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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 of the Exchange Act.

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

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 October 23, 2009: 265,382,892

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 expectations regarding the financial impact of production interruption at our Allston, Massachusetts (Allston) manufacturing facility, which we refer to as the Allston facility, and the expected timing for shipping new Cerezyme and Fabrazyme production;
- our regulatory plans and expectations for approval of alglucosidase alfa produced at the 2000 liter bioreactor, or 2000L, and the 4000 liter bioreactor, or 4000L, scale by the United States Food and Drug Administration, or FDA, and the timing thereof, and our expectations regarding sales of Myozyme in Europe;
- our plans to increase manufacturing capacity for Cerezyme, Fabrazyme and Myozyme and the timing thereof;
- our expectations regarding regulatory action with respect to several pending marketing applications;
- our expectations regarding approval of a new Leukine manufacturing facility;
- our expectations regarding regulatory approval of alemtuzumab for the treatment of multiple sclerosis, or MS, which we refer to as alemtuzumab for MS, and the timing thereof;
- our expectations for sales of Renagel/Renvela and the anticipated drivers for the future growth of these products;
- our assessment of competitors and potential competitors and the anticipated impact of potentially competitive products and services, including generic competition, on our revenues;
- 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 our unrecognized tax benefits;
- 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 impact of recent accounting pronouncements on our financial position and results of operations; and
- our expectations regarding the amortization of intangible assets related to our expected future contingent payments due to Bayer Schering Pharma A.G., or Bayer, Synpac (North Carolina), Inc., or Synpac, 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 possibility that we may encounter additional manufacturing problems due to mechanical failures, viral or bacterial contamination or any other reason, or that we may encounter further supply problems due to low product yields or a determination by a regulatory authority that product produced at our Allston facility or any of our other facilities cannot be released;
- the potential for Gaucher and Fabry disease patients to switch to competitors' products in place of Cerezyme or Fabrazyme or to continue to reduce their doses of our products even after supply stabilizes;
- 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 for alglucosidase alfa produced at the 2000L and 4000L scales and for proposed changes to our manufacturing processes to test for Vesivirus 2117, and the timing of receipt of such approvals;
- our inability to file for U.S. approval for alglucosidase alfa produced using the 4000L process within the expected timeframe due to a failure to obtain FDA approval of the product manufactured using the 2000L process, failure to secure agreement as to strategy, including our decision to file a supplemental biologics license application, or BLA, to the 2000L BLA, or any other reason;
- our ability to manufacture sufficient amounts of our products and maintain sufficient inventories, and to do so in a timely and cost-effective manner;
- our ability and the ability of our collaboration partners to successfully complete preclinical and clinical development of new products and services;
- our ability to expand the use of current and next generation products in existing and new indications;
- regulatory authorities' views regarding the safety, efficacy and risk-benefit profiles of our products and our manufacturing processes;
- 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;
- 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 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;
- the accuracy of our information regarding the products and resources of our competitors and potential competitors;
- competition from lower cost generic or biosimilar products;

- the impact of legislative or regulatory changes, including proposed healthcare reform in the United States;
- 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;
- 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 possibility that our integration of the products and development programs acquired from Bayer may be more costly or time consuming than expected;
- 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®, Fabrazyme®, Thyrogen®, Myozyme®, Renagel®, Renvela®, Campath®, Clolar®, Evoltra®, Mozobil®, Thymoglobulin®, Cholestagel®, Synvisc®, Synvisc-One®, Sepra®, Seprafilm®, Carticel®, Epicel®, MACI® and Hectorol® are registered trademarks, and Lumizyme™ is a trademark, 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 licensed to Genzyme. All other trademarks referred to in this Form 10-Q are the property of their respective owners. All rights reserved.

GENZYME CORPORATION AND SUBSIDIARIES
FORM 10-Q, SEPTEMBER 30, 2009
TABLE OF CONTENTS

		<u>PAGE NO.</u>
PART I.	FINANCIAL INFORMATION	6
ITEM 1.	Financial Statements	6
	Unaudited, Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008	6
	Unaudited, Consolidated Balance Sheets as of September 30, 2009 and December 31, 2008	7
	Unaudited, Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008	8
	Notes to Unaudited, Consolidated Financial Statements	9
ITEM 2.	Management’s Discussion and Analysis of Genzyme Corporation and Subsidiaries’ Financial Condition and Results of Operations	34
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	81
ITEM 4.	Controls and Procedures	81
PART II.	OTHER INFORMATION	82
ITEM 1.	Legal Proceedings	82
ITEM 1A.	Risk Factors	83
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	83
ITEM 6.	Exhibits	83
	Signatures	84

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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues:				
Net product sales	\$ 953,686	\$1,058,296	\$3,106,355	\$3,136,365
Net service sales	102,436	92,586	309,628	269,072
Research and development revenue	1,392	9,402	18,912	26,042
Total revenues	<u>1,057,514</u>	<u>1,160,284</u>	<u>3,434,895</u>	<u>3,431,479</u>
Operating costs and expenses:				
Cost of products sold	296,881	225,691	821,342	683,773
Cost of services sold	62,526	59,517	184,400	174,078
Selling, general and administrative	367,347	331,170	1,039,436	996,861
Research and development	219,275	305,242	636,722	949,900
Amortization of intangibles	71,280	55,295	192,823	166,558
Contingent consideration expense	28,197	—	37,287	—
Total operating costs and expenses	<u>1,045,506</u>	<u>976,915</u>	<u>2,912,010</u>	<u>2,971,170</u>
Operating income	<u>12,008</u>	<u>183,369</u>	<u>522,885</u>	<u>460,309</u>
Other income (expenses):				
Losses on investments in equity securities, net	(651)	(14,129)	(1,332)	(4,201)
Gain on acquisition of business	—	—	24,159	—
Other	616	(133)	(2,419)	940
Investment income	4,544	11,793	14,038	40,015
Interest expense	—	(792)	—	(3,596)
Total other income (expenses)	<u>4,509</u>	<u>(3,261)</u>	<u>34,446</u>	<u>33,158</u>
Income before income taxes	16,517	180,108	557,331	493,467
Provision for income taxes	(522)	(60,512)	(158,276)	(159,036)
Net income	<u>\$ 15,995</u>	<u>\$ 119,596</u>	<u>\$ 399,055</u>	<u>\$ 334,431</u>
Net income per share:				
Basic	<u>\$ 0.06</u>	<u>\$ 0.44</u>	<u>\$ 1.48</u>	<u>\$ 1.25</u>
Diluted	<u>\$ 0.06</u>	<u>\$ 0.42</u>	<u>\$ 1.45</u>	<u>\$ 1.19</u>
Weighted average shares outstanding:				
Basic	<u>268,957</u>	<u>269,176</u>	<u>269,923</u>	<u>267,767</u>
Diluted	<u>273,741</u>	<u>288,179</u>	<u>275,375</u>	<u>286,003</u>

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

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

	<u>September 30, 2009</u>	<u>December 31, 2008</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 679,559	\$ 572,106
Short-term investments	169,153	57,507
Accounts receivable, net	993,206	1,036,940
Inventories	601,939	453,437
Other current assets	164,362	208,040
Deferred tax assets	188,329	188,105
Total current assets	<u>2,796,548</u>	<u>2,516,135</u>
Property, plant and equipment, net	2,695,231	2,306,567
Long-term investments	140,160	344,078
Goodwill	1,402,926	1,401,074
Other intangible assets, net	2,377,025	1,654,698
Deferred tax assets-noncurrent	386,142	269,237
Investments in equity securities	75,872	83,325
Other noncurrent assets	96,384	96,162
Total assets	<u><u>\$9,970,288</u></u>	<u><u>\$8,671,276</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 164,879	\$ 127,869
Accrued expenses	735,446	765,386
Deferred revenue	18,046	13,462
Current portion of contingent consideration obligations	170,478	—
Current portion of long-term debt and capital lease obligations	7,988	7,566
Total current liabilities	<u>1,096,837</u>	<u>914,283</u>
Long-term debt and capital lease obligations	118,154	124,341
Deferred revenue-noncurrent	11,769	13,175
Long-term contingent consideration obligations	834,188	—
Other noncurrent liabilities	294,009	313,484
Total liabilities	<u>2,354,957</u>	<u>1,365,283</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value	—	—
Common stock, \$0.01 par value	2,652	2,707
Additional paid-in capital	5,612,569	5,779,279
Accumulated earnings	1,646,851	1,247,796
Accumulated other comprehensive income	353,259	276,211
Total stockholders' equity	<u>7,615,331</u>	<u>7,305,993</u>
Total liabilities and stockholders' equity	<u><u>\$9,970,288</u></u>	<u><u>\$8,671,276</u></u>

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

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

	Nine Months Ended September 30,	
	2009	2008
Cash Flows from Operating Activities:		
Net income	\$ 399,055	\$ 334,431
Reconciliation of net income to cash flows from operating activities:		
Depreciation and amortization	329,359	276,042
Stock-based compensation	156,141	143,141
Provision for bad debts	14,700	9,065
Contingent consideration expense	37,287	—
Losses on investments in equity securities, net	1,332	4,201
Gain on acquisition of business	(24,159)	—
Deferred income tax benefits	(74,949)	(236,307)
Tax benefits from employee stock-based compensation	10,956	57,149
Excess tax benefits from stock-based compensation	(3,309)	(17,470)
Other	8,517	2,936
Increase (decrease) in cash from working capital changes (excluding impact of acquired assets and assumed liabilities):		
Accounts receivable	53,044	(99,579)
Inventories	20,539	(12,651)
Other current assets	(12,301)	(7,107)
Accounts payable, accrued expenses and deferred revenue	40,369	(19,786)
Cash flows from operating activities	956,581	434,065
Cash Flows from Investing Activities:		
Purchases of investments	(244,208)	(382,954)
Sales and maturities of investments	336,918	412,690
Purchases of equity securities	(7,548)	(87,695)
Proceeds from sales of investments in equity securities	2,365	16,519
Purchases of property, plant and equipment	(480,436)	(433,987)
Distributions from equity method investments	—	5,995
Acquisitions	(57,238)	(16,561)
Purchases of other intangible assets	(29,838)	(82,898)
Other	(7,096)	5,161
Cash flows from investing activities	(487,081)	(563,730)
Cash Flows from Financing Activities:		
Proceeds from the issuance of our common stock	76,125	294,603
Repurchases of our common stock	(413,874)	(143,012)
Excess tax benefits from stock-based compensation	3,309	17,470
Payments of debt and capital lease obligations	(5,908)	(5,281)
Increase (decrease) in bank overdrafts	(17,552)	20,889
Other	(5,237)	2,854
Cash flows from financing activities	(363,137)	187,523
Effect of exchange rate changes on cash	1,090	(6,134)
Increase in cash and cash equivalents	107,453	51,724
Cash and cash equivalents at beginning of period	572,106	867,012
Cash and cash equivalents at end of period	\$ 679,559	\$ 918,736
Supplemental disclosures of non-cash transactions:		
Strategic Transactions—Note 6.		

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

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 genetic disease 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 a 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 and the mobilization of hematopoietic stem cells and is developing a product for the treatment of MS. This unit derives substantially all of its revenue from sales of Campath, clofarabine (which is marketed under the names Clolar and Evoltra), Fludara, Leukine and Mozobil.

Formerly, we included our MS business unit under the caption "Other." As a result of our recent acquisition of certain products and development programs from Bayer, as described under the heading "Acquisition from Bayer" in Note 6., "Strategic Transactions," to these consolidated financial statements, our MS business unit is now material. We have aggregated our Hematologic Oncology and MS reportable segments and now report the activities of these two segments under the caption "Hematologic Oncology." 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."

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

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 have reclassified certain 2008 data to conform to our 2009 presentation. We prepare our unaudited, consolidated financial statements following the requirements of the SEC for interim reporting. As 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, commonly referred to as U.S. GAAP.

In June 2009, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No., or FAS, 168, "*The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles.*" FAS 168 identifies the FASB Accounting Standards Codification™, or ASC, as the authoritative source of U.S. GAAP. Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. FAS 168 is effective for financial statements issued for interim reporting periods ending after September 15, 2009. The ASC does not change or alter existing U.S. GAAP and, therefore, it does not have an impact on our financial position, results of operations or cash flows.

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 Exhibit 13 to 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. The balance sheet data as of December 31, 2008 that is included in this Form 10-Q was derived from our audited financial statements but does not include all disclosures required by U.S. GAAP.

Our unaudited, consolidated financial statements for each period include the accounts of our wholly owned and majority owned subsidiaries. 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 minority interest expense in "Other" in our consolidated statements of operations (representing the ownership interest of the minority owner) because the amount was immaterial for all periods presented. We account for our investments in entities not subject to consolidation using the equity method of accounting if we have a substantial ownership interest (20% to 50%) in or exercise significant influence over the entity. Our consolidated net income includes our share of the earnings or losses of these entities.

Any material subsequent events have been considered for disclosure through the filing date of this Form 10-Q.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

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

Recent Accounting Pronouncements

Periodically, accounting pronouncements and related information on the adoption, interpretation and application of U.S. GAAP are issued or amended by the FASB or the SEC. The following table shows recently issued accounting pronouncements and our position for adoption:

<u>Pronouncements</u>	<u>Relevant Requirements</u>	<u>Issued Date/ Our Effective Dates</u>	<u>Status</u>
<i>FAS 166, "Accounting for Transfers of Financial Assets—an amendment of FASB Statement No. 140."</i>	Improves the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets; the effects of a transfer on its financial position, financial performance and cash flows; and a transferor's continuing involvement, if any, in transferred financial assets.	Issued June 2009. Effective for the first annual reporting period that begins after November 15, 2009.	It is anticipated that FAS 166 will primarily be incorporated into ASC 860, "Transfers and Servicing." We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
<i>FAS 167, "Amendments to FASB Interpretation No. 46(R)."</i>	Improves financial reporting by enterprises involved with variable interest entities and to provide more relevant reliable information to users of financial statements.	Issued June 2009. Effective for the first annual reporting period that begins after November 15, 2009.	It is anticipated that FAS 167 will primarily be incorporated into ASC 810, "Consolidation." We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.

3. Fair Value Measurements

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

- fixed income investments;
- investments in publicly-traded equity securities;
- derivatives; and
- contingent consideration obligations.

Fair Value Measurement—Definition and Hierarchy

Fair value is defined 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, we are permitted to use various valuation approaches, including market, income and cost approaches. We are required to follow an established fair value 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.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements (Continued)

The fair value hierarchy is broken down into three levels based on the reliability of inputs. We have categorized our fixed income, equity securities, derivatives and contingent consideration obligations 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 and liabilities are classified within Level 3 of the fair value hierarchy because they trade infrequently and, therefore, have little or no transparency. The fair value measurement of the contingent consideration obligations related to the acquisition from Bayer is valued using Level 3 inputs.

Valuation Techniques

Fair value is a market-based measure considered from the perspective of a market participant who would buy the asset or assume the liability rather than our own specific measure. All of our fixed income securities are priced using a variety of daily data sources, largely readily-available market data and broker quotes. To validate these prices, we compare the fair values of our fixed income investments using market data from observable and corroborated sources. We also perform the fair value calculations for our derivatives and equity securities using market data from observable and corroborated sources. We determine the fair value of the contingent consideration obligations based on a probability-weighted income approach. The measurement is based on significant inputs not observable in the market. In periods of market inactivity, the observability of prices and inputs may be reduced for certain instruments. This condition could cause an instrument to be reclassified from Level 1 to Level 2 or from Level 2 to Level 3.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements (Continued)

The following tables set forth our assets and liabilities that were accounted for at fair value on a recurring basis as of September 30, 2009 and December 31, 2008 (amounts in thousands):

Description	Balance as of September 30, 2009	Level 1	Level 2	Level 3
Fixed income investments(1):				
Cash equivalents: Money market funds/other	\$ 540,412	\$540,412	\$ —	\$ —
Short-term investments:				
U.S. Treasury notes	47,840	47,840	—	—
Non U.S. Governmental notes	4,100	—	4,100	—
U.S. agency notes	56,110	—	56,110	—
Corporate notes—global	58,014	—	58,014	—
Commercial paper	3,089	—	3,089	—
Total	169,153	47,840	121,313	—
Long-term investments:				
U.S. Treasury notes	14,265	14,265	—	—
Non U.S. Governmental notes	3,232	—	3,232	—
U.S. agency notes	37,023	—	37,023	—
Corporate notes—global	85,640	—	85,640	—
Total	140,160	14,265	125,895	—
Total fixed income investments	849,725	602,517	247,208	—
Equity holdings(1): Publicly-traded equity securities	48,893	48,893	—	—
Derivatives: Foreign exchange forward contracts	(1,002)	—	(1,002)	—
Contingent liabilities(2): Contingent consideration obligations	(1,004,666)	—	—	(1,004,666)
Total assets (liabilities) at fair value	<u>\$ (107,050)</u>	<u>\$651,410</u>	<u>\$246,206</u>	<u>\$(1,004,666)</u>

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	—
Equity holdings(1): Publicly-traded equity securities	56,596	56,596	—	—
Derivatives: Foreign exchange forward contracts	(1,434)	—	(1,434)	—
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) In May 2009, we recorded contingent consideration obligations in connection with our acquisition from Bayer of the worldwide rights to Campath, Fludara, Leukine and alemtuzumab for MS. Changes in the fair value of these contingent consideration obligations are recorded as contingent consideration expense, a component of operating expenses in our consolidated statements of operations.

Changes in the fair value of the our Level 3 contingent consideration obligations during the nine months ended September 30, 2009 were as follows (amounts in thousands):

Contingent consideration obligations related to acquisition from Bayer in May 2009	\$ 964,100
Payments	(9,187)
Contingent consideration expense	37,287
Effect of foreign currency adjustment	12,466
Fair value at September 30, 2009	<u>\$1,004,666</u>

The carrying amounts reflected in our consolidated balance sheets for cash, accounts receivable, other current assets, accounts payable, accrued expenses, current portion of contingent consideration obligations and current portion of long-term debt and capital lease obligations approximate fair value due to their short-term maturities.

