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Committed to patients
and performance.

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Washington, DC 20549



On the cover: Rubén is a Gaucher disease patient in his mid-30s who lives in Buenos Aires, Argentina, and participates in a phase 2 clinical trial of the small-molecule drug eliglustat tartrate. Until recently, Rubén was having trouble moving and was out of work. Now he has found a job as a construction worker.

This page: Doctors diagnosed Amer, a 9-year-old from Magar, Israel, with Pompe disease when he was three months old. Early diagnosis due to family history of the disease led to early treatment. A Myozyme patient since he was nine months old, Amer loves riding his bicycle and studying martial arts.

Genzyme is a leading biotechnology company with a diverse portfolio of important, market-leading therapies, a strong global presence and an exciting pipeline of potentially breakthrough treatments.

Guided by a deep commitment to patients and performance, we met the challenges of 2009 by accelerating efforts to increase capacity, reduce risk, bolster our team and emerge a stronger, more competitive company.

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To our shareholders:

Genzyme develops and delivers breakthrough, quality medicines for patients around the world. By fulfilling this purpose, we create value for you, our shareholders. The operational improvements and organizational changes we are implementing are making us a stronger company. We expect to resume our growth in 2010.

Moving Forward, Regaining Momentum

Last year was the most challenging in our 28-year history. Setbacks in our manufacturing operations hindered our ability to fully supply Cerezyme and Fabrazyme, two of our largest products. As a result, we did not meet our commitment to patients or to shareholders. We take responsibility for the challenges we faced in 2009, and we have made enormous progress in implementing a series of actions to help ensure that we never face these kinds of issues again.

Last year's events overshadowed our historical record of revenue and earnings growth. Over the past decade, our market-leading products generated 19 percent compounded annual revenue growth. We are now in a recovery period, and we expect to get back to delivering sustainable growth this year, while making the investments necessary to strengthen core areas of the company.

Our expansion over the next five years will be driven by our broad portfolio of products, most of which are still in their growth phases. We are maximizing the commercial potential of these products and ensuring they reach patients through our global sales and regulatory infrastructure. In addition, we expect that several products in our late-stage pipeline, notably alemtuzumab for multiple sclerosis, will come to the market in this period and drive further growth.

Diversification Makes Us Stronger

The benefits of our long-term strategy to diversify the company were more apparent in 2009 than ever before. Despite the supply interruption in our Genetic Diseases business segment, we remained profitable and generated cash flow from operating activities of \$1.2 billion. This was possible because of significant revenue growth in all of our other business segments, which grew 24 percent in the fourth quarter and 15 percent for the year, driven by the launch, acquisition and integration of new products:

- Synvisc-One was approved in the U.S. in early 2009 and has quickly become a growth driver for us. The product gained rapid acceptance by patients and physicians because of its convenience: it is the only single-injection viscosupplement for osteoarthritic knee pain. Synvisc-One drove a 25 percent increase in total Synvisc product sales in 2009, and strong growth is anticipated again in 2010 as the product captures market share and also reaches a broader set of patients.
- Mozobil was launched in the U.S. and in Europe last year. Sales exceeded expectations, as physicians quickly adopted the product for its ability to help prepare patients with non-Hodgkin's lymphoma or multiple myeloma to undergo a stem cell transplantation procedure. Mozobil holds exciting potential to help patients with other types of cancer, and we are making the investments in clinical research to realize this promise.

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

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Section

FORM 10-K

APR 27 2010

(Mark One)

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

Washington, DC
110

For the fiscal year ended December 31, 2009

Or

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

For the transition period from _____ to _____

Commission File No. 0-14680

GENZYME CORPORATION

(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction of
incorporation or organization)

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

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

02142
(Zip Code)

(617) 252-7500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of each exchange on which registered

Genzyme Common Stock, \$0.01 par value
("Genzyme Stock")

The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Aggregate market value of voting stock held by non-affiliates of the Registrant as of June 30, 2009: \$14,983,965,792.

Number of shares of Genzyme Stock outstanding as of January 29, 2010: 266,100,031

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Annual Meeting of Shareholders scheduled to be held on May 20, 2010, are incorporated by reference into Part III of this Form 10-K.

NOTE REGARDING REFERENCES TO GENZYME

Throughout this Form 10-K, 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-K contains forward-looking statements. These forward-looking statements include, among others, statements regarding:

- our expectations for creating an inventory buffer for Cerezyme and regarding Fabrazyme supply and a new working cell bank for Fabrazyme;
- our plans to increase bulk and fill-finish manufacturing capacity for Cerezyme, Fabrazyme and Myozyme and the expected timing of completion of these activities and receipt of regulatory approvals;
- our expectations regarding timing of regulatory approval for our new facility to manufacture Thymoglobulin and a new Leukine manufacturing facility;
- our expectations regarding Myozyme/Lumizyme revenues;
- our expectations for sales of Renagel/Renvela and the anticipated factors affecting the future growth of these products, including the proposed rule to establish a bundled payment system to reimburse dialysis providers;
- our expectations regarding the financial impact of production interruption at our Haverhill, England manufacturing facility, and the expected timing of new sevelamer hydrochloride and sevelamer carbonate production;
- our assessment of competitors and potential competitors and the anticipated impact of potentially competitive products and services, including generic competition, on our revenues;
- our estimates of the cost to complete our research and development programs and the estimated timetables for clinical trials, regulatory filings, product approvals and product launches for existing products for use in new indications and for next-generation or new products, including eliglustat tartrate (formerly GENZ-112638), alemtuzumab for the treatment of multiple sclerosis, or MS (which we refer to as alemtuzumab for MS), mipomersen, Mozobil, ataluren, Campath and Clolar;
- 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;
- the protection afforded by our patent rights;
- our expectations regarding our ability to comply, and the cost to comply, with laws and regulations;
- 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 any reason, including mechanical failures, viral or bacterial contamination, cell growth at lower than expected levels, fill-finish issues, or regulatory issues;
- the possibility that we may be unable to produce new sevelamer hydrochloride and/or new sevelamer carbonate at our Haverhill, England facility in the expected time frames due to production problems or regulatory issues;
- the extent to which Gaucher and Fabry disease patients switch to competitors' products in place of Cerezyme or Fabrazyme or continue to reduce their doses of our products even after product supply stabilizes;
- our ability to maintain regulatory approvals for our products, services and manufacturing facilities and processes including our Allston facility; and to obtain approvals in the anticipated timeframes, including United States Food and Drug Administration, or FDA, approval of alglucosidase alfa produced at the 4000L scale, new manufacturing capacity and proposed changes to enhance our manufacturing processes;
- 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 new or current 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;
- 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 obtain and maintain adequate patent and other proprietary rights protection for our products and services and successfully enforce these proprietary rights;
- our reliance on third parties to provide us with materials and services in connection with the manufacture of our products;

- the accuracy of our estimates of the size and characteristics of the markets to be addressed by our products and services, including growth projections;
- market acceptance of our products and services in expanded areas of use and new markets;
- our ability to successfully identify and market our products and services to new patients;
- our ability to 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 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 II, Item 7 of this Form 10-K. 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-K. These statements, like all statements in this Form 10-K, 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-K. Please read that information.

NOTE REGARDING TRADEMARKS

Genzyme®, Cerezyme®, Ceredase®, Fabrazyme®, Thyrogen®, Myozyme®, Renagel®, Renvela®, Campath®, MabCampath®, Clolar®, Evoltra®, Mozobil®, Thymoglobulin®, Cholestagel®, Synvisc®, Synvisc-One®, Septra®, Seprafilm®, Sepramesh®, Sepraspray®, Hylaform®, Carticel®, Epicel®, MACI® and Hectorol® are registered trademarks, and Lumizyme™ and Jonexa™ are trademarks, of Genzyme or its subsidiaries. WelChol® is a registered trademark of Sankyo Pharma, Inc. Aldurazyme® is a registered trademark of BioMarin/Genzyme LLC. Elaprase® is a registered trademark of Shire Human

Genetic Therapies, Inc. Prochymal® and Chondrogen® are registered trademarks of Osiris Therapeutics, Inc. Fludara® and Leukine® are registered trademarks licensed to Genzyme. All other trademarks referred to in this Form 10-K are the property of their respective owners. All rights reserved.

NOTE REGARDING REFERENCES TO THE CODIFICATION

In June 2009, the Financial Accounting Standards Board, or FASB, issued the FASB Accounting Standards Codification™, or ASC. Effective July 1, 2009, the ASC became the single source for all authoritative generally accepted accounting principles, or U.S. GAAP, recognized by the FASB and is required to be applied to financial statements issued for interim and annual periods ending after September 15, 2009. We adopted this guidance in the third quarter of 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; however the ASC does change the way we refer to U.S. GAAP within our financial statements.

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PART I

Item 1. Business

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. We were formed as a Delaware corporation in 1981 and became a Massachusetts corporation in 1991.

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, Aldurazyme and Elaprase.
- 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 and the Septra line of products.
- Hematologic Oncology, which develops, manufactures and distributes products for the treatment of cancer and the mobilization of hematopoietic stem cells. This business is also developing a product for the treatment of MS. The unit derives substantially all of its revenue from sales of Clolar, Mozobil, Campath, Fludara and Leukine.

We report the activities of the following business units under the caption "Other": 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; our genetics business unit, which provides testing services for the oncology, prenatal and reproductive markets; and our diagnostic products, bulk pharmaceuticals and immune mediated disease business units.

Products and Services

Genetic Diseases

Our Genetic Diseases segment derives substantially all of its revenue from the following therapeutic products:

<u>Product</u>	<u>Indication</u>	<u>Approvals</u>
Cerezyme/Ceredase	Type 1 Gaucher disease; Type 3 Gaucher disease (Cerezyme/European Union only)	Ceredase sold commercially since 1991; Cerezyme marketed since 1994; marketing approval received in over 60 countries and commercial sales in over 55 countries.
Fabrazyme	Fabry disease	Marketed since 2001; marketing approval received in over 50 countries and commercial sales in approximately 40 countries; several post-marketing commitments on-going in the United States.
Myozyme	Pompe disease	Marketed since 2006; marketing approval received in approximately 45 countries and commercial sales in approximately 30 countries; several post-marketing commitments ongoing.
Aldurazyme	Mucopolysaccharidosis I (MPS I)	Marketed since 2003; marketing approval received in over 50 countries and commercial sales in approximately 40 countries; several post-marketing commitments on-going.
Elaprase	Mucopolysaccharidosis II (MPS II)	Rights to commercialize the product in Japan and other Asia Pacific countries under an agreement with Shire Human Genetic Therapies Inc., or Shire; marketing approval received in 3 countries.

Cerezyme, Fabrazyme, Myozyme, Aldurazyme and Elaprase are each aimed at treating LSDs with patient populations of less than 10,000 worldwide. We market and sell these products directly to physicians, hospitals, treatment centers, pharmacies and government agencies worldwide through a specialized sales force. Sales are also made through distributors or wholesalers. Additional details on these products are set forth below.

Cerezyme (imiglucerase). We are marketing Cerezyme as an enzyme replacement therapy for the treatment of Gaucher disease, an LSD that can be life-threatening and that is caused by a deficiency in the enzyme glucocerebrosidase. This deficiency causes fatty deposits to build up in certain organs and bones leading to a wide variety of symptoms, including anemia, spleen and liver enlargement and bone deterioration. Treatment with Cerezyme enzyme replacement therapy currently represents the only safe and effective enzyme replacement therapy approved for treatment of Type 1 Gaucher disease. In the European Union, Cerezyme is also approved for the treatment of patients who exhibit clinically significant, non-neurological manifestations of the disease (Type 3 Gaucher disease).

Our results of operations are highly dependent on sales of Cerezyme, although our dependence is lessening as we diversify our product portfolio. Sales of Cerezyme totaled \$793.0 million, or 18% of our total revenues in 2009; \$1.2 billion, or 27% of our total revenue in 2008; and \$1.1 billion, or 30% of our total revenue in 2007. Cerezyme revenues in 2009 reflect the temporary shutdown of our Allston, Massachusetts manufacturing facility, which we refer to as our Allston facility, due to a rare virus. In June 2009, we interrupted production of Cerezyme at this facility after identifying Vesivirus 2117 in a bioreactor used for Cerezyme production. This virus, which impairs the viability of cells used in the manufacturing process, is not known to cause infection in humans. We completed sanitization of our Allston facility and resumed production there in the third quarter of 2009. Cerezyme inventories were not sufficient to avoid shortages, and we resumed Cerezyme shipments in November 2009. In late December 2009, we began shipping vials of Cerezyme on a per-infusion basis to patients around the

world that experienced a treatment interruption in 2009. To more consistently manage the resupply of Cerezyme to patients in approximately 100 countries and reduce interruptions in shipping that occur in the absence of inventory, we are working to build a small inventory buffer. To build this inventory buffer, we intend to ship at 50 percent of demand for an eight-week period beginning February 22, 2010.

Enrollment has begun in two phase 3 studies of eliglustat tartrate (formerly Genz-112638), an oral therapy that could provide an additional treatment option for patients with Gaucher disease.

Fabrazyme (agalsidase beta). We developed Fabrazyme, a recombinant form of the human enzyme alfa-galactosidase, as a treatment for Fabry disease. Fabry disease is an LSD that is caused by a deficiency of the enzyme alfa-galactosidase A, which leads to the progressive accumulation of lipids within cells of the kidneys, heart and other organs. In early 2008, the European Medicines Agency, or EMA, granted full marketing authorization for Fabrazyme, making it the only product on the market for Fabry disease to earn this designation in the European Union. Because kidney failure is associated with Fabry disease, Fabrazyme is sold by our existing sales forces for our LSD and renal products.

Sales of Fabrazyme totaled \$429.7 million, or 10% of our total revenue in 2009; \$494.3 million, or 11% of our total revenue in 2008; and \$424.3 million, or 11% of our total revenue in 2007. Fabrazyme revenues in 2009 reflect the temporary shutdown of our Allston facility due to viral contamination. As with Cerezyme, inventories of Fabrazyme were insufficient to avoid shortages, and we resumed shipments of vials of Fabrazyme in early January 2010. We have been shipping Fabrazyme to meet approximately 30% of global demand, and anticipate continuing to ship at this level through May 2010. We are working to increase the productivity of the Fabrazyme manufacturing process, which has performed at the low end of the historical range since the re-start of production. We have developed a new working cell bank for Fabrazyme and production is underway at the 2000L scale. Pending regulatory approval, output from this process is expected starting in June 2010. If this change is successful, we anticipate that sufficient supply will become available to enable higher dosing for patients on Fabrazyme. Orphan drug status for Fabrazyme, which provided us with exclusive marketing rights for Fabrazyme in the United States for seven years, expires in April 2010.

Myozyme (alglucosidase alfa). We are marketing Myozyme as a therapy for Pompe disease, a progressive, debilitating and often fatal muscle disease resulting from an inherited deficiency of the enzyme alfa-glucosidase. Pompe disease is an LSD that manifests as a broad spectrum of clinical symptoms, with variable rates of progression ranging from rapidly progressive and often fatal within the first year of life to relentlessly progressive resulting in significant morbidity and premature mortality. Myozyme is the first and only treatment approved for Pompe disease and is indicated for all patients with the disorder. Myozyme specifically targets the underlying cause of Pompe disease by replacing the enzyme that is absent or deficient.

We have approval to sell Myozyme that is manufactured using a 160L bioreactor scale process in the United States. The product produced using the 160L scale process has been reserved for infants and children because the smaller scale produces a limited supply of FDA-approved product for the U.S. market. In 2008 and 2009, we had been seeking marketing approval in the United States of alglucosidase alfa produced using a 2000L scale process, which we refer to as Lumizyme in the United States. In November 2009, we received a complete response letter from the FDA regarding our application to produce at the 2000L scale stating that satisfactory resolution of deficiencies related to our Allston facility were required before the Lumizyme application could be approved. We no longer manufacture the product alglucosidase alfa at the 2000L scale. Based on subsequent conversations with the FDA, we decided to seek approval of the product produced using a 4000L bioreactor scale process, which will also be known as Lumizyme in the United States. We submitted an amendment to the 2000L BLA to the FDA in December 2009, which the FDA has assigned a June 17, 2010 action date under the Prescription Drug User Fee Act, or PDUFA. We have provided alglucosidase alfa free of charge to approximately 180 patients since 2007 under a temporary access program and in December 2009, agreed with the FDA to work with the 81 active study sites in the United States to enroll additional

patients into this program. We plan to keep open the temporary access program until commercial approval of 4000L Lumizyme in the United States.

In Europe, we received approval for the 4000L scale process in February 2009 and, as of the first quarter of 2010, the majority of markets outside of the United States have transitioned to the 4000L product.

Aldurazyme (laronidase). In 1998, we formed a joint venture with BioMarin Pharmaceutical Inc., or BioMarin, to develop and market Aldurazyme, a recombinant form of the human enzyme alfa-L-iduronidase, to treat an LSD known as MPS I. MPS I is a progressive, debilitating and often life-threatening disease that encompasses a wide and continuous spectrum of clinical presentations, historically classified as “Hurler,” “Hurler-Scheie” and “Scheie” syndromes.

BioMarin/Genzyme LLC, the joint venture entity, licenses all intellectual property relating to Aldurazyme on a royalty-free basis to BioMarin and us. BioMarin holds the manufacturing rights and we hold the global marketing rights for Aldurazyme. We pay BioMarin a tiered payment ranging from 39.5% to 50% of worldwide net product sales of Aldurazyme.

Elaprase (idursulfase). Elaprase is an enzyme replacement therapy developed by Shire for the treatment of MPS II, also known as Hunter syndrome. Hunter syndrome is a serious progressive genetic disorder, caused by a deficiency or absence of the lysosomal enzyme iduronate-2-sulfatase (I2S), that affects boys almost exclusively. Elaprase treats the underlying cause of Hunter syndrome by replacing the deficient or absent I2S enzyme. We have rights to commercialize the product in Japan and other Asia Pacific countries under an agreement with Shire. We pay Shire a profit sharing payment based on net product sales of Elaprase in our territories.

Cardiometabolic and Renal

Our Cardiometabolic and Renal segment derives substantially all of its revenue from the following products:

Product	Indication(s)	Status
Sevelamer products (Renagel and Renvela)	Control of serum phosphorus in patients with chronic kidney disease, or CKD, on dialysis. In European Union, Renvela also indicated for CKD patients not on dialysis with a serum phosphorous Level 1 ≥ 1.78 mmol/l	Renagel marketed since 1998 and Renvela since 2007; Renagel marketing approval received in over 60 countries and Renvela marketing approval received in approximately 35 countries; commercial sales of sevelamer products in over 60 countries.
Hectorol	Secondary hyperparathyroidism in patients with stages 3 and 4 CKD and patients with stage 5 CKD	Marketed in the United States since 1999; approved in Argentina, Colombia and Trinidad & Tobago in 2009 with commercial sales in two of those countries.
Thyrogen	Adjunctive diagnostic agent used in follow up of patients with well-differentiated thyroid cancer Adjunctive treatment for ablation or destruction of thyroid remnants in patients who have had thyroid removed for the treatment of well-differentiated thyroid cancer	Marketed for this indication since 1998. Marketed for this indication since 2005.

Additional details on these products are set forth below.

Renagel (sevelamer hydrochloride)/Renvela (sevelamer carbonate). Renagel and Renvela are non-absorbed, calcium-free, metal-free phosphate binders for the control of serum phosphorus. Renagel, which is indicated for the treatment of hyperphosphatemia in patients with CKD on dialysis, has been marketed since 1998 and is available in 400mg and 800mg tablets. Renvela is a second generation, buffered form of sevelamer. In March 2008, we launched Renvela for dialysis patients in the United States. In June 2009, the European Commission approved Renvela for the control of serum phosphorous in patients with CKD on dialysis and those not on dialysis with serum phosphorous levels greater or equal to 1.78 mmol/L (5.5mg/dL). Renvela is available as 800mg tablets and as a powder formulation. The powder formulation was approved in the United States and European Union in 2009. In the United States, there are an estimated 393,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are also an estimated 350,000 dialysis patients in Europe, 65,000 in Brazil, 20,000 in Canada and 260,000 in Japan.

In October 2007, an FDA advisory committee voted to recommend that the agency extend the indications for phosphate binder use to patients with hyperphosphatemia who have not progressed to dialysis. We have been in discussions with the FDA regarding the treatment of hyperphosphatemic CKD patients not on dialysis. We will continue discussions with the FDA regarding the treatment of hyperphosphatemic CKD patients not on dialysis, however, we cannot provide an anticipated timeframe for a potential label expansion.

We market our sevelamer therapies in the United States, Europe, Canada, Latin America and Australia directly to nephrologists through a dedicated sales force. In the United States, approximately 85%—90% of our Renagel/Renvela sales are made to three large wholesalers. These wholesalers distribute Renagel/Renvela to retail pharmacies, hospitals and other providers of medication to patients. Chugai Pharmaceutical Co., Ltd. and its partner, Kyowa Hakko Kirin Co., Ltd., have rights to develop and market Renagel in Japan, China and other Pacific Rim countries.

Our sales of Renagel/Renvela (including sales of bulk sevelamer) totaled \$706.6 million, or 16% of our total revenue in 2009; \$677.7 million, or 15% of our total revenue in 2008; and \$602.7 million, or 16% of our total revenue in 2007.

In December 2008, we filed an investigational new drug application, or IND, for our advanced phosphate binder, Genz-644470. However, in November 2009, we discontinued this program because the results of a phase 2/3 clinical study of the advanced phosphate binder did not demonstrate significant improvement in phosphate lowering compared to Renvela.

Hectorol (doxercalciferol). Hectorol is a vitamin D₂ pro-hormone product indicated for the treatment of secondary hyperparathyroidism in patients with stages 3 and 4 CKD (0.5 mcg and 1.0 mcg capsules) and in patients with stage 5 CKD on dialysis (2.5 mcg capsules and injection). Hectorol provides significant parathyroid hormone, or PTH, reductions with minimal impact on calcium and phosphorus levels. In 2009, we launched a customer-preferred vial container to replace the ampule formulation in the United States. We have also filed marketing applications for Hectorol in Brazil, Chile, Israel and Mexico.

We market Hectorol in the United States through a direct sales force focused on nephrologists. Approximately 85%—90% of our U.S. Hectorol capsule sales are made to three large wholesalers, who then sell and distribute the product to retail pharmacies, hospitals and other providers of medication to patients. For Hectorol IV, approximately 85%—90% of our sales are made to three primary wholesalers who then sell and distribute the product to dialysis chains and hospitals. In the United States, approximately 70% of end-stage renal disease patients receive vitamin D. We estimate that there are between 2.0 million and 4.7 million individuals in the United States with stages 3, 4 and 5 CKD who have elevated PTH levels, although only a much smaller number of patients are being treated for the condition.

In 2007, Genzyme filed an IND for the use of Hectorol in psoriasis patients. We initiated a clinical trial in this indication in early 2008, but discontinued the program in 2009 because the phase 2 results did not demonstrate significant improvement in psoriasis patients.

Thyrogen (thyrotropin alfa for injection). Thyrogen is an adjunctive diagnostic agent used in the follow-up of patients with well-differentiated thyroid cancer. We developed this product to allow patients to continue taking their thyroid hormone supplements while they are being screened for residual or recurring thyroid cancer. Thyrogen helps patients avoid the morbidities associated with hypothyroidism, thus increasing the likelihood that they will seek follow-up care. This will ultimately increase the likelihood of early detection of any recurrent disease, which can improve the success rate of subsequent treatment.

We also have approval to market Thyrogen as an adjunctive treatment for ablation or destruction of thyroid remnants in patients who have undergone removal of their thyroid for the treatment of well-differentiated thyroid cancer. This indication complements the diagnostic use of Thyrogen in that it enables use for an additional stage of thyroid cancer management. As in its diagnostic use, Thyrogen allows patients to remain on thyroid hormone therapy while undergoing radioiodine ablation, thus helping prevent the morbidities associated with hypothyroidism.

There are approximately 65,000 new patients diagnosed with differentiated thyroid cancer annually in the United States and European Union combined, and we believe that Thyrogen has the potential to be used with approximately 70% of these patients. Thyrogen is sold commercially in over 50 countries. Thyrogen is marketed by a dedicated sales force, and sold to hospitals and doctors' offices through distributors in the United States, the European Union, Latin America and Asia Pacific. Sato Pharmaceutical Co., Ltd, has rights to sell and distribute Thyrogen in Japan. We currently are pursuing marketing approvals and expanded indication approvals for Thyrogen in several markets.

Biosurgery

Our Biosurgery segment derives substantially all of its revenue from the following products:

Product	Indication(s)	Status
Synvisc/Synvisc-One Jonexa	Treatment of pain associated with osteoarthritis of the knee	Synvisc marketed since 1997 in the United States; Synvisc-One marketed in the European Union since 2008 and United States since 2009; Synvisc is approved in over 70 countries and Synvisc-One in approximately 45 countries for this indication. Jonexa received marketing approval in the European Union in September 2009.
Synvisc	Treatment of pain associated with osteoarthritis of hip	Approved for this indication in the European Union and approximately 30 other countries outside of the United States. Also approved in the European Union and approximately 15 other countries outside the United States for treatment of pain associated with osteoarthritis of the ankle and shoulder.
Sepra family of products	Prevention of adhesions (internal scar tissue) following various abdominal surgical procedures	Seprafilm marketed since 1996; approved and sold commercially in approximately 25 countries.

Additional details on these products are set forth below.

Synvisc/Synvisc-One (hylan G-F 20). Synvisc/Synvisc-One are biomaterial-based products derived from hyaluronan that are used to treat the pain associated with osteoarthritis, or OA, of the knee. Synvisc is a three-injection OA knee pain therapy that we have marketed since 1997 in the United

States. Synvisc-One, our next-generation single-injection product, was approved in the European Union and a number of Asian and Latin American countries in 2007 and in the United States in early 2009. An estimated 10 million of the approximately 14 million people in the United States with osteoarthritis of the knee may be candidates for treatment with Synvisc/Synvisc-One, which represents the major market for these products. Synvisc is sold commercially in approximately 40 countries and Synvisc-One is sold in approximately 20 countries. The products are sold through a direct sales force in the United States and Europe and other larger markets and through distributors in our smaller markets who in turn sell directly to physicians, hospitals and pharmacies.

