not result in issued patents. Patent applications are typically confidential for 18 months following their earliest filing, and because third parties may have filed patent applications for technology covered by our pending patent applications without us being aware of those applications, our patent applications may not have priority over patent applications of others. In addition, our issued patents may not contain claims sufficiently broad to protect us against

Table of Contents

third parties with similar technologies or products, or provide us with any competitive advantage. If a third party initiates litigation regarding our patents, our collaborators' patents, or those patents for which we have license rights, and is successful, a court could declare our patents invalid or unenforceable or limit the scope of coverage of those patents. Governmental patent offices and courts have not always been consistent in their interpretation of the scope and patentability of the subject matter claimed in biotechnology patents. Any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position.

We also rely upon trade secrets, proprietary know-how, and continuing technological innovation to remain competitive. We attempt to protect this information with security measures, including the use of confidentiality agreements with employees, consultants, and collaborators. These individuals may breach these agreements and any remedies available to us may be insufficient to compensate for our damages. Furthermore, our trade secrets, know-how and other technology may otherwise become known or be independently discovered by our competitors.

Some of our products may face competition from lower cost generic or follow-on products.

Some of our drug products, for example Renegel, Renvela, Hectorol, Clolar and Mozobil, are approved under the provisions of the United States Food, Drug and Cosmetic Act that render them susceptible to potential competition from generic manufacturers via the Abbreviated New Drug Application (ANDA) procedure. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the effectiveness of the innovator's patent protection long prior to the generic manufacturer actually commercializing their products the so-called "Paragraph IV" certification procedure. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If such patent infringement lawsuit is made within a statutory 45-day period, then a 30-month stay of FDA approval for the ANDA is triggered. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of Orange Book-listed patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue and to implicate drug products with even relatively modest revenues.

Renegel, Renvela and Hectorol are subjects of ANDAs containing Paragraph IV certifications. Renegel is the subject of three ANDAs containing Paragraph IV certifications. One of the ANDAs contains a Paragraph IV certification that relates only to one of our Orange Book-listed patents, namely our patent that covers features of our tablet dosage form. This patent expires in 2020, and the ANDA applicant alleged that its proposed product would not infringe that patent. We reviewed the Paragraph IV certification and did not initiate patent infringement litigation. The other two ANDA applications contain Paragraph IV certifications challenging additional aspects of the Renegel patent estate, including patents that expire in 2014 and 2013. Specifically, one ANDA applicant seeks to market its generic product prior to the expiration of all of our Orange Book-listed patents, while the other seeks to market its generic product only after the expiration of our Orange Book-listed patents that expire in 2013. We have initiated patent litigation against these latter two ANDA applicants.

Renvela is the subject of two ANDAs containing Paragraph IV certifications. One of the ANDA applicants seeks to market a generic sevelamer carbonate product prior to the expiration of all of our Orange Book-listed patents. We are evaluating this ANDA application and associated legal issues in advance of our May 2009 deadline to initiate patent litigation and trigger the statutory 30-month stay

Table of Contents

of FDA approval for the ANDA. The other ANDA applicant seeks to market its generic product only after the expiration of our Orange Book-listed patents that expire in 2013. We initiated patent litigation against this ANDA applicant.

Our Hecetrol injection product is the subject of two ANDAs containing Paragraph IV certifications. In the first-filed ANDA, the applicant submitted a Paragraph IV certification alleging the invalidity of our patent related to the use of Hecetrol to treat hyperparathyroidism secondary to end-stage renal disease (which patent expires in 2014), and alleging non-infringement of our patent covering our highly purified form of Hecetrol (which patent expires in 2021). We initiated patent infringement litigation in February 2008. We have since granted to this ANDA applicant a covenant not to sue on the Orange Book-listed patent that expires in July 2021. We continue, however, to pursue our claims related to the Orange Book-listed patent that expires in February 2014. A trial on the merits is scheduled for April 2010. The ANDA applicant also has submitted a Paragraph IV certification alleging the invalidity of our patent that claims specific aspects of our Hecetrol vial formulation. We reviewed the Paragraph IV certification related to our vial formulation and did not initiate patent infringement litigation. In the second ANDA application for our Hecetrol injection product, the applicant's Paragraph IV certification alleged that each of our Orange Book-listed patents is either invalid or will not be infringed by the applicant's generic product. We initiated patent infringement litigation in April 2009 against this ANDA applicant.

Other of our products, including Cerezyme, Fabrazyme, Aldurazyme, Myozyme and Campath (so-called "biotech drugs") are not currently considered susceptible to an abbreviated approval procedure, either due to current United States law or FDA practice in approving biologic products. However, the United States Congress has been exploring since 2007 legislation that would establish a procedure for the FDA to accept ANDA-like abbreviated applications for the approval of "follow-on," "biosimilar" or "comparable" biotech drugs. Congress continues to be interested in the issue and the new U.S. presidential administration has also expressed an interest in passing legislation regarding biosimilars. Such legislation has already been adopted in the European Union.