Derivative Instruments

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

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

3. Fair Value Measurements (Continued)

which we do not apply hedge accounting treatment, to further reduce our exposure to changes in 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 within selling, general and administrative expenses, or SG&A, in our consolidated statements of operations. We do not have any derivatives designated as hedging instruments 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 September 30, 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 other current assets and net liability derivatives are included in accrued expenses in our consolidated balance sheets.

The following table summarizes the balance sheet classification of the fair value of these derivatives on both a gross and net basis as of September 30, 2009 and December 31, 2008 (amounts in thousands):

	Unrealized Gain/Loss on Foreign Exchange Forward Contracts			
	Gross		As Reported	
	Asset Derivatives	Liability Derivatives	Asset Derivatives	Liability Derivatives
	Other current assets	Accrued expenses	Other current assets	Accrued expenses
As of:				
September 30, 2009	\$1,770	\$2,772	\$—	\$1,002
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 and nine months ended September 30, 2009 and 2008 was not significant.

The following table summarizes the effect of the unrealized and realized losses related to our foreign exchange forward contracts on our consolidated statements of operations for the three and nine months ended September 30, 2009 and 2008 (amounts in thousands):

<u>Derivative Instrument</u>	<u>Statement of Operations Location</u>	Net (Gain)/Loss Reported			
		Three Months Ended September 30,		Nine Months Ended September 30,	
		2009	2008	2009	2008
Foreign exchange forward contracts	SG&A	\$16,275	\$(28,066)	\$24,173	\$12,127

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):

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Net income—basic	\$ 15,995	\$119,596	\$399,055	\$334,431
Effect of dilutive securities:				
Interest expense and debt fee amortization, net of tax, related to our 1.25% convertible senior notes(1)	—	1,885	—	5,658
Net income—diluted	<u>\$ 15,995</u>	<u>\$121,481</u>	<u>\$399,055</u>	<u>\$340,089</u>
Shares used in computing net income per common share—basic . . .	268,957	269,176	269,923	267,767
Effect of dilutive securities:				
Shares issuable upon the assumed conversion of our 1.25% convertible senior notes(1)	—	9,686	—	9,686
Stock options(2)	3,209	8,081	4,106	7,665
Restricted stock units	1,565	871	1,335	618
Other	10	365	11	267
Dilutive potential common shares	<u>4,784</u>	<u>19,003</u>	<u>5,452</u>	<u>18,236</u>
Shares used in computing net income per common share— diluted(1,2)	<u>273,741</u>	<u>288,179</u>	<u>275,375</u>	<u>286,003</u>
Net income per common share:				
Basic	<u>\$ 0.06</u>	<u>\$ 0.44</u>	<u>\$ 1.48</u>	<u>\$ 1.25</u>
Diluted	<u>\$ 0.06</u>	<u>\$ 0.42</u>	<u>\$ 1.45</u>	<u>\$ 1.19</u>

- (1) Prior to January 1, 2009, the shares issuable upon redemption of \$690.0 million in principal of our 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. There are no similar adjustments to the computation of diluted earnings per share for the three and nine months ended September 30, 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 the corresponding period (amounts in thousands):

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Shares issuable under our stock plans	<u>21,108</u>	<u>3,123</u>	<u>16,474</u>	<u>3,121</u>

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):

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Net income	\$15,995	\$ 119,596	\$399,055	\$334,431
Other comprehensive income (loss):				
Foreign currency translation adjustments	48,546	(172,636)	82,178	(66,963)
Pension liability adjustments, net of tax(1)	—	2,019	—	2,090
Unrealized gains (losses) on securities, net of tax:				
Unrealized gains (losses) arising during the period, net of tax . .	6,358	475	(4,592)	5,186
Reclassification adjustment of (gains) losses included in net income, net of tax	(378)	(141)	(538)	(6,039)
Unrealized gains (losses) on securities, net of tax(2)	5,980	334	(5,130)	(853)
Other comprehensive income (loss)	54,526	(170,283)	77,048	(65,726)
Comprehensive income (loss)	<u>\$70,521</u>	<u>\$ (50,687)</u>	<u>\$476,103</u>	<u>\$268,705</u>

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

(2) Net of \$(3.4) million of tax for the three months ended and \$2.9 million of tax for the nine months ended September 30, 2009, and \$(0.2) million of tax for the three months ended and \$0.5 million of tax for the nine months ended September 30, 2008.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions

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

Element	Prior to January 1, 2009	On or after January 1, 2009
Transaction costs	<ul style="list-style-type: none"> • Capitalized as cost of acquisition 	<ul style="list-style-type: none"> • Expensed as incurred
Exit/Restructuring costs	<ul style="list-style-type: none"> • Capitalized as cost of acquisition if certain criteria were met 	<ul style="list-style-type: none"> • Expensed as incurred at or subsequent to acquisition date
IPR&D	<ul style="list-style-type: none"> • Measured at fair value and expensed on acquisition date, or capitalized as an intangible asset if certain criteria were met 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Recorded at acquisition date only to the extent of negative goodwill • Capitalized as cost of acquisition when contingency was resolved • No subsequent re-measurement 	<ul style="list-style-type: none"> • Measured at fair value and recorded on acquisition date • Re-measured in subsequent periods with an adjustment to earnings
Negative goodwill (excess of the value of acquired assets over consideration transferred)	<ul style="list-style-type: none"> • Offset other long-lived intangibles acquired 	<ul style="list-style-type: none"> • Recognized as a gain in earnings
Changes in deferred tax assets and valuation allowances	<ul style="list-style-type: none"> • Recorded as adjustments to goodwill 	<ul style="list-style-type: none"> • Recorded as tax expense
Adjustments to acquisition accounting	<ul style="list-style-type: none"> • Recorded in the current period financial statements 	<ul style="list-style-type: none"> • Recorded as adjustments to prior period financial statements

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

Acquisition of Assets from Targeted Genetics Corporation

On September 8, 2009, we entered into an agreement with Targeted Genetics Corporation to acquire certain gene therapy manufacturing assets for \$7.0 million. We acquired intellectual property and materials used in manufacturing Adeno-Associated Virus, or AAV, vectors. We paid Targeted Genetics Corporation a nonrefundable upfront payment of \$3.5 million in September 2009 and will also make additional payments totaling \$3.5 million upon achievement of certain technology transfer-based milestones. We recorded a total of \$7.0 million as a charge to research and development expenses for our Genetic Diseases reporting segment in our consolidated statements of operations for the three and nine months ended September 30, 2009. The payment for the milestones and the transition of the technology are all expected to be completed by the first quarter of 2010.

Acquisition from Bayer

On May 29, 2009, we completed a transaction with Bayer to:

- exclusively license worldwide rights to commercialize alemtuzumab for MS;
- exclusively license worldwide rights to alemtuzumab for B-cell chronic lymphocytic leukemia, or B-CLL, and all other indications, except for solid organ transplant, which we refer to as Campath;
- exclusively license Bayer's worldwide rights to the oncology products Fludara and Leukine; and
- acquire a new Leukine manufacturing facility located in Lynnwood, Washington, contingent upon the facility receiving FDA approval, which is expected in 2011.

Prior to this transaction, we shared with Bayer the development and certain commercial rights to alemtuzumab for MS and Campath and received two-thirds of Campath net profits on U.S. sales and a royalty on foreign sales. Under our new arrangement with Bayer, prior to regulatory approval of alemtuzumab for MS, we will have primary responsibility for the product's development while Bayer will continue to fund development at current levels and will participate in the development steering committee. We will have worldwide commercialization rights, with Bayer retaining an option to co-promote alemtuzumab for MS. In exchange for the above, Bayer is eligible to receive the following contingent purchase price payments:

- a percentage of revenues from sales of alemtuzumab for MS capped at a total compensation of \$1.25 billion or ten years, whichever comes first;
- a percentage of the combined revenues from sales of Campath, Fludara and Leukine capped at a total compensation of \$500.0 million or eight years, whichever comes first;
- sales-based milestone payments determined as a percentage of annual worldwide revenues of alemtuzumab for 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, Fludara and Leukine are reached beginning in 2011; and

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

- between \$75.0 million and \$100.0 million for the Leukine manufacturing facility, following the receipt of FDA approval of the facility.

We are using Bayer for certain transition services and are purchasing commercial supply of Fludara and Leukine from Bayer. We have employed certain members of Bayer's commercial teams for all three products and have an opportunity to employ certain members of Bayer's manufacturing team if we acquire the Leukine facility. The transaction has been accounted for as a business combination and is included in our results of operations beginning on May 29, 2009, the date of acquisition. The results for the acquired products are included in our Hematologic Oncology reporting segment. The fair value of the consideration and acquired assets at the date of acquisition consisted of the following (amounts in thousands):

Cash, net of refundable cash deposits	\$ 42,425
Contingent consideration obligations	964,100
Total fair value of total consideration	<u>\$1,006,525</u>
Inventory	\$ 136,400
Developed technology:	
Fludara (to be amortized over 5 years)	182,100
Campath (to be amortized over 10 years)	71,000
Leukine (to be amortized over 12 years)	8,272
IPR&D—alemtuzumab for MS	632,912
Total fair value of assets acquired	<u>1,030,684</u>
Gain on acquisition of business	<u>\$ 24,159</u>

At closing, we paid a total of \$117.1 million to Bayer, of which \$74.6 million was refundable. The remaining non-refundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$59.8 million of the refundable amount was received in July 2009 and \$14.8 million remains due from Bayer as of September 30, 2009. The contingent consideration obligations are net of the continued funding expected to be received from Bayer for the development of alemtuzumab for MS. We determined the fair value of the contingent consideration obligations based on a probability-weighted income approach derived from revenue estimates and probability assessment with respect to regulatory approval of alemtuzumab for MS. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement. The resultant probability-weighted cash flows were then discounted using discount rates of 11% for Campath, Fludara and Leukine and 13% for alemtuzumab for MS.

Of the \$964.1 million total contingent consideration obligations recorded as of the acquisition date, \$529.1 million related to Campath, Fludara and Leukine, and \$435.0 million related to alemtuzumab for MS. Each period we revalue the contingent consideration obligations to their then fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent consideration obligations can result from changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability adjustments with respect to regulatory approval of alemtuzumab for MS.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

As of September 30, 2009, the fair value of the total contingent consideration obligations was \$1.0 billion primarily due to changes in discount periods and management estimates. Accordingly, we recorded contingent consideration expense in our consolidated statements of operations of \$28.2 million for the three months ended and \$37.3 million for the nine months ended September 30, 2009. As of September 30, 2009, we have paid \$9.2 million in contingent consideration payments to Bayer and have not received funding from Bayer for the development of alemtuzumab for MS since May 29, 2009.

At the date of acquisition, alemtuzumab for MS had not reached technological feasibility nor had an alternative future use and is therefore considered to be IPR&D. We recorded the fair value of the purchase price attributable to IPR&D as an indefinite-lived intangible asset. We will test the asset annually for impairment, or earlier if conditions warrant. Amortization of this asset will begin upon regulatory approval based on the then estimated useful life of the asset.

The fair value assigned to purchased IPR&D was estimated by discounting, to present value, the cash flows expected to result from the project once it has reached technological feasibility. We used a discount rate of 16% and cash flows that have been probability-adjusted to reflect the risks of advancement through the product approval process, which we believe are appropriate and representative of market participant assumptions. In estimating future cash flows, we also considered other tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D project and adjusted future cash flows for a charge reflecting the contribution to value these assets.

The fair value of the identifiable assets acquired in this transaction of \$1.03 billion exceeded the fair value of the purchase price of \$1.01 billion. As a result, we recognized a gain on acquisition of business of \$24.2 million in our consolidated statements of operations for the nine months ended September 30, 2009. The fair value of the consideration and assets remain subject to potential adjustments.

SG&A in our consolidated statements of operations for the nine months ended September 30, 2009 includes approximately \$4 million of acquisition-related costs, primarily legal fees, associated with the Bayer transaction. Acquisition-related costs for the three months ended September 30, 2009 were not significant.

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 genetics business unit 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 investments in equity securities in our consolidated balance sheet as of March 31, 2009. As the purchased assets did not qualify as a business combination 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, unless such amount is required to satisfy certain of EXACT Sciences' indemnification obligations.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

Purchase of In-Process Research and Development

Prior to January 1, 2009, IPR&D acquired through a business combination was expensed on the acquisition date in our consolidated financial statements. Effective January 1, 2009, 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.

The following table sets forth the significant IPR&D projects for the companies and assets we acquired between January 1, 2006 and September 30, 2009 (amounts in millions):

<u>Company/Assets Acquired</u>	<u>Purchase Price</u>	<u>IPR&D</u>	<u>Programs Acquired</u>	<u>Discount Rate Used in Estimating Cash Flows</u>	<u>Year of Expected Launch</u>
Bayer (2009)	\$1,006.5	\$415.6 217.3	alemtuzumab for MS—US alemtuzumab for MS—ex-US	16% 16%	2012 2013
		<u>\$632.9(1)</u>			
Bioenvision (2007)	\$ 349.9	<u>\$125.5(2)</u>	Clolar/Evoltra (clofarabine)(3)	17%	2009-2014(4)
AnorMED (2006)	\$ 589.2	<u>\$526.8(2)</u>	Mozobil (stem cell transplant)(5)	15%	2009-2013(4)

- (1) Capitalized as an indefinite-lived intangible asset.
- (2) Expensed on acquisition date.
- (3) 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.
- (4) Year of expected launch reflects both the ongoing launch of products for currently approved indications and the anticipated launch of the products in the future for new indications. We are continuing to launch Clolar/Evoltra and Mozobil on a country-by-country basis as pricing and reimbursement approvals are obtained.
- (5) Mozobil received marketing approval for use in stem cell transplants in the United States in December 2008 and in Europe in July 2009. Mozobil is also being developed for chemosensitization.

Pro Forma Financial Summary

The following pro forma financial summary is presented as if the acquisition from Bayer was completed as of January 1, 2009 and 2008. The pro forma combined results are not necessarily indicative of the actual results that would have occurred had the acquisition been consummated on those dates, or of the future operations of the combined entities. Material nonrecurring charges related to this acquisition, such as a gain on acquisition of business of \$24.2 million, are included in the pro

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

6. Strategic Transactions (Continued)

forma financial summaries for the periods presented (amounts in thousands, except per share amounts):

	Three Months Ended September 30,	Nine Months Ended September 30,	
	2008	2009	2008
Total revenues	\$1,230,149	\$3,535,044	\$3,639,597
Net income	\$ 88,472	\$ 326,590	\$ 227,777
Net income per share:			
Basic	\$ 0.33	\$ 1.21	\$ 0.85
Diluted	\$ 0.31	\$ 1.19	\$ 0.82
Weighted average shares outstanding:			
Basic	269,176	269,923	267,767
Diluted	288,179	275,375	286,003

7. Inventories

	September 30, 2009	December 31, 2008
	(Amounts in thousands)	
Raw materials	\$112,691	\$ 96,986
Work-in-process	287,331	141,094
Finished goods	201,917	215,357
Total	\$601,939	\$453,437

In May 2009, in connection with our acquisition of the worldwide rights to the oncology products Campath, Fludara and Leukine from Bayer, we acquired a total of \$136.4 million of inventory, including \$15.3 million of Campath inventory, \$22.9 million of Fludara inventory and \$98.2 million of Leukine inventory.

In June 2009, we announced that we had interrupted production of Cerezyme and Fabrazyme, and shipments of Cerezyme, at our Allston facility to sanitize the facility after identifying a virus, Vesivirus 2117, in a bioreactor used for Cerezyme production. We recorded charges totaling \$23.7 million for the three months ended and \$37.9 million for the nine months ended September 30, 2009 to cost of products sold in our consolidated statements of operations, for costs related to the remediation of this facility, including the sanitization of the facility, idle capacity and overhead expenses and the write off of certain production materials.

When we suspended production at our Allston facility, we had significant Cerezyme work-in-process material. We decided not to process the majority of this work-in-process material because the material either had expired or we were not sufficiently assured that the material was not contaminated with Vesivirus 2117 and incurred a write off of approximately \$8 million for the nine months ended September 30, 2009. In August 2009, the FDA communicated to us steps it recommends we take prior to forward processing the remaining Cerezyme work-in-process. The steps recommended

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

7. Inventories (Continued)

by the FDA were consistent with the steps that we independently had planned to implement. The remaining Cerezyme work-in-process material expires in mid-2010. If we decide not to process this remaining material or if we process the material and the FDA or another regulatory authority does not allow us to release it, we will incur a write off of approximately \$3 million for the inventory value of this remaining material. We had two lots of Cerezyme in inventory that were finished before production was suspended at our Allston facility. Both lots were released during the third quarter of 2009.

8. Goodwill and Other Intangible Assets

Goodwill

The following table contains the change in our goodwill during the nine months ended September 30, 2009 (amounts in thousands):

	As of December 31, 2008	Adjustments	As of September 30, 2009
Genetic Diseases	\$ 339,563	\$ —	\$ 339,563
Cardiometabolic and Renal	319,882	—	319,882
Biosurgery	7,585	—	7,585
Hematologic Oncology	640,137	—	640,137
Other(1)	93,907	1,852	95,759
Goodwill	<u>\$1,401,074</u>	<u>\$1,852</u>	<u>\$1,402,926</u>

(1) The adjustments to Other include foreign currency revaluation adjustments for goodwill denominated in a foreign currency.