We have been investing in research and clinical trials to expand the use of Synvisc/Synvisc-One to additional joints and through next-generation approaches. Synvisc is approved for the treatment of pain associated with osteoarthritis of the hip in the European Union and approximately 20 other countries outside of the United States. In the European Union, Hong Kong, Israel and Malaysia, Synvisc is also approved for the treatment of pain associated with osteoarthritis of the ankle and shoulder.

Jonexa (hylastan SGL-80). Jonexa is a bacterially fermented product derived from hyaluronan that is indicated for the treatment of pain associated with OA of the knee and administered in one or two injections. We expect to launch Jonexa in select European Union markets and Hong Kong in 2010 because we believe opportunity exists in those markets for a lower cost, more convenient OA treatment option than locally available multiple injection products.

Sepra Products. The Sepra family of products is produced from biomaterials derived from hyaluronan. We market the Sepra products primarily through a direct sales force in the United States, France and Australia, and primarily through distribution arrangements in the rest of the world. The products are sold to hospitals for use during surgery. Our Sepramesh IP hernia mesh product is manufactured and marketed by Davol, Inc., a subsidiary of C.R. Bard, Inc., under a license agreement.

Seprafilm, the first marketed product and largest by sales volume of the Sepra family, is the only FDA-approved product clinically proven to reduce the incidence, extent and severity of postsurgical adhesions following abdominal and pelvic surgery. There are approximately 2 million applicable abdominal and pelvic procedures performed annually in the United States, including 1.3 million Caesarean sections, or C-sections, a largely untapped market. The combined total market for these procedures outside of the United States is approximately equal to the United States market. Sepraspay, a next generation adhesion barrier, is in clinical development to support launch in Europe and regulatory approvals in the United States and Japan.

Hematologic Oncology

Our Hematologic Oncology segment derives substantially all its revenue from the following products:

Product	Indication(s)	Status
Clolar	Pediatric patients ages 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia, or ALL, after at least two prior regimens	Approved for this indication in the United States in 2004.
	Pediatric patients with relapsed or refractory ALL after at least two prior regimens and no other treatment option expected to result in a durable response	Approved for this indication in the European Union in 2006.
Mozobil	For use in combination with granulocyte-colony stimulating factor, or G-CSF, to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma, or NHL, and multiple myeloma, or MM	Approved for this indication in the United States in December 2008.
	For use in combination with G-CSF to enhance mobilization of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and MM whose cells mobilize poorly	Approved for this indication in the European Union in July 2009; commercial sales in approximately 8 European countries.
Campath/ MabCampath	Treatment of B-cell chronic lymphocytic leukemia, or B-CLL	Marketed in the United States since 2001; approved for this indication in the United States since 2007.
	Treatment of B-CLL patients for whom fludarabine combination chemotherapy is not appropriate	Marketed in the European Union since 2001; approved for this indication in the European Union in 2007. The product is approved and commercially available for the treatment of B-CLL in approximately 60 countries.
Fludara	Second-line therapy for B-CLL patients who have failed previous treatment with alkylating agents	Marketed for this indication since 1991; approved in over 100 countries.
	First-line therapy for B-CLL	Marketed for this indication since 2003; approved in over 60 countries for this indication excluding the United States.
	Second-line treatment of low grade NHL	Marketed for this indication since 2000; approved in approximately 30 countries for this indication excluding the United States.
Leukine	Use following induction chemotherapy in older adults with acute myelogenous leukemia, or AML, to shorten time to neutrophil recovery and reduce incidence of severe life threatening infections and infections resulting in death, and four additional indications described below	Approved only in the United States; marketed since 1995.

Additional details on these products are set forth below.

Clolar (clofarabine). Clolar is a purine nucleoside metabolic inhibitor indicated for the treatment of pediatric patients with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. An estimated 700 children worldwide (approximately 300 in the United States) experience a second relapse and require therapy every year. Clolar is marketed under the brand name Clolar in North and South America and as Evoltra elsewhere in the world. Clolar is approved and sold commercially in approximately 30 countries. We market and sell Clolar in the United States primarily through a direct sales force focused on hematologists and oncologists in clinic and hospital settings. Outside the United States, we market the product through direct sales forces but sales are primarily made to wholesalers and other distributors.

We filed for FDA approval 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, we received a complete response letter from the FDA recommending that a randomized, controlled clinical study be conducted for this indication. In addition, we have discussed our adult AML development plans with the EMA's Committee for Human Medicinal Products, or CHMP, and based on the CHMP's feedback, randomized, controlled data would also be required. We are awaiting the availability of additional data from ongoing company- and investigator-sponsored studies before seeking approval for this indication in the United States and European Union. We are conducting a randomized, controlled phase 3 trial comparing Clolar in combination with cytarabine to cytarabine plus placebo in relapsed and refractory adult AML patients 55 years old or older, and results from this trial are expected in late 2010. Clolar has been granted orphan drug status for ALL and AML in both the United States and European Union. We are also developing an oral formulation of Clolar and have initiated clinical trials for the treatment of myelodysplastic syndrome, or MDS.

Mozobil (plerixafor injection). Mozobil is approved for use in the United States in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with MM and NHL and in the European Union in patients with lymphoma and MM whose cells mobilize poorly. Mozobil has been granted orphan drug status in the United States for use to improve the yield of progenitor cells in the apheresis product for subsequent stem cell transplantation following myelosuppressive or myeloablative chemotherapy. We market Mozobil in the United States and European Union primarily through a direct sales force focused on hematologists, oncologists and transplant specialists in clinic and hospital settings. In the United States, sales are made to one distributor who distributes Mozobil to providers of the therapy to patients. In the European Union, sales are made to distributors as well as directly to clinics and hospitals.

It is estimated that approximately 55,000 hematopoietic stem cell transplants are performed each year globally for MM, NHL, Hodgkin's lymphoma, and other conditions. Of these, approximately 20,000 involve allogeneic stem cell transplants, an indication for which Mozobil is not approved. We have begun early preclinical and clinical investigations to explore additional therapeutic indications for Mozobil, including mobilization of hematopoietic stem cells for allogeneic stem cell transplants and tumor sensitization in oncology/hematology indications such as AML.

Campath (alemtuzumab). Campath is a humanized monoclonal antibody indicated as a single agent for the treatment of B-CLL in the United States and indicated for the treatment of patients with B-CLL for whom fludarabine combination therapy is not appropriate in the European Union. We estimate that there are over 13,000 patients in the United States and 16,000 outside of the United States now eligible to receive the product. Campath is approved and sold commercially in approximately 60 countries. Campath is marketed in the United States as Campath and in many countries outside the United States as MabCampath.

Prior to June 2009, we shared with Bayer certain commercialization rights for Campath for the treatment of B-CLL, and the product was marketed and distributed by Bayer or its affiliates. We received two-thirds of Campath net profit on U.S. sales and a royalty on international sales. At the end

of May 2009, we acquired worldwide rights to Campath for the treatment of B-CLL (as well as all other indications, except for solid organ transplant). We market Campath primarily through a dedicated sales force focused on hematologists and oncologists in clinic and hospital settings. In the United States, sales are made to wholesalers who distribute Campath to the providers of the therapy to patients. Outside the United States, sales are also primarily made to wholesalers and other distributors.

We are exploring Campath's use in a variety of combinations. In December 2009, we announced data from a phase 3 clinical trial comparing Campath in combination with Fludara to Fludara alone in patients with relapsed and refractory chronic lymphocytic leukemia, or CLL. Based on the study's positive preliminary findings, we intend to seek regulatory approvals to further broaden the Campath label to include the use of this combination regimen.

We have completed enrollment in two phase 3 clinical trials of alemtuzumab for MS. We expect to obtain data from these trials in 2011. At the end of May 2009, we acquired from Bayer worldwide rights to commercialize alemtuzumab for MS. Prior to this transaction, we shared with Bayer development and commercial rights to alemtuzumab for MS. Under our revised arrangement with Bayer, prior to regulatory approval, we have primary responsibility for the product's development while Bayer continues to fund development at the levels specified under the previous agreement and participates in a development steering committee. We have worldwide commercialization rights, with Bayer retaining an option to co-promote alemtuzumab for MS.

Fludara (fludarabine phosphate). Fludara is a purine nucleotide analog that inhibits the synthesis of new DNA and thus prevents leukemia cells from multiplying. Fludara has been approved for the treatment of B-CLL and also for low-grade NHL. Fludara is approved in approximately 100 countries. We market an oral formulation of Fludara in the European Union, Latin America and Asia, and the product is marketed by Sanofi-Aventis as Oforta™ in the United States. For the IV formulation, our marketing efforts are primarily focused outside of the United States. Sales are primarily made to wholesalers and other distributors who distribute Fludara to providers of the therapy to patients.

Leukine (sargramostim). Leukine is a colony stimulating factor that helps fight infection and disease in appropriate patients by enhancing immune cell function. Leukine is the only growth factor approved in the United States for use following induction chemotherapy in older adults with AML to shorten the time to neutrophil recovery and reduce the incidence of severe and life-threatening infections and infections resulting in death. Leukine also has been approved in the United States for use in four additional indications: myeloid reconstitution following allogeneic and autologous bone marrow transplantation, peripheral blood stem cell, or PBSC, mobilization and subsequent myeloid reconstitution in patients undergoing PBSC transplantation, and bone marrow transplantation failure or engraftment delay. We market Leukine primarily through a direct sales force focused on hematologists and oncologists in clinic and hospital settings. Sales are made to wholesalers who distribute Leukine to providers of the therapy to patients.

Competition

We are engaged in segments of the human healthcare products and services industry that are highly competitive. Our competitors in the United States and elsewhere include major pharmaceutical, biotechnology, diagnostic testing and medical device companies, and generic and biosimilar manufacturers. Some of these competitors may have more extensive research and development, regulatory, manufacturing, production and sales and marketing capabilities. Some competitors may have greater financial resources. These companies may succeed in developing products and services that are more effective or more economical than any that we have or may develop and may also prove to be more successful than we are in manufacturing, marketing and selling products and services. In addition, technological advances or different approaches developed by one or more of our competitors may

render our products and services obsolete, less effective or uneconomical. Each of our products and services faces different competitive challenges, and we describe many of them below.

Genetic Diseases

Cerezyme. Zavesca® is currently the only other marketed product aimed at treating Gaucher disease. Zavesca is a small molecule oral therapy marketed by Teva Pharmaceutical Industries Ltd. in Israel and Actelion Ltd. in the United States, European Union and other markets. Zavesca has been approved for use in patients with mild to moderate Type 1 Gaucher disease for whom enzyme replacement therapy is unsuitable. To date, virtually all Gaucher disease patients who have received enzyme therapy have experienced strong clinical benefits with few side effects, so Zavesca has not had a significant impact on our sales of Cerezyme.

Shire plc is developing velaglucerase, a gene-activated human glucocerebrosidase therapy for the treatment of Gaucher disease, and Protalix Biotherapeutics Ltd., or Protalix, is developing taliglucerase, a plant-derived human glucocerebrosidase, or prGCD, therapy. In August 2009, Shire submitted a New Drug Application, or NDA, to the FDA for its therapy, and in December 2009, Protalix submitted its NDA to the FDA. The FDA has granted “fast track” designation for both companies’ NDAs and granted orphan drug status for both therapies. Shire’s application has received a PDUFA date of February 28, 2010. In February 2010, Protalix announced that the FDA has requested additional data regarding the Chemistry, Manufacturing and Controls, or CMC, section of its NDA. Shire also submitted a Marketing Authorization Application, or MAA, to the EMA for its therapy in November 2009. In addition, Shire’s and Protalix’s therapies are currently being provided to patients in the United States under a treatment investigational new drug, or treatment IND, protocol, as well as to patients in the European Union through pre-approval access programs. In December 2009, Protalix and Pfizer entered into an agreement to develop and commercialize Protalix’s therapy, with Protalix retaining rights in Israel.

Other competitors could develop competitive products based on protein replacement therapy, small molecule or gene therapy approaches. Orphan drug status for Cerezyme, which provided us with exclusive marketing rights for Cerezyme in the United States for seven years, expired in 2001.

Fabrazyme. Replagal®, Shire’s enzyme replacement therapy for Fabry disease, competes with Fabrazyme in the European Union and many other countries outside the United States. Although Fabrazyme has marketing exclusivity in the United States until April 2010 due to its orphan drug status, Replagal is currently available to U.S. Fabry patients under an FDA-approved treatment IND protocol. Shire has submitted a biologics license application, or BLA, with the FDA for Replagal and been granted “fast track” designation. Amicus Therapeutics is conducting in the United States a phase 3 clinical trial of Amigal™, its experimental small molecule pharmacological chaperone treatment for Fabry disease, and has been in discussions with the EMA about a separate phase 3 clinical trial for registration in the European Union.

Myozyme. Myozyme has marketing exclusivity in the United States until 2013 and in the European Union until 2016 due to its orphan drug status. Amicus Therapeutics, or Amicus, is developing a small molecule pharmacologic chaperone treatment for Pompe disease. Amicus initiated a phase 2 clinical trial in June 2008, but announced in February 2009 that they had suspended enrollment for this trial and had received notice from the FDA that the trial is on clinical hold. In October 2009, Amicus initiated another phase 1 study of its treatment.

Aldurazyme. Aldurazyme has marketing exclusivity in the United States until April 2010 and in the European Union until 2013 due to its orphan drug status. There are currently no other biopharmaceutical products on the market to treat MPS I. For some patients, particularly Hurler

patients under two years of age, hematopoietic stem cell transplantation may be an appropriate treatment.

Elaprase. There are currently no other biopharmaceutical products on the market to treat MPS II.

Cardiometabolic and Renal

Renagel(sevelamer carbonate)/Renvela (sevelamer hydrochloride). Sevelamer is the most prescribed phosphate binder in the United States. Phosphate binders are currently the only available therapeutic treatments for hyperphosphatemia, or elevated serum phosphorus levels, in CKD patients on dialysis. In addition to Renagel and Renvela, there are several phosphate binder options available, including PhosLo®, a prescription calcium acetate preparation sold by Fresenius Medical Care, and Fosrenol®, a prescription lanthanum carbonate sold by Shire. Generic formulations of PhosLo manufactured by Roxane Laboratories, Inc. and Sandoz were launched in the United States in 2008 and 2009. Fosrenol is marketed in the United States, Europe, Canada and Latin America. Other products used as phosphate binders include over-the-counter calcium-based antacids such as TUMS® and metal-based options such as aluminum and magnesium. Our core patents protecting Renagel and Renvela expire in 2014 in the United States and in Europe in 2015. However, our Renagel and Renvela patents are the subjects of Abbreviated New Drug Application, or ANDA, filings in the United States by generic drug manufacturers as described in more detail in Part I, Item 3 “Legal Proceedings” of this report and in the “Risk Factors” section of Part II, Item 7 under the heading “Some of our products may face competition from lower cost generic or follow-on products.”

The doses necessary for calcium products to achieve adequate reductions in phosphate absorption can lead to harmful side effects such as hypercalcemia. Evidence suggests that increasing doses of calcium-based binders may lead to cardiac calcification. Aluminum hydroxide, a metal-based treatment option, is more effective at lowering phosphorus, but it is infrequently used because aluminum absorbed from the intestinal tract accumulates in the tissues of patients with chronic kidney failure, causing aluminum-related osteomalacia, anemia and dementia. Lanthanum, the metal-based option marketed by Shire as Fosrenol, is an effective phosphate binder but with limited long-term safety data. Several animal studies suggest lanthanum absorption may lead to harmful toxicities.

Hectorol. To manage secondary hyperparathyroidism in CKD patients, clinicians base their treatment decisions on safety, efficacy and cost. For CKD patients who have not advanced to dialysis, clinicians typically use a vitamin D₃ or vitamin D₂ analog to manage PTH levels. Oral calcitriol, a vitamin D₃ analog, is the market leader and is primarily used first line. Roche Pharmaceuticals, a division of F. Hoffman-LaRoche Ltd., or Roche, markets oral calcitriol (brand name Rocaltrol®) and Teva markets a generic version. The two vitamin D₂ analogs used to control secondary hyperparathyroidism are Hectorol (doxercalciferol capsules) and Zemplar® (paricalcitol capsules). Zemplar capsules are marketed and manufactured by Abbott Laboratories, Inc., or Abbott.

Most dialysis patients receive injectable vitamin D rather than oral vitamin D to manage secondary hyperparathyroidism. For patients on dialysis, vitamin D₂ analogs, such as Hectorol (doxercalciferol injection) and Zemplar (paricalcitol injection) are primarily used. Zemplar injection is marketed by Abbott and is viewed to offer similar efficacy and safety to Hectorol. Intravenous calcitriol, known as Calcijex®, is a Vitamin D₃ that is manufactured by Abbott. Calcijex is rarely used in the dialysis market for management of secondary hyperparathyroidism.

Since 2004, Amgen, Inc., or Amgen, has been marketing an oral calcimimetic agent (brand name Sensipar®) for the treatment of secondary hyperparathyroidism in patients with CKD on dialysis. Sensipar is marketed around the world and is typically used in combination with a vitamin D analog and a phosphate binder.

Thyrogen. Thyrogen has no competitive product in the market. The medical alternative to Thyrogen is to withdraw the patient from thyroid hormone replacement therapy, which makes the patient hypothyroid and may cause many of the co-morbidities associated with hypothyroidism.

Biosurgery

Synvisc/Synvisc-One. Synvisc/Synvisc-One face competition from other viscosupplementation products in the United States and international markets. These other products compete with Synvisc/Synvisc-One based on price and product performance. Current competition for Synvisc/Synvisc-One includes Supartz®, a product manufactured by Seikagaku Kogyo that is sold in the United States by Smith & Nephew Orthopaedics and in Japan by Kaken Pharmaceutical Co. under the name Artz®; Hyalgan®, produced by Fidia Farmaceutici S.p.A. and marketed in the United States by Sanofi-Aventis; Orthovisc®, produced by Anika Therapeutics, Inc. and marketed in the United States by Johnson & Johnson and marketed outside the United States through distributors; Euflexxa®, a product manufactured and sold by Ferring Pharmaceuticals in the United States and Europe; and Durolane®, manufactured by Q-Med AB and marketed outside the United States by Smith & Nephew Orthopedics. Additional lower cost local products are also available in markets outside the United States.

Durolane and Euflexxa are produced by bacterial fermentation, as opposed to Synvisc/Synvisc-One, which are avian-sourced. Production via bacterial fermentation may represent a competitive advantage for these products. In addition, the treatment protocol for Durolane is single-injection, which is approved in the European Union, but not in the United States. We have received approval to market Synvisc-One in the European Union and the United States. We believe that single injection products will have a competitive advantage over multiple injection products. We are aware of various viscosupplementation products on the market or in development, including some that are pursuing single injection delivery, but are unaware of any products that have physical properties of viscosity, elasticity or molecular weight comparable to those of Synvisc/Synvisc-One. Single injection products include: Anika's Monovisc™, which is marketed in the European Union and under PMA review with the FDA; Seikagaku Kogyo's Gel-200, which received a non-approvable letter from the FDA in January 2010; and Durolane, which was not recommended for approval by an FDA advisory panel in the second quarter of 2009. Anika has announced that it expects to receive FDA approval of Monovisc in the second half of 2010. We are also unaware of any products that achieve our duration of efficacy with only three injections or any other single injection products with duration of efficacy comparable to Synvisc-One.

Sepra Products. The Sepra products face competition from other adhesion prevention technologies. Another competitive factor affecting the use of Sepra products is the extent to which surgeons continue to treat patients using procedures for which the Sepra products are indicated. For example, Seprafilm adhesion barrier is not indicated for use in laparoscopic procedures, so adoption by surgeons of new laparoscopic procedures could have the effect of limiting Seprafilm adhesion barrier adoption.

Seprafilm does not have significant on-label direct competition in the area of digestive surgery in the United States, but does compete with other products in gynecologic surgery indications. Baxter Healthcare currently markets Adept® Adhesion Reduction Solution, which is a liquid solution approved in the United States for gynecologic laparoscopic adhesiolysis. The labeled indications for Seprafilm and Adept are mutually exclusive, though off-label use of each may result in limited competition. Gynecare Worldwide, a division of Ethicon, Inc., a Johnson & Johnson company, markets Interceed®, a sheet adhesion barrier similar in intended use to Seprafilm with an indicated use only for open gynecological procedures. In Japan, Seprafilm competes with Interceed. We are aware of additional products that are in clinical development. In Europe and other markets that accept the CE mark, Seprafilm competes with several adhesion prevention products.

Hematologic Oncology

Clolar. Since FDA approval in December 2004, Clolar has become the standard of care in its labeled indication for the treatment of pediatric patients ages 1 to 21 years old with relapsed or refractory ALL after at least two prior regimens. Other therapies available for patients in second relapse include cytarabine and mitoxantrone. These agents are available as generics with no significant commercial promotion. Arranon® (nelarabine), marketed by GlaxoSmithKline, or GSK, 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. There are a limited number of anti-cancer agents in clinical trials for the treatment of relapsed pediatric ALL patients, including epratuzamab, which is being developed by Immunomedics, Inc.

Mozobil. The primary competition for Mozobil is existing methodologies for mobilizing stem cells, which include the use of various chemotherapy agents in combination with growth factors and the use of growth factors alone. Mozobil is the first known small molecule indicated in combination with G-CSF to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with NHL and MM. Mozobil offers advantages over existing methodologies because, for certain patients, Mozobil will allow them to mobilize a sufficient number of stem cells to proceed to autologous stem cell transplant, which they may not have been able to achieve with the existing methodologies. For a larger segment of the patient population, in contrast to existing methodologies, Mozobil may decrease the number of apheresis sessions required to collect a sufficient number of stem cells. Accordingly, the predictability of stem cell mobilization associated with the use of Mozobil may result in more efficient use of a transplant center's apheresis machines and staff time. We are aware of other stem cell mobilization agents under preclinical or clinical development.

Campath. Campath has become a well-established therapy for the treatment of B-CLL patients since its initial FDA approval in May 2001. Other therapies administered to patients with B-CLL include single agent and combination chemotherapy regimens and rituximab, which is marketed as Rituxan® by Biogen Idec, Inc. and Genentech, Inc. in the United States and as MabThera® by Roche outside of the United States. In 2008, Cephalon, Inc. began marketing Treanda® (bendamustine) in the United States, a chemotherapy approved for the treatment of B-CLL. In October 2009, Arzerra™ (ofatumumab), which is marketed by GSK, was approved in the United States for the treatment of patients with CLL refractory to fludarabine and alemtuzumab. Other therapies under clinical study for the treatment of B-CLL include lenalidomide, flavopiridol and several next-generation anti-CD 20 antibodies.

Fludara. Treatment regimens using Fludara are the standard of care in CLL patients worldwide and commonly used in NHL and relapsed AML patients. The primary competition for both the IV and oral formulations of Fludara are IV generics.

Leukine. Leukine primarily competes with two colony stimulating growth factors, Neupogen® (filgrastim) and Neulasta® (pegfilgrastim), both of which are marketed by Amgen. Neupogen and Leukine are both short acting and dosed daily, while Neulasta, a pegylated version of Neupogen, is dosed weekly. Neupogen and Neulasta are broadly indicated for chemotherapy induced-neutropenia. Leukine, on the one hand, and Neupogen and Neulasta, on the other hand, have different mechanisms of actions. Neupogen and Neulasta stimulate proliferation and differentiation of neutrophils, a lineage of hematopoietic progenitor cells. Leukine stimulates not only the proliferation and differentiation of neutrophils, but other cell types such as macrophages and dendritic cells.

Strategic Alliances

We have entered into strategic alliances with third parties that give us the right to develop, manufacture, market and/or sell products. Our most significant current alliances for investigational therapies are described below. These alliances reduce the risk of incurring all the research and development expenses associated with a product candidate and ultimately not ending up with a revenue-generating product. However, the gross margins on products developed through a strategic alliance are generally lower than the gross margins on un-partnered products because profits from alliance products are shared with our strategic partners.

Bayer—Development of alemtuzumab for MS.

The terms of our collaboration with Bayer for the development of alemtuzumab for MS are described above under the heading “Products and Services—Hematologic Oncology”.

Osiris Therapeutics, Inc.

In October 2008, we entered into a strategic alliance with Osiris Therapeutics, Inc., or Osiris, whereby we obtained an exclusive license to develop and commercialize Prochymal and Chondrogen, mesenchymal stem cell products, outside of the United States and Canada. Osiris will commercialize Prochymal and Chondrogen in the United States and Canada. We paid Osiris a total of \$130.0 million in nonrefundable upfront payments in 2008 and 2009. The results of these programs are primarily included in our immune mediated diseases business unit, which are reported under the category “Other” in our segment disclosures.

Osiris will be responsible for completing, at its own expense, all clinical trials of Prochymal for the treatment of Graft-versus-Host Disease, or GvHD, and Crohn’s disease, both of which are in phase 3 trials, and clinical trials of Prochymal and Chondrogen through phase 2 for all other indications. Osiris will be responsible for 60% and we will be responsible for 40% of the clinical trial costs for phase 3 and 4 clinical trials of Prochymal (other than for the treatment of GvHD and Crohn’s disease) and Chondrogen. Osiris is eligible to receive:

- up to \$500.0 million in development and regulatory milestone payments for all indications of Prochymal and up to \$100.0 million for Chondrogen, unless we elect to opt out of further development of Chondrogen; and
- up to \$250.0 million in sales milestones for all indications of Prochymal and up to \$400.0 million in sales milestones for all indications of Chondrogen for the prevention and treatment of conditions of articulating joints.

Osiris is also eligible to receive tiered royalties from us on sales of Prochymal and Chondrogen outside of the United States and Canada. In September 2009, Osiris announced that its two phase 3 trials evaluating Prochymal for the treatment of acute GvHD failed to meet their primary endpoints.

PTC Therapeutics, Inc.

In July 2008, we entered into a strategic alliance with PTC Therapeutics, Inc., or PTC, to develop and commercialize ataluren (formerly known as PTC124), PTC’s novel oral therapy in late-stage development for the treatment of nonsense-mutation-mediated Duchenne muscular dystrophy, or DMD, and nonsense-mutation-mediated cystic fibrosis, or CF. Under the terms of our license and collaboration agreement, PTC will commercialize ataluren in the United States and Canada, and we will commercialize the treatment in all other countries. We paid PTC a nonrefundable upfront payment of \$100.0 million. At its own expense, PTC will conduct and be responsible for the phase 2b trial of ataluren in DMD, the phase 2b trial of ataluren in CF and two proof-of-concept studies in other indications to be determined. Once these four studies have been completed, we and PTC will share

research and development costs for ataluren equally. We and PTC will each bear the sales and marketing and other costs associated with the commercialization of ataluren in our respective territories. PTC is eligible to receive up to \$337.0 million in milestone payments as follows:

- up to \$165.0 million in development and approval milestones, the majority of which would be paid upon the receipt of approvals obtained outside of the United States and Canada; and
- up to \$172.0 million in sales milestones, commencing if and when annual net sales for ataluren outside of the United States and Canada reach \$300.0 million and increasing in increments through revenues of \$2.4 billion.