If an ANDA filer or any other generic manufacturer were to receive approval to sell a generic or follow-on version of one of our products, that product would become subject to increased competition and our revenues for that product would be adversely affected.

Guidelines, recommendations and studies published by various organizations can reduce the use of our products.

Professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases may publish guidelines, recommendations or studies to the healthcare and patient communities from time to time. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration, cost-effectiveness, and use of related therapies. Organizations like these have in the past made recommendations about our products and products of our competitors. Recommendations, guidelines or studies that are followed by patients and healthcare providers could result in decreased use of our products. The perception by the investment community or stockholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect prevailing market price for our common stock. In addition, our success also depends on our ability to educate patients and healthcare providers about our products and their uses. If these education efforts are not effective, then we may not be able to increase the sales of our existing products or successfully introduce new products to the market.

Table of Contents

We may be required to license patents from competitors or others in order to develop and commercialize some of our products and services, and it is uncertain whether these licenses would be available.

Third party patents may cover some of the products or services that we or our strategic partners are developing or producing. A patent is entitled to a presumption of validity and accordingly, we face significant hurdles in any challenge to a patent. In addition, even if we are successful in challenging the validity of a patent, the challenge itself may be expensive and require significant management attention.

To the extent valid third party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services, and payments under them would reduce our profits from these products and services. We may not be able to obtain these licenses on favorable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third party patent, we may be unable to market some of our products and services, which would limit our profitability.

Legislative or regulatory changes may adversely impact our business.

The United States government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact:

the pricing of healthcare products and services in the United States or internationally; and

the amount of reimbursement available from governmental agencies or other third party payors.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing may cause our revenue to decline, and we may need to revise our research and development programs. The pricing and reimbursement environment for our products may change in the future and become more challenging due to among other reasons, policies advanced by the new presidential administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of its new authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, increased costs to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

If our strategic alliances are unsuccessful, our operating results will be adversely impacted.

Several of our strategic initiatives involve alliances with other biotechnology and pharmaceutical companies. The success of these arrangements is largely dependent on technology and other intellectual property contributed by our strategic partners or the resources, efforts, and skills of our partners. Disputes and difficulties in such relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of these alliances are reduced or eliminated when strategic partners:

terminate the agreements covering the strategic alliance or limit our access to the underlying intellectual property;

fail to devote financial or other resources to the alliances and thereby hinder or delay development, manufacturing or commercialization activities;

Table of Contents

fail to successfully develop, manufacture or commercialize any products; or

fail to maintain the financial resources necessary to continue financing their portion of the development, manufacturing, or commercialization costs of their own operations.

Furthermore, payments we make under these arrangements may exacerbate fluctuations in our financial results. In addition, under some of our strategic alliances, we make upfront and milestone payments well in advance of commercialization of products with no assurance that we will ever recoup these payments. We also may make equity investments in our strategic partners, as we did with EXACT Sciences in January 2009 and Isis in February 2008. Our strategic equity investments are subject to market fluctuations, access to capital and other business events, such as initial public offerings, the completion of clinical trials and regulatory approvals, which can impact the value of these investments. If any of our strategic equity investments decline in value and remain below cost for an extended duration, we may be required to write off our investment.

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

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

Importation of products may lower the prices we receive for our products.

In the United States and abroad, many of our products are subject to competition from lower-priced versions of our products and competing products from other countries where government price controls or other market dynamics result in lower prices for such products. Our products that require a prescription in the United States may be available to consumers in markets such as Canada, Mexico, Taiwan and the Middle East without a prescription, which may cause consumers to seek out these products in these lower priced markets. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere that target American purchasers, an increase in U.S.-based businesses affiliated with these Canadian pharmacies and other factors. Most of these foreign imports are illegal under current United States law. However, the volume of imports continues to rise due to the limited enforcement resources of the FDA and the United States Customs Service, and there is increased political pressure to permit such imports as a mechanism for expanding access to lower-priced medicines. The importation of lower-priced versions of our products into the United States and other markets adversely affects our profitability. This impact could become more significant in the future.

We may require significant additional financing, which may not be available to us on favorable terms, if at all.

As of March 31, 2009, we had \$981.8 million in cash, cash equivalents and short- and long-term investments, excluding our investments in equity securities.

Table of Contents

We intend to use substantial portions of our available cash for:

product development and marketing;

business combinations and strategic business initiatives;

the remaining \$1.02 billion available under our ongoing stock repurchase program;

upgrading our information technology systems;

expanding existing and constructing new manufacturing facilities;

contingent payments under business combinations, license and other agreements, including payments related to our license of mipomersen from Isis, ataluren from PTC, and Prochymal and Chondrogen from Osiris, including the additional \$55.0 million upfront license fee we are obligated to pay Osiris on July 1, 2009;

expanding staff; and

working capital and satisfaction of our obligations under capital and operating leases.

In addition, we have several outstanding legal proceedings. Involvement in investigations and litigation can be expensive and a court may ultimately require that we pay expenses and damages. As a result of legal proceedings, we may also be required to pay fees to a holder of proprietary rights in order to continue certain operations.