We are required to perform impairment tests related to our goodwill annually and whenever events or changes in circumstances suggest that the carrying value of an intangible asset may not be recoverable. We completed the required annual impairment tests for our \$1.4 billion of net goodwill in the third quarter of 2009 and determined that no impairment charges were required.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

8. Goodwill and Other Intangible Assets (Continued)

Other Intangible Assets

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

	As of September 30, 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
Finite-lived other intangible assets:						
Technology(1)	\$2,180,620	\$ (824,819)	\$1,355,801	\$1,919,074	\$ (692,235)	\$1,226,839
Distribution rights(2) . .	428,478	(213,451)	215,027	399,768	(170,892)	228,876
Patents	188,651	(128,307)	60,344	194,560	(121,763)	72,797
License fees	98,833	(45,422)	53,411	98,123	(39,824)	58,299
Customer lists	86,526	(41,328)	45,198	83,729	(34,271)	49,458
Trademarks	60,596	(46,264)	14,332	60,556	(42,194)	18,362
Other	—	—	—	2,039	(1,972)	67
Total finite-lived other intangible assets	3,043,704	(1,299,591)	1,744,113	2,757,849	(1,103,151)	1,654,698
Indefinite-lived other intangible assets:						
IPR&D(3)	632,912	—	632,912	—	—	—
Total other intangible assets	<u>\$3,676,616</u>	<u>\$(1,299,591)</u>	<u>\$2,377,025</u>	<u>\$2,757,849</u>	<u>\$(1,103,151)</u>	<u>\$1,654,698</u>

- (1) Includes an additional \$261.4 million of gross technology intangible assets resulting from our acquisition of the worldwide rights to the oncology products Campath, Fludara and Leukine from Bayer in May 2009. Of this amount:
- \$71.0 million is related to Campath and will be amortized over ten years;
 - \$182.1 million is related to Fludara and will be amortized over five years; and
 - \$8.3 million is related to Leukine and will be amortized over twelve years.
- (2) Includes an additional \$29.8 million for the nine months ended September 30, 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. To date, \$275.4 million of the maximum amount payable under the agreement has been paid. We anticipate completing the contingent royalty payments to Wyeth by the first quarter of 2010.
- (3) Includes capitalized IPR&D totaling \$632.9 million related to our acquisition of the worldwide rights to alemtuzumab for MS from Bayer in May 2009, including \$415.6 million related to the development of the product for sale in the United States and \$217.3 million for the development of the product for sale outside of the United States.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

8. Goodwill and Other Intangible Assets (Continued)

All of our finite-lived other intangible assets are amortized over their estimated useful lives.

As of September 30, 2009, the estimated future amortization expense for our finite-lived other intangible assets for the remainder of fiscal year 2009, the four succeeding fiscal years and thereafter is as follows (amounts in thousands):

<u>Year Ended December 31,</u>	<u>Estimated Amortization Expense(1,2)</u>
2009 (remaining three months)	\$ 74,587
2010	319,597
2011	319,968
2012	224,474
2013	162,750
Thereafter	658,545

(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 may be required to make to Wyeth and 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 may be required to make to Synpac. These contingent payments will be recorded as intangible assets when the payments are accrued; and
- the technology intangible assets resulting from our acquisition of the worldwide rights to the oncology products Campath, Leukine and Fludara, of which:
 - the assets related to Campath and Leukine are being amortized on a straight-line basis; and
 - the asset related to Fludara is being amortized based on the forecasted future sales of Fludara.

(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.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

9. Investments in Equity Securities

We recorded the following losses on investments in equity securities, net of charges for impairment of investments, for the periods presented (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Gross gains (losses) on investments in equity securities	\$ (36)	\$ (8,819)	\$ 422	\$ 2,398
Less: charges for impairment of investments	(615)	(5,310)	(1,754)	(6,599)
Losses on investments in equity securities, net	<u>\$(651)</u>	<u>\$(14,129)</u>	<u>\$(1,332)</u>	<u>\$(4,201)</u>

Gross gains (losses) on investments in equity securities for both the three and nine months ended September 30, 2008 includes a charge of \$10.0 million to write off the purchase price of an exclusive option to acquire equity in a private company as a result of our termination of the option agreement prior to the exercise deadline. Gross gains (losses) for the nine months ended September 30, 2008 also includes a gain of \$10.3 million recorded in the second quarter of 2008 resulting from the liquidation of our investment in the common stock of Sirtris for net cash proceeds of \$14.8 million.

Charges for impairment of investments for all periods presented represents the write down of our investments in certain venture capital funds to fair value at the end of each period.

At September 30, 2009, our stockholders' equity includes \$14.2 million of unrealized gains and \$0.2 million of unrealized losses related to our strategic investments in equity securities.

10. Revolving Credit Facility

As of September 30, 2009, we had approximately \$12 million of outstanding standby letters of credit and no borrowings, resulting in approximately \$338 million of available credit 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 September 30, 2009, we were in compliance with these covenants.

11. Stockholders' Equity

Stock Repurchase

In May 2007, our board of directors authorized a stock repurchase program to repurchase 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. The board authorized the expenditure of up to \$1.5 billion to purchase those shares. 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. The manner of the purchase, the amount that we spend and the number of shares we ultimately purchase will be 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 nine months ended September 30, 2009, we repurchased 7,500,000 shares of our common stock under this program at an average price of \$55.16 per share for a total of \$413.9 million

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

11. Stockholders' Equity (Continued)

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 13,000,000 shares of our common stock at an average price of \$60.63 per share for a total of \$788.5 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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Pre-tax stock-based compensation expense, net of estimated forfeitures, charged to:				
Cost of products and services sold(1)	\$ (7,575)	\$ (6,926)	\$ (22,379)	\$ (19,751)
Selling, general and administrative expense	(24,648)	(24,222)	(86,301)	(79,015)
Research and development expense	(14,058)	(14,645)	(47,374)	(43,322)
Total	(46,281)	(45,793)	(156,054)	(142,088)
Less: tax benefit from stock options	12,700	14,025	40,433	43,396
Total stock-based compensation expense, net of tax . . .	<u>\$(33,581)</u>	<u>\$(31,768)</u>	<u>\$(115,621)</u>	<u>\$ (98,692)</u>
Effect per common share:				
Basic	<u>\$ (0.12)</u>	<u>\$ (0.12)</u>	<u>\$ (0.43)</u>	<u>\$ (0.37)</u>
Diluted	<u>\$ (0.12)</u>	<u>\$ (0.11)</u>	<u>\$ (0.42)</u>	<u>\$ (0.35)</u>

(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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Stock-based compensation expense capitalized to inventory	\$3,623	\$3,486	\$12,764	\$10,482

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

At September 30, 2009, there was \$278.6 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 2.0 years.

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

12. Commitments and Contingencies

Legal Proceedings

On July 29, 2009 and August 3, 2009, two purported securities class action lawsuits were filed in the U.S. District Court for the District of Massachusetts against us and our President and Chief Executive Officer. The lawsuits were filed on behalf of those who purchased our common stock during the period from June 26, 2008 through July 21, 2009 and allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Each of the suits is premised upon allegations that we made materially false and misleading statements and omissions by failing to disclose instances of viral contamination at two of our manufacturing facilities and our receipt of a list of inspection observations from the FDA related to one of the facilities, which detailed observations of practices that the FDA considered to be deviations from “Good Manufacturing Practices,” or GMP. The plaintiffs seek unspecified damages and reimbursement of costs, including attorneys’ and experts’ fees. We intend to defend these lawsuits vigorously. We are not able to predict the outcome of these lawsuits or estimate the amount or range of any possible loss we might incur if we do not prevail in final, non-appealable determinations of these matters. Therefore, we have not accrued any amounts in connection with these contingencies.

Beginning in August 2009, we have received six letters from alleged shareholders demanding that our board of directors take action on our behalf to remedy breaches of fiduciary duty by our directors and officers. The demand letters are primarily premised on allegations that we made materially false and misleading disclosures and failed to disclose material information to shareholders with respect to manufacturing issues and compliance with GMP. Several of the letters also assert that certain of our officers and directors took advantage of their knowledge of material non-public information about Genzyme to illegally sell stock they personally held in Genzyme. Our board of directors has designated a special committee of three independent directors to oversee the investigation of the allegations made in the demand letters and to recommend to the independent directors of the board whether any action should be instituted on our behalf against any officer or director. The committee has retained independent legal counsel. If the independent members of our board of directors were to make a determination that it was in our best interest to institute an action against any officers or directors, any monetary recovery would be to our benefit.

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 and in September 2009, Abbott agreed to pay Church & Dwight approximately \$27 million to settle the lawsuit. 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. The supply agreement between Abbott and Wyntek provides for dispute resolution through an arbitration proceeding in the event that the parties are unable to reach agreement on the indemnification amount.

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

12. Commitments and Contingencies (Continued)

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 statements of operations for the three months 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 insurers have denied coverage, and therefore, we have not recorded a receivable for any potential recovery from our insurers. In our lawsuit against our primary insurer, the court granted the insurer's motion to dismiss the suit in October 2009. We are currently evaluating whether to appeal this judgment.

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 affect on our consolidated financial position or results of operations.

13. Provision for Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Amounts in thousands)			
Provision for income taxes	\$522	\$60,512	\$158,276	\$159,036
Effective tax rate	3%	34%	28%	32%

Our effective tax rate for all periods presented 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;
- non-deductible stock-based compensation expenses totaling \$9.5 million for the three months ended and \$41.0 million for the nine months ended September 30, 2009, as compared to \$8.8 million for the three months ended and \$25.6 million for the nine months ended September 30, 2008; and
- \$2.1 million of tax credit benefits from the 2008 tax provision to tax return reconciliation and effective settlements of state tax audits.

In addition, our provision for income taxes includes income tax benefits of \$2.6 million for the three months ended and \$7.8 million for the nine months ended September 30, 2009. The income tax benefits result from the reversal of a portion of our U.S. tax reserves due to a remeasurement of our uncertain income tax position liabilities based on new information arising in the second and third quarter of 2009.

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

13. Provision for Income Taxes (Continued)

We are currently under IRS audit for the tax years 2006 to 2007 and various states and foreign jurisdictions for various years. We believe that we have provided sufficiently for all audit exposures. We reasonably expect that our unrecognized tax benefits will decrease by approximately \$15 million within the next twelve months as we receive clarification of certain tax issues as a result of the audit process. Settlement of these audits or the expiration of the statute of limitations on the assessment of income taxes for any tax year will likely 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.

14. Segment Information

We present segment information in a manner consistent with the method we use to report this information to our management. 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. In addition, we now aggregate our MS and Hematologic Oncology reporting segments under the caption "Hematologic Oncology." The activities of our MS reporting unit were formerly reported under the caption "Other." We have revised our 2008 segment disclosures to conform to our 2009 presentation.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues:				
Genetic Diseases(1)	\$ 354,288	\$ 561,165	\$1,459,491	\$1,668,515
Cardiometabolic and Renal	261,160	243,599	752,122	714,722
Biosurgery	145,647	122,962	404,496	365,839
Hematologic Oncology(2)	87,989	34,054	192,183	96,506
Other	207,937	198,119	625,102	584,672
Corporate	493	385	1,501	1,225
Total	<u>\$1,057,514</u>	<u>\$1,160,284</u>	<u>\$3,434,895</u>	<u>\$3,431,479</u>
Income (loss) before income taxes:				
Genetic Diseases(1)	\$ 124,356	\$ 259,392	\$ 809,297	\$ 982,569
Cardiometabolic and Renal(3)	114,123	98,670	323,053	48,520
Biosurgery	40,277	23,453	102,360	70,910
Hematologic Oncology(2)	(78,449)	(33,798)	(135,690)	(109,211)
Other(4)	30,227	6,993	66,854	30,374
Corporate(5)	(214,017)	(174,602)	(608,543)	(529,695)
Total	<u>\$ 16,517</u>	<u>\$ 180,108</u>	<u>\$ 557,331</u>	<u>\$ 493,467</u>

(1) Includes:

- the impact of supply constraints for Cerezyme and Fabrazyme due to the temporary suspension of production at our Allston facility in June 2009; and

GENZYME CORPORATION AND SUBSIDIARIES
Notes to Unaudited, Consolidated Financial Statements (Continued)

14. Segment Information (Continued)

- a charge of \$100.0 million recorded in July 2008 for a nonrefundable upfront fee we paid to PTC Therapeutics, Inc., or PTC, related to our collaboration agreement with PTC to develop and commercialize ataluren for the treatment of genetic diseases caused by nonsense mutations, including Duchenne muscular dystrophy, cystic fibrosis and hemophilia.
- (2) The results of operations of acquired companies and assets and the amortization expense related to acquired intangible assets are included in segment results beginning on the date of acquisition.
- (3) Includes a charge of \$175.0 million recorded in June 2008 and a charge of \$69.9 million recorded in February 2008 as license fees payments to Isis Pharmaceuticals, Inc., or Isis, for exclusive, worldwide rights to mipomersen.
- (4) Includes a charge of \$18.2 million recorded to research and development expense in our consolidated statements of operations in January 2009 for intellectual property we acquired from EXACT Sciences.
- (5) Loss before income taxes for Corporate includes our corporate, general and administrative and corporate science activities, all of our stock-based compensation expenses, as well as net gains on our 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.

Segment Assets

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

	September 30, 2009	December 31, 2008
Segment Assets(1):		
Genetic Diseases	\$1,543,651	\$1,520,586
Cardiometabolic and Renal	1,305,361	1,366,970
Biosurgery	493,586	497,813
Hematologic Oncology(2)	1,998,962	1,024,674
Other	871,767	773,058
Corporate(3)	3,756,961	3,488,175
Total	\$9,970,288	\$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) In May 2009, we acquired the worldwide rights to the oncology products Campath, Fludara and Leukine and alemtuzumab for MS from Bayer for \$42.4 million of cash, net of refundable

GENZYME CORPORATION AND SUBSIDIARIES

Notes to Unaudited, Consolidated Financial Statements (Continued)

14. Segment Information (Continued)

deposits, and \$964.1 million of contingent consideration obligations. Total assets for the acquisition as of May 29, 2009, the date of acquisition, include (amounts in millions):

	<u>Amount</u>	<u>Business Segment</u>
Inventory	\$ 136.4	Hematologic Oncology
Developed technology	261.4	Hematologic Oncology
IPR&D	<u>632.9</u>	Hematologic Oncology
Total	<u>\$1,030.7</u>	

- (3) 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):

	<u>September 30, 2009</u>	<u>December 31, 2008</u>
Cash, cash equivalents, short- and long-term investments in debt securities	\$ 988,872	\$ 973,691
Deferred tax assets, net	574,471	457,342
Property, plant & equipment, net	1,721,787	1,524,442
Investments in equity securities	75,872	83,325
Other	<u>395,959</u>	<u>449,375</u>
Total	<u>\$3,756,961</u>	<u>\$3,488,175</u>

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.

Note: All references to increases or decreases for the three months ended September 30, 2009 are as compared to the three months ended September 30, 2008. All references to increases or decreases for the nine months ended September 30, 2009 are as compared to the nine months ended September 30, 2008, unless otherwise noted.

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 genetic disease 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 a 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 and the mobilization of hematopoietic stem cells and is developing a product for the treatment of MS. This unit derives substantially all of its revenue from sales of Campath, clofarabine (which is marketed under the names Clolar and Evoltra), Fludara, Leukine and Mozobil.

Formerly, we included our MS business unit under the caption "Other." As a result of our recent acquisition of certain products and development programs from Bayer, as described under the heading "Strategic Transactions—Acquisition from Bayer," below, our MS business unit is now material. We have aggregated our Hematologic Oncology and MS reporting segments and now report the activities

of these two segments under the caption “Hematologic Oncology.” 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.”

STRATEGIC TRANSACTIONS

Acquisition of Assets from Targeted Genetics Corporation

On September 8, 2009, we entered into an agreement with Targeted Genetics Corporation to acquire certain gene therapy manufacturing assets for \$7.0 million. We acquired intellectual property and materials used in manufacturing AAV vectors. We paid Targeted Genetics Corporation a nonrefundable upfront payment of \$3.5 million in September 2009 and will also make additional payments totaling \$3.5 million upon achievement of certain technology transfer-based milestones. We recorded a total of \$7.0 million as a charge to research and development expenses for our Genetic Diseases reporting segment in our consolidated statements of operations for the three and nine months ended September 30, 2009. The payment for the milestones and the transition of the technology are all expected to be completed by the first quarter of 2010.

Acquisition from Bayer

On May 29, 2009, we completed a transaction with Bayer to:

- exclusively license worldwide rights to commercialize alemtuzumab for MS;
- exclusively license worldwide rights to alemtuzumab for B-CLL and all other indications, except for solid organ transplant, which we refer to as Campath;
- exclusively license Bayer’s worldwide rights to the oncology products Fludara and Leukine; and
- acquire a new Leukine manufacturing facility located in Lynnwood, Washington, contingent upon the facility receiving FDA approval, which is expected in 2011.

Prior to this transaction, we shared with Bayer the development and certain commercial rights to alemtuzumab for MS and Campath and received two-thirds of Campath net profits on U.S. sales and a royalty on foreign sales. Under our new arrangement with Bayer, prior to regulatory approval of alemtuzumab for MS, we will have primary responsibility for the product’s development while Bayer will continue to fund development at current levels and will participate in the development steering committee. We will have worldwide commercialization rights, with Bayer retaining an option to co-promote alemtuzumab for MS. In exchange for the above, Bayer is eligible to receive the following contingent purchase price payments:

- a percentage of revenues from sales of alemtuzumab for MS capped at a total compensation of \$1.25 billion or ten years, whichever comes first;
- a percentage of the combined revenues from sales of Campath, Fludara and Leukine capped at a total compensation of \$500.0 million or eight years, whichever comes first;

- sales-based milestone payments determined as a percentage of annual worldwide revenues of alemtuzumab for 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, Fludara and Leukine are reached beginning in 2011; and
- between \$75.0 million and \$100.0 million for the Leukine manufacturing facility, following the receipt of FDA approval of the facility.