PTC is also eligible to receive tiered royalties from sales of ataluren outside of the United States and Canada. The results of our ataluren program are included in the results of our Genetic Diseases segment disclosures.

Isis Pharmaceuticals, Inc.

In January 2008, we entered into a strategic alliance with Isis Pharmaceuticals, Inc., or Isis, whereby we obtained an exclusive, worldwide license to develop and commercialize mipomersen, a lipid-lowering drug targeting apolipoprotein B-100, which is currently being developed for the treatment of familial hypercholesterolemia, or FH, an inherited disorder that causes exceptionally high levels of LDL-cholesterol. Under our agreements with Isis, we paid Isis a \$175.0 million upfront nonrefundable license fee and also paid Isis \$150.0 million to purchase five million shares of Isis common stock. Isis will be responsible, at its own expense, for up to \$125.0 million for the development of mipomersen. Thereafter, we and Isis will share development costs for mipomersen equally. The initial funding commitment by Isis and shared development funding commitment end when the mipomersen program is profitable. In the event the research and development of mipomersen is terminated prior to Isis completing its funding obligation, we are not entitled to any refund of our \$175.0 million upfront payment. Isis is eligible to receive up to \$750.0 million in commercial milestone payments and up to \$825.0 million in development and regulatory milestone payments.

We will be responsible for funding sales and marketing expenses until mipomersen revenues are sufficient to cover such costs. Profits on mipomersen initially will be allocated 70% to us and 30% to Isis. The profit ratio would be adjusted on a sliding scale if and as annual revenues for mipomersen ramp up to \$2.0 billion, at which point we would share profits equally with Isis. The results of our mipomersen program are included in the results of our cardiovascular business unit, which are reported in our Cardiometabolic and Renal segment disclosures.

Manufacturing and Raw Materials

Manufacturing

Our manufacturing operations consist of bulk manufacturing, formulation, and fill-finish or tableting activities for our products and product candidates for both commercial and clinical purposes. We also use third party contractor manufactures to produce or assist in the production of certain of our existing products and clinical product candidates. Manufacturing for each of our business segments is described in more detail below.

Genetic Diseases. We currently produce bulk Cerezyme and Fabrazyme at our Allston facility; bulk Fabrazyme and 160L Myozyme at a small-scale manufacturing facility in Framingham, Massachusetts; and 4000L Myozyme at our manufacturing facility in Geel, Belgium. Bulk Aldurazyme is produced by BioMarin. We fill-finish Cerezyme and Myozyme at our facility in Waterford, Ireland and fill-finish Cerezyme, Myozyme, and Fabrazyme at our Allston facility. We are working with a third party contract manufacturer to transfer fill-finish activities to the contract manufacturer for a portion of our

Fabrazyme, Cerezyme and Myozyme production. Aldurazyme is fill-finished by separate third party contract manufacturers.

Cardiometabolic and Renal. At our manufacturing facility in Haverhill, England, we manufacture the majority of our supply requirements for sevelamer hydrochloride (the active ingredient in Renagel) and sevelamer carbonate (the active ingredient in Renvela). We also rely on one contract manufacturer for the production of bulk sevelamer. Tableting operations for Renagel, and tableting and powder operations for Renvela, are conducted at our Waterford facility.

For Hectorol, we contract out the bulk manufacturing to one contract manufacturer and the fill-finish work for the capsule to one contract manufacturer. We fill-finish the vial formulation of Hectorol at our manufacturing facility in Ridgefield, New Jersey. We manufacture bulk Thyrogen at our small-scale facility in Framingham, Massachusetts and fill-finish the product at our Allston facility. We are working to transfer fill-finish of this product to a contract manufacturer.

Biosurgery. All of the production for Synvisc/Synvisc-One and our other hyaluronan-based products takes place at our Ridgefield, New Jersey facility. We produce bulk hyaluronic acid and finish and package the Septra family of products at our biomaterials manufacturing facility in Framingham, Massachusetts.

Hematologic Oncology. We currently contract out bulk manufacturing and fill-finish work for our Hematologic Oncology products. In 2009, we received approval from the European Union to begin bulk manufacturing Campath at our Geel facility but are using supply from our contract manufacturer to meet demand. We expect to apply for U.S. approval of this facility for Campath bulk manufacturing in 2010.

Manufacturing Investments

Our manufacturing operations require significant capital investments, both for maintenance and regulatory compliance as well as for expanding current facilities and building new facilities. Our key manufacturing projects include:

- construction of a new manufacturing facility in Framingham, Massachusetts with capacity for production of bulk Fabrazyme and bulk Cerezyme. The plant will include four 2000L bioreactors. The first engineering runs for Fabrazyme are expected to begin in the first half of 2010, with FDA approval for commercial production of Fabrazyme currently anticipated in 2011;
- addition of a third 4000L bioreactor at our Geel facility for the production of bulk Myozyme, which is currently anticipated to be approved in 2011;
- expanding fill-finish capacity at our Waterford facility, which will increase our internal filling capacity for our lyophilized products, including Genetics Diseases products, by four fold. We currently anticipate approval for the new capacity in 2011; and
- construction of a new manufacturing facility in Lyon, France for bulk production of Thymoglobulin, which is expected to be approved in 2011.

Raw Materials

Some raw materials and components needed for manufacturing our products are provided by third party suppliers. Most of the principal materials we use in our manufacturing operations are available from more than one source and in quantities adequate to meet our needs. However, 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 regulatory authority

approves another supplier. In addition, there may be only one available source for a particular chemical or component.

Also, certain raw materials required for the manufacturing of our products are derived from biological sources, including bovine serum and human serum albumin. Such raw materials are difficult to procure and may be subject to contamination or recall. Although these materials are subject to extensive testing to demonstrate they are contaminate free, there is a risk that a contaminant, such as viruses, may not be detected. Some countries in which we market our products may restrict the use of biologically derived substances in the manufacture of drugs. We have been investigating alternatives to biological sources and alternative manufacturing processes that do not require the use of biologically-sourced raw materials. Implementation of any of these alternatives would require regulatory approval.

Patents, License Agreements and Trademarks

In general, we pursue a policy of obtaining patent protection both in the United States and in selected countries outside the United States for subject matter we consider patentable and important to our business. Patents owned by us that we consider important to our business include the following:

Genetic Diseases

Cerezyme is protected by U.S. Patent Nos. 5,236,838 which expires on August 17, 2010; 5,549,892 which expires on August 27, 2013; 6,451,600 which expires on September 17, 2019; and corresponding international counterparts. Myozyme is protected by U.S. Patent Nos. 6,118,045 which expires on August 18, 2018; 7,351,410 which expires on October 29, 2020 and 7,655,226 which expires on December 16, 2019; and corresponding international counterparts.

Cardiometabolic and Renal

Renagel and Renvela are protected by U.S. Patent Nos. 5,667,775 which expires on September 16, 2014; 5,496,545, 6,509,013, 7,014,846 and 7,459,151 which expire on August 11, 2013; and corresponding international counterparts. Renagel is also protected by U.S. Patent No. 6,733,780, which expires on October 18, 2020; and corresponding international counterparts. Renvela is also protected by U.S. Patent No. 6,858,203 which expires on September 20, 2013; and corresponding international counterparts. Hectorol is protected by U.S. Patent Nos. 5,602,116 which expires on February 11, 2014; 5,869,472 which expires on February 9, 2016; and corresponding international counterparts. In addition, Hectorol for injection is protected by U.S. Patent No. 7,148,211 which expires September 14, 2023. Thyrogen is protected by U.S. Patent Nos. 5,240,832 and 5,674,711 which expire on August 31, 2010; 5,602,006 which expires on February 11, 2014; 5,658,760, which expires on August 19, 2014; and corresponding international counterparts.

Biosurgery

Synvisc is protected by U.S. Patent Nos. 5,143,724 which expires on August 8, 2011; 5,399,351 which expires on March 21, 2012; and corresponding international counterparts. Seprafilm is protected by U.S. Patent No. 5,527,893 which expires on June 18, 2013; and corresponding international counterparts.

Hematologic Oncology

Mozobil is protected by U.S. Patent Nos. 5,583,131 which expires on December 10, 2013; 6,987,102 which expires on July 22, 2023; and corresponding international counterparts.

In addition, a portion of our proprietary position is based upon patents that we have licensed from others either through collaboration or traditional license agreements. These licenses generally are

worldwide, exclusive, for a fixed duration and require us to use reasonable or diligent efforts to develop and commercialize the relevant product and to pay on-going royalties on product sales. Our licensed patents that we consider important to our business include the following:

- Fabrazyme is protected by U.S. Patent No. 5,356,804, which is licensed from Mount Sinai School of Medicine of the City of New York and expires on September 27, 2015.
- Aldurazyme is protected by numerous U.S. patents licensed from BioMarin and Harbor-UCLA Research and Education Institute, and international counterparts. U.S. Patent Nos. 6,426,208, 7,041,487 and 7,354,576 expire on November 12, 2019. U.S. Patent No. 6,569,661 expires on April 23, 2020. U.S. Patent Nos. 6,585,971 and 6,858,206 expire on July 1, 2020.
- Myozyme is protected by U.S. Patent No. 7,056,712, which is licensed from Duke University and Synpac Pharmaceuticals (U.K.) Limited and expires on February 26, 2023, and international counterparts.
- Thyrogen is protected by U.S. Patent No. 5,840,566, which is licensed from Sloan-Kettering Institute for Cancer Research and expires on November 24, 2015.
- Clolar is protected by U.S. Patent No. 5,661,136, which is licensed from Southern Research Institute and expires January 14, 2018, and international counterparts.
- Campath is protected by U.S. Patent Nos. 5,846,534 and 6,569,430, which are licensed from British Technology General and expire on December 8, 2015, and international counterparts.
- Fludara (oral formulation) is protected by U.S. Patent Nos. 7,547,776 and 7,148,207, which are licensed from Alcafleu Management GmbH & Co. KG (Alcafleu) and expire December 10, 2018 and December 20, 2022, respectively, and international counterparts.
- Leukine is protected by U.S. Patent Nos. 5,393,870 and 5,229,496, which are licensed from Alcafleu and expire on July 20, 2010. Leukine is also protected by U.S. Patent No. 5,391,485, which is licensed from Bayer and expires on February 21, 2012.

Generally, patents issued in the United States are effective for:

- the longer of 17 years from the date of issue or 20 years from the earliest effective filing date of the corresponding patent application if filed prior to June 8, 1995; and
- 20 years from the earliest filing date for patent applications filed on or after June 8, 1995.

In some cases, the patent term can be extended to recapture a portion of the term lost during FDA regulatory review. The duration of foreign patents varies in accordance with local law.

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position in our product areas. We generally require our employees, consultants and collaborators who have access to our proprietary information to sign confidentiality agreements.

Our patent position and proprietary technology are subject to certain risks and uncertainties. We reference information about these risks and uncertainties in Item 1A., “Risk Factors,” of this report. We encourage you to read that information, which we are incorporating into this section by reference.

Our products and services are sold around the world under brand-name trademarks and service-marks. Trademark protection continues in some countries as long as the mark is used; in other countries, as long as it’s registered. Registrations generally are for fixed, but renewable, terms. We consider our registered trademarks Genzyme®, Cerezyme®, Ceredase®, Fabrazyme®, Thyrogen®, Myozyme®, Renagel®, Renvela®, Hectorol®, Thymoglobulin®, Campath®, MabCampath®, Clolar®, Evoltra®, Mozobil®, Synvisc®, Synvisc-One®, Carticel®, MACI®, GlucaMesh®, GlucaTex®, Septra®,

Seprafilm®, Seprigel®, Seprapack®, Sepramesh®, Sepraspay®, Hylaform®, Lipobridge® Captique®, Epicel®, OSOM®, N-geneous®, Direct LDL®, GlyPro®, InSight®, and AFP4®, together with our trademarks, Lumizyme™, Jonexa™, Lymphoglobuline™, Cholestigel™, Hylashield Nite™, SAGE™, LongSAGE™ and SPHERE™, BioMarin/Genzyme LLC's registered trademark Aldurazyme®, Shire's registered trademark Elaprase®, and Alcaflu's registered trademarks Fludara® and Leukine®, in the aggregate, to be of material importance to our business.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture, commercialization, pricing and reimbursement of our products and services.

FDA Approval

Most of our products and services require approval from the FDA and corresponding agencies in other countries before they can be marketed. In the United States, we market products that the FDA classifies as either "drugs," "biologics" or "devices." The activities required before drugs or biologics may be marketed in the United States include:

- preclinical laboratory tests, *in vitro* and *in vivo* preclinical studies and formulation and stability studies;
- the submission to the FDA of an application for human clinical testing, which is known as an IND application;
- adequate and well controlled human clinical trials to demonstrate the safety and effectiveness of the drug or biologic;
- the submission of a NDA for a drug or a BLA for a biologic; and
- the approval by the FDA of the NDA or BLA.

The FDA reviews all available data relating to safety, efficacy and quality and assesses the risk/benefit of a product before granting approval. The data assessed by the FDA in reviewing a BLA or NDA includes animal or pre-clinical testing data, chemistry and manufacturing controls data and clinical safety and efficacy data.

The FDA may grant accelerated approval for drugs and biologics on the basis of a surrogate endpoint reasonably likely to predict clinical benefit. In such cases, we are required to conduct post-approval clinical studies to confirm the clinical benefit of the surrogate endpoint that was the basis of the accelerated approval. These clinical studies require the collection of additional data before full approval will be given and can often be long-term commitments. Although the FDA has not historically invoked its authority to withdraw an accelerated approval, it may do so. We currently have a number of products approved under the accelerated approval mechanism.

Products that are classified as devices also require some form of FDA approval prior to marketing. Devices are classified as Class I, II or III, depending upon FDA requirements to assure their safety and effectiveness. In general, Class I and Class II devices are devices whose safety and effectiveness can reasonably be assured through general or specific controls, respectively. Class III devices are life sustaining or life supporting, or are of substantial importance in preventing impairment to health or pose an unreasonable risk of adverse effect. They are implantable devices or new devices which have been found not to be substantially equivalent to legally marketed devices. The steps required for approval of a Class III device include:

- preclinical laboratory tests and *in vitro* and *in vivo* preclinical studies;
- the submission to the FDA and approval of an Investigational Device Exemption, or IDE, application to allow initiation of clinical testing;
- human clinical studies to prove safety and effectiveness of the device;
- the submission of a Pre-Marketing Approval application, or PMA; and
- the approval by the FDA of the PMA.

Typically, clinical testing of devices involves initial testing to evaluate safety and feasibility and expanded trials to collect sufficient data to prove safety and effectiveness. In addition, the procedures and the facilities used to manufacture the device are subject to review and approval by the FDA.

A device (other than a Class III device) that is proven to be substantially equivalent to a device marketed prior to May 28, 1976, when government regulations for devices were first introduced, can be marketed after clearance of a 510(k) application rather than the filing of an IDE application and a PMA. The 510(k) application must contain a description of the device, its methods of manufacture and quality control procedures and the results of testing to demonstrate that the device is substantially equivalent to the device already marketed.

The time and expense required to perform the clinical testing necessary to obtain FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. Even after initial FDA approval has been obtained, we could very likely be required to conduct further studies to provide additional data on safety or efficacy or, should we desire, to gain approval for the use of a product as a treatment for additional clinical indications. In addition, use of these products during testing and after marketing approval has been obtained could reveal side effects which, if serious, could limit uses, require a Risk Evaluation & Mitigation Strategy, or REMS, or in the most serious cases, result in a market withdrawal of the product or expose us to product liability claims. We are also subject to monetary penalties if we do not meet the timelines agreed to with the FDA for any post-approval requirements.

Approval Outside of the United States

For marketing outside the United States, we are subject to foreign regulatory requirements governing human clinical testing and marketing approval for our products. These requirements vary by jurisdiction, differ from those in the United States and may require us to perform additional pre-clinical or clinical testing regardless of whether FDA approval has been obtained. The amount of time required to obtain necessary approvals may be longer or shorter than that required for FDA approval. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Our initial focus for obtaining marketing approval outside the United States is typically the European Union. European Union regulations and directives generally classify health care products either as medicinal products, medical devices or *in vitro* diagnostics. For medicinal products, marketing approval may be sought using one of three main procedures: the centralized procedure of the EMA,

the decentralized/mutual recognition procedure or the national procedure (approval by one country only).

Under the centralized procedure, which is mandatory for biotechnology derived products, orphan designated products and products for specific therapeutic areas, applications are submitted to the EMA for an authorization which is valid for the European Community. The EMA ensures a thorough evaluation of the application by the CHMP, which draws from its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, CHMP adopts a positive opinion that is transmitted to the European Commission for the marketing authorization to be granted.

Under the decentralized/mutual recognition procedure, a company selects a single EU member state to review its marketing authorization, and if approved, submits the authorization to other member states. The mutual recognition/decentralized procedure allows a company to receive national marketing authorizations through a coordinated process with EU member states. In the national procedure, the application is submitted simultaneously in selected or all member states. After a marketing authorization has been granted, a company must submit periodic safety reports to the EMA (for the centralized procedure) or to the national health authorities (for the decentralized/mutual recognition and national procedures). These marketing authorizations must be renewed after each five year period. Since the EU does not have jurisdiction over reimbursement or pricing matters in its member states, it is necessary to deal with individual countries on such matters.

In July 2007, the European Commission's Regulation on Penalties entered into force. This regulation enables the European Commission to impose sanctions on companies for non-completion of post-marketing commitments. These range from a fine of 10% of global revenue to removal of the product from the market.

European Union regulations for products classified as medical devices have been implemented. Devices, such as our Septra products, must receive marketing approval through a centralized procedure in which the device receives a CE Mark allowing distribution to all member states of the European Union. The CE Mark certification requires us to receive International Standards Organization certification for each facility involved in the manufacture or distribution of the device. This certification comes only after the development of an all inclusive quality system, which is reviewed for compliance to International Quality Standards by a licensed "Notified Body" working within the European Union. After certification is received, a product dossier is reviewed that attests to the product's compliance with European Union directive 93/42 EEC for medical devices. Only after this point is a CE Mark granted.

Other Government Regulation

Good Manufacturing Practices. The FDA, the EMA and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacture of pharmaceutical and biologic products prior to approving a product. If, after receiving approval from regulatory agencies, a company makes a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required. All facilities and manufacturing techniques used for the manufacture of Genzyme's products must comply with applicable regulations governing the production of pharmaceutical products known as "Good Manufacturing Practices," or GMP.

The FDA, the EMA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may issue warning or similar letters or may seek civil, criminal, or administrative sanctions against us.

In February 2009, we received a warning letter from the FDA following the agency's inspection of our Allston facility in September and October 2008 and issuance of a list of inspection observations known as a Form 483, which outlined deficiencies at the facility. The FDA re-inspected the plant in October and November of 2009 and provided us with another Form 483 outlining deficiencies at the facility, which were mainly related to the fill-finish capabilities at the facility. We are working with the FDA to resolve the issues identified in the warning letter and the 2009 Form 483. Failure to correct the deviations cited in the FDA's warning letter and the 2009 Form 483 could result in further regulatory action, including the imposition of a consent decree or suspension of our license to manufacture products at the facility.

Orphan Drug Act. The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven year exclusive marketing period in the United States for that product. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period. 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.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside the United States, including the European Union. The orphan legislation in the European Union is available for therapies addressing chronic debilitating or life-threatening conditions that affect five or fewer out of 10,000 persons or are financially not viable to develop. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. The market exclusivity may be extended to twelve years if sponsors complete a pediatric investigation plan agreed upon with the relevant committee of the EMA.

Regulation of Genetic Testing Services and Diagnostic Products. Our genetic testing services are subject to various federal and state laws and regulations, which among other things, require that our clinical laboratories be licensed and comply with various operational, personnel and quality requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely.

In September 2007, the FDA issued a final guidance regarding the manufacturing of Analyte Specific Reagents, or ASR, for use in laboratory developed tests. The guidance clearly defined requirements for quality systems, labeling, registering and marketing of ASRs. Increased FDA enforcement regarding the manufacturing and sale of ASR reagents and increased enforcement regarding the sale of Research Use Only, or RUO, and Investigational Use Only, or IUO, reagents and instruments for clinical diagnostic purposes could potentially lead to significant increased costs for manufacturing, and possible supply interruptions as suppliers attempt to comply with these newly defined requirements. Collectively, these activities may impact the ability for a clinical laboratory to introduce new tests or new technologies.

With respect to our diagnostic products, the FDA has regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories. Like other medical devices, *in vitro* diagnostic, or IVD, products are divided into three classes according to the level of regulatory control needed to assure safety and effectiveness. Genzyme's current IVD products are either Class I or Class II, and are either exempt from pre-market notification or require a 510(k) submission.

Clinical Trial Registries and Results Databases. Since 2005, the company has posted information about ongoing and completed clinical trials on its own website and other widely accessible sites, including the NIH-sponsored <http://www.clinicaltrials.gov>. In 2007, changes in both federal and state laws expanded the scope of trials requiring registration and public disclosure, increased the amount of information required to be included with the registration, and established new requirements for disclosing the results of completed trials. The 2007 legislation (Food and Drug Administration Amendment Act of 2007, or the FDAAA of 2007) triggered a revision of our internal procedures to ensure compliance with the expanded requirements.

Specifically, the federal legislation requires disclosure of ongoing applicable clinical trials (including, for the first time, specified device trials as well as drug trials) in <http://www.clinicaltrials.gov> within 21 days of first patient enrolled and of all pediatric post market device surveillance studies. In addition, beginning September 2008, the existing clinical trials registry was expanded to include a clinical trials results database. Full expansion is to be completed by September 2010. Results of completed applicable clinical trials must be disclosed in the results database within 1 year of trial completion, unless an extension is granted for pending regulatory action. The company will continue to reassess its policies to seek to ensure that all applicable trials are registered and results disclosed. Failure to meet the requirements could result in penalties including civil monetary penalties.

Pediatric Regulation. The FDAAA of 2007 reauthorized the Best Pharmaceuticals for Children Act, or BPCA, and the Pediatric Research Equity Act, or PREA. BPCA continues to offer manufacturers a 6-month market exclusivity incentive to conduct pediatric clinical studies at the request of the FDA. PREA requires manufacturers to file pediatric assessments, which may include actual pediatric data, a deferral of the pediatric obligation, or a waiver of the pediatric requirement, at the time of filing for all new drug and biologic submissions, as well as for certain supplemental applications. Pursuant to PREA, the FDA has the authority to require sponsors to conduct pediatric research as a contingency of the approval of an application or supplement or as a post-approval commitment. Under both BPCA and PREA, the FDA has the authority to mandate a pediatric label change subsequent to the filing of pediatric clinical data as well as publicly disseminate FDA reviews of pediatric clinical study data. The FDA's increased oversight and authority regarding pediatric studies and subsequent labeling changes may result in regulatory delays and additional development costs for Genzyme.

In 2007, the EU Regulation on Medicines for Pediatric Use became effective. This regulation introduced new obligations on pharmaceutical companies to conduct research on their medicines in children, and subject to various conditions, offers the possibility of incentives for doing so, including exclusivity extensions.

Other Laws and Regulations. Our operations are or may be subject to various federal, state and local laws, regulations and recommendations relating to the marketing of products and relationships with treating physicians, data protection, safe working conditions, laboratory and manufacturing practices, the export of products to certain countries, and the purchase, storage, movement, use and disposal of hazardous or potentially hazardous substances used in connection with our research work and manufacturing operations, including radioactive compounds and infectious disease agents. Although we believe that our safety procedures comply with the standards prescribed by federal, state and local regulations, the risk of contamination, injury or other accidental harm cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result and any liabilities could exceed our resources. We are also subject to a variety of federal, state and local environmental protection measures. Our efforts to comply with these regulations did not during 2009, and are not expected during 2010, to have a material effect upon our capital expenditures, cash flows, earnings or competitive position.

Sales and Marketing

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback and false claims statutes. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify “safe harbors” or exemptions for certain payment arrangements that do not violate the federal anti-kickback statute. Genzyme seeks to comply with the safe harbors where possible. Due to the breadth of the statutory provisions, and the lack of guidance in the form of regulations or court decisions addressing some industry activities, it is possible that our practices might be challenged under anti-kickback or related laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Promotion of drugs for uses outside their labeled indications, so called “off-label” promotion, recently has led to several financially significant settlement agreements by companies under the False Claims Act.

Our activities relating to the sale and marketing of, and price reporting for, our products are subject to scrutiny under these fraud and abuse laws. Violations of these laws may result in criminal and/or civil sanctions, including fines and civil monetary penalties, as well as possible exclusion from federal health care programs, including Medicare and Medicaid. Federal and state authorities are paying increased attention to the pharmaceutical, biotechnology and medical device industries in enforcement of these laws, and we have been named in several legal proceedings alleging violations. We are subject to similar fraud and abuse laws outside the United States.

Legislation and regulations have been enacted by, or are pending in, various states to regulate sales and marketing practices of pharmaceutical, biotechnology and medical device manufacturers. These initiatives generally involve limitations or prohibitions on, and reporting to state agencies of, financial interactions between manufacturers and health care professionals and institutions. Similar initiatives have been introduced in Congress and provisions relating to public disclosure of gifts or other marketing-related transfers of value may be included in health reform legislation currently pending final congressional action. We have dedicated resources that monitor these developments and work to comply appropriately with them. We are subject to similar regulations outside of the United States.

Laws and regulations have been promulgated at federal and state levels in the United States and in foreign countries intended to combat counterfeit drug products or, in some foreign jurisdictions, to facilitate foreign country-specific pharmaceutical reimbursement programs. We seek to comply with those federal, state and foreign “pedigree” or similar laws or rules to the extent currently in effect. We have allocated resources to develop interoperable electronic systems to seek to comply with forthcoming product serialization and track and trace requirements.