Recently, the general economic, global capital and credit market conditions in the United States and other parts of the world have deteriorated significantly and have adversely affected access to capital and increased the cost of capital. However, we continue to believe that our available cash, investments and cash flow from operations, together with our revolving credit facility and other available debt financing, will be adequate to meet our operating, investing and financing needs in the foreseeable future. We currently do not rely on short-term borrowing to fund our operations and, as a result, we do not believe that existing global capital and credit market conditions will have a significant impact on our near-term liquidity. We are closely monitoring our liquidity as well as the condition of these markets. If these conditions continue or become worse, our future cost of debt and equity capital and our future access to capital markets could be adversely affected. We cannot guarantee that we will be able to obtain any additional financing in the future or extend any existing financing arrangements on favorable terms, or at all.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk

We are exposed to potential loss from exposure to market risks represented principally by changes in foreign exchange rates, interest rates and equity prices. At March 31, 2009, we held derivative contracts in the form of foreign exchange forward contracts. We also held a number of other financial instruments, including investments in marketable securities and we had debt securities outstanding. We do not hold derivatives or other financial instruments for speculative purposes.

Equity Price Risk

We hold investments in a limited number of U.S. and European equity securities. We estimated the potential loss in fair value due to a 10% decrease in the equity prices of each marketable security held at March 31, 2009 to be \$2.8 million, as compared to \$5.7 million at December 31, 2008. This estimate assumes no change in foreign exchange rates from quarter-end spot rates and excludes any potential risk associated with securities that do not have a readily determinable market value.

Table of Contents

Interest Rate Risk

We are exposed to potential loss due to changes in interest rates. Our principal interest rate exposure is to changes in U.S. interest rates. Instruments with interest rate risk include short- and long-term investments in fixed income securities and a fixed rate capital lease. To estimate the potential loss due to changes in interest rates, we performed a sensitivity analysis using the instantaneous adverse change in interest rates of 100 basis points across the yield curve.

On this basis, we estimate the potential loss in net fair value of our interest-bearing instruments to be \$7.3 million as of March 31, 2009, as compared to \$6.2 million as of December 31, 2008. The increase is primarily a result of a decrease in the amount and duration of the fixed income investment portfolio, which provides less of an offset to the increase in the fair value of our capital lease.

Foreign Exchange Risk

As a result of our worldwide operations, we may face exposure to potential adverse movements in foreign currency exchange rates. Exposures to currency fluctuations that result from sales of our products in foreign markets are partially offset by the impact of currency fluctuations on our international expenses. We use foreign exchange forward contracts to further reduce our exposure to changes in exchange rates, primarily to offset the earnings effect from foreign currency assets and liabilities. We also hold a limited amount of foreign currency denominated equity securities.

As of March 31, 2009, we estimate the potential loss in fair value of our foreign exchange forward contracts and foreign equity holdings that would result from a hypothetical 10% adverse change in exchange rates to be \$25.4 million, as compared to \$26.9 million as of December 31, 2008. The change from the prior period is due to a decrease in our net foreign exchange forward contracts. Since the contracts hedge mainly transactional exchange exposures, any changes in the fair values of the contracts would be offset by changes in the underlying values of the hedged items.

ITEM 4. CONTROLS AND PROCEDURES

As of March 31, 2009, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness 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 (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2009.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended March 31, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We periodically become subject to legal proceedings and claims arising in connection with our business. Although we cannot predict the outcome of these additional proceedings and claims, we do not believe the ultimate resolution of any of these existing matters would have a material adverse effect on our financial position or results of operations.

ITEM 1A. RISK FACTORS

We incorporate by reference our disclosure related to risk factors which is set forth under the heading "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial

Table of Contents

Condition and Results of Operations Risk Factors" in Part I., Item 2. of this Quarterly Report on Form 10-Q.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The following table provides information about our repurchases of our equity securities during the quarter ended March 31, 2009:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2009-January 31, 2009				\$ 1,125,521,738
February 1, 2009-February 28, 2009				\$ 1,125,521,738
March 1, 2009-March 31, 2009	2,000,000	\$ 53.55	2,000,000	\$ 1,018,427,338
Total	2,000,000(1)	\$ 53.55(2)	2,000,000	

-
- (1) In May 2007, our board of directors authorized a stock repurchase program to repurchase up to an aggregate maximum amount of \$1.5 billion or 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. During the first quarter of fiscal 2009, we repurchased 2,000,000 shares of our common stock under this program for \$107.1 million of cash, including fees.
- (2) Represents the weighted average price paid per share for repurchases of our common stock made during the first quarter of fiscal 2009.

ITEM 6. EXHIBITS

- (a) Exhibits

See the Exhibit Index following the signature page to this report on Form 10-Q.

Table of Contents

GENZYME CORPORATION AND SUBSIDIARIES

FORM 10-Q, MARCH 31, 2009

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
31.1	Certification of the Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of the Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.1	Certification of the Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002. Furnished herewith.
32.2	Certification of the Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002. Furnished herewith.