We are using Bayer for certain transition services and are purchasing commercial supply of Fludara and Leukine from Bayer. We have employed certain members of Bayer's commercial teams for all three products and have an opportunity to employ certain members of Bayer's manufacturing team if we acquire the Leukine facility. The transaction has been accounted for as a business combination and is included in our results of operations beginning on May 29, 2009, the date of acquisition. The results for the acquired products are included in our Hematologic Oncology reporting segment. The fair value of the consideration and acquired assets at the date of acquisition consisted of the following (amounts in thousands):

Cash, net of refundable cash deposits	\$ 42,425
Contingent consideration obligations	964,100
Total fair value of total consideration	<u>\$1,006,525</u>
Inventory	\$ 136,400
Developed technology:	
Fludara (to be amortized over 5 years)	182,100
Campath (to be amortized over 10 years)	71,000
Leukine (to be amortized over 12 years)	8,272
IPR&D—alemtuzumab for MS	<u>632,912</u>
Total fair value of assets acquired	<u>1,030,684</u>
Gain on acquisition of business	<u>\$ 24,159</u>

At closing, we paid a total of \$117.1 million to Bayer, of which \$74.6 million was refundable. The remaining non-refundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$59.8 million of the refundable amount was received in July 2009 and \$14.8 million remains due from Bayer as of September 30, 2009. The contingent consideration obligations are net of the continued funding expected to be received from Bayer for the development of alemtuzumab for MS. We determined the fair value of the contingent consideration obligations based on a probability-weighted income approach derived from revenue estimates and probability assessment with respect to regulatory approval of alemtuzumab for MS. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement. The resultant probability-weighted cash flows were then discounted using discount rates of 11% for Campath, Fludara and Leukine and 13% for alemtuzumab for MS.

Of the \$964.1 million total contingent consideration obligations recorded as of the acquisition date, \$529.1 million related to Campath, Fludara and Leukine, and \$435.0 million related to alemtuzumab for MS. Each period we revalue the contingent consideration obligations to their then fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent consideration obligations can result from changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability adjustments with respect to regulatory approval of alemtuzumab for MS.

As of September 30, 2009, the fair value of the total contingent consideration obligations was \$1.0 billion primarily due to changes in discount periods and management estimates. Accordingly, we recorded contingent consideration expense in our consolidated statements of operations of \$28.2 million for the three months ended and \$37.3 million for the nine months ended September 30, 2009. As of September 30, 2009, we have paid \$9.2 million in contingent consideration payments to Bayer and have not received funding from Bayer for the development of alemtuzumab for MS since May 29, 2009.

At the date of acquisition, alemtuzumab for MS had not reached technological feasibility nor had an alternative future use and is therefore considered to be IPR&D. We recorded the fair value of the purchase price attributable to IPR&D as an indefinite-lived intangible asset. We will test the asset annually for impairment, or earlier if conditions warrant. Amortization of this asset will begin upon regulatory approval based on the then estimated useful life of the asset.

The fair value assigned to purchased IPR&D was estimated by discounting, to present value, the cash flows expected to result from the project once it has reached technological feasibility. We used a discount rate of 16% and cash flows that have been probability-adjusted to reflect the risks of advancement through the product approval process, which we believe are appropriate and representative of market participant assumptions. In estimating future cash flows, we also considered other tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D project and adjusted future cash flows for a charge reflecting the contribution to value these assets.

The fair value of the identifiable assets acquired in this transaction of \$1.03 billion exceeded the fair value of the purchase price of \$1.01 billion. As a result, we recognized a gain on acquisition of business of \$24.2 million in our consolidated statements of operations for the nine months ended September 30, 2009. The fair value of the consideration and assets remain subject to potential adjustments.

SG&A in our consolidated statements of operations for the nine months ended September 30, 2009 includes approximately \$4 million of acquisition-related costs, primarily legal fees, associated with the Bayer transaction. Acquisition-related costs for the three months ended September 30, 2009 were not significant.

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 genetics business unit 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 investments in equity securities in our consolidated balance sheet as of March 31, 2009. As the purchased assets did not qualify as a business combination 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, unless such amount is required to satisfy certain of EXACT Sciences' indemnification obligations.

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. Excluding the addition of our policy for contingent consideration expense, 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 and our policy for accounting for contingent consideration expense 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 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;
- **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.

Our provisions for product sales allowances reduced gross product sales as follows (amounts in thousands):

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Product sales allowances:								
Contractual adjustments	\$ 160,132	\$ 153,800	\$ 6,332	4%	\$ 445,362	\$ 362,813	\$82,549	23%
Discounts	6,628	5,655	973	17%	19,668	16,663	3,005	18%
Sales returns	7,019	8,434	(1,415)	(17)%	22,917	20,103	2,814	14%
Total product sales allowances	\$ 173,779	\$ 167,889	\$ 5,890	4%	\$ 487,947	\$ 399,579	\$88,368	22%
Total gross product sales	\$1,127,466	\$1,226,184	\$(98,718)	(8)%	\$3,594,302	\$3,535,943	\$58,359	2%
Total product sales allowances as a percent of total gross product sales	15%	14%	(6)%		14%	11%	>100%	

Total product sales allowances increased for the three and nine months ended September 30, 2009 largely due to the impact of price increases implemented after the second quarter of 2008, primarily for our Cardiometabolic and Renal reporting segment, the addition of sales of Campath, Fludara and Leukine, which we acquired from Bayer in May 2009, and changes in our overall product mix.

Total estimated product sales allowance reserves and accruals in our consolidated balance sheets increased approximately 17% to approximately \$246 million as of September 30, 2009, as compared to approximately \$210 million as of December 31, 2008, primarily due to changes in the timing of certain payments and approximately \$10 million of additional contractual fees in the third quarter of 2009. Our actual results have not differed materially from amounts recorded. The annual variation has been less than 0.5% of total product sales for the last three years.

Distributor Fees

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.

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 September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Distributor fees:								
Included in contractual adjustments and recorded as a reduction to product sales	\$4,211	\$3,437	\$ 774	23%	\$11,224	\$ 9,723	\$1,501	15%
Charged to SG&A	<u>3,371</u>	<u>3,519</u>	<u>(148)</u>	(4)%	<u>10,400</u>	<u>10,039</u>	<u>361</u>	4%
Total distributor fees . .	<u>\$7,582</u>	<u>\$6,956</u>	<u>\$ 626</u>	9%	<u>\$21,624</u>	<u>\$19,762</u>	<u>\$1,862</u>	9%

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.

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 before our competitors develop and commercialize products for the same indications, or at all. 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 date 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. Effective January 1, 2009, all 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 then estimated useful life of the asset.

None of the incomplete technology programs we have acquired through our business combinations prior to January 1, 2009 had 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. In May 2009, we acquired the worldwide rights to the oncology products Campath, Fludara and Leukine and alemtuzumab for MS. The transaction was accounted for as a business combination. At the date of acquisition, alemtuzumab for MS had not reached technological feasibility nor had an alternative future use and is therefore considered to be IPR&D. Accordingly, we capitalized the \$632.9 million fair value of the IPR&D for alemtuzumab for MS, which is included in Other intangible assets, net in our consolidated balance sheet as of September 30, 2009. Of this amount, \$415.6 million is related to the development of the product for sale in the United States and \$217.3 million is related to the development of the product for sales outside of the United States. Amortization of these capitalized IPR&D assets will commence upon our receipt of the necessary approvals to sell alemtuzumab for MS in each geographic area. We currently anticipate receiving approval for alemtuzumab for MS in the United States in 2012 and outside of the United States starting in 2013. We will test our capitalized IPR&D assets annually for potential impairment, or earlier if conditions warrant.

Contingent Consideration Expense

Each period we revalue the contingent consideration obligations associated with certain acquisitions to their then fair value and record increases in the fair value as contingent consideration expense and record decreases in the fair value as a reduction of contingent consideration expense. Increases or decreases in the fair value of the contingent consideration obligations can result from changes in assumed discount periods and rates, changes in the assumed timing and amount of revenue estimates and changes in assumed probability adjustments with respect to regulatory approval. Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, future business and economic conditions, as well as changes in any of the assumptions described above, can materially impact the amount of contingent consideration expense we record in any given period.

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 September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Product revenue	\$ 953,686	\$1,058,296	\$(104,610)	(10)%	\$3,106,355	\$3,136,365	\$(30,010)	(1)%
Service revenue	102,436	92,586	9,850	11%	309,628	269,072	40,556	15%
Total product and service revenue	1,056,122	1,150,882	(94,760)	(8)%	3,415,983	3,405,437	10,546	—
Research and development revenue	1,392	9,402	(8,010)	(85)%	18,912	26,042	(7,130)	(27)%
Total revenues	<u>\$1,057,514</u>	<u>\$1,160,284</u>	<u>\$(102,770)</u>	<u>(9)%</u>	<u>\$3,434,895</u>	<u>\$3,431,479</u>	<u>\$ 3,416</u>	<u>—</u>

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 mucopolysaccharidosis I, or 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 patients with chronic kidney disease, or CKD, on dialysis and in Europe in CKD patients both on and not on dialysis with serum phosphorous above a certain level, Hectorol for the treatment of secondary hyperparathyroidism in CKD patients, 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 for the treatment of pain associated with osteoarthritis of the knee, and the Sepra line of products, such as Seprafilm, for the prevention of adhesions following various surgical procedures in the abdomen and pelvis;
- Hematologic Oncology products, including Campath and Fludara for the treatment of B-CLL, Clolar/Evoltra for the treatment of pediatric ALL after at least two prior regimens, Leukine for the reduction of the incidence of severe and life-threatening infections in older adult patients with acute myeloid leukemia, or AML, following chemotherapy and certain other uses, and Mozobil for the mobilization of hematopoietic stem cells; 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.

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

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Genetic Diseases	\$354,288	\$ 561,165	\$(206,877)	(37)%	\$1,459,466	\$1,668,172	\$(208,706)	(13)%
Cardiometabolic and Renal	260,999	243,511	17,488	7%	751,885	714,502	37,383	5%
Biosurgery	134,557	112,373	22,184	20%	370,798	331,799	38,999	12%
Hematologic Oncology	87,982	25,904	62,078	>100%	176,746	74,204	102,542	>100%
Other product revenue	115,860	115,343	517	—	347,460	347,688	(228)	—
Total product revenue	<u>\$953,686</u>	<u>\$1,058,296</u>	<u>\$(104,610)</u>	(10)%	<u>\$3,106,355</u>	<u>\$3,136,365</u>	<u>\$ (30,010)</u>	(1)%

Genetic Diseases

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
(Amounts in thousands)								
Cerezyme	\$ 93,599	\$309,280	\$(215,681)	(70)%	\$ 687,656	\$ 932,943	\$(245,287)	(26)%
Fabrazyme	115,161	125,619	(10,458)	(8)%	371,664	368,702	2,962	1%
Myozyme	85,980	76,663	9,317	12%	232,645	221,209	11,436	5%
Aldurazyme	40,331	38,236	2,095	5%	116,358	113,742	2,616	2%
Other Genetic Diseases	19,217	11,367	7,850	69%	51,143	31,576	19,567	62%
Total Genetic Diseases	<u>\$354,288</u>	<u>\$561,165</u>	<u>\$(206,877)</u>	(37)%	<u>\$1,459,466</u>	<u>\$1,668,172</u>	<u>\$(208,706)</u>	(13)%

Genetic Diseases product revenue decreased for the three and nine months ended September 30, 2009 primarily due to the temporary suspension of production at our Allston facility in June 2009, resulting in supply constraints for Cerezyme and Fabrazyme, and unfavorable exchange rate fluctuations, offset in part by continued growth in sales volume for Myozyme, Aldurazyme and Elaprase.

The decreases in Cerezyme revenue for the three and nine months ended September 30, 2009 are primarily due to the temporary suspension of production at our Allston facility and the resulting supply constraint for Cerezyme and contractual fees, which adversely impacted revenue by approximately \$209 million for the three months ended September 30, 2009 and by approximately \$222 million for the nine months ended September 30, 2009. The weakening of foreign currencies against the U.S. dollar adversely impacted Cerezyme revenue by \$5.3 million for the three months ended September 30, 2009 and by \$49.8 million for the nine months ended September 30, 2009.

The decrease in Fabrazyme revenue for the three months ended September 30, 2009 is primarily due to the temporary suspension of production at our Allston facility and the resulting supply constraint for Fabrazyme, which adversely impacted Fabrazyme revenue by approximately \$25 million for the three months ended September 30, 2009. The weakening of foreign currencies against the U.S. dollar adversely impacted Fabrazyme revenue by \$1.6 million for the three months ended September 30, 2009.

The increase in Fabrazyme revenue for the nine months ended September 30, 2009 is primarily due to increased patient identification worldwide as Fabrazyme was introduced to new markets prior to the supply constraint. The increase in the sales volume of Fabrazyme was offset, in part, by a decrease of \$16.6 million for the nine months ended September 30, 2009 attributable to the weakening of foreign currencies against the U.S. dollar.

On June 16, 2009, we announced that we had interrupted production of Cerezyme and Fabrazyme, and shipments of Cerezyme, at our Allston facility after identifying a virus, Vesivirus 2117, in a bioreactor used for Cerezyme production. The virus we identified impairs the viability of cells used in the manufacturing process and is not known to cause infection in humans. We completed sanitization of the facility and resumed production there in the third quarter of 2009.

When we suspended production at our Allston facility, we had significant Cerezyme work-in-process material. We decided not to process the majority of this work-in-process material because the material either had expired or we were not sufficiently assured that the material was not contaminated with Vesivirus 2117 and incurred a write off of approximately \$8 million for the inventory value of this material in the second quarter of 2009. We also had two lots of Cerezyme in inventory that were finished before production was suspended at our Allston facility. Both lots were released during the third quarter of 2009.

In August 2009, the FDA communicated to us steps it recommends we take prior to forward processing the remaining Cerezyme work-in-process. The steps recommended by the FDA were consistent with the steps that we independently had planned to implement. The remaining Cerezyme work-in-process material expires in mid-2010. If we decide not to process this remaining material or if we process the material and the FDA or another regulatory authority does not allow us to release it, we will incur a write off of approximately \$3 million for the inventory value of this remaining material.

Our results of operations are dependent on sales of Cerezyme and any reduction in revenue from sales of this product adversely affects our results of operations. Cerezyme and Fabrazyme inventories have not been sufficient to avoid shortages during the period of suspended production and recovery. The temporary suspension of production at our Allston facility has and will continue to adversely affect our Cerezyme and Fabrazyme revenues for 2009. Sales of Cerezyme were approximately 9% of our total revenue for the three months ended September 30, 2009 and approximately 20% for the nine months ended September 30, 2009, which reflect periods of supply constraint, as compared to approximately 27% for both the three and nine months ended September 30, 2008. We expect Cerezyme revenue for the fourth quarter of 2009 also to be significantly adversely affected by the supply constraint and, therefore, expect that total Cerezyme revenue for 2009 will be significantly lower than 2008.

We expect that newly produced Cerezyme will be available for shipment at the end of November and that the first shipments of new Fabrazyme will occur in late December. We expect that we will be able to meet anticipated demand for these therapies in the first quarter of 2010. We are constructing additional manufacturing capacity for Cerezyme and Fabrazyme in Framingham, Massachusetts to support the anticipated future growth of these two products. The plant, which will include four 2000L bioreactors, is expected to be mechanically complete by the end of 2009 and FDA approval for commercial production is anticipated in 2011 for Fabrazyme and in 2012 for Cerezyme.

Sales of Myozyme increased for the three and nine months ended September 30, 2009 due to the identification of new patients and expanded supply following European approval in February 2009 of product produced at our Belgium facility at the 4000L scale. Sales of Myozyme were adversely impacted by decreases of \$3.5 million for the three months ended September 30, 2009 and \$21.4 million for the nine months ended September 30, 2009 attributable to the weakening of foreign currencies against the U.S. dollar.

We have approval to sell Myozyme (alglucosidase alfa) that is manufactured using a 160L scale process in 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. Myozyme produced using a 2000L scale process has been approved for sale in many countries outside of the United States. In Europe, we also had approval to sell Myozyme produced using a 2000L scale process and in February 2009 received approval for a 4000L scale process.

In May 2008, we submitted a BLA to the FDA seeking marketing approval of alglucosidase alfa produced using the 2000L scale process, which we refer to as Lumizyme. In February 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 May 2009, we submitted documentation to address the items in the CR Letter. The submission included the REMS, the final label, and clinical data requested by the FDA from our Pompe Registry. The FDA has agreed that our Pompe Registry data can fulfill the requirements for a verification study to demonstrate the clinical benefit of Lumizyme.

In addition, the FDA's CR Letter stated that before the FDA would approve Lumizyme, we would need to resolve issues identified in a Warning Letter related to our Allston facility that we received in February 2009, on the same day as the CR Letter. An FDA inspector inspected the plant in May 2009 as a follow up to the Warning Letter. At the end of July 2009, the FDA informed us that it will re-inspect our Allston facility to verify that all corrective and preventative actions identified in the February Warning Letter have been implemented. The FDA indicated that all promised actions had not been either fully or adequately implemented at the time of the May inspection, such as identifying measures to prevent column rousing; inspection and preventative maintenance, or PM, of remaining chromatography columns; revision of PM scheduled inspection to every nine months for Chromaflow columns and an annual inspection for all other column types; revision of column packing records to include internal inspection; development of on the job training for preventative maintenance and division of maintenance responsibility; and implementation of the revised transfer/transport procedures for cryoshippers. In addition, recent remediation of the Allston facility in response to the Vesivirus 2117 contamination employed cleaning procedures using sodium hypochlorite and vaporized hydrogen peroxide treatment of columns. The cleaning validation will be reviewed during the next inspection along with our investigation and other remediation efforts related to the identification of the virus at our Allston facility. The FDA is currently inspecting the facility.