Pricing and Reimbursement

Sales of our products and services depends, in part, on the availability and extent of reimbursement from third party payors, including governments and private insurance plans. Governments may regulate access to, prices of or reimbursement levels for our products to control costs or to affect levels of use of our products, and private insurers may be influenced by government reimbursement methodologies. Efforts by third party payors to reduce costs could decrease revenue from sales of our products and services.

Aspects of the U.S. System

We participate in the Medicaid rebate program. Under the Medicaid rebate program, we pay a quarterly rebate for each unit of drug product that is reimbursed by Medicaid. The amount of the rebate for each product is set by law as a minimum 15.1% of the average manufacturer price, or AMP, of that product, or if it is greater, the difference between AMP and the best price, or BP, available from Genzyme to any customer. The rebate amount also includes an inflation adjustment if AMP increases greater than inflation. The inflation adjustment can cause the rebate amount to be significantly higher than the minimum 15.1% rebate mentioned above, particularly following our periodic price increases. The rebate amount is recomputed each quarter based on our reports of our current AMP and best price for each of our products. In addition, we are required to report AMP on a monthly basis. Computations are based on complex rules issued by the Medicaid program informally in the past and formalized in 2007 by regulations that went into effect October 2007.

We have policies and procedures in place that we update as Medicaid guidance changes and we have updated our policies and procedures to be consistent with the 2007 regulations. We follow those policies and procedures when calculating our AMPs and BPs. The terms of our participation in the Medicaid program impose an obligation to correct the prices reported in previous months and quarters, if necessary. Any such corrections could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we were found to have knowingly submitted false information to the government, in addition to other penalties available to the government, the statute provides for civil monetary penalties for each claim containing false information. In addition, Congress could increase the minimum discount of 15.1% or increase the number of Medicaid-eligible individuals, thereby increasing our discounts to the Medicaid program and to other entities that receive discounts comparable to the Medicaid rebate. The health reform legislation currently pending final congressional action includes an increase in both the rebate and the number of eligible individuals.

Participation in the Medicaid rebate program requires us to extend comparable discounts under the Public Health Service, or PHS, pharmaceutical pricing program. The PHS pricing program extends discounts to community health clinics and other entities that receive health services grants from the PHS, as well as the many hospitals that serve a disproportionate share of financially needy patients. Failure to extend mandated discounted pricing to eligible providers would expose us to retroactive pricing corrections and penalties. Congress could increase the number of entities that receive discounts under the PHS program in the future thereby increasing the amounts of discounts required by federal law.

Medicare Part B covers drugs that are administered by physicians to Medicare patients, including our injected and infused drugs. Currently, Medicare reimburses physicians who purchase our Part B covered drugs an amount equal to the drug's average sales price, or ASP, plus 6% and hospitals that use our Part B drugs in the outpatient setting an amount equal to ASP+4%. Medicare has issued regulations and other guidance on how manufacturers are to calculate ASP. We have policies and procedures in place that are consistent with the Medicare rules and we calculate ASPs every quarter in accordance with those policies and procedures. Medicare uses our calculated ASPs to set reimbursement. If we were to miscalculate ASP, then Medicare reimbursement also would be incorrect and we would be exposed to potential penalties such as those described in the Medicaid rebate program description above.

Part D of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or Medicare Part D, provides coverage to enrolled Medicare patients for self-administered drugs such as pills, tablets and creams, that do not need to be injected or infused by a physician. These include our products Renvela, Renagel and oral Hectorol. However, Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own

Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. Vendors solicit discounted pricing from manufacturers and commonly condition formulary placement on the availability of manufacturer discounts. Renagel/Renvela and Hectorol currently are well-positioned on the majority of formularies of nation-wide prescription drug plans participating in the Medicare Part D program as well as many of the large regional plans. The U.S. Congress could significantly change the Medicare Part D program in the future, including requiring the federal government to negotiate discounts for our drugs or matching mandatory discounts to those required in other federal programs.

We also are required to offer discounted pricing to federal agencies via the Federal Supply Schedule, or FSS. FSS pricing is negotiated periodically with the Department of Veterans Affairs, or VA. Although FSS pricing is negotiated, it is intended to not exceed the price that we charge our most-favored non-federal customer for the drug. The minimum discount is statutorily set at approximately 24%. However, an inflation penalty applies and can cause the discount to increase significantly, particularly following our periodic price increases. The VA has issued complex regulations and other guidance on how manufacturers are to calculate annual increases in the FSS prices. We have policies and procedures in place that are consistent with these complex VA rules and we calculate FSS prices every quarter in accordance with those policies and procedures. If we were to miscalculate FSS prices, then federal agencies would pay incorrect amounts for our drugs and we would be exposed to potential penalties, including ineligibility of our drugs for reimbursement by federal agencies, state Medicaid programs and the PHS, and possibly false claims liability.

The TriCare retail program provides reimbursement for military personnel and their dependents when they purchase drugs from retail pharmacies instead of at military pharmacies. Prior to January 28, 2008, the Department of Defense was eligible for FSS pricing only on drugs dispensed by their military pharmacies and not on drugs dispensed by retail pharmacies. On January 28, 2008, federal legislation became effective that extended FSS pricing to the TriCare retail program. The Department of Defense subsequently issued regulations that have been the subject of litigation. During the pendency of the litigation, we, like many manufacturers, entered into a rebate agreement with the Department of Defense that extends FSS pricing to the TriCare program effective June 26, 2009. The TriCare retail program generally affects only our oral products because our injectable products would rarely, if ever, be purchased by patients at a retail pharmacy.

Reimbursement Outside of the United States

Outside the United States our products are paid for by a variety of payors, with governments being the primary source of payment. In many countries the government closely regulates drug pricing and reimbursement and often has significant discretion in determining whether a product will be reimbursed at all and, if it is, how much will be paid. Negotiating prices with governmental authorities can delay patient access to and commercialization of our products. Payors in many countries use a variety of cost-containment measures that can include referencing prices in other countries and using those reference prices to set their own price, mandatory price cuts and rebates. This international patchwork of price regulation has led to different prices across countries and some cross-border trade in our products from markets with lower prices.

Employees

As of December 31, 2009, we, together with all of our consolidated subsidiaries, had approximately 12,000 employees worldwide.

Research and Development Costs

Our research and development costs were \$865.3 million in 2009, \$1.3 billion in 2008, and \$737.7 million in 2007. These costs consist of the cost of our own independent research and development efforts and the costs associated with collaborative research and development and in-licensing arrangements. Research and development costs, including upfront fees and milestones paid to collaboration partners, are expensed as incurred if the underlying products have not received regulatory approval and have no future alternative use.

Financial Information about Segments and Geographic Areas

We have provided the information required by Items 101(b) and 101(d) of Regulation S-K under the heading "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations" and in Note Q., "Segment Information," to our consolidated financial statements set forth in Item 8 of this Form 10-K. We are incorporating that information into this section by reference.

Available Information

You may obtain a free copy of our Form 10-K, our Form 10-Q and Form 8-K, and amendments to those reports, as soon as reasonably practicable after we file them with the SEC, on our website at <http://www.genzyme.com> or by contacting our Investor Relations department at 1-617-252-7570. The reference to our website is not intended to incorporate information on our website into this document.

Item 1A. Risk Factors

We incorporate our disclosure related to risk factors into this section by reference from Item 7 of this Form 10-K under the heading "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition and Results of Operations—Risk Factors."

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our operations are conducted in owned and leased facilities located throughout the world. We lease all of our facilities except for certain facilities in:

- Geel, Belgium (land subject to 99 year leasehold);
- Haverhill, Maidstone and West Malling, England;
- San Diego, California; Allston (land subject to 65 year leasehold), Framingham and Waltham, Massachusetts; Ridgefield, New Jersey; and Santa Fe, New Mexico in the United States;
- Waterford, Ireland (land subject to 999 year leasehold); and
- Lyon, France.

Leases for our facilities contain typical commercial lease provisions, including renewal options, rent escalators and tenant responsibility for operating expenses.

Our administrative activities are concentrated at facilities we have leased in: Cambridge and Framingham, Massachusetts and San Antonio, Texas in the United States; Naarden and Almere, The Netherlands; Tokyo, Japan; and Rio de Janeiro, Brazil. Our sales and marketing activities are principally located in Cambridge, Massachusetts and in sales offices located in major cities throughout the world. We conduct our product research and development activities primarily at our laboratory

facilities in Framingham and Waltham, Massachusetts; San Antonio, Texas; and San Diego, California in the United States, and at our Cambridge, England facility. In addition, our genetics testing business has nine laboratories located in the United States.

Our principal manufacturing facilities are used for the large-scale production of therapeutic proteins and enzymes, including Cerezyme, Fabrazyme, Myozyme and Thyrogen; renal products, including Renagel/Renvela and Hectorol; immunosuppressive agents, including Thymoglobulin; our oncology product Campath; biomaterials, including Synvisc/Synvisc-One and the Sepra family of anti-adhesion products; bulk hyaluronic acid; and human-cell processing services, including Carticel, Matrix-induced Autologous Chondrocyte Implantation, or MACI, and Epicel. The facilities also are used for the receipt of contract manufactured products and materials for Hectorol, Renagel, Campath, Clolar, Fludara, Leukine, Cholestagel and Mozobil. We are also producing late-stage clinical materials, using gene therapy, at our gene therapy operations facility in San Diego, California. The following table identifies our principal manufacturing facilities by business segment. For further information about these facilities and the manufacture of our products, see “Manufacturing and Raw Materials” in Part I, Item 1 of this Form 10-K.

<u>Principal Manufacturing Facility</u>	<u>Business Segment(s)</u>
Allston, Massachusetts	Genetic Diseases
Framingham, Massachusetts (two facilities)	Genetic Diseases, Biosurgery, Cardiometabolic and Renal
Ridgefield, New Jersey	Cardiometabolic and Renal, Biosurgery
Geel, Belgium	Genetic Diseases, Hematologic Oncology
Haverhill, England	Cardiometabolic and Renal
Lyon, France	Other (Thymoglobulin)
Waterford, Ireland	Genetic Diseases, Cardiometabolic and Renal, Other (Thymoglobulin)

Item 3. Legal Proceedings

Federal Securities Litigation

In July 2009 and August 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 lawsuits 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 GMP. The plaintiffs seek unspecified damages and reimbursement of costs, including attorneys’ and experts’ fees. In November 2009, the lawsuits were consolidated and a lead plaintiff appointed. We intend to defend this lawsuit vigorously.

Shareholder Demand Letters

Since August 2009, we have received nine letters from shareholders demanding that our board of directors take action on behalf of Genzyme Corporation to remedy alleged breaches of fiduciary duty by our directors and certain executive officers. The demand letters are primarily premised on allegations regarding our disclosures to shareholders with respect to manufacturing issues and compliance with GMP and our processes and decisions related to manufacturing at our Allston facility. Several of the letters also assert that certain of our executive 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 behalf of Genzyme Corporation 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 the benefit of Genzyme Corporation. The special committee's investigation is ongoing.

Shareholder Derivative Actions

In December 2009, two actions were filed by shareholders derivatively for Genzyme's benefit in the U.S. District Court for the District of Massachusetts against our board of directors and certain of our executive officers after a ninety day period following their respective demand letters had elapsed (the "District Court Actions"). In January 2010, a derivative action was filed in Massachusetts Superior Court by a shareholder who has not issued a demand letter (the "January State Court Action"). In February 2010, a derivative action was filed in Massachusetts Superior Court by a shareholder after a ninety day period following the shareholder's demand letter had elapsed. The derivative actions in general are based on allegations that our directors and certain executive officers breached their fiduciary duties by causing Genzyme to make purportedly false and misleading or inadequate disclosures of information regarding manufacturing issues, compliance with GMP, ability to meet product demand, expected revenue growth, and approval of Lumizyme. The actions also allege that certain of our directors and executive officers took advantage of their knowledge of material non-public information about Genzyme to illegally sell stock they personally held in Genzyme. The plaintiffs generally seek, among other things, judgment in favor of Genzyme for the amount of damages sustained by Genzyme as result of the alleged breaches of fiduciary duty, disgorgement to Genzyme of proceeds that certain of our directors and executive officers received from sales of Genzyme stock and all proceeds derived from their service as directors or executives of Genzyme, and reimbursement of plaintiffs' costs, including attorneys' and experts' fees. The plaintiffs in the District Court Actions have agreed to a joint stipulation consolidating and staying these cases until our board of directors has had sufficient time to exercise its duties and complete an appropriate investigation, which is ongoing. We have filed a motion to dismiss or, in the alternative, stay the January State Court Action. We intend to defend these lawsuits vigorously.

Renegel and Renvela Patent Litigation

Beginning in January 2009, we received notices from Lupin Ltd. and Lupin Pharmaceuticals, Inc., collectively Lupin, and Impax Laboratories, Inc., or Impax, that each had submitted to the FDA ANDAs containing Paragraph IV certifications and that each is seeking approval to market generic versions of Renegel (sevelamer hydrochloride) and Renvela (sevelamer carbonate).

Lupin was at the time seeking to market generic 400mg and 800mg sevelamer hydrochloride tablets and generic 800mg sevelamer carbonate tablets prior to the expiration of all of our Orange Book-listed patents protecting Renegel 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 alleged 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"). In May 2009, we amended the complaint against Lupin to include an allegation that Lupin's proposed sevelamer hydrochloride products infringe U.S. Patent No. 7,459,151, which also expires in 2013. Lupin filed an answer and counterclaims, alleging that our asserted patents are invalid and/or not infringed by Lupin's proposed generic sevelamer hydrochloride products and that our unasserted U.S. Patent No. 6,733,780, which expires in 2020 (the "780 Patent"), is not infringed by Lupin's proposed

generic sevelamer hydrochloride products. In August 2009, Lupin's claim relating to the '780 Patent was dismissed with prejudice. 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, 7,014,846 and 7,459,151, which expire in 2013, and the '775 Patent, which expires in 2014. Lupin filed an answer and counterclaims, alleging that our asserted patents are invalid and/or not infringed by Lupin's proposed generic sevelamer carbonate products. In September 2009, all claims relating to the patents protecting Renagel and Renvela that expire in 2013 were dismissed without prejudice. At this time Lupin is challenging only the '775 Patent.

Impax is seeking to market generic 400mg and 800mg sevelamer hydrochloride tablets and generic 800mg 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 alleged that Impax's proposed sevelamer products infringe the '775 Patent. Impax filed an answer and counterclaims with respect to both suits, alleging that the '775 Patent and '780 Patent are invalid and/or not infringed by Impax's proposed generic sevelamer products. In September 2009, Impax dismissed its claims relating to the '780 Patent without prejudice. At this time Impax is challenging only the '775 Patent.

In May 2009, we received notice that Sandoz, Inc., or Sandoz, had submitted to the FDA an ANDA containing a Paragraph IV certification and that Sandoz is seeking approval to market generic 400mg and 800mg sevelamer hydrochloride tablets after the expiration of the patents protecting Renagel that expire in 2013. In July 2009, we filed a complaint against Sandoz in the U.S. District Court for the District of Maryland alleging that Sandoz's proposed generic products infringe the '775 Patent. Sandoz filed an answer and counterclaims alleging that the '775 Patent and '780 Patent are invalid and/or not infringed by Sandoz's proposed generic sevelamer hydrochloride products. We have moved for an order dismissing Sandoz's counterclaims with respect to the '780 Patent, Sandoz opposed our motion and we await the court's decision.

In August 2009, we received notice that Endo Pharmaceuticals Inc., or Endo, had amended its ANDA to include a Paragraph IV certification with respect to the '775 Patent and that Endo is seeking approval to market generic 400mg and 800mg sevelamer hydrochloride tablets after the expiration of the patents protecting Renagel that expire in 2013. In October 2009, we filed a complaint against Endo in the U.S. District Court for the District of Maryland alleging that Endo's proposed generic products infringe the '775 Patent. Endo filed an answer and counterclaims, alleging that the '775 Patent is invalid and/or not infringed by Endo's proposed generic sevelamer hydrochloride products. At this time Endo is challenging only the '775 Patent.

Hectorol Patent Litigation

In January 2008, we received notice that Pentech Pharmaceuticals, Inc., or Pentech, had submitted to the FDA an ANDA containing a Paragraph IV certification and that Pentech is seeking approval to market a generic version of our Hectorol injection ampule product prior to the expiration of the following Orange Book-listed patents: U.S. Patent Nos. 6,903,083, which expires in 2021 (the "'083 Patent"), 5,602,116, which expires in 2014 (the "'116 Patent") and 5,707,980, which expired in August 2008 (the "'980 Patent"). In February 2008, we along with Bone Care International, LLC, or Bone Care, for whom we are the sole member, filed a lawsuit in the U.S. District Court for the Northern District of Illinois. In the complaint, we alleged that Pentech's proposed injection ampule product infringed both the '083 and '116 Patents. We granted Pentech a covenant not to sue on the '980 Patent in April 2008 and on the '083 Patent in April 2009. In August 2009, the '083 Patent was dedicated to the public. We continue to pursue our claims related to the '116 Patent.

After we filed the lawsuit, Pentech assigned all interest in its ANDA to Cobrek Pharmaceuticals, Inc., or Cobrek. In June 2008, we filed an amended complaint to add Cobrek as a

defendant. In September 2009, Pentech and Cobrek amended their pleadings to include a claim for attorneys' fees. This amendment relates to our assertion of both the '116 and '083 Patents. A trial relating to the '116 Patent is anticipated to take place in May or June 2010.

In December 2008, we received approval to market a new formulation of Hectorol that could be packaged in a single dose vial. This formulation is additionally protected by U.S. Patent No. 7,148,211 (the "211 Patent"). In November 2009, we received notice that Cobrek submitted to the FDA an amended or supplemental ANDA containing a Paragraph IV certification and that Cobrek is seeking approval to market a generic version of our Hectorol injection vial product prior to the expiration of the Orange Book-listed '083, '116, '980 and '211 Patents. In January 2010, we filed a lawsuit in the U.S. District Court for the Northern District of Illinois alleging Cobrek's proposed injection vial product infringes the '116 and '211 Patents. Currently, the '211 Patent is the subject of an *inter partes* re-examination proceeding before the United States Patent and Trademark Office, or USPTO, that was initiated by Cobrek.

In March 2009, we received notice that Eagle Pharmaceuticals, Inc., or Eagle, had submitted to the FDA an ANDA containing a Paragraph IV certification and that Eagle is seeking approval to market a generic version of our Hectorol injection ampule product prior to the expiration of our Orange Book-listed patents protecting the product. In April 2009, we and Bone Care filed a complaint against Eagle in the U.S. District Court for the District of Delaware alleging that Eagle's proposed product infringes the '116 Patent. Eagle filed an answer and counterclaims alleging that the '116 Patent is invalid and/or not infringed and seeking declaratory judgment that the '083 and '211 Patents are invalid and/or not infringed by Eagle's proposed injection ampule product. In November 2009, Eagle's claims relating to the '083 and '211 Patents were dismissed without prejudice.

In June 2009, we received notice that Sandoz had submitted to the FDA an ANDA containing a Paragraph IV certification and that Sandoz is seeking approval to market a generic version of our Hectorol injection ampule product prior to the expiration of our Orange Book-listed patents protecting the product. In July 2009, we and Bone Care filed a complaint against Sandoz in the U.S. District Court for the District of Delaware alleging that Sandoz's proposed injection ampule product infringes the '116 Patent. Sandoz filed an answer and counterclaims, alleging the '980 Patent is expired, unenforceable and not infringed by its proposed products and that the '116, '083 and '211 Patents are invalid and not infringed. We have moved for an order dismissing Sandoz's counterclaims with respect to the '083, '211 and '980 Patents, Sandoz opposed our motion and we await the court's decision.

In June 2009 we also received notice that Roxane Laboratories, Inc., or Roxane, had submitted to the FDA an ANDA containing a Paragraph IV certification and that Roxane is seeking approval to market a generic version of our Hectorol capsule products prior to the expiration of our Orange Book-listed patents protecting these products. In July 2009, we filed a complaint against Roxane in the U.S. District Court for the District of Delaware alleging that Roxane's proposed capsule products infringe the '116 Patent. Roxane filed an answer, but asserted no counterclaims.

Fabrazyme Patent Litigation

In October 2009, Shelbzyme LLC filed a complaint against us in the U.S. District Court for the District of Delaware alleging infringement of U.S. patent 7,011,831 by "making, using, selling and promoting a method for the treatment of" Fabry disease. The '831 patent, which is directed to a method for treating Fabry disease, was issued in March 2006 and expired in March 2009. The plaintiffs seek damages for past infringement, including treble damages for alleged willful infringement and reimbursement of costs including attorney fees. We intend to defend this suit vigorously.

Other Matters

We are party to a legal action brought by Kayat Trading Limited, or Kayat, pending before the District Court in Nicosia, Cyprus. Kayat alleges that we breached a 1996 distribution agreement under which we granted Kayat the right to distribute melatonin tablets in the Ukraine, primarily by not providing products or by providing non-conforming products. Kayat further claims that due to the alleged breach, it suffered lost profits that Kayat claims it would have received under agreements it alleges it had entered into with subdistributors. Kayat also alleges common law fraud and violations of Mass. Gen. L. c. 93A and RICO. Kayat filed its suit on August 8, 2002 and a trial began in Cyprus in December 2009. Kayat seeks damages for its legal claims and for expenses it claims it has incurred, including legal fees and advertising, promotion and other out-of-pocket expenses. We believe we acted appropriately in all regards, including properly terminating the agreement when we decided to exit the melatonin business, and we intend to defend this lawsuit vigorously.

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 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 4. Submission of Matters to a Vote of Security Holders

None.

Executive Officers of the Registrant

The following is a list of our executive officers, their ages as of February 1, 2010 and their positions with Genzyme:

<u>Name</u>	<u>Age</u>	<u>Title</u>
Henri A. Termeer	63	Chairman of the Board of Directors; President and Chief Executive Officer
Zoltan A. Csimma	68	Senior Vice President; Chief Human Resources Officer
Thomas J. DesRosier	55	Senior Vice President; General Counsel; Chief Legal Officer
James A. Geraghty	55	Senior Vice President
David P. Meeker, M.D.	55	Executive Vice President, Genetic Diseases, Biosurgery & Corporate Operations
Richard A. Moscicki, M.D.	57	Senior Vice President, Biomedical & Regulatory Affairs; Chief Medical Officer
Alan E. Smith, Ph.D.	64	Senior Vice President, Research; Chief Scientific Officer
Sandford D. Smith	62	Executive Vice President; President, International Group
Peter Wirth	59	Executive Vice President, Legal and Corporate Development; Secretary
Michael S. Wyzga	54	Executive Vice President, Finance; Chief Financial Officer

Mr. Termeer has served as our President and a Director since October 1983, as Chief Executive Officer since December 1985 and as Chairman of our board of directors since May 1988. For ten years prior to joining Genzyme, Mr. Termeer worked for Baxter International Laboratories, Inc., a manufacturer of human health care products. Mr. Termeer is a director of ABIOMED, Inc., or ABIOMED, and Chairman of the Federal Reserve Bank of Boston.

Mr. Csimma has held the title Senior Vice President and Chief Human Resources Officer since March 2006. He joined us in July 2000 as Senior Vice President, Human Resources. Prior to joining Genzyme, he served as Vice President, Human Resources of Wyeth Ayerst Research, a pharmaceutical

research organization, from August 1998 to July 2000. During that time, Mr. Csimma also served as Site Head, Genetics Institute, for Wyeth Ayerst. From May 1988 to August 1998, he served as Vice President, Human Resources and Operations of Genetics Institute, Inc., a biotechnology company, which was integrated into Wyeth Ayerst in March 1998.

Mr. DesRosier has served as Senior Vice President and General Counsel since October 2000 and as Chief Legal Officer since May 2008. Mr. DesRosier joined Genzyme in 1999 as Senior Vice President and Chief Intellectual Property Counsel. Before he joined Genzyme, Mr. DesRosier was assistant general counsel for patents at American Home Products Corp. Mr. DesRosier has also served as Vice President and Chief Patent Counsel for Genetics Institute Inc. and held several intellectual property positions at E.I. DuPont de Nemours and Company and New England Nuclear Corp.

Mr. Geraghty has served as a Senior Vice President of Genzyme since May 2003 and, prior to that, as Vice President since May 2001. He was President of Genzyme Europe from 1998 to 2002 and served as General Manager of Genzyme's cardiovascular business from 2004 to 2008. He currently oversees Genzyme's strategic initiatives in emerging markets and global health. He serves as a Director of GTC Biotherapeutics (formerly Genzyme Transgenics Corporation) where he was Chairman from 1998 to 2001, and President and Chief Executive Officer from its founding in 1993 until 1997. Prior to joining Genzyme, Mr. Geraghty was Vice President of Marketing and Strategic Planning for Baxter/Caremark International. He has also worked as a consultant on international health care strategy at Bain and Company.

Dr. Meeker has served as Executive Vice President since May 2008, with responsibility for our Genetic Diseases and Biosurgery businesses and our corporate manufacturing operations. From May 2008 until March 2009, he had responsibility for our transplant business. From March 2003 until May 2008, he served as Senior Vice President and President, LSD Therapeutics. Dr. Meeker joined Genzyme in 1994 and served as Vice President, Medical Affairs from October 1996 until June 1998; as Senior Vice President Medical Affairs from June 1998 through May 2000; and as Senior Vice President Genzyme Europe from May 2000 until March 2003. Prior to joining Genzyme, Dr. Meeker was director of the Pulmonary Critical Care Fellowship at the Cleveland Clinic. He was also an assistant professor of medicine at Ohio State University.

Dr. Moscicki has served as Senior Vice President, Biomedical & Regulatory Affairs since May 2008 and Chief Medical Officer since September 1996. From September 1996 until May 2008, he served as Senior Vice President, Clinical, Medical and Regulatory Affairs. Dr. Moscicki joined us in March 1992 as Medical Director, became Vice President, Medical Affairs in early 1993 and served as Vice President, Clinical, Medical and Regulatory Affairs from December 1993 until September 1996. Since 1979, he has also been a physician staff member at the Massachusetts General Hospital and a faculty member at the Harvard Medical School.

Dr. Alan Smith joined us in August 1989 as Senior Vice President, Research, and became Chief Scientific Officer in September 1996. Prior to joining Genzyme, he served as Vice President—Scientific Director of Integrated Genetics, Inc., from November 1984 until its acquisition by us in August 1989. From October 1980 to October 1984, Dr. Smith was head of the Biochemistry Division of the National Institute for Medical Research, Mill Hill, London, England and from 1972 to October 1980, he was a member of the scientific staff at the Imperial Cancer Research Fund in London, England.