Inspectors visited our Allston facility in August 2009 on behalf of the European Medicines Agency, or EMEA. We recently received correspondence from the EMEA confirming that, based on that inspection, the operations in our Allston facility are in general compliance with the principles and guidelines of good manufacturing practice as laid down in Commission Directive 2003/94/EC.

In order to provide more capacity in our Allston facility for Cerezyme and Fabrazyme, we have transitioned all Myozyme/Lumizyme production to our 4000L Belgium facility, where we are adding a third 4000L bioreactor, and are no longer manufacturing the product at the 2000L scale. FDA approval of the 4000L process will be necessary to expand supply and support an increase in U.S. sales. We have received FDA approval to transition U.S. patients in the Myozyme Temporary Access Program from the product produced at the 2000L scale to that produced at the 4000L scale. The FDA's target action date under the Prescription Drug User Fee Act, or PDUFA, for Lumizyme is November 14, 2009. We expect to submit a supplemental BLA for the 4000L process upon approval of Lumizyme. A standard review period is four months, which would mean an FDA action date by the end of March 2010. We expect Myozyme sales in Europe to continue to increase in the fourth quarter of 2009.

Aldurazyme revenue increased for the three and nine months ended September 30, 2009 due to increased patient identification worldwide as Aldurazyme was introduced into new markets. The weakening of foreign currencies against the U.S. dollar adversely impacted Aldurazyme revenue by \$1.5 million for the three months ended September 30, 2009 and \$8.7 million for the nine months ended September 30, 2009.

Other Genetic Diseases product revenue increased for the three and nine months ended September 30, 2009 primarily due to an increase in sales of Elaprase driven by the identification of new patients and the strengthening of the Japanese yen against the U.S. dollar, which positively impacted revenue by \$1.6 million for the three months ended September 30, 2009 and \$3.4 million for the nine months ended September 30, 2009.

Cardiometabolic and Renal

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
(Amounts in thousands)								
Renagel/Renvela (including sales of bulk sevelamer)	\$181,702	\$170,992	\$10,710	6%	\$527,699	\$508,253	\$19,446	4%
Hectorol	36,869	33,825	3,044	9%	98,880	93,753	5,127	5%
Thyrogen	41,691	38,153	3,538	9%	123,377	111,386	11,991	11%
Other Cardiometabolic and Renal	737	541	196	36%	1,929	1,110	819	74%
Total Cardiometabolic and Renal	<u>\$260,999</u>	<u>\$243,511</u>	<u>\$17,488</u>	7%	<u>\$751,885</u>	<u>\$714,502</u>	<u>\$37,383</u>	5%

In October 2007, the FDA granted marketing approval for Renvela, a second generation buffered form of Renagel, for the control of serum phosphorus in patients with CKD on dialysis. In March 2008, we launched Renvela tablets in the United States and a powder form of Renvela was approved in the United States in August 2009. In June 2009, the European Commission approved Renvela for the control of serum phosphorus in patients with CKD. The approval includes patients not on dialysis with serum phosphorus levels ≥ 1.78 mmol/L (5.5mg/dL) and covers both the tablet and powder formulations.

Sales of Renagel/Renvela, including sales of bulk sevelamer, increased for the three and nine months ended September 30, 2009 due to increased end-user demand and Renagel price increases in the United States after the second quarter of 2008, offset in part by price 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 \$5.4 million for the three months ended September 30, 2009 and \$29.6 million for the nine months ended September 30, 2009 and had no impact on sales of Renvela.

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 and we have been in discussions with the FDA regarding the treatment of hyperphosphatemic CKD patients not on dialysis. There is no PDUFA date associated with this process and we cannot provide an anticipated timeframe for the FDA's decision on this indication.

We expect sales of Renagel/Renvela to continue to increase. Adoption rates for Renagel/Renvela are expected to trend favorably as a result of the introduction of Renvela globally, including in Europe for hyperphosphatemic patients who are not on dialysis and in a powder formulation, the potential label expansion in the United States to include hyperphosphatemic patients who are not on dialysis, and the introduction of a powder formulation in the United States expected in the fourth quarter of 2009.

Sales of Hectorol increased for the three and nine months ended September 30, 2009 primarily due to price increases in the fourth quarter of 2008 and the second quarter of 2009 and an increase in sales volume due to the launch of Hectorol 1mcg capsule formulation in August 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 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 Renagel/Renvela or Hectorol, our revenues from those products would be adversely affected.

In addition, our ability to maintain sales of Renagel/Renvela and Hectorol will depend on many other factors, including the availability of coverage and reimbursement under patients’ health insurance and prescription drug plans and the ability of health care providers to improve patients’ compliance with their prescribed doses. 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 Renagel/Renvela and Hectorol with our wholesalers could impact the revenue from our Cardiometabolic and Renal reporting segment that we record from period to period.

The Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, directs the Centers for Medicare and Medicaid Services, or CMS, to include payment for drugs and biologicals that are used to treat end stage renal disease, or ESRD, in the prospective payment system used to reimburse dialysis providers. In September 2009, CMS proposed changes to the prospective payment system that would, in accordance with MIPPA, include drugs and biologicals used to treat ESRD in the bundled payment amount for dialysis treatments. The bundled rate is proposed to include drugs and biologicals that are currently reimbursed separately by Medicare, including intravenous Vitamin D analogs and their oral equivalents such as Hectorol, and oral phosphate binders such as Renagel/Renvela. CMS is accepting comments on the proposed rule through November 16, 2009 and will issue a final rule in 2010 with an anticipated implementation date of January 2011. There is controversy around the inclusion of drugs and biologicals that do not have an intravenous counterpart in the bundled payment amount because some observers have interpreted MIPPA to apply only to those oral drugs and biologicals that have an intravenous counterpart such as oral Hectorol. In response to this controversy, one of the healthcare reform bills being considered by Congress calls for the inclusion of certain oral drugs such as Renagel/Renvela as part of the ESRD bundled payment beginning in 2011. We are in the process of evaluating the potential impact of the proposed bundling on our business. We cannot predict whether CMS’s final rule or the final bill on healthcare reform would include Renagel/Renvela in the bundled payment.

Sales of Thyrogen increased for the three months ended September 30, 2009 primarily due to worldwide volume growth, driven by an increase in the use of the product in thyroid remnant ablation procedures and a price increase in July 2009. Sales of Thyrogen increased for the nine months ended September 30, 2009 primarily due to worldwide volume growth, driven by a significant increase in the use of the product in thyroid remnant ablation procedures. The weakening of foreign currencies against the U.S. dollar adversely impacted Thyrogen revenue by \$0.9 million for the three months ended September 30, 2009 and \$6.0 million for the nine months ended September 30, 2009.

Biosurgery

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
	(Amounts in thousands)							
Synvisc/Synvisc-One	\$ 87,526	\$ 67,513	\$20,013	30%	\$233,114	\$194,582	\$38,532	20%
Septra products	37,831	33,001	4,830	15%	108,173	98,385	9,788	10%
Other Biosurgery	9,200	11,859	(2,659)	(22)%	29,511	38,832	(9,321)	(24)%
Total Biosurgery	<u>\$134,557</u>	<u>\$112,373</u>	<u>22,184</u>	20%	<u>\$370,798</u>	<u>\$331,799</u>	<u>38,999</u>	12%

Biosurgery product revenue increased for the three and nine months ended September 30, 2009. Revenue from Synvisc/Synvisc-One increased for the three and nine months ended September 30, 2009 primarily due to the addition of Synvisc-One sales in the United States. We received marketing approval for Synvisc-One in the United States in February 2009.

Sepra products revenue increased for the three and nine months ended September 30, 2009 primarily due to greater penetration of Seprafilm into Japan and other international markets, the expanded use of Seprafilm in C-sections and gynecological procedures and a price increase we implemented in the first quarter of 2009.

Other Biosurgery product revenue decreased for the three and nine months ended September 30, 2009 primarily due to a decrease in revenue associated with the development and commercialization of dermal filler products with Mentor Corporation.

The weakening of foreign currencies against the U.S. dollar adversely impacted Biosurgery product revenue by \$2.7 million for the nine months ended September 30, 2009. The weakening of foreign currencies against the U.S. dollar had no significant impact on revenue for the three months ended September 30, 2009.

Hematologic Oncology

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
(Amounts in thousands)								
Hematologic Oncology . . .	<u>\$87,982</u>	<u>\$25,904</u>	<u>\$62,078</u>	>100%	<u>\$176,746</u>	<u>\$74,204</u>	<u>\$102,542</u>	>100%

Hematologic Oncology product revenue increased for the three and nine months ended September 30, 2009 primarily due to the addition of sales of Mozobil in the United States and Europe, increased demand for Clolar in the United States, and the addition of sales of Campath, Fludara and Leukine in the second quarter of 2009. The weakening of foreign currencies against the U.S. dollar adversely impacted Hematologic Oncology product revenue by \$0.6 million for the three months ended September 30, 2009 and \$2.8 million for the nine months ended September 30, 2009.

We are developing the intravenous formulation of clofarabine for new indications, including first-line and relapsed or refractory adult AML. In November 2008, we filed 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. In October 2009, the FDA provided a complete response letter regarding the company's supplemental NDA for Clolar to treat previously untreated adults age 60 years or older with AML who have at least one unfavorable prognostic factor recommending that a randomized, controlled clinical study be conducted for label expansion of Clolar in this indication. In addition, we have discussed our adult AML development plans with the EMEA's Committee for Human Medicinal Products, or CHMP, and based on the CHMP's feedback, await the availability of additional data before seeking approval for this indication in Europe. We are conducting a randomized, placebo-controlled phase 3 trial comparing clofarabine in combination with cytarabine to cytarabine alone in relapsed and refractory adult AML patients 55 years old or older and results from this trial are expected in 2011. 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 in the United States by the FDA in December 2008 for stem cell mobilization in patients with non-Hodgkin's lymphoma and multiple myeloma for subsequent autologous stem cell transplants. In July 2009, the European Commission approved our marketing authorization application for Mozobil in Europe. In Europe, Mozobil is indicated to enhance stem cell

mobilization in preparation for autologous stem cell transplants in patients with lymphoma and multiple myeloma whose cells mobilize poorly.

Other Product Revenue

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
(Amounts in thousands)								
Total Other product revenue	\$115,860	\$115,343	\$517	—	\$347,460	\$347,688	\$(228)	—

Other product revenue increased slightly for the three months ended September 30, 2009 due to increases in sales of transplant products, primarily Thymoglobulin, and an increase in demand for certain diagnostic products, offset by a decrease in demand for pharmaceutical products. Sales of Thymoglobulin increased by \$8.1 million for the three months ended September 30, 2009 primarily due to higher sales volume resulting from increased utilization of Thymoglobulin in transplant procedures worldwide.

Other product revenue decreased slightly for the nine months ended September 30, 2009 primarily due to a decrease in demand for pharmaceutical products, offset by increases in sales of transplant products, primarily Thymoglobulin, and an increase in demand for certain diagnostic products. Sales of Thymoglobulin increased by \$23.8 million for the nine months ended September 30, 2009 primarily due to higher sales volume resulting from increased utilization of Thymoglobulin in transplant procedures worldwide and a constraint in supply for the first half 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 and oncology diagnostic testing services, which are included in Other service revenue.

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

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Genetic Diseases	\$ —	\$ —	\$ —	—	\$ 25	\$ 343	\$ (318)	(93)%
Cardiometabolic and Renal . . .	5	32	(27)	(84)%	60	47	13	28%
Biosurgery	10,443	9,928	515	5%	31,619	31,958	(339)	(1)%
Hematologic Oncology	—	424	(424)	(100)%	737	1,258	(521)	(41)%
Other service revenue	91,988	82,202	9,786	12%	277,187	235,466	41,721	18%
Total service revenue	\$102,436	\$92,586	\$9,850	11%	\$309,628	\$269,072	\$40,556	15%

Other service revenue increased for the three and nine months ended September 30, 2009 primarily due to increased volume from existing and new clients in both reproductive and oncology diagnostic testing services.

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 September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
International product and service revenue	\$493,664	\$578,744	\$(85,080)	(15)%	\$1,651,764	\$1,770,426	\$(118,662)	(7)%
% of total product and service revenue	47%	50%			48%	52%		

International product and service revenue decreased for the three and nine months ended September 30, 2009 primarily due to decreases in international sales volume for Cerezyme and Fabrazyme due to supply constraints and the weakening of foreign currencies against the U.S. dollar. The weakening of foreign currencies against the U.S. dollar adversely impacted total product and service revenue by \$19.9 million for the three months ended September 30, 2009 and by \$151.3 million for the nine months ended September 30, 2009. These decreases were offset in part by growth in the international sales volume of Myozyme, Aldurazyme, Elaprase, Synvisc/Synvisc-One, Campath, Clolar/Evoltra, Thymoglobulin, Fludara and the addition of sales of Mozobil in Europe in the third quarter of 2009.

GROSS PROFIT AND MARGINS

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

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Gross product profit . . .	\$656,805	\$832,605	\$(175,800)	(21)%	\$2,285,013	\$2,452,592	\$(167,579)	(7)%
Product margin	69%	79%			74%	78%		
Gross service profit . . .	\$ 39,910	\$ 33,069	\$ 6,841	21%	\$ 125,228	\$ 94,994	\$ 30,234	32%
Service margin	39%	36%			40%	35%		
Total gross product and service profit	\$696,715	\$865,674	\$(168,959)	(20)%	\$2,410,241	\$2,547,586	\$(137,345)	(5)%
Total product and service margin	66%	75%			71%	75%		

Gross Product Profit and Product Margin

Our overall gross product profit decreased for the three and nine months ended September 30, 2009 primarily due to:

- decreased sales volume for Cerezyme and Fabrazyme;
- \$23.7 million of charges for the three months ended September 30, 2009 and \$37.9 million of charges for the nine months ended September 30, 2009 for the costs related to the remediation of our Allston facility, including idle capacity and clean up expenses, as well as the write off of approximately \$8 million for the nine months ended September 30, 2009 for Cerezyme work-in-process material for which there were no comparable amounts for the same periods of 2008.

These decreases were offset, in part, by:

- increased sales volume for Myozyme, Aldurazyme and Elaprase;
- price increases for Renagel and Hectorol, the addition of sales of Renvela, which was launched in the United States for patients with CKD on dialysis, and increased sales volume for Thyrogen;
- increased sales volume for Synvisc/Synvisc-One and Septrafilm;

- the addition of sales of Mozobil, which was launched in the United States in December 2008 and in Europe in August 2009, the increase in worldwide sales of Clolar/Evoltra and the addition of sales of Fludara and Leukine in the second quarter of 2009; and
- increased sales volume for Thymoglobulin.

Product margin decreased for the three and nine months ended September 30, 2009 primarily due to:

- higher unit costs for Cerezyme and Fabrazyme;
- \$23.7 million of charges for the three months ended September 30, 2009 and \$37.9 million of charges for the nine months ended September 30, 2009 for the costs related to the remediation of our Allston facility, including idle capacity and clean up expenses, as well as the write off of approximately \$8 million for the nine months ended September 30, 2009 for Cerezyme work-in-process material for which there were no comparable amounts for the same periods of 2008;
- the addition of sales of Fludara and Leukine and additional sales of Campath in the second quarter of 2009, all of which are lower margin products;
- \$17.7 million for the three months ended September 30, 2009 and \$24.4 million for the nine months ended September 30, 2009 for the amortization of inventory step-up of Campath, Fludara and Leukine, for which there were no comparable amounts in the same periods of 2008; and
- the increase in sales volume for Myozyme, Aldurazyme, and Elaprase, all of which are lower margin products.

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 for the three and nine months ended September 30, 2009 primarily due to increases in Carticel revenue and revenue from our reproductive and oncology diagnostic testing services.

Total service margin increased for the three and nine months ended September 30, 2009 primarily due to efficiencies resulting from prior period investments in our testing services processes and increased sales volume, attributable to both existing and new clients, for our reproductive and oncology diagnostic testing services.

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 September 30,		Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease) % Change		
	2009	2008		2009	2008			
Selling, general and administrative expenses	\$367,347	\$331,170	\$36,177	11%	\$1,039,436	\$996,861	\$42,575	4%
% of total revenue	35%	29%			30%	29%		

SG&A increased for the three and nine months ended September 30, 2009 primarily due to spending increases of:

- \$7.0 million for the three months ended September 30, 2009 and \$7.7 million for the nine months ended September 30, 2009 for Cardiometabolic and Renal, primarily due to increased sales and marketing expenses for the three months ended September 30, 2009 related to the Renvela and Hectorol 1mcg formulation launches and increased litigation expenses for Renagel/Renvela and Hectorol for the nine months ended September 30, 2009;
- \$2.5 million for the three months ended September 30, 2009 and \$7.9 million for the nine months ended September 30, 2009 for Biosurgery, primarily due to ongoing activities related to the Synvisc-One launch;
- \$12.7 million for the three months ended September 30, 2009 and \$28.2 million for the nine months ended September 30, 2009 for Hematologic Oncology, primarily due to legal costs and transition services related to our acquisition from Bayer and sales and marketing expenses to support the addition of Campath, Fludara and Leukine, sales force expansion to support the launch of Mozobil in the United States and its launch in Europe in the third quarter of 2009 and increased selling and marketing expenses for Clolar/Evoltra in Europe;
- \$9.1 million for the nine months ended September 30, 2009 for Other, primarily due to a \$13.4 million increase for the nine months ended September 30, 2009 for our genetics business unit, primarily due to personnel additions and maintenance costs related to an internally developed enterprise software system. This increase was offset in part by a decrease in spending of \$3.4 million for diagnostic products for the nine months ended September 30, 2009; and
- \$17.5 million for the three months ended September 30, 2009 and \$20.6 million for the nine months ended September 30, 2009 for Corporate, primarily due to an increase in litigation expense for the three months ended September 30, 2009 and increases in stock-based compensation and litigation expense for the nine months ended September 30, 2009.