Mr. Sandford Smith has held the title of Executive Vice President since June 2006, Senior Vice President since January 2003 and President of our International Group since January 2000, with responsibility for the commercial activities for our products outside of the United States. He joined us in April 1996 and served as Vice President and General Manager of our International Group and President of our Therapeutics business. Prior to joining Genzyme, Mr. Smith served as President and Chief Executive Officer of Repligen Corporation. Before joining Repligen Corporation, Mr. Smith also

served as Vice President of Business Development and Strategic Planning for the Pharmaceutical Group of Bristol-Myers Squibb Company.

Mr. Wirth joined us in January 1996 and has served as Executive Vice President since September 1996 with responsibility for our corporate development and legal activities. From September 1996 until May 2008, he also served as our Chief Legal Officer. From 2001 through October 2005, Mr. Wirth had responsibility for our drug discovery and development business. In addition, from September 1996 until June 2003, Mr. Wirth was responsible for our Oncology business. Prior to joining Genzyme, Mr. Wirth was a partner at Palmer and Dodge, a Boston law firm, where he was head of the firm's technology group.

Mr. Wyzga has served as Executive Vice President, Finance since May 2003 and as Chief Financial Officer since July 1999. He joined us in February 1998 as Vice President and Corporate Controller and served as Senior Vice President, Corporate Controller from January 1999 until July 1999. He served as Senior Vice President, Finance from July 1999 until May 2003 and as Chief Accounting Officer from January 1999 until November 2008. From February 1997 to February 1998, Mr. Wyzga served as Chief Financial Officer of Sovereign Hill Software, Inc., a software company, and from 1991 to 1997 held various senior management positions with CACHELINK Corporation and Lotus Development Corporation. Prior to November 11, 2009, Mr. Wyzga was also a director of Altus Pharmaceuticals Inc., a developer of protein therapeutics that, on that date, filed a voluntary petition for relief under Chapter 7 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on The Nasdaq Global Select Market ("NASDAQ®") system under the symbol "GENZ".

As of February 17, 2010, there were 3,169 stockholders of record of our common stock.

The following table sets forth, for the periods indicated, the high and low sale price of our common stock as reported by NASDAQ.

	<u>High</u>	<u>Low</u>
2009:		
First Quarter	\$73.75	\$50.05
Second Quarter	63.47	50.83
Third Quarter	58.43	47.09
Fourth Quarter	57.27	47.55
2008:		
First Quarter	\$82.08	\$67.38
Second Quarter	76.76	65.21
Third Quarter	83.97	67.00
Fourth Quarter	81.16	57.61

We have never paid any cash dividends on any series of our common stock and we do not anticipate paying cash dividends in the foreseeable future.

Issuer Purchases of Equity Securities

Stock Repurchase Program

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 vary based on a range of factors, including share price. The program does not obligate us to acquire any particular amount of common stock and the program may be suspended at any time at our discretion.

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.

During the fourth quarter of 2009, we did not repurchase any common stock.

Item 6. Selected Financial Data

The following financial data of Genzyme Corporation and Subsidiaries should be read in conjunction with our audited, consolidated financial statements and related notes contained in Part II, Item 8, "Financial Statements and Supplementary Data," to this Form 10-K. These selected financial data may not be indicative of our future financial performance or condition due to the risks and uncertainties associated with operating our business, including those described under the caption "Risk Factors" in Part II, Item 7, "Management's Discussion and Analysis of Genzyme Corporation and Subsidiaries' Financial Condition," to this Form 10-K (amounts in thousands except per share data):

CONSOLIDATED STATEMENTS OF OPERATIONS DATA

	For the Years Ended December 31,				
	2009	2008	2007	2006	2005
Revenues:					
Net product sales	\$4,076,665	\$4,196,907	\$3,457,778	\$2,887,409	\$2,453,303
Net service sales	418,518	366,091	326,326	282,118	261,379
Research and development revenue	20,342	42,041	29,415	17,486	20,160
Total revenues	4,515,525	4,605,039	3,813,519	3,187,013	2,734,842
Operating costs and expenses:					
Cost of products sold(1,2)	1,136,937	913,267	715,504	536,388	462,177
Cost of services sold(1)	249,139	235,295	211,826	199,283	170,475
Selling, general and administrative(1,3)	1,428,596	1,338,190	1,187,184	1,010,400	787,839
Research and development(1,4)	865,257	1,308,330	737,685	649,951	502,657
Amortization of intangibles	266,305	226,442	201,105	209,355	181,632
Contingent consideration expense(5)	65,584	—	—	—	—
Charges for impaired intangible assets and goodwill(6)	—	2,036	—	219,245	—
Purchase of in-process research and development(7)	—	—	106,350	552,900	29,200
Total operating costs and expenses	4,011,818	4,023,560	3,159,654	3,377,522	2,133,980
Operating income (loss)	503,707	581,479	653,865	(190,509)	600,862
Other income (expenses):					
Equity in income of equity method investments	—	201	7,398	15,705	151
Gain (loss) on investments in equity securities, net(8)	(56)	(3,340)	13,067	73,230	5,698
Gain on acquisition of business(9)	24,159	—	—	—	—
Other	(1,719)	356	3,295	8,373	10,417
Investment income	17,642	51,260	70,196	56,001	31,429
Interest expense	—	(4,418)	(12,147)	(15,478)	(19,638)
Total other income	40,026	44,059	81,809	137,831	28,057
Income (loss) before income taxes(1)	543,733	625,538	735,674	(52,678)	628,919
(Provision for) benefit from income taxes(1,6)	(121,433)	(204,457)	(255,481)	35,881	(187,430)
Net income (loss)(1)	\$ 422,300	\$ 421,081	\$ 480,193	\$ (16,797)	\$ 441,489
Net income (loss) per share:					
Basic(1)	\$ 1.57	\$ 1.57	\$ 1.82	\$ (0.06)	\$ 1.73
Diluted(1)	\$ 1.54	\$ 1.50	\$ 1.74	\$ (0.06)	\$ 1.65

CONSOLIDATED BALANCE SHEET DATA

	December 31,				
	2009	2008	2007	2006	2005
Cash and investments(10)	\$ 1,049,700	\$ 973,691	\$1,460,394	\$1,285,604	\$1,089,102
Working capital	1,722,673	1,601,852	1,137,904	1,338,062	1,114,976
Total assets	10,060,724	8,671,276	8,314,375	7,191,188	6,878,865
Long-term contingent consideration obligations, including current portion(5)	1,015,236	—	—	—	—
Long-term debt, capital lease obligations and convertible debt, including current portion	124,600	131,907	810,373	816,029	820,113
Stockholders' equity	7,683,652	7,305,993	6,612,937	5,660,711	5,149,867
There were no cash dividends paid.					

- (1) For the years ended December 31, 2009, 2008 and 2007, we recorded pre-tax stock-based compensation expense, which was allocated based on the functional cost center of each employee as follows (amounts in thousands, except per share amounts):

	For the Years Ended December 31,		
	2009	2008	2007
Cost of products and services sold	\$ (32,314)	\$ (27,555)	\$ (25,677)
Selling, general and administrative	(110,410)	(102,745)	(106,172)
Research and development	(61,391)	(56,673)	(58,101)
Total	(204,115)	(186,973)	(189,950)
Less: tax benefit of stock options	53,434	56,740	58,148
Stock-based compensation expense, net of tax	<u>\$(150,681)</u>	<u>\$(130,233)</u>	<u>\$(131,802)</u>
Net loss per share—basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.49)</u>	<u>\$ (0.50)</u>

- (2) Includes charges of:
- \$107.2 million recorded in 2009, consisting primarily of \$45.5 million for idle capacity, clean up and other costs related to the remediation of our Allston facility, approximately \$11 million for the write off of Cerezyme work-in-process material and \$43.5 million for the amortization of inventory step-up of Campath, Fludara and Leukine.
 - \$9.2 million recorded in the first quarter of 2009 and \$12.6 million recorded in 2008 for the write off of inventory associated with terminated production runs of Myozyme at our Belgium facility; and
 - \$20.9 million recorded in 2007 to write off Thymoglobulin inventory which did not meet our specifications for saleable product.
- (3) Includes a charge of \$64.0 million recorded in 2007 to settle the litigation related to the consolidation of our former tracking stocks.
- (4) Includes charges of:
- \$7.0 million recorded in September 2009 for amounts accrued or paid to acquire certain gene therapy manufacturing assets from Targeted Genetics Corporation;
 - \$18.2 million recorded in January 2009 for the purchase of intellectual property from EXACT Sciences;
 - \$16.0 million recorded in December 2008 for the license or purchase of certain intellectual property and technology relating to transactions with two third parties;
 - \$130.0 million recorded in October 2008 for amounts accrued or paid to Osiris as an upfront, nonrefundable license fee;
 - \$100.0 million recorded in July 2008 as a nonrefundable upfront license fee payment to PTC;
 - \$244.9 million recorded in 2008 for license fee payments to Isis; and
 - \$25.0 million recorded in 2007 for an upfront milestone payment paid to Ceregene Inc., or Ceregene, for the development and commercialization of CERE-120, a gene therapy product candidate.

- (5) In May 2009, we recorded contingent consideration obligations in connection with our acquisition from Bayer. Changes in the fair value of these contingent consideration obligations are recorded as contingent consideration expense.
- (6) Includes charges for impaired intangible assets and goodwill of \$219.2 million pre-tax (\$149.4 million after tax) recorded in 2006 to write off the goodwill of our genetics business unit.
- (7) Includes charges for pre-tax in-process research and development, or IPR&D, incurred in connection with the following acquisitions:
 - 2007—Bioenvision Inc., or Bioenvision;
 - 2006—AnorMED Inc., or AnorMED; and
 - 2005—Avigen, Inc., or Avigen, Bone Care and Verigen;
- (8) For 2007, includes a pre-tax gain of \$10.8 million recorded on the sale of our entire investment in the common stock of Therapeutic Human Polyclonals Inc., or THP. For 2006, includes a \$69.4 million gain on the sale of our entire investment in Cambridge Antibody Technology Group plc, or CAT.
- (9) Includes a gain recorded in 2009 related to our acquisition of certain products and development programs from Bayer. The fair value of the identifiable assets acquired exceeded the fair value of the purchase price for the transaction.
- (10) Includes cash, cash equivalents, and short- and long-term investments in debt securities.

Item 7. Management's Discussion and Analysis of 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 "Risk Factors" below. These risks and uncertainties could cause actual results to differ materially from those forecasted in forward-looking statements or implied by past results and trends. Forward-looking statements are statements that attempt to project or anticipate future developments in our business; we encourage you to review the examples of forward-looking statements under "Note Regarding Forward-Looking Statements" at the beginning of this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated), and we undertake no obligation to update or revise the statements in light of future developments.

INTRODUCTION

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

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, Aldurazyme and Elaprase;
- 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 and the Septra line of products; and
- Hematologic Oncology, which develops, manufactures and distributes products for the treatment of cancer and the mobilization of hematopoietic stem cells. This business is also developing a product for the treatment of MS. The unit derives substantially all of its revenue from sales of Clolar, Mozobil, Campath, Fludara and Leukine.

Formerly, we included our MS business unit under the caption "Other." As a result of our acquisition of certain products and development programs from Bayer in the second quarter of 2009, as described under the heading "Strategic Transactions—Acquisition from Bayer," our MS business unit is now material. We have aggregated our Hematologic Oncology reporting segment and MS business unit and now report the activities of these two reporting units 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 genetic testing 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 genetic testing 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 report our corporate, general and administrative operations and corporate science activities under the caption “Corporate.”

We have revised our 2008 and 2007 segment disclosures to conform to our 2009 presentation.

STRATEGIC TRANSACTIONS

We classify nonrefundable fees paid outside of a business combination for the acquisition or licensing of products that have not received regulatory approval and have no future alternative use as research and development expense.

2009:

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, equipment 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 an additional \$2.5 million in the fourth quarter of 2009 as certain technology transfer-based milestones were achieved. The remaining \$1.0 million of technology transfer-based milestone payments were paid in January 2010. The purchased assets did not qualify as a business combination and have not reached technological feasibility nor have alternative future use. Therefore, 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 in 2009.

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 (we refer to alemtuzumab for oncology indications 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 have primary responsibility for the product’s development while Bayer continues to fund development at the levels specified under the previous agreement and participates in a development steering committee. We 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	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 \$113.2 million to Bayer, of which \$70.8 million was refundable. The remaining nonrefundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$61.8 million of the refundable amount was received in 2009. As of December 31, 2009, \$8.9 million remains due from Bayer. 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 December 31, 2009, the fair value of the total contingent consideration obligations was \$1.02 billion primarily due to changes in discount periods and management estimates. Accordingly, we recorded contingent consideration expense in our consolidated statements of operations of \$65.6 million in 2009. As of December 31, 2009, we have paid \$36.4 million in contingent consideration payments to Bayer and have received \$10.0 million in 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 in 2009.

Selling, general and administrative expenses, or SG&A, in our consolidated statements of operations in 2009 includes approximately \$5 million of acquisition-related costs, primarily legal fees, associated with the Bayer transaction.

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 in March 2009.

2008:

Strategic Alliance with Osiris

In October 2008, we entered into a strategic alliance with Osiris, whereby we obtained an exclusive license to develop and commercialize Prochymal and Chondrogen, mesenchymal stem cell products, outside of the United States and Canada. Osiris will commercialize Prochymal and Chondrogen in the United States and Canada. We paid Osiris a nonrefundable upfront payment of \$75.0 million in November 2008, and an additional \$55.0 million nonrefundable upfront license fee on July 1, 2009. The results of these programs are primarily included in our immune mediated diseases business unit, which are reported under the category "Other" in our segment disclosures.

Osiris will be responsible for completing, at its own expense, all clinical trials of Prochymal for the treatment of GvHD and Crohn's disease, and clinical trials of Prochymal and Chondrogen through successful completion of phase 2 for all other indications. Osiris will be responsible for 60% and we will be responsible for 40% of the clinical trial costs for phase 3 and 4 clinical trials of Prochymal (other than for the treatment of GvHD and Crohn's disease) and Chondrogen. Osiris is eligible to receive:

- up to \$500.0 million in development and regulatory milestone payments for all indications of Prochymal and up to \$100.0 million for Chondrogen, unless we elect to opt out of further development of Chondrogen; and
- up to \$250.0 million in sales milestones for all indications of Prochymal and up to \$400.0 million in sales milestones for all indications of Chondrogen for the prevention and treatment of conditions of articulating joints.

Osiris is also eligible to receive tiered royalties from us on sales of Prochymal and Chondrogen outside of the United States and Canada. In September 2009, Osiris announced that its two phase 3 trials evaluating Prochymal for the treatment of acute GvHD failed to meet their primary endpoints.

Strategic Alliance with PTC

In July 2008, we entered into a collaboration agreement with PTC to develop and commercialize ataluren (formerly known as PTC124), PTC's novel oral therapy in late-stage development for the treatment of nonsense-mutation-mediated DMD, and nonsense-mutation-mediated CF. Under the terms of the agreement, PTC will commercialize ataluren in the United States and Canada, and we will commercialize the treatment in all other countries. In connection with the collaboration agreement, we paid PTC a nonrefundable upfront payment of \$100.0 million, which we recorded as a charge to research and development expense for our Genetic Diseases segment in our consolidated statements of operations during the third quarter of 2008. At its own expense, PTC will conduct and be responsible for the phase 2b trial of ataluren in DMD, the phase 2b trial of ataluren in CF and two proof-of-concept studies in other indications to be determined. Once these four studies have been completed, we and PTC will share research and development costs for ataluren equally. We and PTC will each bear the sales and marketing and other costs associated with the commercialization of ataluren in our respective territories. PTC is eligible to receive up to \$337.0 million in milestone payments as follows:

- up to \$165.0 million in development and approval milestones, the majority of which would be paid upon the receipt of approvals obtained outside of the United States and Canada; and
- up to \$172.0 million in sales milestones, commencing if and when annual net sales for ataluren outside of the United States and Canada reach \$300.0 million and increasing in increments through revenues of \$2.4 billion.

PTC is also eligible to receive tiered royalties from sales of ataluren outside of the United States and Canada. The results of our ataluren program are included in the results of our Genetic Diseases segment disclosures.

Strategic Alliance with Isis

On January 7, 2008, we entered into a strategic alliance with Isis, whereby we obtained an exclusive, worldwide license to develop and commercialize mipomersen, a lipid-lowering drug targeting apolipoprotein B-100, which is currently being developed for the treatment of FH, an inherited disorder that causes exceptionally high levels of LDL-cholesterol. In February 2008, we made a nonrefundable payment to Isis of \$150.0 million, of which \$80.1 million was recorded as an other noncurrent asset in our consolidated balance sheets based on the fair value of the five million shares of

Isis common stock we acquired in connection with the transaction. Due to certain trading restrictions, we classify this investment as other noncurrent assets. We allocated the remaining \$69.9 million to the mipomersen license, which we recorded as a charge to research and development expense in our consolidated statements of operations during the first quarter of 2008.

In June 2008, we finalized the terms of our license and collaboration agreement with Isis and paid Isis an additional \$175.0 million upfront nonrefundable license fee. Under the terms of the agreement, Isis will be responsible, at its own expense, for up to \$125.0 million for the development of mipomersen. Thereafter, we and Isis will share development costs for mipomersen equally. The initial funding commitment by Isis and shared development funding would end when the mipomersen program is profitable. In the event the research and development of mipomersen is terminated prior to Isis completing their funding obligation, we are not entitled to any refund of our \$175.0 million upfront payment. Isis is eligible to receive up to \$750.0 million in commercial milestone payments and up to \$825.0 million in development and regulatory milestone payments.

We will be responsible for funding sales and marketing expenses until mipomersen revenues are sufficient to cover such costs. Profits on mipomersen initially will be allocated 70% to us and 30% to Isis. The profit ratio would be adjusted on a sliding scale if and as annual revenues for mipomersen ramp up to \$2.0 billion, at which point we would share profits equally with Isis. The results of our mipomersen program are included in the results of our cardiovascular business unit, which are reported in our Cardiometabolic and Renal segment disclosures.

We account for our investment in Isis common stock on a cost basis due to certain trading restrictions imposed by Isis that prohibit us from selling our holdings of Isis common stock until the earlier of:

- January 7, 2012;
- the first commercial sale of product under our agreement with Isis; or
- termination or reversion of the product license granted to us under the agreement.

As of December 31, 2009, our investment in Isis common stock had a carrying value of \$80.1 million, or \$16.02 per share, and a fair market value of \$55.6 million, or \$11.11 per share. The closing price per share of Isis common stock exhibited volatility in 2009 and has remained below our historical cost since September 1, 2009, with closing prices subsequent to that date ranging from a high of \$15.69 per share to a low of \$9.94 per share. We considered all available evidence in assessing the decline in value of our investment in Isis common stock, including investment analyst reports and Isis's expected results and future outlook, and we believe that the investment can be expected to recover to at least our historical cost. Currently, the average 12-month price estimate for Isis common stock among some analysts is approximately \$16 per share. As a result of our analysis, as of December 31, 2009, we consider the \$24.6 million unrealized loss on our investment in Isis common stock to be a temporary loss. We will continue to review the fair value of our investment in Isis common stock in comparison to our historical cost and in the future, if the decline in value has become "other than temporary," we will write down our investment in Isis common stock to its then current market value and record an impairment charge to our consolidated statements of operations.

2007:

The following acquisition was accounted for as a business combination and, accordingly, we have included its results of operations in our consolidated statements of operations from the date of acquisition.

Bioenvision

Effective October 23, 2007, we completed our acquisition of Bioenvision through the culmination of a two-step process consisting of a tender offer completed in July 2007, and a merger approved in October 2007. We paid gross consideration of \$366.5 million in cash, including \$362.0 million for the outstanding shares of Bioenvision common and preferred stock and options to purchase shares of Bioenvision common stock, and approximately \$5 million for acquisition costs. The transaction was accounted for as a business combination and is included in the results of our Hematologic Oncology reporting segment. The acquisition of Bioenvision provided us with the exclusive, worldwide rights to clofarabine.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

The significant accounting policies and methods used in the preparation of our consolidated financial statements are described in Note A., "Summary of Significant Accounting Policies," to our consolidated financial statements set forth in Item 8 of this Form 10-K. The preparation of consolidated financial statements under U.S. GAAP requires us to make certain estimates and judgments that affect reported amounts of assets, liabilities, revenues, expenses, and disclosure of contingent assets and liabilities in our financial statements. Our actual results could differ from these estimates under different assumptions and conditions. We believe that the following critical accounting policies affect the significant judgments and estimates used in the preparation of our consolidated financial statements:

- Revenue Recognition;
- Stock-Based Compensation;
- Income Taxes;
- Inventories;
- Long-Lived and Intangible Assets;
- Asset Impairments;
- Contingent Consideration Expense; and
- Investments in Debt and Equity Securities.

Revenue Recognition

Product Sales

We recognize revenue from product sales when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured. For sales to distributors that do not or can not bear the risk of loss, we recognize revenue when the product is sold through to hospitals or other healthcare providers. The timing of product shipments and receipts by the customer can have a significant impact on the amount of revenue recognized in a particular period. A significant portion of our products are sold at least in part through wholesalers and specialty distributors, along with direct sales to hospitals, homecare providers, government agencies and physicians. Consequently, our net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of our major distributors and other trade buyers, which may result from seasonality, pricing, wholesaler buying decisions or other factors. Inventory in the distribution channel consists of inventory held by wholesalers and specialty distributors, who are our customers, and inventory held by their retail customers, such as pharmacies and hospitals. Our revenue in a particular period can be affected by increases or decreases in channel inventories. Significant increases in wholesaler or retail inventories could result in reduced purchases in subsequent

periods, or product returns from the distribution channel due to overstocking, low end-user demand or product expiration.

We use a variety of data sources to determine the amount of inventory in the distribution channel. For most product lines, we receive data on sales and inventory levels directly from our primary customers. For key product lines in our Cardiometabolic and Renal, Genetic Diseases and Hematologic Oncology areas, our data sources also include prescription and wholesaler data purchased from external data providers. As part of our efforts to limit the amount of Cardiometabolic and Renal, Genetic Diseases and Hematologic Oncology inventory held by distributors and to gain improved visibility into the distribution channel, we have executed agreements to limit the amounts of inventory they carry and to provide us ongoing reports to verify distributor inventory levels and sales data.

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. We also consider the product's lifecycle and possible competition pending, including generic 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):

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Product sales allowances:							
Contractual adjustments	\$ 633,605	\$ 505,027	\$ 377,852	\$128,578	25%	\$127,175	34%
Discounts	26,775	23,390	20,037	3,385	14%	3,353	17%
Sales returns	34,663	23,214	15,342	11,449	49%	7,872	51%
Total product sales allowances	<u>\$ 695,043</u>	<u>\$ 551,631</u>	<u>\$ 413,231</u>	<u>\$143,412</u>	26%	<u>\$138,400</u>	33%
Total gross product sales	<u>\$4,771,708</u>	<u>\$4,748,539</u>	<u>\$3,871,009</u>	<u>\$ 23,169</u>	—	<u>\$877,530</u>	23%
Total product sales allowances as a percent of total gross product sales	15%	12%	11%				

Total product sales allowances increased in 2009, as compared to 2008, largely due to the impact of price increases implemented after the second quarter of 2008, primarily for our Cardiometabolic and Renal reporting segment, increased sales returns reserves for Hectorol based on our experience with returns for the product, the addition of \$36.4 million of product sales allowances related to sales of Campath, Fludara and Leukine, which we acquired from Bayer in May 2009, approximately \$8 million of additional accrued contractual fees and changes in our overall product mix. Total product sales allowances as a percentage of total gross product sales increased in 2009, as compared to 2008, primarily due to decreased sales volumes for Cerezyme and Fabrazyme as a result of supply constraints for which there was not a proportionate decrease in product sales allowances because these products generally have lower sales allowances. Our product sales allowances for 2009 do not include any estimates or allowances related to the proposed U.S. healthcare reform legislation currently pending final congressional action. We cannot be certain when the healthcare reform legislation will be enacted, if at all, and if enacted, what effect the new law will have on our product sales allowances.

Total product sales allowances increased in 2008, as compared to 2007, primarily due to an increase in overall gross product sales and changes in rebate rates and product mix. The increase in sales returns allowances in 2008, as compared to 2007, is primarily due to increased sales returns allowances for our Cardiometabolic and Renal segment due to a Renagel/Renvela price increase in August 2008 and revisions to our estimates of the volume of product returns for our Cardiometabolic and Renal segment as well as our Biosurgery segment.

Total estimated product sales allowance reserves and accruals in our consolidated balance sheets increased approximately 12% to approximately \$236 million as of December 31, 2009, as compared to approximately \$210 million as of December 31, 2008, primarily due to changes in the timing of certain payments and approximately \$8 million of additional accrued contractual fees in 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, is appropriately 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 is

appropriately 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):

	Year Ended December 31,			09/08	09/08	08/07	08/07
	2009	2008	2007	Increase/ (Decrease)	Increase/ (Decrease) % Change	Increase/ (Decrease)	Increase/ (Decrease) % Change
Distributor fees:							
Included in contractual adjustments and recorded as a reduction to product sales	\$22,308	\$23,368	\$18,483	\$(1,060)	(5)%	\$4,885	26%
Charged to SG&A	13,350	13,514	13,190	(164)	(1)%	324	2%
Total distributor fees	<u>\$35,658</u>	<u>\$36,882</u>	<u>\$31,673</u>	<u>\$(1,224)</u>	<u>(3)%</u>	<u>\$5,209</u>	<u>16%</u>

Collaborations

We evaluate revenue from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting. We recognize revenue for a delivered item in a multiple element arrangement upon determination that:

- the delivered items have value to the customer on a stand-alone basis;
- there is objective and reliable evidence of fair value of the undelivered items; and
- delivery or performance is probable and within our control for any delivered items that have a right of return.

The determination that multiple elements in an arrangement meet the criteria for separate units of accounting requires us to exercise our judgment.

We determine whether we should recognize revenue on a gross or net basis based on the relevant facts and circumstances which relate primarily to whether we act as a principal or agent in the process of generating revenues for the revenue transactions.