These increases were partially offset by decreases of \$5.4 million for the three months ended September 30, 2009 and \$36.1 million for the nine months ended September 30, 2009 attributable to the weakening of foreign currencies against the U.S. dollar.

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 September 30,		Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease) % Change	Increase/ (Decrease) % Change	
	2009	2008		2009	2008			
Research and development expenses	\$219,275	\$305,242	\$(85,967)	(28)%	\$636,722	\$949,900	\$(313,178)	(33)%
% of total revenue	21%	26%			19%	28%		

Research and development expenses decreased for the three and nine months ended September 30, 2009 including a decrease of \$1.9 million for the three months ended September 30, 2009 and a decrease of \$12.1 million for the nine months ended September 30, 2009 due to the weakening of foreign currencies against the U.S. dollar, as well as:

- an \$88.4 million decrease in spending for the three months ended September 30, 2009 and a \$86.3 million decrease in spending for the nine months ended September 30, 2009 on our Genetic Diseases research and development programs, primarily due to charges of \$100.0 million recorded in July 2008 for a nonrefundable upfront payment to PTC related to our collaboration

agreement with PTC to develop and commercialize ataluren, for which there were no comparable amounts in 2009. This decrease was partially offset by \$7.0 million of charges for the three and nine months ended September 30, 2009 related to our transaction with Targeted Genetics Corporation in September 2009; and

- a \$246.3 million decrease in spending for the nine months ended September 30, 2009 on our Cardiometabolic and Renal research and development programs, primarily due to charges of \$69.9 million recorded in February 2008 and \$175.0 million recorded in September 2008 for a license fees paid to Isis for exclusive, worldwide rights to mipomersen, for which there were no comparable amounts for 2009.

These decreases were partially offset by spending increases of:

- \$12.8 million for the three months ended and \$21.9 million for the nine months ended September 30, 2009 on our Hematologic Oncology research and development programs, primarily due to a \$9.2 million increase in spending for the three months ended and a \$27.2 million increase in spending for the nine months ended September 30, 2009 for the development of alemtuzumab for MS. These increases were partially offset by decreases in expenses related to our Mozobil NDA submission for the three and nine months ended September 30, 2008, for which there were no comparable amounts for the same periods of 2009; and
- \$8.6 million for the nine months ended September 30, 2009 on research and development programs included under the category “Other,” primarily due to a payment of \$18.2 million to EXACT Sciences for the purchase of intellectual property in January 2009. This increase was partially offset by a decrease in spending for our immune mediated disease business unit for the three and nine months ended September 30, 2009.

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 September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
Amortization of intangibles . . .	\$71,280	\$55,295	\$15,985	29%	\$192,823	\$166,558	\$26,265	16%
% of total revenue	7%	5%			6%	5%		

Amortization of intangibles expense increased for the three and nine months ended September 30, 2009 primarily due to the acquisition of the worldwide marketing and distribution rights to the oncology products Campath, Fludara and Leukine from Bayer and 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. In addition, we also calculate amortization for the technology intangible assets for Fludara based on forecasted future sales of Fludara. As a result, we expect amortization of intangibles expense to fluctuate over the next five years based on the future contingent payments to Wyeth and Synpac, as well as changes in the forecasted revenue for Fludara.

Contingent Consideration Expense

The following table provides information regarding the change in contingent consideration expense during the periods presented (amounts in thousands):

	Three Months Ended September 30,		Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease) % Change	Increase/ (Decrease) % Change	
	2009	2008		2009	2008			
Contingent consideration expense	\$28,197	\$—	\$28,197	N/A	\$37,287	\$—	\$37,287	N/A
% of total revenue	3%				1%			

In June 2009, we recorded contingent consideration obligations totaling \$964.1 million for the estimated acquisition date fair value of the contingent royalty and milestone payments due to Bayer based on future sales and the successful achievement of certain sales volumes for Campath, Fludara and Leukine and for alemtuzumab for MS.

Any change in the fair value of the contingent consideration obligations subsequent to the acquisition date, including changes from events after the acquisition date, such as changes in our estimates of the sales volume for these products, will be recognized in earnings in the period the estimated fair value changes. The fair value estimates are based on the probability weighted sales volumes to be achieved for Campath, Fludara, Leukine and for alemtuzumab for MS over the earn-out period for each product. A change in the fair value of the acquisition-related contingent consideration obligations could have a material affect on our statement of operations and financial position in the period of the change in estimate.

As of September 30, 2009, the fair value of the total contingent consideration obligations was \$1.0 billion primarily due to changes in discount periods and management estimates. Accordingly, we recorded contingent consideration expenses totaling \$28.2 million for the three months ended and \$37.3 million for the nine months ended September 30, 2009 in our consolidated statements of operations to reflect the increase in the fair value.

Purchase of In-Process Research and Development

Prior to January 1, 2009, IPR&D acquired through a business combination was expensed on the acquisition date in our consolidated financial statements. Effective January 1, 2009, 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.

At the time of our acquisition from Bayer in May 2009, alemtuzumab for MS had not reached technological feasibility nor had an alternative future use and is therefore considered to be IPR&D. We recorded the fair value of the purchase price attributable to IPR&D as an indefinite-lived intangible asset on our consolidated balance sheet. We will test the asset annually for impairment, or earlier if conditions warrant. Amortization of this asset will begin upon regulatory approval based on the then estimated useful life of the asset.

Management assumes responsibility for determining the IPR&D valuation. The fair value assigned to purchased IPR&D was estimated by discounting, to present value, the cash flows expected to result from the project once it has reached technological feasibility. We used a discount rate of 16% and cash flows that have been probability-adjusted to reflect the risks of advancement through the product approval process, which we believe are appropriate and representative of a market participant assumption. In estimating future cash flows, we also considered other tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D project and adjusted future cash flows for a charge reflecting the contribution to value of these assets.

The following table sets forth the significant IPR&D projects for the companies and assets we acquired between January 1, 2006 and September 30, 2009 (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
Bayer (2009)	\$1,006.5	\$415.6	alemtuzumab for MS—US	16%	2012	\$349.5
		217.3	alemtuzumab for MS—ex-US	16%	2013	\$176.9
		<u>\$632.9(1)</u>				
Bioenvision (2007)	\$ 349.9	\$125.5(2)	Clolar/Evoltra (clofarabine)(3)	17%	2009-2014(4)	\$ 33.5
AnorMED (2006)	\$ 589.2	\$526.8(2)	Mozobil (stem cell transplant)(5)	15%	2009-2013(4)	\$ 22.1

(1) Capitalized as an indefinite-lived intangible asset.

(2) Expensed on acquisition date.

(3) Clofarabine, which is approved for the treatment of relapsed and refractory pediatric 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.

(4) Year of expected launch reflects both the ongoing launch of the products for currently approved indications and the anticipated launch of the products in the future for new indications. We are continuing to launch Clolar/Evoltra and Mozobil on a country-by-country basis as pricing and reimbursement approvals are obtained.

(5) Mozobil received marketing approval for use in stem cell transplants in the United States in December 2008 and in Europe in July 2009. Mozobil is also being developed for chemosensitization.

OTHER INCOME AND EXPENSES

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
	(Amounts in thousands)							
Losses on investments in equity securities, net	\$ (651)	\$(14,129)	\$13,478	95%	\$(1,332)	\$(4,201)	\$ 2,869	68%
Gain on acquisition of business	—	—	—	N/A	24,159	—	24,159	N/A
Other	616	(133)	749	>100%	(2,419)	940	(3,359)	>(100)%
Investment income	4,544	11,793	(7,249)	(61)%	14,038	40,015	(25,977)	(65)%
Interest expense	—	(792)	792	100%	—	(3,596)	3,596	100%
Total other income (expenses)	<u>\$4,509</u>	<u>\$(3,261)</u>	<u>\$ 7,770</u>	<u>>100%</u>	<u>\$34,446</u>	<u>\$33,158</u>	<u>\$ 1,288</u>	<u>4%</u>

Losses on Investments in Equity Securities, Net

We recorded the following losses on investments in equity securities, net of charges for impairment of investments, for the periods presented (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Gross gains (losses) on investments in equity securities	\$ (36)	\$(8,819)	\$ 422	\$ 2,398
Less: charges for impairment of investments	(615)	(5,310)	(1,754)	(6,599)
Losses on investments in equity securities, net	<u>\$(651)</u>	<u>\$(14,129)</u>	<u>\$(1,332)</u>	<u>\$(4,201)</u>

Gross gains (losses) on investments in equity securities for both the three and nine months ended September 30, 2008 includes a charge of \$10.0 million to write off the purchase price of an exclusive option to acquire equity in a private company as a result of our termination of the option agreement prior to the exercise deadline. Gross gains (losses) for the nine months ended September 30, 2008 also includes a gain of \$10.3 million recorded in the second quarter of 2008 resulting from the liquidation of our investment in the common stock of Sirtris for net cash proceeds of \$14.8 million.

Charges for impairment of investments for all periods presented represents the write down of our investments in certain venture capital funds to fair value at the end of each period.

At September 30, 2009, our stockholders' equity includes \$14.2 million of unrealized gains and \$0.2 million of unrealized losses related to our strategic investments in equity securities.

Gain on Acquisition of Business

We recorded a gain on acquisition of business of \$24.2 million for the nine months ended September 30, 2009 related to our acquisition of the worldwide rights to the oncology products Campath, Fludara, Leukine and alemtuzumab for MS from Bayer. The fair value of the identifiable assets acquired of \$1.03 billion exceeded the fair value of the purchase price for the transaction of \$1.01 billion.

Investment Income

Our investment income decreased for the three and nine months ended September 30, 2009 primarily due to a decrease in our average portfolio yield and lower average cash and investment balances.

Interest Expense

Our interest expense decreased for the three and nine months ended September 30, 2009 primarily due to the redemption of the \$690.0 million in principal of our 1.25% convertible senior notes on December 1, 2008.

PROVISION FOR INCOME TAXES

	Three Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change	Nine Months Ended September 30,		Increase/ (Decrease)	Increase/ (Decrease) % Change
	2009	2008			2009	2008		
	(Amounts in thousands)							
Provision for income taxes	\$522	\$60,512	\$(59,990)	(99)%	\$158,276	\$159,036	\$(760)	—
Effective tax rate	3%	34%			28%	32%		

Our effective tax rate for all periods presented 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;
- non-deductible stock-based compensation expenses totaling \$9.5 million for the three months ended and \$41.0 million for the nine months ended September 30, 2009, as compared to \$8.8 million for the three months ended and \$25.6 million for the nine months ended September 30, 2008; and

- \$2.1 million of tax credit benefits from the 2008 tax provision to tax return reconciliation and effective settlements of state tax audits.

In addition, our provision for income taxes includes income tax benefits of \$2.6 million for the three months ended and \$7.8 million for the nine months ended September 30, 2009. The income tax benefits for 2009 result from the reversal of a portion of our U.S. tax reserves due to a remeasurement of our uncertain income tax position liabilities based on new information arising in the second and third quarter of 2009.

We are currently under IRS audit for the tax years 2006 to 2007 and various states and foreign jurisdictions for various years. We believe that we have provided sufficiently for all audit exposures. We reasonably expect that our unrecognized tax benefits will decrease by approximately \$15 million within the next twelve months as we receive clarification of certain tax issues as a result of the audit process. Settlement of these audits or the expiration of the statute of limitations on the assessment of income taxes for any tax year will likely 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.

On May 4, 2009, U.S. President Barack Obama proposed significant changes to the U.S. international tax laws that would limit U.S. deductions for expenses related to un-repatriated foreign-source income and modify the U.S. foreign tax credit and “check-the-box” rules. We cannot determine whether these proposals will be enacted into law or what, if any, changes may be made to such proposals prior to their being enacted into law. If the U.S. tax laws change in a manner that increases our tax obligation, our results of operations could suffer.

LIQUIDITY AND CAPITAL RESOURCES

We continue to generate cash from operations. We had cash, cash equivalents and short-and long-term investments of \$988.9 million at September 30, 2009 and \$973.7 million at December 31, 2008.

The following is a summary of our statements of cash flows for the nine months ended September 30, 2009 and 2008:

Cash Flows from Operating Activities

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

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities:		
Net income	\$399,055	\$ 334,431
Non-cash charges, net	455,875	238,757
Increase (decrease) in cash from working capital changes (excluding impact of acquired assets and assumed liabilities)	<u>101,651</u>	<u>(139,123)</u>
Cash flows from operating activities	<u>\$956,581</u>	<u>\$ 434,065</u>

Cash provided by operating activities increased \$522.5 million for the nine months ended September 30, 2009, driven by a \$64.6 million increase in net income as a result of a decrease of \$277.3 million, net of tax, in payments for strategic transactions for the nine months ended September 30, 2009 as compared to the same period of 2008. Additionally, net income in the nine months ended September 30, 2009 was lower as a result of decreased Cerezyme and Fabrazyme revenue due to supply constraints following our temporary suspension of production at our Allston facility in June 2009.

Operating activities were also impacted by a \$240.8 million decrease in cash used for working capital and a \$217.1 million increase in non-cash charges, net. The increase in non-cash charges, net, for the nine months ended September 30, 2009, as compared to the same period of 2008, is primarily attributable to:

- a \$53.3 million increase in depreciation and amortization expenses;
- a \$13.0 million increase in stock-based compensation expense;
- a \$37.3 million contingent consideration expense related to the contingent consideration obligations recorded as a result of our acquisition from Bayer in May 2009; and
- a \$161.4 million decrease in the deferred income tax benefits.

These increases were offset, in part, by a \$24.2 million gain on acquisition of business recorded in June 2009 related to our acquisition of the worldwide rights to Campath, Fludara, Leukine and alemtuzumab for MS from Bayer.

Cash Flows from Investing Activities

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

	Nine Months Ended September 30,	
	2009	2008
Cash flows from investing activities:		
Net sales of investments, excluding investments in equity securities	\$ 92,710	\$ 29,736
Net purchases of investments in equity securities	(5,183)	(71,176)
Purchases of property, plant and equipment	(480,436)	(433,987)
Distributions from equity method investments	—	5,995
Acquisitions	(57,238)	(16,561)
Purchases of other intangible assets	(29,838)	(82,898)
Other investing activities	(7,096)	5,161
Cash flows from investing activities	<u>\$(487,081)</u>	<u>\$(563,730)</u>

For the nine months ended September 30, 2009, net purchases of capital expenditures accounted for significant cash outlays for investing activities. During the nine months ended September 30, 2009, we used \$480.4 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, France and Belgium, planned improvements at our Allston facility, the additional manufacturing capacity we are constructing in Framingham, Massachusetts and capitalized costs of an internally developed enterprise software system. In addition, we used \$57.2 million in connection with our acquisition of the worldwide rights to Campath, Fludara, Leukine and alemtuzumab for MS from Bayer. At closing, we paid a total of \$117.1 million to Bayer, of which \$74.6 million was refundable. The remaining non-refundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$59.8 million of the refundable amount was received in July 2009 and \$14.8 million remains due from Bayer as of September 30, 2009.

For the nine months ended September 30, 2008, investing activities used:

- \$80.1 million to purchase 5,000,000 shares of Isis common stock in February 2008;
- \$434.0 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, the United Kingdom, Belgium and France, the construction of a new research and development facility in

Framingham, Massachusetts, planned improvements at our facility in Allston, Massachusetts and capitalized costs of an internally developed enterprise software system for our genetics business unit;

- \$60.0 million in cash for a milestone payment to Wyeth in May 2008; and
- \$16.6 million in cash to settle the appraisal demand with substantially all of the Bioenvision dissenters in September 2008.

Cash Flows from Financing Activities

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

	Nine Months Ended September 30,	
	2009	2008
Cash flows from financing activities:		
Proceeds from the issuance of our common stock	\$ 76,125	\$ 294,603
Repurchases of our common stock	(413,874)	(143,012)
Excess tax benefits from stock-based compensation	3,309	17,470
Payments of debt and capital lease obligations	(5,908)	(5,281)
Increase (decrease) in bank overdrafts	(17,552)	20,889
Other financing activities	(5,237)	2,854
Cash flows from financing activities	<u>\$(363,137)</u>	<u>\$ 187,523</u>

Cash provided by financing activities decreased by \$550.7 million for the nine months ended September 30, 2009, primarily driven by a \$218.5 million decrease in proceeds from the issuance of our common stock due to fewer stock option exercises and a \$270.9 million increase in cash used to repurchase shares of our common stock under the stock repurchase program described below.

In May 2007, our board of directors authorized a stock repurchase program to repurchase 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. The board authorized the expenditure of up to \$1.5 billion to purchase those shares. 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 nine months ended September 30, 2009, we repurchased 7,500,000 shares of our common stock under this program at an average price of \$55.16 per share for a total of \$413.9 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 13,000,000 shares of our common stock at an average price of \$60.63 per share for a total of \$788.5 million in cash, including fees.

Revolving Credit Facility

As of September 30, 2009, we had approximately \$12 million of outstanding standby letters of credit and no borrowings, resulting in approximately \$338 million of available credit 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 September 30, 2009, we were in compliance with these covenants.