Stock-Based Compensation

We are required to recognize stock-based compensation expense in our financial statements for all share-based payment awards, including stock options and restricted stock units, or RSUs, made to employees and directors based upon the grant date fair value of those awards.

We estimate the fair value of each stock option grant using the Black-Scholes option pricing model. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs. The key assumptions in the Black-Scholes model are the risk-free interest rate, the dividend yield, the expected option life (in years) and the expected volatility of the price of Genzyme Stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect on the date of grant. The dividend yield percentage is zero because we do not currently pay dividends nor intend to do so during the expected option life. We use historical data on exercises of our stock options and other factors to estimate the expected option life (in years), or term, of the share-based payments granted. We estimate the expected volatility rate for our stock options based on historical volatility of

our stock over the expected term of the equity award granted. We determine separate volatility rates for each enrollment under our employee stock purchase plan, or ESPP, based on the period from the commencement date of each enrollment to each applicable purchase date. Changes in these input variables would affect the amount of expense associated with stock-based compensation. The compensation expense recognized for all share-based awards is net of estimated forfeitures. We estimate forfeiture rates based on historical analysis of option forfeitures. If actual forfeitures should vary from estimated forfeitures, adjustments to stock-based compensation expense may be required in future periods.

Income Taxes

We use the asset and liability method of accounting for deferred income taxes. We are subject to income taxes in both the United States and numerous foreign jurisdictions; however, our most significant tax jurisdictions are the U.S. federal and states. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. These judgments, estimates and assumptions involve:

- interpreting the tax laws in various jurisdictions in which we operate;
- analyzing changes in tax laws, regulations, and treaties, foreign currency exchange restrictions; and
- estimating our levels of income, expenses and profits in each jurisdiction and the potential impact of that income on the tax liability in any given year.

We operate in many jurisdictions where the tax laws relating to the pricing of transactions between related parties are open to interpretation, which could potentially result in tax authorities asserting additional tax liabilities with no offsetting tax recovery in other countries.

Uncertainties exist with respect to the interpretation of complex tax regulations and the amount and timing of future taxable income. Given the wide range of international business relationships and the long-term nature and complexity of existing contractual agreements, differences arising between the actual results and the assumptions made, or future changes to such assumptions, could necessitate adjustments to the tax benefit and provision in future periods. We establish what we believe to be reasonable provisions for possible consequences of audits by the tax authorities of the respective countries. The amount of such provisions is based on various factors, such as experience with previous tax audits and differing interpretations of tax regulations by the taxable entity and the responsible tax authority. Such differences in interpretation may arise on a wide variety of issues depending on the conditions prevailing in the respective domicile. We develop our cumulative probability assessment of the measurement of uncertain tax positions using internal expertise, experience and judgment. Estimates are refined as additional information becomes known. Any outcome upon settlement that differs from our initial estimate may result in additional or lower tax expense in future periods. However, we do not believe it is possible to reasonably estimate the potential impact of changes to the assumptions, estimates and judgments identified because the resulting change to our tax liability, if any, is dependent on numerous factors, including among others: changes in tax law, the amount and nature of additional taxes potentially asserted by local tax authorities; the willingness of local tax authorities to negotiate a fair settlement through an administrative process; the impartiality of the local courts; and the potential for changes in the tax paid to one country to either produce, or fail to produce, an offsetting tax change in other countries.

We apply a two-step approach to recognize and measure uncertain tax positions (tax contingencies). The first step is to evaluate the tax position for recognition by determining if the weight

of available evidence indicates it is more likely than not that the tax position will be sustained based on the technical merits of the tax position. The second step is the measurement of the tax benefit, which is the largest amount, using cumulative probability measure, which is likely to be realized upon ultimate audit settlement, including resolution of related appeals or litigation processes, if any. We consider many factors, including the factors described above, when evaluating and estimating our tax positions and tax benefits, which requires periodic adjustments and may not accurately forecast actual outcomes.

Inventories

We value inventories at cost or, if lower, fair value. We determine cost using the first-in, first-out method. We analyze our inventory levels quarterly and write down inventory, as a charge to cost of sales that has become obsolete due to anticipated product expiration, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. Expired inventory is disposed of and the related costs are written off. If actual market conditions are less favorable than those projected by management, additional inventory write downs may be required.

We capitalize inventory produced for commercial sale, which may result in the capitalization of inventory prior to regulatory approval of a product. In no event is inventory capitalized prior to the completion of a phase 3 clinical trial. If a product is not approved for sale, it would result in the write off of the inventory and a charge to earnings.

We periodically review our inventories for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than the value we estimate, or if there are any further determinations that inventory will not be marketable based on estimates of demand, additional inventory write downs will be required. Additionally, our products are subject to strict quality control and monitoring throughout the manufacturing process. Periodically, certain lots of inventory may fail to meet our quality specifications during the manufacturing process or prior to sale, or may expire. For such lots, we consider the factors affecting the decline in quality of the lot and assess the likelihood that the lot can be reworked into saleable product, or whether the lot is unmarketable. We record a charge to cost of products sold in our consolidated statement of operations to write off the value of any unmarketable inventory in the period in which we determine that the product no longer meets our criteria for saleable product. The determination of what factors may cause a lot to fail to meet our quality standards, the assessment of whether we can rework the lot within the scope of the approved manufacturing process for the product and the likelihood that we can complete such rework in a timely fashion involve judgments that can affect the amount and timing of the charges we record to write off the value of unmarketable inventory.

In 2009, we wrote off approximately \$11 million of Cerezyme work-in-process material related to the costs for the remediation of our Allston facility and \$9.2 million of Myozyme inventory costs related to terminated production runs at our Belgium facility. In 2008, we wrote off Myozyme inventory costs of \$12.6 million related to terminated production runs at our Belgium facility.

Long-Lived and Intangible Assets

Property, Plant and Equipment

As of December 31, 2009, there was \$2.8 billion of net property, plant and equipment on our consolidated balance sheet. We generally depreciate property, plant and equipment using the straight-line method over its estimated economic life, which ranges from 3 to 40 years. Determining the economic lives of property, plant and equipment requires us to make significant judgments that can materially impact our operating results. If our estimates require adjustment, it could have a material impact on our reported results.

In the ordinary course of our business, we incur substantial costs to purchase and construct property, plant and equipment. The treatment of costs to purchase or construct these assets depends on the nature of the costs and the stage of construction. Costs incurred in the initial design and evaluation phase, such as the cost of performing feasibility studies and evaluating alternatives, are charged to expense. Qualifying costs incurred in the committed project planning and design phase, and in the construction and installation phase, are capitalized as part of the cost of the asset. We stop capitalizing costs when an asset is substantially complete and ready for its intended use. Determining the appropriate period during which to capitalize costs, and assessing whether particular costs qualify for capitalization, requires us to make significant judgments. These judgments can have a material impact on our reported results.

Equipment and facilities used to manufacture products subject to FDA or other governmental regulation are required to comply with standards of those regulatory agencies. The activities necessary to obtain approval from these regulatory agencies are referred to as validation costs. We capitalize the cost of validating new equipment and facilities for the underlying manufacturing process. We begin capitalization when we consider the product and manufacturing process to have demonstrated technological feasibility, and end capitalization when the asset is substantially complete and ready for its intended use. Costs capitalized include incremental labor and direct material, and incremental fixed overhead. Determining whether to capitalize validation costs requires judgment, and can have a significant impact on our reported results. Also, if we were unable to successfully validate the manufacturing process for any future product, we would have to write off to current operating expense any validation costs that had been capitalized during the unsuccessful validation process. Costs to initiate new projects in an existing facility are treated as start-up costs and expensed as incurred. As of December 31, 2009, capitalized validation costs, net of accumulated depreciation, were \$19.4 million.

Goodwill and Other Intangible Assets

As of December 31, 2009, there was approximately \$1.4 billion of net goodwill and \$2.3 billion of net other intangible assets on our consolidated balance sheet. We amortize finite intangible assets using the straight-line method over their estimated economic lives, which range from 1 and 15 years, or using the economic use method if that method results in significantly greater amortization than the straight-line method. Determining the economic lives of acquired finite intangible assets requires us to make significant judgment and estimates, and can materially impact our operating results. For certain acquired finite intangible assets, we may be required to make additional payments contingent upon meeting certain sales targets. We record amortization expense for these intangibles based on estimated future sales of the related products and include in the determination of amortization all contingent payments that we believe are probable of being made. We apply this amortization model to our Synvisc distribution rights (acquired from Wyeth), our license agreement with Synpac related to Myozyme patents and our technology intangible assets for Fludara related to our acquisition from Bayer. We review the sales forecasts of these products on a quarterly basis and assess the impact changes in the forecasts have on the rate of amortization and the likelihood that contingent payments will be made. Adjustments to amortization expense resulting from changes in estimated sales are reflected prospectively.

IPR&D

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 IPR&D 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.

Asset Impairments

Impairment of Goodwill and Indefinite-Lived IPR&D

We are required to periodically test goodwill and IPR&D classified as indefinite-lived assets for impairment and to amortize other intangible assets over their useful lives unless these lives are determined to be indefinite.

We test goodwill using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is

greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the fair values, the carrying value of the goodwill must be written down to its implied fair value. We determine the fair values by discounting, to present value, the estimated future cash flow of the reporting unit, which includes various analyses, assumptions and estimates including discount rates, projected results and estimated cash flows.

Effective January 1, 2009, all IPR&D we acquire through business combinations on or after January 1, 2009 is capitalized as an intangible asset on our consolidated balance sheets and periodically tested for impairment. We test our indefinite-lived IPR&D assets for impairment by comparing the face value of each IPR&D asset to our carrying value for the asset. If the carrying value is greater than the fair value of the asset, we are required to write down the value of the IPR&D asset to its implied fair value. We continue to test our indefinite-lived IPR&D assets for potential impairment until the projects are completed or abandoned.

We are required to perform impairment tests annually, which we perform in the third quarter of every year, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. In December 2008, we filed an IND for our advanced phosphate binder, Genz-644470. However, in November 2009, we discontinued this program because the results of a phase 2/3 clinical study of the advanced phosphate binder did not demonstrate significant improvement in phosphate lowering compared to Renvela. Upon discontinuation of this program, we updated the annual goodwill impairment test that had been performed for our renal reporting unit in the third quarter of 2009. We determined that the fair value of our renal reporting unit continued to exceed its carrying value, and, therefore, no impairment charge was required as a result of the termination of our advanced phosphate binder program. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition specifically regarding product development, market conditions and cash flows that were used to determine the valuation of goodwill and intangibles. When we perform impairment tests in future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment charges.

Impairment of Tangible and Intangible Assets, Other Than Goodwill, and Finite-Lived IPR&D

We periodically evaluate long-lived assets for potential impairment. We perform these evaluations whenever events or changes in circumstances suggest that the carrying value of an asset or group of assets is not recoverable. Upon discontinuation of the development of our advanced phosphate binder, as described above, we also tested the long-lived assets of our renal reporting unit for potential impairment. We determined that the fair value of the long-lived assets of our renal reporting unit continued to exceed their carrying value and, therefore, no impairment charge was required as a result of the termination of this program. In evaluating long-lived assets for potential impairment, we make several significant estimates and judgments, including:

- determining the appropriate grouping of assets at the lowest level for which cash flows are available;
- estimating future cash flows associated with the asset or group of assets; and
- determining an appropriate discount rate to use in the analysis.

Use of different estimates and judgments could yield significantly different results in this analysis and could result in materially different asset impairment charges.

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 and expense 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.

Investments in Debt and Equity Securities

We invest a portion of our excess cash balances in short-term and long-term marketable debt securities. The earnings on our investment portfolios may be adversely affected by changes in interest rates, credit ratings, collateral value, the overall strength of credit markets, and other factors that may result in other than temporary declines in the value of the securities.

We also invest in equity securities as part of our strategy to align ourselves with technologies and companies that fit with our strategic direction. Most often we will collaborate on scientific programs and research with the issuers of the securities.

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. To validate these prices, we compare the fair market values of our fixed income investments using market data from observable and corroborated sources. We also perform the fair value calculations for our derivative and equity securities using market data from observable and corroborated sources. In periods of market inactivity, the observability of prices and inputs may be reduced for certain instruments.

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):

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Product revenue	\$4,076,665	\$4,196,907	\$3,457,778	\$(120,242)	(3)%	\$739,129	21%
Service revenue	418,518	366,091	326,326	52,427	14%	39,765	12%
Total product and service revenue . .	4,495,183	4,562,998	3,784,104	(67,815)	(1)%	778,894	21%
Research and development revenue . .	20,342	42,041	29,415	(21,699)	(52)%	12,626	43%
Total revenues	<u>\$4,515,525</u>	<u>\$4,605,039</u>	<u>\$3,813,519</u>	<u>\$(89,514)</u>	<u>(2)%</u>	<u>\$791,520</u>	<u>21%</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 MPS I; and
 - Elaprase for the treatment of MPS II.
- Cardiometabolic and Renal products, including:
 - Renagel/Renvela and bulk sevelamer for the reduction of elevated serum phosphorus levels in patients with 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; 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
 - 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 leukemia and lymphoma;
 - Clolar for the treatment of acute leukemia;
 - Leukine for the reduction of the incidence of severe and life-threatening infections in older adult patients with AML following chemotherapy and certain other uses; and
 - Mozobil for the mobilization of hematopoietic stem cells.
- 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):

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Genetic Diseases	\$1,774,519	\$2,226,329	\$1,766,479	\$(451,810)	(20)%	\$459,850	26%
Cardiometabolic and Renal	1,010,932	955,925	832,017	55,007	6%	123,908	15%
Biosurgery	513,682	445,688	381,430	67,994	15%	64,258	17%
Hematologic Oncology	284,858	101,217	68,947	183,641	>100%	32,270	47%
Other product revenue	492,674	467,748	408,905	24,926	5%	58,843	14%
Total product revenue	<u>\$4,076,665</u>	<u>\$4,196,907</u>	<u>\$3,457,778</u>	<u>\$(120,242)</u>	<u>(3)%</u>	<u>\$739,129</u>	<u>21%</u>

2009 As Compared to 2008

Genetic Diseases

Manufacturing and Regulatory Issues in 2009

In June 2009, we interrupted production of Cerezyme and Fabrazyme 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. Cerezyme and Fabrazyme inventories were not sufficient to avoid shortages.

In February 2009, we received a warning letter from the FDA following the agency's inspection of our Allston facility in September and October 2008 and issuance of a Form 483 outlining deficiencies at the facility. The FDA re-inspected the plant in October and November 2009 and provided us with another Form 483 outlining deficiencies at the facility, which were mainly related to the fill-finish capabilities at the facility.

We are moving forward with several expansion projects that will result in an increase of our biologics manufacturing capacity. These projects include a new facility in Framingham, Massachusetts with capacity to produce bulk Fabrazyme and bulk Cerezyme, and the addition of a third 4000L scale bioreactor at our Geel, Belgium facility for the production of bulk Myozyme. We currently anticipate receiving approval for the additional Fabrazyme and Myozyme capacity in 2011. We are working with a third party contract manufacturer to transfer fill-finish activities to the contract manufacturer for a portion of our Fabrazyme, Cerezyme and Myozyme production. In addition, the fill-finish area of the Waterford facility is also being expanded to accommodate the long-term growth of our Genetic Diseases products and, we currently anticipate receiving approval of this new capacity in 2011.

In 2009, we also continued to pursue FDA approval of alglucosidase alfa produced using a larger bioreactor scale process, which we refer to as Lumizyme in the United States. Since 2008, we had been seeking approval of the product in the United States using a 2000L scale process, but we stopped manufacturing the product at this scale in 2009. In November 2009, we received a complete response letter from the FDA regarding our application to produce at the 2000L scale stating that satisfactory resolution of deficiencies related to our Allston facility were required before the Lumizyme application could be approved. Based on subsequent conversations with the FDA, we decided to seek approval of the product produced using a 4000L scale process, which will also be known as Lumizyme in the United States. We submitted an amendment to the 2000L BLA to the FDA in December 2009, which the FDA has assigned a June 17, 2010 PDUFA date. Production of alglucosidase alfa at the larger 4000L scale is required to fulfill global demand. In Europe, we received approval for the 4000L scale

process in February 2009 and, as of the first quarter of 2010, the majority of markets outside of the United States have transitioned to the 4000L scale product.

Genetic Diseases Product Revenue

	2009	2008	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Genetic Diseases:				
Cerezyme	\$ 793,024	\$1,238,977	\$(445,953)	(36)%
Fabrazyme	429,690	494,260	(64,570)	(13)%
Myozyme	324,545	296,176	28,369	10%
Aldurazyme	155,065	151,321	3,744	2%
Other Genetic Diseases	72,195	45,595	26,600	58%
Total Genetic Diseases	<u>\$1,774,519</u>	<u>\$2,226,329</u>	<u>\$(451,810)</u>	(20)%

Genetic Diseases product revenue decreased for 2009 primarily due to:

- the temporary suspension of production at our Allston facility in June 2009 during a time of already low levels of inventory for Cerezyme and Fabrazyme, resulting in supply constraints for Cerezyme and Fabrazyme and increased contractual fees for Cerezyme; and
- unfavorable exchange rate fluctuations; offset in part by
- continued growth in sales volume for Myozyme, Aldurazyme and Elaprase.

Cerezyme and Fabrazyme

The supply constraint and increased contractual fees for Cerezyme adversely impacted Cerezyme revenue by \$398.1 million for 2009. The weakening of foreign currencies against the U.S. dollar also adversely impacted Cerezyme revenue by \$46.3 million for 2009. 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. Sales of Cerezyme were approximately 18% of our total revenue for 2009, which reflect periods of supply constraint, as compared to approximately 27% for 2008. We resumed Cerezyme shipments in November 2009. In late December 2009, we began shipping vials of Cerezyme on a per-infusion basis to patients around the world that experienced a treatment interruption in 2009. To more consistently manage the resupply of Cerezyme to patients in approximately 100 countries and reduce interruptions in shipping that occur in the absence of inventory, we are working to build a small inventory buffer. To build this inventory buffer, we intend to ship at 50% of demand for an eight-week period beginning February 22, 2010.

The supply constraint for Fabrazyme adversely impacted Fabrazyme revenue by \$46.4 million for 2009. The weakening of foreign currencies against the U.S. dollar also adversely impacted Fabrazyme revenue by \$13.2 million for 2009, as compared to 2008. We resumed shipments of vials of Fabrazyme in early January 2010. We have been shipping Fabrazyme to meet approximately 30% of global demand, and anticipate continuing to ship at this level through May 2010. We are working to increase the productivity of the Fabrazyme manufacturing process, which has performed at the low end of the historical range since the re-start of production. We have developed a new working cell bank for Fabrazyme and production is underway at the 2000L scale. Pending regulatory approval, output from this process is expected starting in June 2010. If this change is successful, we anticipate that sufficient supply will become available to enable higher dosing for patients on Fabrazyme.

The Cerezyme and Fabrazyme supply constraints resulting from the suspension of production at our Allston facility have created opportunities for our competitors and our future sales may be negatively affected by competitive products that are being developed by Shire and Protalix. After our products experienced supply constraints, Shire and Protalix were able to offer their developmental therapies for the treatment of Gaucher disease to patients in the United States through an FDA-approved treatment IND protocol and to patients in the European Union and other countries through pre-approval access programs. Shire submitted a NDA to the FDA for its therapy in August 2009 and an MAA to the EMA in November 2009. In the United States, Shire's application is being reviewed by the FDA under priority review with a PDUFA date of February 28, 2010. Protalix submitted its NDA to the FDA in December 2009. Outside of the United States, Fabrazyme currently competes with Replagal, a product marketed by Shire. The FDA, however, has approved a treatment IND for Replagal and Shire has submitted a BLA with the FDA for this product and been granted "fast track" designation. Some Gaucher and Fabry patients may have switched to one of our competitors' therapies during the period of supply constraint and there is a risk that they may not switch back to our products, which would result in the loss of additional revenue for us. In addition, the institution of treatment guidelines and dose conservation measures during the supply constraint present the risk that physicians and patients will not resume regular treatment or dosage levels after the supply constraint has ended, potentially resulting in further loss of revenue for us.

Myozyme/Lumizyme

Myozyme revenue increased in 2009 due to European approval in February 2009 of the product produced at our Belgium facility using the 4000L scale process. The weakening of foreign currencies against the U.S. dollar adversely impacted Myozyme revenue by \$14.2 million for 2009, as compared to 2008.

We have provided alglucosidase alfa free of charge to approximately 180 patients since 2007 under a temporary access program, and in December 2009 we agreed with the FDA to work with the 81 active study sites in the United States to enroll additional patients into this program. We plan to keep open the temporary access program until commercial approval of Lumizyme produced using the 4000L scale process in the United States. We have received a June 17, 2010 PDUFA date in connection with our supplemental BLA for Lumizyme produced at the 4000L scale. If the FDA approves Lumizyme, we would expect revenues for the product to increase in 2011.

Aldurazyme

Aldurazyme revenue increased for 2009, as compared to 2008, 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 \$6.3 million for 2009, as compared to 2008.

Other Genetic Diseases

Other Genetic Diseases product revenue increased in 2009, as compared to 2008. Sales of Elaprase were \$72.2 million in 2009, as compared to \$45.6 million in 2008, primarily due to the continued identification of new patients in our territories. Revenue also increased due to the strengthening of the Japanese yen against the U.S. dollar, which positively impacted revenue by \$4.3 million for 2009, as compared to 2008.

Cardiometabolic and Renal

	2009	2008	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change
(Amounts in thousands)				
Cardiometabolic and Renal:				
Renagel/Renvela (including sales of bulk sevelamer)	\$ 706,589	\$677,729	\$28,860	4%
Hectorol	130,757	128,153	2,604	2%
Thyrogen	170,644	148,448	22,196	15%
Other Cardiometabolic and Renal . . .	2,942	1,595	1,347	84%
Total Cardiometabolic and Renal . .	<u>\$1,010,932</u>	<u>\$955,925</u>	<u>\$55,007</u>	6%

Sales of Renagel/Renvela, including sales of bulk sevelamer, increased for 2009, as compared to 2008, 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. The weakening of foreign currencies against the U.S. dollar adversely impacted Renagel revenue by \$21.8 million for 2009, as compared to 2008.

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 where it is also indicated for treatment of hyperphosphatemic patients who are not on dialysis;
- approval of the powder formulation; and
- the potential label expansion in the United States to include hyperphosphatemic patients who are not on dialysis.

We manufacture the majority of our supply requirements for sevelamer hydrochloride (the active ingredient in Renagel) and sevelamer carbonate (the active ingredient in Renvela) at our manufacturing facility in Haverhill, England. In December 2009, equipment failure caused an explosion and fire at this facility, which damaged some of the equipment used to produce these active ingredients as well as the building in which the equipment was located. As a result, we have temporarily suspended production of sevelamer hydrochloride and sevelamer carbonate at this facility while repairs are made. We anticipate that the facility will resume production of sevelamer hydrochloride in the second quarter of 2010 and sevelamer carbonate in the fourth quarter of 2010. We have adequate supply levels to meet the current demand for both Renagel and Renvela and do not anticipate there will be any supply constraints for either Renagel or Renvela while the facility undergoes repairs. During the temporary suspension of production at this facility, we expect to incur additional charges to cost of products sold in our consolidated statements of operations for 2010 for both Renagel and Renvela related to repairs, shutdown and idle capacity expenses. We expect to submit claims to our insurers for reimbursement of portions of the expenses incurred in connection with the explosion, fire and resulting interruption of business. We cannot be certain at this time the level of reimbursement, if any, that we will receive from our insurers for these expenses.

Sales of Hectorol increased for 2009, as compared to 2008, primarily due to price increases in the fourth quarter of 2008 and the second and fourth quarters of 2009. Sales of Hectorol also include an increase in sales volume due to the addition of the Hectorol 1mcg capsule formulation in August 2009. These increases were offset in part by increased sales returns reserves for Hectorol based on our experience for returns for the product.

Renagel/Renvela and Hectorol currently compete with several other marketed products and will have additional competitors in the future. Competitive products, especially if they are lower cost generic or follow-on products, will negatively impact the revenues we recognize from Renagel/Renvela and Hectorol. See “Some of our products may face competition from lower cost generic or follow-on products,” under the heading “Risk Factors” below.

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 establish a bundled payment system to reimburse dialysis providers treating patients with end stage renal disease, or ESRD. In September 2009, CMS proposed changes to the prospective payment system that would 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 will issue a final rule in 2010 with an anticipated implementation date of January 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 would include phosphate binders in the bundled payment.

Sales of Thyrogen increased for 2009, as compared to 2008, 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. The weakening of foreign currencies against the U.S. dollar adversely impacted Thyrogen revenue by \$3.8 million for 2009, as compared to 2008.

Biosurgery

	2009	2008	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Biosurgery:				
Synvisc/Synvisc-One	\$328,533	\$263,094	\$ 65,439	25%
Sepra products	148,538	133,663	14,875	11%
Other Biosurgery	36,611	48,931	(12,320)	(25)%
Total Biosurgery	<u>\$513,682</u>	<u>\$445,688</u>	<u>\$ 67,994</u>	15%

Biosurgery product revenue increased for 2009, as compared to 2008. Revenue from Synvisc/Synvisc-One increased for 2009, as compared to 2008, 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 2009, as compared to 2008, primarily due to greater penetration of Seprafilm in 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 2009, as compared to 2008, 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 did not have a significant impact on Biosurgery product revenue for 2009, as compared to 2008.

Hematologic Oncology

	2009	2008	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Hematologic Oncology	\$284,858	\$101,217	\$183,641	>100%

Hematologic Oncology product revenue increased for 2009, as compared to 2008, primarily due to:

- the addition of a total of \$109.6 million of sales of Campath, Fludara and Leukine beginning in the second quarter of 2009 as a result of our acquisition from Bayer;
- a \$54.0 million increase in sales of Mozobil due to the launch of the product in the United States in December 2008 and in Europe in August 2009; and
- increased worldwide demand for Clolar.

These increases were offset, in part, by the weakening of foreign currencies against the U.S. dollar which adversely impacted Hematologic Oncology revenue by \$1.8 million for 2009, as compared to 2008.

Mozobil was approved by the FDA in December 2008 for stem cell mobilization in patients with NHL and MM for subsequent autologous stem cell transplants. In July 2009, the European Commission approved Mozobil to enhance stem cell mobilization in preparation for autologous stem cell transplants in patients with lymphoma and MM whose cells mobilize poorly.