Contractual Obligations

As of September 30, 2009, we had committed to make the following payments under contractual obligations (amounts in millions):

Contractual Obligations	Payments Due by Period						
	Total	October 1, 2009 through December 31, 2009	2010	2011	2012	2013	After 2013
Long-term debt obligations(1)	\$ 23.5	\$ 0.1	\$ 1.6	\$ 1.6	\$ 1.7	\$ 1.8	\$ 16.7
Capital lease obligations(1)	153.6	3.9	15.5	15.5	15.5	16.8	86.4
Operating leases(1)	250.1	16.9	53.8	39.1	29.1	16.5	94.7
Contingent payments(2)	1,896.2	88.7	236.8	148.5	97.5	287.8	1,036.9
Interest obligations(3)	9.1	0.2	1.1	1.1	1.0	0.9	4.8
Defined pension benefit plans payments	19.7	0.3	1.2	1.3	1.5	1.7	13.7
Unconditional purchase obligations . .	175.9	14.6	56.4	56.4	48.5	—	—
Capital commitments(4)	1,092.8	194.5	537.0	246.8	114.5	—	—
Total contractual obligations	<u>\$3,620.9</u>	<u>\$319.2</u>	<u>\$903.4</u>	<u>\$510.3</u>	<u>\$309.3</u>	<u>\$325.5</u>	<u>\$1,253.2</u>

- (1) See Note L, “Long-term Debt and Leases” to our consolidated financial statements included in Exhibit 13 to our 2008 Form 10-K for additional information on long-term debt and lease obligations.
- (2) For all periods presented consists primarily of a total of \$1.88 billion of contingent royalty and milestone payments that we are obligated to pay to Bayer based on future sales and the successful achievement of certain sales volumes for Campath, Fludara and Leukine and alemtuzumab for MS.

Bayer is also eligible to receive a payment between \$75.0 million and \$100.0 million for a new Leukine manufacturing facility located in Lynnwood, Washington upon the facility receiving FDA approval, which is expected in 2011. We have not included any amounts for the contingent payments for this facility because we cannot be certain that the FDA will approve the facility or do so in the anticipated timeframe.

From time to time, as a result of mergers, acquisitions or license arrangements, we may enter into agreements under which we may be obligated to make contingent payments upon the occurrence of certain events, and/or royalties on sales of acquired products or distribution rights. The actual amounts for and the timing of contingent payments may depend on numerous factors outside of our control, including the success of our preclinical and clinical development efforts with respect to the products being developed under these agreements, the content and timing of decisions made by the United States Patent and Trademark Office, the FDA and other regulatory authorities, the existence and scope of third party intellectual property, the reimbursement and competitive landscape around these products, the volume of sales or gross margin of a product in a specified territory and other factors described under the heading “Risk Factors” below. Because we cannot predict with certainty the amount or specific timing of contingent payments, we have included amounts for contingent payments that we believe are probable of being paid in our contractual obligations table. See Note 6, “Strategic Transactions,” to our consolidated financial statements included in this Form 10-Q for additional information on our transaction with Bayer.

Contingent payments also exclude any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. Other noncurrent liabilities in our consolidated balance sheets includes approximately \$29 million

as of September 30, 2009 and approximately \$40 million as of December 31, 2008 of long-term liabilities associated with uncertain tax positions.

- (3) Represents interest payment obligations related to the promissory notes to three former shareholders of Equal Diagnostics, a company we acquired in 2005, and the mortgage payable we assumed in connection with the purchase of land and a manufacturing facility we formerly leased in Framingham, Massachusetts.
- (4) Consists of contractual commitments to vendors that we have entered into as of September 30, 2009 related to our outstanding capital and internally developed software projects. Our estimated cost of completion for assets under construction as of September 30, 2009 is as follows (amounts in millions):

<u>Location</u>	<u>Cost to Complete at September 30, 2009</u>
Framingham, Massachusetts, U.S (approximately 35% for software development)	\$ 520.5
Westborough, Massachusetts, U.S. (primarily software development)	128.6
Lyon, France	37.0
Geel, Belgium	57.9
Waterford, Ireland	42.3
Allston, Massachusetts, U.S.	134.3
Ridgefield, New Jersey, U.S.	5.5
Haverhill, United Kingdom	42.6
Other	124.1
Total estimated cost to complete	<u>\$1,092.8</u>

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 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;
- repurchasing the remaining 7,000,000 shares of our common stock available under our ongoing stock repurchase program;
- upgrading our information technology systems;
- expanding and maintaining existing and constructing additional manufacturing facilities, including investing significant funds to expand our Allston and Belgium facilities and to construct a new manufacturing facility for Cerezyme and Fabrazyme;
- implementing process improvements and system updates for our biologics manufacturing operations;
- 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, as well as contingent consideration obligations related to our acquisition of the worldwide rights to the oncology products Campath, Fludara and Leukine and alemtuzumab for MS from Bayer;

- 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 may not 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. Such entities are included in our consolidated statements of operations if we qualify as the primary beneficiary. Entities not subject to consolidation 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 “Other” in our consolidated statements of operations because the amounts are not material for all periods presented. We also acquire companies in which we agree to pay contingent consideration based on attaining certain thresholds.

Recent Accounting Pronouncements

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

Pronouncements	Relevant Requirements	Issued Date/ Our Effective Dates	Status
<i>FAS 166, “Accounting for Transfers of Financial Assets— an amendment of FASB Statement No. 140.”</i>	Improves the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets; the effects of a transfer on its financial position, financial performance and cash flows; and a transferor’s continuing involvement, if any, in transferred financial assets.	Issued June 2009. Effective for the first annual reporting period that begins after November 15, 2009.	It is anticipated that FAS 166 will primarily be incorporated into ASC 860, “Transfers and Servicing.” We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
<i>FAS 167, “Amendments to FASB Interpretation No. 46(R).”</i>	Improves financial reporting by enterprises involved with variable interest entities to provide more relevant and reliable information to users of financial statements.	Issued June 2009. Effective for the first annual reporting period that begins after November 15, 2009.	It is anticipated that FAS 167 will primarily be incorporated into ASC 810, “Consolidation.” We are evaluating the impact this pronouncement will have, if any, on our consolidated financial statements.

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. In addition, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements. We refer you to our “Cautionary Note Regarding Forward-Looking Statements,” which identifies forward-looking statements in this report. The risks described below are not the only risks we face. Additional risk and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business, financial condition or results of operations.

Manufacturing problems have caused inventory shortages and unanticipated costs and may do so in the future.

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 processing steps that are more difficult 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 from the normal process, 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 off 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. We also have had to write off work-in-process materials and incur other charges and expenses associated with a viral contamination at two of our facilities, which are described below. 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 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. For example, we manufacture all of our bulk Cerezyme and most of our bulk Fabrazyme products at our Allston facility and, in 2009, transitioned all of our larger scale bulk Myozyme production to our Belgium facility. In some cases, we contract out the manufacturing of our products to third parties, of which there are only a limited number capable of executing the manufacturing processes we require. A number of factors could cause production interruptions at our facilities or the facilities of our third party providers, including equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers.

In June 2009, we announced that we had detected a virus, Vesivirus 2117, that impairs cell growth in one of the bioreactors used at our Allston facility to produce Cerezyme. We believe the virus was likely introduced through a raw material used in the manufacturing process. We temporarily interrupted bulk production at the plant to sanitize the facility, which affected production of Cerezyme and Fabrazyme. Cerezyme and Fabrazyme inventories were not sufficient to meet global demand during the period of suspended production and restoration of operations. In 2009, we confirmed that Vesivirus

2117 was the cause of declines in cell productivity in one previous instance in 2008 at our Allston facility and one previous instance in 2008 at our Belgium facility. We were able to detect the virus in 2009 at our Allston facility using a highly specific assay we had developed after standard tests were unable to identify the cause of the productivity declines that occurred in 2008. We are in the process of adding steps to increase the robustness of our raw materials screening, process monitoring for viruses and viral removal processes, some of which steps could be subject to regulatory approval. However, given the nature of biologics manufacturing, contamination issues could occur in the future from time to time at our facilities and some of these issues could materially and adversely affect our operating results.

In connection with sanitizing our Allston facility and resuming production there, we were required to dismantle, reassemble and test all of our equipment in a short period of time. We also restarted production at Allston in more bioreactors and more quickly than is customary when we start production at a facility. The steps in successfully producing our biologic products are highly complex and in the normal course are subject to equipment failures and other production difficulties, such as cell growth at lower than expected levels. If we experience such difficulties, we may not be able to produce new Cerezyme and Fabrazyme within our expected timeframes or in the expected quantities. In addition, since resuming production at Allston, we have been processing bulk drug material in smaller batches, which leads to faster availability of final product but also leads to losses in process efficiency and lower overall volume.

The Cerezyme and Fabrazyme supply constraints resulting from the suspension of production at our Allston facility have created opportunities for our competitors.

Outside of the United States, Fabrazyme competes with Replagal[®], a product marketed by Shire plc. Shire has announced that the FDA has approved a treatment IND for Replagal and that it will support emergency IND requests. Shire also has announced its plans to file for U.S. approval of Replagal in the fourth quarter of 2009. With respect to Cerezyme, the FDA has approved a treatment IND for each of Protalix's and Shire's enzyme replacement therapies in development for the treatment of Gaucher disease. Both therapies are in phase 3 development. Shire has announced positive results from the final two phase 3 studies of its therapy and completed its submission of an NDA to the FDA. In addition, Shire has announced that it is engaging with national and regional authorities outside the United States to seek pre-approval access to its Gaucher therapy and has accelerated its manufacturing timeline by almost 18 months. Protalix also has announced positive results from a pivotal phase 3 study of its therapy. The FDA has granted "fast track" designation for both companies' NDAs and granted orphan drug status to Protalix's therapy. It is expected that Protalix will offer its therapy, if approved, at a significantly discounted price to Cerezyme.

The FDA's approval of treatment protocols for Protalix's and Shire's therapies allows physicians to treat Fabry and Gaucher disease patients with the therapies ahead of commercial availability in the United States. In addition, Zavesca[®] is currently approved in the United States for patients with Gaucher disease for whom enzyme replacement therapy is unsuitable. If Fabry patients decide to use Replagal or Gaucher patients decide to use one of our competitors' developmental therapies or Zavesca during the period of supply constraint, there is a risk that they may not switch back to Genzyme's products once inventories have stabilized, which would result in the loss of additional revenue for Genzyme. In addition, treatment guidelines and dose conservation for the products present the risk that physicians and patients do not resume regular treatment levels after the supply constraint has ended.

In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug. As a result of the Fabrazyme supply constraint, we received a request from the FDA's Office of Orphan Products Development in July 2009 to provide a

detailed explanation of the measures being taken to assure the availability of sufficient quantities of Fabrazyme within a reasonable time to meet the needs of patients. We also received the same request from the FDA in July 2009 with respect to Myozyme because of the limited supply of product produced using the 160L scale process in the United States. We have responded to the FDA's requests, but have not received any determination from the agency for either product. Fabrazyme currently has marketing exclusivity in the United States until April 2010 and Myozyme has exclusivity in the United States until April 2013, in each case due to its orphan drug status. We believe that orphan drug exclusivity is only one factor in the commercial success of our products. For example, these products may be protected by patents and other means. However, if the FDA were to withdraw exclusive approval for Fabrazyme or Myozyme, our competitors could have an opportunity to receive marketing approval in the United States for their products earlier than the current exclusivity expiration dates for Fabrazyme and Myozyme.

If the FDA believes that we have repeatedly violated GMP requirements, it could pursue enforcement action against us.

In a Form FDA 483 issued in October 2008 and in a follow up Warning Letter issued in February 2009, the FDA has detailed observations from its 2008 inspection of our Allston facility considered to be significant deviations from GMP compliance. As a follow up to the February Warning Letter, the FDA conducted an inspection of the Allston plant in May 2009. At the end of July 2009, the FDA informed us that its May inspection at Allston found all promised actions had not yet been fully implemented and that some actions were inadequate. In that same letter, the FDA informed us that it will re-inspect our Allston facility to verify that all corrective and preventative actions have been implemented and to evaluate our compliance. The FDA is now in the process of re-inspecting our Allston facility. In addition to verifying that we have responded appropriately to issues identified in the Warning Letter, we expect that the FDA will also review our Vesivirus 2117 contamination investigation and follow-up actions.

We have some Cerezyme material in inventory that was being processed at the time of suspension of production due to viral contamination at our Allston facility, although we have already discarded the majority of this Cerezyme work-in-process inventory. The FDA has communicated to us steps it recommends we take prior to forward processing any of the remaining Cerezyme work-in-process. The steps recommended by the FDA are consistent with the steps that we independently had planned to implement. The FDA also has stated that any further processing of the Cerezyme work-in-process is at our own risk. The remaining Cerezyme work-in-process material expires in mid-2010. If we decide to process the material, the FDA may not agree with our decision and could determine that processing of the material was not in compliance with GMP. In such case, the FDA could prevent us from releasing the material, require us to re-sanitize the Allston facility and/or pursue an enforcement action, including seeking a consent decree, if the FDA determines that we do not have adequate control over the manufacturing of our products due to our manufacturing issues.

FDA consent decrees often include reimbursements to the government for inspection costs, due dates for specific actions, and penalties for noncompliance. In connection with a consent decree, the FDA may dictate which products we can produce and the quantities of those products. The FDA may also appoint a third party to oversee our manufacturing operations under a consent decree. Consent decrees usually remain in effect for five years or more. If a consent decree were imposed, we would incur substantial additional expenses and may not be able to produce some or all of our products.

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 need to:

- conduct substantial research and development;
- undertake preclinical and clinical testing, sampling activity and other costly and time-consuming measures;
- develop and scale-up manufacturing processes; and
- pursue marketing and manufacturing 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
- 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 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.

In addition, 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 addressed negative safety signals. Clinical data are subject to varied interpretations, and regulatory authorities may disagree with our assessments of 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.

We are also developing new products, such as mipomersen, Prochymal and ataluren, through strategic alliances and collaborations. If we are unable to manage these external 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.

If we fail to increase sales of several existing products and services or to commercialize new products and services 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 Cerezyme, Renagel/Renvela, Synvisc/Synvisc-One, Fabrazyme, Myozyme, Aldurazyme, Thymoglobulin, Thyrogen, Clolar/Evoltra, Campath, Fludara, Leukine, Mozobil and diagnostic testing services.

Our ability to increase sales depends 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 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.

We expect regulatory action regarding several of our existing products in the coming months. Regulatory authorities denying or delaying these approvals would adversely impact our projected revenue and income growth. For example, we have encountered delays in receiving marketing approval in the United States for alglucosidase alfa produced using a 2000L scale process, which has adversely impacted our revenues and earnings as well as our ability to file for FDA approval for alglucosidase alfa produced using a 4000L scale process. The FDA is currently inspecting our Allston facility where alglucosidase alfa produced using the 2000L scale process was produced. If the inspection process takes longer than anticipated or if the inspection results in observations that cannot be addressed before our November 14, 2009 PDUFA date for the 2000L scale product, we may experience further delays in gaining FDA approval of the 2000L and 4000L scale products. We could face additional delays or supply constraints with this product or other products.

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 MS, 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. For example, we recently received a complete response letter from the FDA for Clolar's use in adult AML. The agency recommended a randomized, controlled clinical study be conducted for label expansion of Clolar in this indication. We intend to request a meeting with the FDA to discuss the optimal path forward.

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

The human healthcare products and services industry is extremely competitive. Other organizations, including pharmaceutical, biotechnology, device and diagnostic testing companies, and 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. As described under the heading “*Manufacturing problems may cause product launch delays, inventory shortages, recalls and unanticipated costs and create opportunities for our competitors,*” the virus at our Allston facility and associated production interruption, as well as the delay in our receipt of FDA approval of alglucosidase alfa produced at the 2000L scale, has provided new opportunities for our competitors that we did not anticipate.

Zavesca® is currently the only other marketed product aimed at treating Gaucher disease, the disease addressed by Cerezyme. Zavesca is a small molecule oral therapy that has been approved in the United States, European Union, Israel and six other countries for use in patients with mild to moderate Type 1 Gaucher disease for whom enzyme replacement therapy is unsuitable. Zavesca has been sold in the European Union since 2003 and in the United States since 2004. The FDA has approved a treatment IND for each of Protalix’s and Shire’s enzyme replacement therapies for the treatment of Gaucher disease, which allows physicians to treat Gaucher patients with the therapies ahead of commercial availability in the United States. In addition, Shire has submitted its NDA to the FDA and Protalix expects to complete its NDA submission before the end of 2009.

Replagal® is a competitive enzyme replacement therapy for Fabry disease, the disease addressed by Fabrazyme, that is approved for sale outside of the United States. In addition, while Fabrazyme has received orphan drug designation, which provides us with seven years of market exclusivity expiring in April 2010 for the product in the United States, the FDA has approved a treatment IND for Replagal, which allows physicians to treat Fabry patients with the therapy ahead of commercial availability in the United States. We are aware of a company that initiated a phase 3 clinical trial in June 2009 of an oral chaperone medication to treat 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.

Renagel/Renvela competes with several other products for the control of elevated phosphorus levels in patients with chronic kidney failure on hemodialysis, including PhosLo®, a prescription calcium acetate preparation marketed in the United States and Fosrenol®, a prescription lanthanum carbonate 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.

Current competition for Synvisc and Synvisc-One includes: Supartz®/ Artz®; Hyalgan®; Orthovisc®; Euflexxa™; Monovisc™, which is marketed in Europe and Turkey; and Durolane®, which is marketed in Europe and Canada. Durolane and Euflexxa are produced by bacterial fermentation, which may provide these products a competitive advantage over avian-sourced 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; Rituxan[®]/MabThera[®], which is marketed globally; and Treanda[®], which is marketed 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 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. In addition, there are anti-cancer agents in clinical trials for the treatment of relapsed pediatric ALL patients.

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.

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 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) in the United States, may from time-to-time make unilateral changes to reimbursement rates for our products and services. For example, the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, directs CMS to include payment for drugs and biologicals that are used to treat ESRD in the prospective payment system used to reimburse dialysis providers. In September 2009, CMS proposed changes to the prospective payment system that would, in accordance with MIPPA, include drugs and biologicals used to treat ESRD in the bundled payment amount for dialysis treatments. The bundled rate is proposed to include drugs and biologicals that are currently reimbursed separately by Medicare, including intravenous Vitamin D analogs and their oral equivalents such as Hectorol, and oral phosphate binders such as Renagel/Renvela. CMS is accepting comments on the proposed rule through November 16, 2009 and will issue a final rule in 2010 with an anticipated implementation date of January 2011. In addition, one of the healthcare reform bills being considered by Congress calls for the inclusion of certain oral drugs such as Renagel/Renvela as part of the ESRD bundled payment beginning in 2011. Changes to reimbursement rates 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. In addition, when a new product is approved, the availability of government and private reimbursement for that product is uncertain as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our product candidates.

The American Recovery and Reinvestment Act of 2009 provided significant funding for the federal government to conduct comparative effectiveness research. Although the U.S. Congress indicated that these studies are intended to improve the quality of health care, outcomes of such studies could influence reimbursement decisions. If, for example, any of our products or services were determined to be less cost-effective than alternatives, reimbursement for those products or services could be affected.

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 are spending considerable resources building and seeking regulatory approvals for our manufacturing facilities. These facilities may not prove sufficient to meet demand for our products or we may not have excess capacity at these facilities. For example, we have been operating with lower than usual inventories for Cerezyme and Fabrazyme because we had allocated capacity for Myozyme production at the Allston plant to meet Myozyme's worldwide growth. When we interrupted production of Cerezyme and Fabrazyme at the facility in June 2009 in order to sanitize the facility after identifying a virus in a bioreactor used to produce Cerezyme, inventories of Cerezyme and Fabrazyme were not sufficient to avoid product shortages during the period of suspended production and recovery. We are constructing a new manufacturing facility for Cerezyme and Fabrazyme in Framingham, Massachusetts, expanding our Allston facility, and adding an additional 4000L bioreactor to produce Myozyme at our Belgium facility. If we experience a delay in completing these capacity expansions or securing regulatory approval for the new capacity, we will not be able to build inventories in our expected timeframe.

Building our facilities is expensive, and our ability to recover these costs will depend on increased revenue from the products produced at the facilities. In addition, to maintain product supply and to adequately prepare to launch a number of our late-stage product candidates, we must successfully implement a number of manufacturing projects on schedule, operate our facilities at appropriate

production capacity, optimize manufacturing asset utilization, continue our use of third-party contract manufacturers and maintain a state of regulatory compliance.

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 2000L bioreactors is a different product than alglucosidase alfa produced in our 160 liter bioreactors and required us to submit a separate BLA for the 2000L product. This delay in receipt of FDA approval has had an adverse effect on our revenue and earnings, and will continue to have an adverse effect until we receive FDA approval of alglucosidase alfa produced in our 4000L bioreactors.

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.

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 cause similar fluctuations. In addition, some of our products, including Synvisc/Synvisc-One are subject to seasonal fluctuation in demand.

Our activities, products and services are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.

Products that have received regulatory approval for commercial sale are subject to extensive continuing regulations relating to, among other things, testing, manufacturing, quality control, labeling and promotion. Failure to comply with applicable regulatory requirements could result 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 manufacturing activities or product sales, imports 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 or seizing products; and
- criminal prosecution.

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 the therapy could prompt a regulatory authority to impose restrictions on us or delay approvals for new products or could cause us to voluntarily adopt restrictions, including withdrawal of one or more of our products or services from the market. In connection with a periodic facility inspection, we received a Warning Letter from the FDA in 2007 that addressed certain of our manufacturing procedures at our Thymoglobulin production facility in Lyon, France. The FDA 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 facility considered to be significant deviations from GMP. An FDA inspector inspected the plant in May 2009 as a follow up to the Warning Letter. At the end of July 2009, the FDA informed us that it will re-inspect our Allston facility to verify that all corrective and preventative actions identified in the February Warning Letter have been implemented. In its July letter, the FDA indicated that all promised actions had not been either fully or adequately implemented at the time of the May inspection. During the re-inspection, the FDA will also review our remediation efforts related to the identification of a virus at our Allston facility that required us to temporarily halt production there. If the FDA were to identify issues during its re-inspection, the FDA could be prompted to delay Lumizyme approval or impose restrictions on our production of Cerezyme and Fabrazyme at the facility.

In recent years, several states, including California, Vermont, Maine, Minnesota, Massachusetts, New Mexico and West Virginia, in addition to the District of Columbia, have enacted legislation requiring biotechnology and pharmaceutical companies to establish marketing compliance programs and file periodic reports on sales, marketing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and related regulations.

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. For example, we believe that a virus that we detected in one of our bioreactors used at our Allston facility to produce Cerezyme was likely introduced through a raw material used in the manufacturing process.

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 those 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, to recall products previously shipped or impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation. 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 available on a timely basis or at all.

Our financial results are dependent on sales of Cerezyme.

Sales of Cerezyme, our enzyme-replacement product for patients with Gaucher disease, totaled \$687.7 million for the nine months ended September 30, 2009, representing approximately 20% of our total revenue. Because our business is dependent on Cerezyme, negative trends in revenue from this product could have, and have had, an adverse effect on our results of operations and cause the value of our common stock to decline. In addition, we will lose revenue if alternative treatments gain commercial acceptance, if our marketing activities are restricted, or if coverage, pricing or reimbursement is limited. 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.

In June 2009, we temporarily suspended production of Cerezyme at our Allston facility after identifying a virus in a bioreactor used for producing Cerezyme, which has resulted in a period of supply constraint for the product. As a result of the supply constraint, the FDA has approved treatment protocols submitted by two companies developing alternative treatments for Gaucher disease. Approval of these treatment protocols allows physicians to treat Gaucher patients with these therapies ahead of commercial availability in the United States. There is a risk that if patients decide to use one of these developmental therapies, they may not switch back to Cerezyme when our inventories of the product have stabilized. In addition, treatment guidelines developed for Cerezyme during the supply constraint recommend missing doses or infusing less product. There is a risk that physicians and patients do not resume regular treatment levels after the supply constraint has ended.

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 anticipate when we decide 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 the acquired assets will enhance the long-term strength of our business. These transactions, however, often depress our earnings and our returns on capital 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, or require us to incur significant debt.

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;
- 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 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 revenue; however, this trend changed during the fourth quarter of 2008 and adversely impacted our revenue during the first nine months 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 revenue for the remainder of 2009.

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

Sales of our products and services 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 and service 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 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.

We are or may become a party to litigation or other proceedings in the ordinary course of our business. 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;
- 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 have initiated patent infringement litigation against several generic manufacturers. In addition we are the subject of two purported securities class action lawsuits and have received letters from alleged shareholders demanding that our board of directors take action on our behalf to remedy breaches of fiduciary duty by our directors and officers. We are also currently involved in other litigation matters and investigations 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, and third parties with whom we do business sometimes bring breach of contract 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 stocks 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 revenue for the nine months ended September 30, 2009. We expect that international product and service sales will continue to account for a significant percentage of our revenue for the foreseeable future. In addition, we have direct investments in a number of subsidiaries outside of the United States. 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, such policies and procedures may not 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, 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 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 Renagel, Renvela, Hectorol, Clolar, Mozobil, Cerezyme and Thyrogen 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 product by submitting a “Paragraph IV” certification in which the applicant claims that the innovator’s patent is invalid or will not be infringed by the manufacture, use, or sale of the generic product. 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 patents listed in the FDA’s Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative pharmaceuticals. We expect this trend to continue and to implicate drug products with even relatively modest revenues.

Renegel/Renvela and Hectorol are subjects of ANDA’s containing Paragraph IV certifications. Renegel is the subject of ANDA’s submitted by four companies and Renvela is the subject of ANDA’s submitted by two companies containing Paragraph IV certifications. We have initiated patent litigation against these ANDA applicants. At issue in the lawsuits are patents protecting Renegel and Renvela that expire in 2014. If we are unsuccessful in these lawsuits, a generic manufacturer may launch its generic product prior to the expiration of our Orange Book-listed patents covering Renegel and Renvela.

Our Hectorol injection product is the subject of ANDA’s submitted by four companies containing Paragraph IV certifications. We have initiated patent litigation against three of these ANDA applicants and are pursuing claims with respect to our patent related to the use of Hectorol to treat hyperparathyroidism secondary to end-stage renal disease, which expires in 2014 (the “2014 patent”). The fourth ANDA applicant submitted a paragraph IV certification with respect to only one patent, our patent that claims specific aspects of our Hectorol vial formulation and expires in 2023. We reviewed the Paragraph IV certification related to our vial formulation and did not initiate patent infringement litigation. Our Hectorol .5 mg and 2.5 mg capsule products are the subject of one ANDA containing a Paragraph IV certification with respect to our 2014 patent. This ANDA filer is seeking approval for its generic .5 mg capsule for use only in pre-dialysis patients, thus avoiding our patent. We expect the FDA to approve the applicant’s .5 mg product. We will continue to pursue patent litigation with respect to the applicant’s generic 2.5 mg capsule product. If we are unsuccessful in our patent infringement lawsuits against the ANDA filers, a generic manufacturer may launch its generic product prior to the expiration of our Orange-Book listed patents covering Hectorol.

Other of our products, including Fabrazyme, Aldurazyme, Myozyme, Campath and Leukine (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 revenue for that product would be adversely affected.

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

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 services and those of our competitors. Recommendations, guidelines or studies that are followed by patients and healthcare providers could result in decreased use of our products or services. The perception by the investment community or stockholders that recommendations, guidelines or studies will result in decreased use of our products or services 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 services and their uses. If these education efforts are not effective, then we may not be able to increase the sales of our existing products and services or successfully introduce new products and services to the market.

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. In addition, such changes could cause our stock price to decline or experience periods of volatility. 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. For example, the Centers for Medicare & Medicaid Services and the U.S. House of Representatives have proposed that Medicare payment for phosphate binders and vitamin D analogs be bundled into the packaged composite rate paid by Medicare to dialysis clinics as reimbursement for most of the dialysis-related services provided to Medicare patients. If these product classes are bundled into the composite rate as proposed, separate Medicare reimbursement will no longer be available for Renegel/Renvela or Hectorol.

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 or distribution of approved products.

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.

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

As of September 30, 2009, we had \$988.9 million in cash, cash equivalents and short- and long-term investments, excluding our investments in equity securities.

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

- product development and marketing;
- business combinations and strategic business initiatives;
- repurchasing the remaining 7,000,000 shares of our common stock available under our ongoing stock repurchase program;
- upgrading our information technology systems;
- expanding and maintaining existing and constructing new manufacturing facilities, including investing significant funds to expand our Allston and Belgium facilities and to construct a new manufacturing facility for Cerezyme and Fabrazyme;
- implementing process improvements and system updates for our biologics manufacturing operations;

- 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 as well as contingent consideration obligations related to our acquisition of the worldwide rights to the oncology products Campath, Fludara, Leukine and alemtuzumab for MS from Bayer;
- 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 may not 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

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 September 30, 2009, we held a number of financial instruments, including investments in marketable securities and derivative contracts in the form of foreign exchange forward contracts. We do not hold derivatives or other financial instruments for speculative purposes. There have been no material changes in our market risks during the nine months ended September 30, 2009 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2008.

ITEM 4. CONTROLS AND PROCEDURES

As of September 30, 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 September 30, 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 September 30, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Shareholder Demand Letters

Beginning in August 2009, we have received six letters from alleged shareholders demanding that our board of directors take action on our behalf to remedy breaches of fiduciary duty by our directors and officers. The demand letters are primarily premised on allegations that we made materially false and misleading disclosures and failed to disclose material information to shareholders with respect to manufacturing issues and compliance with GMP. Several of the letters also assert that certain of our officers and directors took advantage of their knowledge of material non-public information about Genzyme to illegally sell stock they personally held in Genzyme. Our board of directors has designated a special committee of three independent directors to oversee the investigation of the allegations made in the demand letters and to recommend to the independent directors of the board whether any action should be instituted on our behalf against any officer or director. The committee has retained independent legal counsel. If the independent members of our board of directors were to make a determination that it was in our best interest to institute an action against any officers or directors, any monetary recovery would be to our benefit.

Renagel and Renvela Patent Litigation Updates

As reported in our Form 10-Q for the quarter ended June 30, 2009, we received notices beginning in 2009 from Lupin Ltd. and Lupin Pharmaceuticals, collectively Lupin, and Impax Laboratories, Inc., or Impax, that each had submitted to the FDA abbreviated new drug applications, or ANDAs, containing Paragraph IV certifications seeking approval to market generic versions of Renagel (sevelamer hydrochloride) and Renvela (sevelamer carbonate).

Lupin had been seeking to market generic 400 mg and 800 mg sevelamer hydrochloride tablets and generic 800 mg sevelamer carbonate tablets prior to the expiration of all of our Orange Book-listed patents protecting Renagel and Renvela. In March 2009, we filed a complaint against Lupin in the U.S. District Court for the District of Maryland. In the complaint, we allege that Lupin's proposed sevelamer hydrochloride products infringe U.S. Patent Nos. 5,496,545, 6,509,013, and 7,014,846, which expire in 2013, and U.S. Patent No. 5,667,775, which expires in 2014 (the "'775 Patent"). Lupin filed an answer and counterclaim, alleging that our asserted patents are invalid and/or not infringed by Lupin's proposed generic sevelamer hydrochloride products. In May 2009, we filed a complaint against Lupin in the same court alleging that Lupin's proposed sevelamer carbonate product infringes U.S. Patent Nos. 5,496,545, 6,509,013, 6,858,203 and 7,014,846 and 7,459,151, which expire in 2013, and the '775 Patent. In September 2009, Lupin dismissed without prejudice all of its claims relating to the patents protecting Renagel and Renvela that expire in 2013 and at this time is challenging only the '775 Patent.

Impax is seeking to market generic 400 mg and 800 mg sevelamer hydrochloride tablets and generic 800 mg sevelamer carbonate tablets after the expiration of the patents protecting Renagel and Renvela that expire in 2013. We filed complaints against Impax in the U.S. District Court for the District of Maryland for patent infringement with respect to Renagel in March 2009 and with respect to Renvela in April 2009. In both complaints, we allege that Impax's proposed sevelamer products infringe the '775 patent. Impax filed an answer and counterclaim with respect to both suits. In its counterclaim, Impax alleges that the '775 Patent and U.S. Patent No. 6,773,780, which expires in October 2020 (the "'780 Patent") are invalid and/or not infringed by Impax's proposed generic sevelamer products. In September 2009, Impax dismissed its claim relating to the '780 Patent.

We also are subject to other legal proceedings and claims arising in connection with our business. Although we cannot predict the outcome of these proceedings and claims, we do not believe that the

ultimate resolution of any of these existing matters would have a material adverse effect on our consolidated 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 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 September 30, 2009:

<u>Period</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs</u>
July 1, 2009-July 31, 2009	—	—	—	\$1,018,427,338
August 1, 2009-August 31, 2009	500,000	\$55.50	500,000	\$ 990,679,488
September 1, 2009-September 30, 2009	5,000,000	\$55.78	5,000,000	\$ 711,797,363
Total	<u>5,500,000(1)</u>	<u>\$55.75(2)</u>	<u>5,500,000</u>	

- (1) In May 2007, our board of directors authorized a stock repurchase program to repurchase 20,000,000 shares of our outstanding common stock over a three year period that began in June 2007. The board authorized the expenditure of up to \$1.5 billion to purchase those shares. During the third quarter of fiscal 2009, we repurchased 5,500,000 shares of our common stock under this program for \$306.7 million of cash, including fees.
- (2) Represents the weighted average price paid per share for repurchases of our common stock made during the third quarter of fiscal 2009.

ITEM 6. EXHIBITS

- (a) Exhibits

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

GENZYME CORPORATION AND SUBSIDIARIES

FORM 10-Q, SEPTEMBER 30, 2009

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
*3.1	Restated Articles of Organization of Genzyme, as amended. Filed as Exhibit 3.1 to Genzyme's Form 10-Q for the quarter ended June 30, 2006.
*3.2	By-laws of Genzyme, as amended. Filed as Exhibit 3.1 to Genzyme's Form 8-K filed May 25, 2007.
10.1	2007 Director Equity Plan, as amended. Filed herewith.
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.
101.INS	XBRL Instance Document. Furnished herewith.
101.SCH	XBRL Taxonomy Extension Schema. Furnished herewith.
101.CAL	XBRL Extension Calculation Linkbase. Furnished herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase. Furnished herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase. Furnished herewith.

* Indicates exhibit previously filed with the SEC and incorporated herein by reference. Exhibits filed with Forms 10-Q and 8-K of Genzyme Corporation were filed under Commission File No. 0-14680.

**Certification Pursuant to
Rules 13a-14(a) and 15d-14(a) Under The Securities Exchange Act of 1934, as Amended**

I, Henri A. Termeer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genzyme Corporation (the “Registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
5. The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal controls over financial reporting.

Date: November 2, 2009

/s/ HENRI A. TERMEER

Henri A. Termeer
Chief Executive Officer

**Certification Pursuant to
Rules 13a-14(a) and 15d-14(a) Under The Securities Exchange Act of 1934, as Amended**

I, Michael S. Wyzga, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genzyme Corporation (the “Registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
5. The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal controls over financial reporting.

Date: November 2, 2009

/s/ MICHAEL S. WYZGA

Michael S. Wyzga
Chief Financial Officer

**Certification by the Chief Executive Officer Pursuant to
18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. Section 1350, I, the undersigned Chief Executive Officer of Genzyme Corporation (the "Company"), hereby certify that the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2009 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ HENRI A. TERMEER

Henri A. Termeer
Chief Executive Officer
November 2, 2009

**Certification by the Chief Financial Officer Pursuant to
18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. Section 1350, I, the undersigned Chief Financial Officer of Genzyme Corporation (the “Company”), hereby certify that the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2009 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL S. WYZGA

Michael S. Wyzga
Chief Financial Officer
November 2, 2009