We are developing the intravenous formulation of Clolar for new indications, including first-line and relapsed or refractory adult AML. In November 2008, we filed a supplemental 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, we received a complete response letter from the FDA recommending that a randomized, controlled clinical study be conducted for this indication. In addition, we have discussed our adult AML development plans with the EMA's CHMP and based on the CHMP's feedback, randomized, controlled data would also be required. We are awaiting the availability of additional data from ongoing company- and investigator-sponsored studies before seeking approval for this indication in the United States and the European Union. We are conducting a randomized, controlled phase 3 trial comparing Clolar in combination with cytarabine to cytarabine plus placebo in relapsed and refractory adult AML patients 55 years old or older, and results from this trial are expected in late 2010. We are also developing an oral formulation of Clolar and have initiated clinical trials for the treatment of MDS.

Other Product Revenue

	2009	2008	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Other Product Revenue	\$492,674	\$467,748	\$24,926	5%

Other product revenue increased for 2009, as compared to 2008, 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 \$34.2 million for 2009, as compared to 2008, primarily due to higher sales volume resulting from increased utilization of Thymoglobulin in transplant procedures worldwide.

2008 As Compared to 2007

Genetic Diseases

	2008	2007	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Genetic Diseases:				
Cerezyme	\$1,238,977	\$1,133,153	\$105,824	9%
Fabrazyme	494,260	424,284	69,976	16%
Myozyme	296,176	200,728	95,448	48%
Aldurazyme	151,321	—	151,321	N/A
Other Genetic Diseases	45,595	8,314	37,281	>100%
Total Genetic Diseases	\$2,226,329	\$1,766,479	\$459,850	26%

Genetic Diseases product revenue increased for 2008, as compared to 2007, due to continued growth in sales of Cerezyme, Fabrazyme and Myozyme, the inclusion of Aldurazyme sales in our results of operations beginning on January 1, 2008, as a result of our restructured relationship with BioMarin and BioMarin/Genzyme LLC, and the introduction of Elaprase in the Japanese market in the fourth quarter of 2007.

The growth in sales of Cerezyme for 2008, as compared to 2007, is attributable to our continued identification of new Gaucher disease patients, particularly in international markets. We implemented a 3% price increase for Cerezyme in the United States in November 2007 and a 4% price increase for Cerezyme in the United States in August 2008. These price increases accounted for \$12.2 million of the additional Cerezyme revenue for 2008, as compared to 2007. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Cerezyme revenue by \$33.0 million in 2008, as compared to 2007.

The increase in sales of Fabrazyme for 2008, as compared to 2007, is primarily attributable to increased patient identification worldwide as Fabrazyme is introduced into new markets. We established a 3% price increase in the United States for Fabrazyme in November 2007 and a 4% increase for Fabrazyme in the United States in August 2008. These price increases accounted for \$6.5 million of additional Fabrazyme revenue for 2008, as compared to 2007. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Fabrazyme revenue by \$16.6 million in 2008, as compared to 2007.

Sales of Myozyme increased in 2008 as compared to 2007. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Myozyme revenue by \$7.0 million for 2008, as compared to 2007.

Effective January 1, 2008, we, BioMarin and BioMarin/Genzyme LLC restructured our relationship regarding the manufacturing, marketing and sale of Aldurazyme and entered into several new agreements. BioMarin/Genzyme LLC no longer engages in commercial activities related to Aldurazyme and solely:

- holds the intellectual property relating to Aldurazyme and other collaboration products; and
- engages in research and development activities that are mutually selected and funded by BioMarin and us, the costs of which are shared equally.

Under the restructured relationship, BioMarin/Genzyme LLC licensed all intellectual property relating to Aldurazyme and other collaboration products on a royalty-free basis to BioMarin and us. BioMarin holds the manufacturing rights and we hold the global marketing rights. We pay BioMarin a tiered payment ranging from 39.5% to 50% of worldwide net product sales of Aldurazyme. Aldurazyme product revenue was \$151.3 million for 2008. Prior to January 1, 2008, we were commercializing Aldurazyme on behalf of BioMarin/Genzyme LLC in the United States, Canada, the European Union, Latin America and the Asia-Pacific regions and continuing to launch Aldurazyme on a country-by-country basis as pricing and reimbursement approvals were obtained. BioMarin/Genzyme LLC's Aldurazyme product revenue recorded by BioMarin/Genzyme LLC was \$123.7 million for 2007. The increase in Aldurazyme sales of \$27.7 million for the year ended December 31, 2008, as compared to the same period of 2007, is primarily attributable to increased patient identification worldwide as Aldurazyme was introduced into new markets. We also implemented a 3% price increase for Aldurazyme in the United States in November 2007 and a 4% price increase for Aldurazyme in the United States in August 2008. These price increases accounted for \$1.0 million of additional Aldurazyme revenue for 2008, as compared to 2007. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Aldurazyme revenue by \$3.0 million for 2008, as compared to 2007.

Other Genetic Diseases product revenue increased in 2008, as compared to 2007. The increase is due to the launch of Elaprase in Japan in the fourth quarter of 2007 and the continued identification of new patients in our territories.

Cardiometabolic and Renal

	2008	2007	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Cardiometabolic and Renal:				
Renagel/Renvela (including sales of bulk sevelamer)	\$677,729	\$602,670	\$ 75,059	12%
Hectorol	128,153	115,708	12,445	11%
Thyrogen	148,448	113,587	34,861	31%
Other Cardiometabolic and Renal . . .	1,595	52	1,543	>100%
Total Cardiometabolic and Renal . .	<u>\$955,925</u>	<u>\$832,017</u>	<u>\$123,908</u>	15%

Sales of Renagel/Renvela, including sales of bulk sevelamer, increased for 2008, as compared to 2007, primarily due to increased end-user demand, which accounted for \$13.9 million of the additional revenue and a Renagel price increase in the United States, which accounted for \$24.4 million of the additional Renagel revenue. The strengthening of foreign currencies, primarily the Euro, against the

U.S. dollar, positively impacted Renagel revenue by \$13.0 million for 2008. Sales of Renagel/Renvela, including sales of bulk sevelamer, were 15% of our total revenues for 2008, as compared to 16% for 2007.

Sales of Hectorol increased for 2008, as compared to 2007, primarily due to Hectorol price increases in the third quarter of 2007 and in the second and fourth quarters of 2008, which accounted for \$11.7 million of the additional revenue for 2008.

Sales of Thyrogen increased for 2008, as compared to 2007. We implemented a 9.7% price increase for Thyrogen in the United States in April 2007 and a 15% price increase for Thyrogen in the United States in April 2008. These price increases accounted for \$11.7 million of additional Thyrogen revenue for 2008. In addition, worldwide volume growth, driven by a significant increase in the use of the product in thyroid remnant ablation procedures, positively impacted Thyrogen revenue by \$24.2 million for 2008. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Thyrogen revenue by \$3.1 million for 2008, as compared to 2007.

Biosurgery

	2008	2007	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
(Amounts in thousands)				
Biosurgery:				
Synvisc/Synvisc-One	\$263,094	\$242,319	\$20,775	9%
Septra products	133,663	104,318	29,345	28%
Other Biosurgery	48,931	34,793	14,138	41%
Total Biosurgery	<u>\$445,688</u>	<u>\$381,430</u>	<u>\$64,258</u>	17%

Biosurgery product revenue increased for 2008, as compared to 2007. Septrafilm revenue increased \$27.7 million for the year ended December 31, 2008, as compared to the same period of 2007, primarily due to greater penetration of the product into the United States, Japanese and European markets and expanded use of Septrafilm in C-sections and gynecological procedures.

The combined revenues of Synvisc/Synvisc-One increased for 2008, as compared to 2007, primarily due to an expanded sales and marketing investment and the initiation of direct sales of the product in Latin America.

The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted Biosurgery product revenue by \$1.1 million for 2008, as compared to 2007.

Other Biosurgery product revenue increased for 2008, as compared to 2007, due primarily to \$9.6 million of revenue for 2008, related to a dermal filler we are developing with and manufacturing for sale to Mentor Corporation for which there was no comparable amount in 2007.

Hematologic Oncology

	2008	2007	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
(Amounts in thousands)				
Hematologic Oncology	<u>\$101,217</u>	<u>\$68,947</u>	<u>\$32,270</u>	47%

Hematologic Oncology product revenue increased for 2008, as compared to 2007, primarily due to the addition of sales of Clolar outside of North America, which rights we acquired in connection with our acquisition of Bioenvision in October 2007.

Other Product Revenue

	2008	2007	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
	(Amounts in thousands)			
Other Product Revenue	\$467,748	\$408,905	\$58,843	14%

Other product revenue increased in 2008, as compared to 2007, primarily due to:

- a \$17.4 million increase in sales of transplant products for 2008, as compared to 2007, primarily due to an 11% increase in the worldwide average sales price of Thymoglobulin and growth in sales volume resulting from increased utilization of Thymoglobulin in transplant procedures worldwide. The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted transplant product revenue by \$3.5 million for 2008, as compared to 2007;
- a \$31.1 million increase in sales of diagnostic products for 2008, as compared to 2007, due to increased demand and to the acquisition of certain diagnostic assets from Diagnostic Chemicals Limited, or DCL, in December 2007; and
- a \$9.6 million increase in sales of WelChol for 2008, as compared to 2007, due to bulk sales and royalties earned as a result of increased demand from our U.S. marketing partner, Sankyo Pharma, Inc., or Sankyo.

Service Revenue

We derive service revenue 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
- genetics business unit, which provides reproductive and oncology diagnostic testing services, and is included in Other service revenue.

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Genetic Diseases	\$ 25	\$ 363	\$ —	\$ (338)	(93)%	\$ 363	N/A
Cardiometabolic and Renal	74	58	51	16	28%	7	14%
Biosurgery	45,640	42,767	39,880	2,873	7%	2,887	7%
Hematologic Oncology	742	1,682	980	(940)	(56)%	702	72%
Other	372,037	321,221	285,415	50,816	16%	35,806	13%
Total service revenue	\$418,518	\$366,091	\$326,326	\$52,427	14%	\$39,765	12%

2009 As Compared to 2008

Other service revenue increased for 2009, as compared to 2008, due to a \$50.9 million increase in revenues for our genetics business unit. The increase in the genetics business unit revenue is primarily attributable to increased volume from existing and new clients in both reproductive and oncology diagnostic testing services.

The weakening of foreign currencies against the U.S. dollar for 2009, as compared to 2008, did not have a significant impact on service revenue.

2008 As Compared to 2007

Other service revenue increased for 2008, as compared to 2007, primarily due to a \$35.4 million increase in genetics revenue. The increase in genetics revenue is primarily attributable to continued growth in sales of genetic testing and prenatal screening services as well as growth in demand for certain testing services for patients diagnosed with cancer.

Service revenue attributable to our Biosurgery reporting segment increased for 2008, as compared to 2007. The increase is primarily due to higher demand for MACI and a 6.5% price increase for Carticel in July 2008.

The strengthening of foreign currencies against the U.S. dollar for 2008, as compared to 2007, did not have a significant impact on service revenue.

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):

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
International product and service revenue	\$2,139,296	\$2,344,093	\$1,815,160	\$(204,797)	(9)%	\$528,933	29%
% of total product and service revenue	48%	51%	48%				

2009 As Compared to 2008

International product and service revenue decreased for 2009, as compared to 2008, primarily due to:

- decreases in international sales volume for Cerezyme and Fabrazyme for 2009 due to supply constraints; and
- the weakening of foreign currencies against the U.S. dollar, which adversely impacted total product and service revenue by \$115.3 million for 2009.

These decreases were offset in part by:

- growth in the international sales volume of Myozyme, Aldurazyme, Elaprase, Thyrogen, Synvisc/Synvisc-One, Septrafilm, Clolar and Thymoglobulin for 2009; and
- the addition of international sales of Fludara in the second quarter of 2009 and Mozobil in Europe in the third quarter of 2009.

International product and service revenue as a percentage of total product and service revenue decreased for 2009, as compared to 2008, primarily due to:

- decreases in the overall sales volume for Cerezyme and Fabrazyme for 2009 due to supply constraints;
- the addition of sales of Leukine, sold exclusively in the United States, in the second quarter of 2009; and
- the weakening of foreign currencies against the U.S. dollar, which adversely impacted our total international revenue.

2008 As Compared to 2007

The increase in international product and service revenue for 2008, as compared to 2007, is primarily due to a \$278.1 million increase in the combined international sales of Renagel, Cerezyme, Fabrazyme and Myozyme, primarily due to an increase in the number of patients using these products in the European Union, South America and the Asia Pacific rim. In addition, in 2008 we began to record worldwide Aldurazyme revenue and revenue for Clolar sold outside North America. Revenue generated outside the United States for Aldurazyme was \$121.1 million for 2008, which had been recorded as joint venture revenue by BioMarin/Genzyme LLC in 2007. Revenue generated outside the United States for Clolar was \$25.8 million for 2008. There were no comparable amounts prior to our acquisition of Bioenvision in October 2007.

The strengthening of foreign currencies, primarily the Euro, against the U.S. dollar, positively impacted total product and service revenue by \$89.7 million in 2008, as compared to 2007.

International product and service revenue as a percentage of total product and service revenue increased due primarily to the addition of revenue generated outside the United States for Aldurazyme and outside North America for Clolar as well as the strengthening of foreign currencies against the U.S. dollar in 2008, which positively impacted our total international revenue.

Research and Development Revenue

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Genetic Diseases	\$ —	\$ —	\$ 1,059	\$ —	N/A	\$(1,059)	(100)%
Cardiometabolic and Renal	332	200	1,200	132	66%	(1,000)	(83)%
Biosurgery	2,493	2,645	5,337	(152)	(6)%	(2,692)	(50)%
Hematologic Oncology	14,834	36,148	18,601	(21,314)	(59)%	17,547	94%
Other	706	1,815	1,604	(1,109)	(61)%	211	13%
Corporate	1,977	1,233	1,614	744	60%	(381)	(24)%
Total research and development revenue	<u>\$20,342</u>	<u>\$42,041</u>	<u>\$29,415</u>	<u>\$(21,699)</u>	<u>(52)%</u>	<u>\$12,626</u>	<u>43%</u>

2009 As Compared to 2008

Total research and development revenue decreased for 2009, as compared to 2008, due to a decrease in Hematologic Oncology research and development revenue as a result of our acquisition from Bayer and termination of the Campath profit share arrangement. As of May 29, 2009, the effective date of our acquisition from Bayer, we ceased recognizing research and development revenue for Bayer's reimbursement of a portion of the development costs for alemtuzumab for MS. The fair value of the research and development costs to be reimbursed by Bayer is accounted for as an offset to the contingent consideration obligations for alemtuzumab for MS.

2008 As Compared to 2007

Total research and development revenue increased for 2008, as compared to 2007, primarily due to an increase in revenue recognized by our Hematologic Oncology reporting segment. Hematologic Oncology research and development revenue increased primarily due to our increase in spending for the development of alemtuzumab under our collaboration with Bayer, Bayer's reimbursement of a portion of these development expenses, particularly in the multiple sclerosis development program and a \$6.0 million payment received in December 2008 from Shire plc related to the vesting of an

assignment by AnorMED of certain product rights to Shire. This was the last milestone payment due from Shire related to these product rights.

GROSS PROFIT AND MARGINS

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Gross product profit	\$2,939,728	\$3,283,640	\$2,742,274	\$(343,912)	(10)%	\$541,366	20%
Product margin	72%	78%	79%				
Gross service profit	\$ 169,379	\$ 130,796	\$ 114,500	\$ 38,583	29%	\$ 16,296	14%
Service margin	40%	36%	35%				
Total gross product and service profit	\$3,109,107	\$3,414,436	\$2,856,774	\$(305,329)	(9)%	\$557,662	20%
Total product and service margin .	69%	75%	75%				

Gross Product Profit and Product Margin

2009 As Compared to 2008

Our overall gross product profit decreased for 2009, as compared to 2008, primarily due to:

- decreased sales volume for Cerezyme and Fabrazyme; and
- a total of \$107.2 million of charges for 2009 for which there are no comparable amounts for 2008, including:
 - \$45.5 million for idle capacity, clean up and other costs related to the remediation of our Allston facility;
 - approximately \$11 million for the write off of Cerezyme work-in-process material;
 - \$43.5 million for the amortization of inventory step-up of Campath, Fludara and Leukine; and
 - \$7.3 million of other manufacturing-related charges.

These decreases were offset, in part, by:

- increased sales volume for Myozyme, Aldurazyme and Elaprase;
- the addition of sales of Renvela, which was launched in the United States in 2008 for patients with CKD on dialysis and in the European Union in June 2009 for patients with CKD on dialysis and hyperphosphatemic patients not on dialysis;
- increased sales volume for Thyrogen;
- increased sales volume for Synvisc/Synvisc-One and Septrafilm;
- the addition of sales of Fludara and Leukine in the second quarter of 2009, the addition of sales of Mozobil, which was launched in the United States in December 2008 and in Europe in August 2009, and an increase in worldwide sales of Clolar; and
- increased sales volume for Thymoglobulin.

Product margin decreased for 2009, as compared to 2008, primarily due to:

- higher unit costs for Cerezyme and Fabrazyme;
- the increase in sales volume for Myozyme, Aldurazyme, and Elaprase, all of which are lower margin products;

- a total of \$107.2 million of charges for 2009, as described above, for which there are no comparable amounts for 2008; and
- the addition of sales of Fludara and Leukine and additional sales of Campath beginning in the second quarter of 2009, all of which are lower margin products.

Our gross product profit and product margin for 2009 were also impacted by the unfavorable effect of foreign exchange rates on product sales outside of the United States, offset, in part, by the favorable effect of such rates on the cost of those products.

Gross product profit and product margin for both periods were also adversely affected by manufacturing-related charges of \$9.2 million for 2009 and \$12.6 million for 2008 to write off Myozyme inventory costs related to terminated production runs at our Belgium facility,

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

2008 As Compared to 2007

Our overall gross product profit increased for 2008, as compared to 2007. This is primarily due to:

- increased sales volume for Cerezyme, Fabrazyme, Myozyme and Elaprase;
- increased unit volumes and price increases for Renagel and Hectorol;
- the addition of sales of Renvela, which was launched for patients with CKD on dialysis in the United States in March 2008;
- increased sales volume for Thyrogen;
- increased sales for Septrafilm;
- improved margin for Hylaform due to milestone payments received in 2008 for which there were no comparable amounts received in 2007;
- higher demand for Campath worldwide, and an increase in worldwide sales of Clolar due to our acquisition of Bioenvision in October 2007; and
- improved margin for diagnostic products due to our acquisition of diagnostic assets from DCL in December 2007.

Our product margin in 2008 was impacted by the favorable effect of foreign exchange rates in our manufacturing sites outside the United States as well as by the timing of inventory produced in prior periods and sold in the fourth quarter.

Total gross product profit as a percentage of product revenue decreased for 2008, as compared to 2007, due to the increase in sales of Myozyme and Elaprase, the addition of Aldurazyme to the results, all of which have lower than average margins, to higher unit costs for Cerezyme and Fabrazyme and to the write off of Myozyme inventory costs of \$12.6 million related to terminated production runs during 2008 at our Belgium facility. These decreases in product margin as a percentage of product revenue were partially offset by a decrease in manufacturing-related charges recorded in 2008, as compared to 2007.

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

2009 As Compared to 2008

Our overall gross service profit increased for 2009, as compared to 2008, primarily due to increases in revenue from our reproductive and oncology diagnostic testing services and Carticel revenue.

Total service margin increased for 2009, as compared to 2008, 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.

2008 As Compared to 2007

Our overall gross service profit increased for 2008, as compared to 2007. The increases were primarily attributable to increases in revenue from our genetic testing and prenatal screening services and the increase in demand for certain testing services for patients diagnosed with cancer.

Total service margin as a percent of total service revenue increased for 2008, as compared to 2007, due to an increase in MACI and Carticel revenue and genetic testing revenue.

OPERATING EXPENSES

Selling, General and Administrative Expenses

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Selling, general and administrative expenses	\$1,428,596	\$1,338,190	\$1,187,184	\$90,406	7%	\$151,006	13%
% of total revenue	32%	29%	31%				

2009 As Compared to 2008

SG&A increased for 2009, primarily due to spending increases of:

- \$8.8 million for 2009, for Cardiometabolic and Renal, primarily due to increased patent litigation expenses for Renegel/Renvela and Hectorol for 2009;
- \$15.5 million for 2009, for Biosurgery, primarily due to ongoing activities related to the Synvisc-One launch;
- \$42.2 million for 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 in Europe;
- \$15.6 million for 2009, for Other, primarily due to personnel additions and software maintenance costs for our genetics business unit; and
- \$23.1 million for 2009, for Corporate, primarily due to increases in litigation expense and stock-based compensation for 2009, as compared to 2008.

These increases were partially offset by a decrease of \$22.3 million for 2009, attributable to the weakening of foreign currencies against the U.S. dollar and a decrease of \$11.0 million of realized unhedged transactional foreign currency loss for 2009, as compared to 2008.

2008 As Compared to 2007

SG&A increased for 2008, as compared to 2007, primarily due to spending increases of:

- \$46.3 million for Genetic Diseases, primarily due to costs incurred related to Aldurazyme, which were recorded by BioMarin/Genzyme LLC in the same period of 2007, combined with expanded marketing activities for Cerezyme, Fabrazyme and Myozyme;
- \$31.2 million for Cardiometabolic and Renal, primarily due to sales force expansion and restructuring to support the Renvela launch;
- \$20.3 million for Biosurgery, primarily due to the expansion of our Sepra sales force combined with additional marketing activities;
- \$18.6 million for Hematologic Oncology, primarily due to the inclusion of Bioenvision activities and increased domestic marketing expenses for Clolar and our investment in international programs, personnel and to costs related to the preparation of the launch of Mozobil;
- \$34.6 million for Other, primarily due to personnel additions in our genetics business unit and increased spending associated with our acquisition of diagnostic assets from DCL in December 2007;
- an increase of \$10.6 million due to the strengthening of foreign currencies against the U.S. dollar, primarily the Euro; and
- an increase of \$24.1 million of realized unhedged transactional foreign currency loss.

These increases were partially offset by a decrease in SG&A for Corporate because we recorded a \$64.0 million charge in June 2007 for the settlement of the litigation related to the consolidation of our former tracking stocks for which there was no comparable amount recorded in 2008.

Research and Development Expenses

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Research and development expenses	\$865,257	\$1,308,330	\$737,685	\$(443,073)	(34)%	\$570,645	77%
% of total revenue	19%	28%	19%				

2009 As Compared to 2008

Research and development expenses decreased for 2009, as compared to 2008, primarily due to:

- an \$82.4 million decrease in spending for 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, for which there were no comparable amounts in 2009. This decrease was partially offset by \$7.0 million of charges for 2009 related to our transaction with Targeted Genetics Corporation in September 2009;
- a \$248.6 million decrease in spending for 2009, on our Cardiometabolic and Renal research and development programs, primarily due to charges of \$244.9 million recorded in 2008 for license fees paid to Isis for exclusive, worldwide rights to mipomersen, for which there were no comparable amounts for 2009;
- an \$129.5 million decrease in spending for 2009, on research and development programs included under the category "Other," due to an \$148.2 decrease in spending for our immune mediated disease business unit for 2009 primarily due to charges of \$130.0 million in

nonrefundable upfront license fees paid to Osiris in 2008 related to our collaboration to develop and commercialize Prochymal and Chondrogen, for which there were no comparable amounts in 2009. This decrease was partially offset by a payment of \$18.2 million to EXACT Sciences for the purchase of intellectual property in January 2009; and

- a decrease of \$7.6 million for 2009 due to the weakening of foreign currencies against the U.S. dollar.

These decreases were partially offset by a spending increase in 2009 of:

- \$32.0 million on our Hematologic Oncology research and development programs, primarily due to a \$33.6 million increase in spending for 2009 for the development of alemtuzumab for MS. This increase was partially offset by a decrease in expenses related to our Mozobil NDA submission for 2008, for which there were no comparable amounts in 2009.

2008 As Compared to 2007

Research and development expenses increased for 2008, as compared to 2007, primarily due to:

- spending increases of \$149.6 million on certain Genetic Diseases research and development programs, including a \$100.0 million nonrefundable upfront fee paid to PTC related to our collaboration to develop and commercialize ataluren, and the addition of Aldurazyme expenses as a result of the restructuring of our relationship with BioMarin/Genzyme LLC;
- spending increases of \$244.9 million for Cardiometabolic and Renal research and development programs, consisting of \$175.0 million and \$69.9 million recorded in February 2008 in license fees paid to Isis for exclusive, worldwide rights to mipomersen;
- spending increases of \$58.2 million on Hematologic Oncology research and development programs, primarily on the development of alemtuzumab for MS and Mozobil, due to NDA filing activity and pre-launch activity and the addition of Bioenvision expenses for the development of Clolar for adult AML;
- spending increases of \$143.9 million on research and development programs included under the category "Other," including \$130.0 million in nonrefundable upfront license fees paid to Osiris related to our collaboration to develop and commercialize Prochymal and Chondrogen; and
- increases of \$8.7 million due to the strengthening of foreign currencies against the U.S. dollar, primarily the Euro.

These increases were partially offset by spending decreases in 2008 of:

- \$34.7 million on certain Genetic Diseases research and development programs, including a \$25.0 million upfront payment to Ceregene in June 2007 in connection with a collaboration agreement for the development and commercialization of CERE-120 for which there was no comparable amount paid in 2008, and an \$8.4 million decrease in spending due to the termination in February 2007 of our joint venture with Dyax Corp., or Dyax for the development of DX-88 for the treatment of hereditary angioedema, or HAE; and
- \$20.8 million on our Cardiometabolic and Renal research and development programs due to the termination of our late stage clinical trial for tolevamer and a decrease in clinical expenses related to Hectorol.

Amortization of Intangibles

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Amortization of intangibles	\$266,305	\$226,442	\$201,105	\$39,863	18%	\$25,337	13%
% of total revenue	6%	5%	5%				

2009 As Compared to 2008

Amortization of intangibles expense increased for 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 H, "Goodwill and Other Intangible Assets," to our consolidated financial statements included in Item 8 of this Form 10-K, we calculate amortization expense for the Synvisc sales and marketing rights we reacquired from Wyeth and the Myozyme patent and technology under 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.

2008 As Compared to 2007

Amortization of intangibles expense increased for 2008, as compared to 2007, primarily due to the acquisition of technology in connection with our acquisition of Bioenvision in October 2007, and the acquisition of customer lists and trademarks in connection with our acquisition of diagnostic assets from DCL in December 2007.

Contingent Consideration Expense

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

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
Contingent consideration expense	\$65,584	\$ —	\$ —	\$65,584	N/A	N/A	N/A
% of total revenue	1%	N/A	N/A				

2009 As Compared to 2008

In June 2009, we recorded contingent consideration obligations totaling \$964.1 million for the 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. For 2009, the change in the fair value of the contingent consideration was primarily due to changes in discount periods and management estimates.

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. All IPR&D we acquire through business combinations on or after January 1, 2009 is 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 December 31, 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	\$445.3	alemtuzumab for MS—US	16%	2012	\$190.7(1)
		\$187.6	alemtuzumab for MS—ex-US	16%	2013	\$ 96.6(2)
		\$632.9(3)				
Bioenvision (2007)	\$ 349.9	\$125.5(4)	Clolar(5)	17%	2010-2016(6)	\$ 27.7
AnorMED (2006)	\$ 589.2	\$526.8(4)	Mozobil (stem cell transplant)(7)	15%	2016	\$ 19.3

- (1) Does not include anticipated reimbursements from Bayer totaling approximately \$49 million.
- (2) Does not include anticipated reimbursements from Bayer totaling approximately \$18 million.
- (3) Capitalized as an indefinite-lived intangible asset.
- (4) Expensed on acquisition date.
- (5) Clolar is approved for the treatment of relapsed and refractory pediatric ALL. The IPR&D projects for Clolar are related to the development of the product for the treatment of other medical issues.
- (6) 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.
- (7) 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 tumor sensitization.

Charge for Impaired Goodwill

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 asset may not be recoverable. For 2009 and 2008, we completed the required annual impairment tests for our \$1.4 billion of goodwill that had been recorded as of September 30, 2009 and \$1.4 billion of goodwill that had been recorded as of September 30, 2008 and determined that no impairment charge was required. We discuss our assessment of goodwill for potential impairment under the heading “Critical Accounting Policies—Asset Impairments—Impairment of Goodwill” included in this report.

OTHER INCOME AND EXPENSES

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
(Amounts in thousands)							
Equity in income of equity method investments	\$ —	\$ 201	\$ 7,398	\$ (201)	(100)%	\$ (7,197)	(97)%
Gains (losses) on investments in equity securities, net	(56)	(3,340)	13,067	3,284	98%	(16,407)	>(100)%
Gain on acquisition of business	24,159	—	—	24,159	N/A	N/A	N/A
Other	(1,719)	356	3,295	(2,075)	>(100)%	(2,939)	(89)%
Investment income	17,642	51,260	70,196	(33,618)	(66)%	(18,936)	(27)%
Interest expense	—	(4,418)	(12,147)	4,418	(100)%	7,729	(64)%
Total other income	<u>\$40,026</u>	<u>\$44,059</u>	<u>\$ 81,809</u>	<u>\$ (4,033)</u>	(9)%	<u>\$(37,750)</u>	(46)%

2009 As Compared to 2008

Gains (Losses) on Investments in Equity Securities, net

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

	2009	2008
Gross gains (losses) on investments in equity securities	\$1,734	\$13,259
Less: charges for impairment of investments	(1,790)	(16,599)
Losses on investments in equity securities, net	<u>\$ (56)</u>	<u>\$(3,340)</u>

Gross gains (losses) on investments in equity securities includes a gain of \$10.3 million in 2008 resulting from the liquidation of our investment in the common stock of Sirtris Pharmaceuticals, Inc., or Sirtris, for net cash proceeds of \$14.8 million.

Charges for impairment of investments for both periods presented includes the write down of our investments in certain venture capital funds to fair value at the end of each period. Charges for impairment of investments for 2008 also 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.

At December 31, 2009, our stockholders' equity includes \$13.1 million of unrealized gains and \$0.9 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 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 2009, as compared to 2008, primarily due to a decrease in our average portfolio yield and lower average cash and investment balances.

Interest Expense

Our net interest expense decreased to zero for 2009, as compared to 2008, primarily due to the redemption of the \$690.0 million in principal of our 1.25% convertible senior notes in December 2008. Interest expense for 2008 includes \$10.9 million of interest related to these notes for which there are no comparable amounts in 2009. In addition, capitalized interest decreased \$6.7 million for 2009, as compared to 2008, due to the decreased amount of interest expense available for capitalization as a result of the redemption of these notes.

2008 As Compared to 2007

Equity in Income of Equity Method Investments

Equity in income of equity method investments decreased by 97% to \$0.2 million in 2008, as compared to 2007 primarily due to \$21.1 million of charges in 2007 related to our investment in Bioenvision common stock, including a \$19.1 million charge for IPR&D, representing our proportionate share of the fair value of the IPR&D programs of Bioenvision for which there are no comparable amounts in 2008 because we completed our acquisition of Bioenvision in October 2007. These charges were offset in part by our portion of the net income of BioMarin/Genzyme LLC of \$30.1 million in 2007 for which there was no comparable amount in 2008 since, beginning January 1, 2008, as a result of our restructured relationship with BioMarin, we no longer account for BioMarin/Genzyme LLC using the equity method of accounting.

Gains (Losses) on Investments in Equity Securities, net

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

	<u>2008</u>	<u>2007</u>
Gross gains (losses) on investments in equity securities:	\$ 13,259	\$13,067
Less: charges for impairment of investments	(16,599)	—
Gains (losses) on investments in equity securities, net	<u>\$ (3,340)</u>	<u>\$13,067</u>

In 2008, we recorded a \$10.3 million gain resulting from the liquidation of our investment in the common stock of Sirtris for net cash proceeds of \$14.8 million.

In 2007, we purchased an exclusive option to acquire equity in a private company for \$10.0 million in cash. We terminated the option agreement prior to the deadline for exercise and as a result, we recorded a charge of \$10.0 million in 2008 to write off the purchase price of the option. We also recorded a charge of \$6.6 million in 2008 to write down our investments in certain equity securities and venture capital funds to fair value as the unrealized losses were determined to be other than temporary.

In 2007, we recorded a \$10.8 million gain in connection with the sale of our entire investment in the capital stock of THP, which had a zero cost basis, for net cash proceeds of \$10.8 million.

Other

As a result of the restructuring of our relationship with BioMarin/Genzyme LLC, effective January 1, 2008, we began consolidating the results of BioMarin/Genzyme LLC. We recorded BioMarin's portion of this joint venture's income in 2008 as minority interest in our consolidated statements of operations.

Investment Income

Our investment income decreased for 2008, as compared to 2007, primarily due to a decrease in the average portfolio yield in the United States and lower average cash balances outside the United States, offset in part by higher average U.S. cash balances.

Interest Expense

Our interest expense decreased for 2008, as compared to 2007, primarily due to a \$4.5 million increase in capitalized interest, which resulted in a decrease in interest expense. Additionally, there was a \$2.2 million decrease in interest expense in 2008 related to asset retirement obligations and a \$1.0 million decrease in interest expense in 2008 due to the redemption of the \$690.0 million in principal of our 1.25% convertible senior notes in December 2008.

PROVISION FOR INCOME TAXES

	2009	2008	2007	09/08 Increase/ (Decrease)	09/08 Increase/ (Decrease) % Change	08/07 Increase/ (Decrease)	08/07 Increase/ (Decrease) % Change
	(Amounts in thousands)						
Provision for income taxes	\$121,433	\$204,457	\$255,481	\$(83,024)	(41)%	\$(51,024)	(20)%
Effective tax rate	22%	33%	35%				

Our provisions for income taxes were at rates other than the U.S. federal statutory tax rate for the following reasons:

	For the Years Ended December 31,		
	2009	2008	2007
Tax provision at U.S. statutory rate	35.0%	35.0%	35.0%
Domestic manufacturing benefits	(4.3)	(2.1)	(0.5)
Legal settlements	—	—	3.0
Audit settlements	—	(1.3)	0.5
Stock compensation	2.2	1.5	1.3
Tax credits	(5.5)	(3.9)	(3.5)
Foreign rate differential	(3.2)	1.4	(2.1)
Other	(1.9)	2.1	1.0
Effective tax rate	<u>22.3%</u>	<u>32.7%</u>	<u>34.7%</u>

Our effective tax rate for 2009 was impacted by:

- non-deductible stock-based compensation expenses totaling \$33.5 million for 2009;
- the tax benefits related to tax credits of \$30.0 million; and
- domestic manufacturing benefits of \$23.5 million.

Our effective tax rates for 2008 and 2007 were impacted by:

- non-deductible stock compensation expenses of \$34.0 million in 2008 and \$32.0 million in 2007;
- \$5.1 million of tax benefits recorded in 2008 to our income tax provision reflecting the resolution of various issues related to the settlement of IRS audits for the tax years 2004 to 2005. In conjunction with those settlements, we reduced our tax reserves by \$4.9 million and recorded current and deferred tax benefits for the remaining portion of the settlement amounts;

- the charge for IPR&D of \$106.4 million recorded in October 2007 in connection with our acquisition of Bioenvision, of which \$100.3 million was deductible and taxed at rates other than the U.S. statutory income tax rate and \$6.1 million was non-deductible; and
- a non-deductible charge of \$64.0 million for the settlement of the Biosurgery tracking stock suit in August 2007.

In addition, our overall tax rate has changed significantly due to fluctuations in our income before taxes, which was \$543.7 million in 2009, \$625.5 million in 2008, and \$735.7 million in 2007.

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 within the next twelve months by approximately \$13 million as a result of the resolution of tax examinations in major tax jurisdictions. 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.

Research and Development Programs

Our research and development programs are focused on the areas of medicine where we market commercial products, namely rare inherited disorders, renal disease, transplant and immune diseases, orthopaedics, oncology and diagnostic and predictive testing. We also conduct research in cardiovascular disease, neurodegenerative diseases and other areas of unmet medical needs. Before we can commercialize our development-stage products, we will need to:

- conduct substantial research and development;
- undertake pre-clinical and clinical testing;
- develop and scale-up manufacturing processes and validate facilities; and
- pursue marketing authorization and other regulatory approvals and, in some countries, pricing approvals.

This process is risky, expensive, and may take several years. We cannot guarantee that we will be able to successfully develop any product, or that we would be able to recover our development costs upon commercialization of a product that we successfully develop.

Below is a brief description of our significant research and development programs:

Program	Program Description or Indication	Development Status at December 31, 2009	Year of Expected Product Launch
Eliglustat tartrate (formerly GENZ-112638)	Gaucher disease	Two-year data of phase 2 study results were released in the first quarter of 2010. Two global, multi-center phase 3 clinical trials have started enrollment in the third quarter of 2009.	2013
Ataluren(1)	Nonsense-mutation-mediated DMD and CF	Results of phase 2b trial in DMD are expected during the first half of 2010. Phase 3 trial in CF began enrolling patients in the second half of 2009. Phase 2a trial in hemophilia is underway.	2011
Mipomersen(2)	Reduction of LDL cholesterol	Enrollment in four phase 3 clinical trials has been completed. Top line results of the phase 3 study of mipomersen in patients with homozygous familial hypercholesterolemia were released in the third quarter of 2009. Top line results of the phase 3 study of mipomersen in patients with heterozygous familial hypercholesterolemia were released in the first quarter of 2010.	2011
Campath(3)	B-CLL	The FDA granted front-line approval of Campath for CLL in the United States in the third quarter of 2007 and in the European Union in the fourth quarter of 2007. Phase 3 clinical trial comparing Campath in combination with Fludara (FluCAM) to Fludara alone in patients with previously treated CLL was completed and data were released in 2009.	2011
Clolar(3)	Pediatric and adult leukemias, Myelodysplastic Syndromes (MDS)	In pediatric leukemias, data are expected from a phase 1/2 study in 2010, and a phase 1 study exploring a new combination opened in late 2009. In frontline adult leukemia, the phase 2 study that was the basis of our NDA in 2008 will complete long-term follow-up in 2010. In relapsed/refractory adult leukemia, a phase 3 study completed enrollment in late 2009 and data are expected in late 2010 and may be the basis for regulatory filings to the FDA and EMA in 2011 with approval anticipated in 2012. In high-risk MDS, a phase 2 study continues enrollment. Multiple investigator-sponsored studies in various pediatric and adult leukemias, MDS and bone marrow transplant conditioning are being supported in the United States and the European Union. Clinical studies in Japan for both pediatric and adult leukemia are expected to begin in 2010 and studies in China are planned.	2010 through 2016
Mozobil(4)	Tumor sensitization	Ongoing phase 1 clinical trial in CLL and phase 1/2 trial in AML.	2016
Alemtuzumab for MS(5)	Multiple Sclerosis	Two phase 3 trials are ongoing. Data from the trials are expected to be available in 2011 and approval is anticipated in 2012.	2012

- (1) We entered into a collaboration agreement with PTC to develop and commercialize ataluren in July 2008. Under the terms of the agreement, PTC will commercialize ataluren in the United States and Canada, and we will commercialize the treatment in all other countries.
- (2) We obtained an exclusive, worldwide license to develop and commercialize mipomersen from Isis in January 2008.
- (3) We acquired the program in connection with the December 2004 acquisition of ILEX Oncology, and with respect to Clolar, rights outside of North America, were acquired in connection with the October 2007 acquisition of Bioenvision.
- (4) We acquired the program in connection with the November 2006 acquisition of AnorMED.
- (5) We obtained exclusive license worldwide rights to commercialize alemtuzumab for MS in connection with our acquisition from Bayer in May 2009.

The aggregate actual and estimated research and development expense for the programs described above is as follows (amounts in millions):

Costs incurred for the year ended December 31, 2008	\$286.1
Costs incurred for the year ended December 31, 2009	\$188.3
Cumulative costs incurred as of December 31, 2009	\$714.5
Estimated costs to complete as of December 31, 2009	\$800 to \$1,000

Our current estimates of the time and investment required to develop these products are forward-looking statements and may change depending on the approach we take to pursue them, the results of preclinical and clinical studies, and the content and timing of decisions made by the FDA, the EMA and other regulatory authorities. We cannot provide assurance that any of these programs will ever result in products that can be marketed profitably. In addition, we cannot guarantee that we will be able to develop and commercialize products before our competitors develop and commercialize products for the same indication. If certain of our development-stage programs do not result in commercially viable products, our results of operations could be materially adversely affected.

Liquidity and Capital Resources

We continue to generate cash from operations. We had cash, cash equivalents and short- and long-term investments of \$1.05 billion at December 31, 2009 and 2008.

The following is a summary of our statements of cash flows for 2009 and 2008:

Cash Flows from Operating Activities

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

	<u>2009</u>	<u>2008</u>
Cash flows from operating activities:		
Net income	\$ 422,300	\$421,081
Non-cash charges, net	641,608	428,709
Increase (decrease) in cash from working capital changes (excluding impact of acquired assets and assumed liabilities)	<u>115,129</u>	<u>(90,615)</u>
Cash flows from operating activities	<u>\$1,179,037</u>	<u>\$759,175</u>

Cash provided by operating activities increased \$419.9 million for 2009, as compared to 2008, driven by a \$212.9 million increase in non-cash charges, net and a \$205.7 million increase in working capital. Net income increased in 2009, as compared to 2008, primarily due to a decrease in charges, net of tax, for strategic transactions with third parties. In 2008, we had a total of \$474.9 million of charges related to strategic transactions with Osiris, PTC and Isis. In 2009, charges for strategic transactions with Targeted Genetics and EXACT Sciences totaled \$25.2 million. This decrease in charges was offset, in part, by a decrease in Cerezyme and Fabrazyme revenue due to supply constraints following our temporary suspension of production at our Allston facility in June 2009.

The increase in non-cash charges, net, for 2009, as compared to 2008, is primarily attributable to:

- a \$81.7 million increase in depreciation and amortization expenses;
- a \$16.6 million increase in stock-based compensation expense;

- a total of \$65.6 million of contingent consideration expenses related to an increase in the fair value of the contingent consideration obligations recorded as a result of our acquisition from Bayer in May 2009; and
- a \$99.5 million decrease in the deferred income tax benefits.

These increases were offset, in part, by a \$24.2 million non-cash gain on acquisition of business recorded in June 2009 related to our acquisition from Bayer.

Cash Flows from Investing Activities

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

	<u>2009</u>	<u>2008</u>
Cash flows from investing activities:		
Net sales of investments, excluding investments in equity securities	\$ 93,069	\$ 188,127
Net purchases of investments in equity securities	(4,366)	(80,062)
Purchases of property, plant and equipment	(661,713)	(597,562)
Distributions from equity method investments	—	4,844
Acquisitions	(51,336)	(16,561)
Purchases of other intangible assets	(41,883)	(92,183)
Other investing activities	(5,195)	11,857
Cash flows from investing activities	<u>\$(671,424)</u>	<u>\$(581,540)</u>

For 2009, net purchases of capital expenditures accounted for significant cash outlays for investing activities. During 2009, we used \$661.7 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 \$51.3 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 \$113.2 million to Bayer, of which \$70.8 million was refundable. The remaining nonrefundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$61.8 million of the refundable amount was received in 2009. As of December 31, 2009 \$8.9 million remains due from Bayer.

During 2008, investing activities used:

- \$597.6 million in cash to fund the purchase of property, plant and equipment, primarily related to the ongoing expansion of our manufacturing capacity in Ridgefield, New Jersey, the Republic of Ireland, England, Belgium and France, completion of construction of a new research and development facility in Framingham, Massachusetts, planned improvements at our manufacturing facility in Allston, Massachusetts, and capitalized costs of an internally developed enterprise software system for our genetics business;
- \$60.0 million in cash for a milestone payment to Wyeth in May 2008; and
- \$80.1 million in cash to purchase five million shares of Isis common stock in February 2008 which amount is included in other noncurrent assets on our consolidated balance sheet.

These cash outlays were partially offset by \$193.7 million of net sales of investments and cash proceeds from the sale of investments in equity securities.

Cash Flows from Financing Activities

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

	<u>2009</u>	<u>2008</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	\$ 100,521	\$ 318,753
Repurchases of common stock	(413,874)	(143,012)
Excess tax benefits from stock-based compensation	3,305	18,445
Payments of debt and capital lease obligations	(7,492)	(693,961)
Increase in bank overdrafts	896	25,760
Payment of long-term contingent consideration obligation . . .	(26,417)	—
Other financing activities	6,445	7,772
Cash flows from financing activities	<u>\$(336,616)</u>	<u>\$(466,243)</u>

Cash used by financing activities decreased by \$129.6 million for 2009, as compared to 2008, primarily driven by the redemption of \$690.0 million senior convertible notes on December 1, 2008 described below for which there is no comparable payment in 2009. In addition, this decrease was impacted by a \$218.2 million decrease in proceeds from the issuance of our common stock due to fewer stock option exercises, a \$270.9 million increase in cash used to repurchase shares of our common stock under our stock repurchase program and \$26.4 million in contingent consideration payments to Bayer for which there were no comparable payments made in 2008.

Revolving Credit Facility

In July 2006, we entered into a five-year \$350.0 million senior unsecured revolving credit facility with JPMorgan Chase Bank, N.A., as administrative agent, Bank of America, N.A., as syndication agent, ABN AMRO Bank N.V., Citizens Bank of Massachusetts and Wachovia Bank, National Association, as co-documentation agents, and a syndicate of lenders, which we refer to as our 2006 revolving credit facility. The proceeds of loans under our 2006 revolving credit facility can be used to finance working capital needs and for general corporate purposes. We may request that our 2006 revolving credit facility be increased at any time by up to an additional \$350.0 million in the aggregate, subject to the agreement of the lending banks, as long as no default or event of default has occurred or is continuing and certain other customary conditions are satisfied. Borrowings under our 2006 revolving credit facility will bear interest at various rates depending on the nature of the loan.

As of December 31, 2009, we had approximately \$17 million of outstanding standby letters of credit issued against this facility and no borrowings, resulting in approximately \$333 million of available credit under our 2006 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 December 31, 2009, we were in compliance with these covenants.

Contractual Obligations

As of December 31, 2009, we had committed to make the following payments under contractual obligations (amounts in millions):

Contractual Obligations	Payments Due by Period						
	Total	2010	2011	2012	2013	2014	After 2014
Long-term debt obligations(1)	\$ 23.4	\$ 1.6	\$ 1.6	\$ 1.7	\$ 1.8	\$ 1.8	\$ 14.9
Capital lease obligations(1)	149.6	15.4	15.4	15.5	16.9	18.9	67.5
Operating leases(1)	414.2	79.9	69.3	52.6	33.9	27.5	151.0
Contingent payments(2)	1,865.1	201.7	211.6	117.1	297.8	481.2	555.7
Interest obligations(3)	8.9	1.1	1.1	1.0	0.9	0.9	3.9
Defined pension benefit plans payments	32.4	2.0	1.9	2.2	2.4	2.9	21.0
Unconditional purchase obligations	130.5	71.8	28.1	19.6	7.0	2.0	2.0
Capital commitments(4)	898.8	663.7	184.6	50.5	—	—	—
Total contractual obligations	<u>\$3,522.9</u>	<u>\$1,037.2</u>	<u>\$513.6</u>	<u>\$260.2</u>	<u>\$360.7</u>	<u>\$535.2</u>	<u>\$816.0</u>

(1) See Note L, “Long-term Debt and Leases,” to our consolidated financial statements included in Item 8 of this Form 10-K for additional information on long-term debt and lease obligations.

(2) For all periods presented consists primarily of a total of \$1.85 billion of contingent royalty and milestone payments, the value of which has not been risk adjusted or discounted, 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.

Contingent payments also include a \$20.0 million milestone payment to Synpac estimated to be in 2010 once sales of Myozyme reach \$400.0 million. Contingent payments 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.

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 C, “Strategic Transactions,” to our consolidated financial statements included in Item 8 of this Form 10-K for additional information on our transaction with Bayer.

(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 December 31, 2009 related to our outstanding capital and internally developed software projects. Our estimated cost of completion for assets under construction as of December 31, 2009 is as follows (amounts in millions):

<u>Location</u>	<u>Cost to Complete at December 31, 2009</u>
Framingham, Massachusetts, United States (approximately 35% for software development)	\$396.6
Westborough, Massachusetts, United States (primarily software development)	101.0
Lyon, France	20.0
Geel, Belgium	34.0
Waterford, Ireland	27.8
Allston, Massachusetts, United States	119.0
Ridgefield, New Jersey, United States	2.0
Haverhill, England	25.0
Other	<u>173.4</u>
Total estimated cost to complete	<u>\$898.8</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:

- expanding and maintaining existing and constructing additional manufacturing facilities, including investing significant funds to expand our Allston, Geel, Belgium and Waterford, Ireland facilities and constructing a new manufacturing facility with capacity for Cerezyme and Fabrazyme;
- implementing process improvements and system updates for our biologics manufacturing operations;
- 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, including installation and implementation of a new enterprise resource planning system worldwide;
- contingent payments under business combinations, license and other agreements, including a milestone payment to Synpac once sales of Myozyme reach \$400.0 million, as well as 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 (for more information on these payments please read Note C.,

“Strategic Transactions,” to our consolidated financial statements included in Item 8 of this Form 10-K);

- litigation expenses;
- 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 is not only expensive, but 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

Periodically, accounting pronouncements and related information on the adoption, interpretation and application of U.S. GAAP are issued or amended by the FASB or other standard setting bodies. Changes to the ASC are communicated through Accounting Standards Updates, or ASU’s. The

following table shows FASB ASU's recently issued that could affect our disclosures, and our position for adoption:

Accounting Standards Update	Relevant Requirements of Accounting Standards Update	Issued Date/Our Effective Dates	Status
ASC 860-20, "Accounting for Transfers of Financial Assets."	Update 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.	We adopted the update as of January 1, 2010. We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
ASC 810-20, "Control of Partnerships and Similar Entities."	Update improves financial reporting by enterprises involved with variable interest entities and 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.	We will adopt the provisions of this update for the first quarter of 2011. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.
ASU No. 2009-13 "Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force."	Establishes the accounting and reporting guidance for arrangements under which a vendor will perform multiple revenue-generating activities. Specifically, the provisions of this update address how to separate deliverables and how to measure and allocate arrangement consideration to one or more units of accounting.	Issued October 2009. Effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted.	We will adopt the provisions of this update for the first quarter of 2010. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.
ASU No. 2009-17 "Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities."	This update consists of amendments to ASC 810, "Consolidation," which change how a company determines when an entity that is insufficiently capitalized or is not controlled through voting should be consolidated. This is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance.	Issued December 2009. Effective the first interim or annual reporting period after December 15, 2009.	We will adopt the provisions of this update for the first quarter of 2010. We do not expect the provisions of this update to have a material impact on our consolidated financial statements.

Accounting Standards Update	Relevant Requirements of Accounting Standards Update	Issued Date/Our Effective Dates	Status
<i>ASU No. 2010-02 "Accounting and Reporting for Decreases in Ownership of a Subsidiary—a Scope Clarification."</i>	Amends ASC 810-10, "Consolidation," and related guidance within U.S. GAAP to clarify what the scope of the decrease in ownership of subsidiaries does and does not apply to.	Issued January 2010. Effective the first interim or annual reporting period after December 15, 2009.	We will adopt the provisions of this update for the first quarter of 2010. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.
<i>ASU No. 2010-06 "Improving Disclosures about Fair Value Measurements."</i>	Requires new disclosures and clarifies some existing disclosure requirements about fair value measurements codified within ASC 820, "Fair Value Measurements and Disclosures," including significant transfers into and out of Level 1 and Level 2 investments of the fair value hierarchy. Also requires additional information in the roll forward of Level 3 investments including presentation of purchases, sales, issuances, and settlements on a gross basis. Further clarification for existing disclosure requirements provides for the disaggregation of assets and liabilities presented, and the enhancement of disclosures around inputs and valuation techniques.	Issued January 2010. Effective for the first interim or annual reporting period beginning after December 15, 2009, except for the additional information in the roll forward of Level 3 investments. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim reporting periods within those fiscal years.	We will adopt the provisions of this update for the first quarter of 2010. We are currently assessing the impact the provisions of this update 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 bovine serum and human serum albumin. Such raw materials are difficult to procure and may be 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 and, therefore, have limited or no redundant manufacturing capacity in these products. For example, we manufacture all of our bulk Cerezyme and most of our bulk Fabrazyme products at our Allston facility, all of our bulk Myozyme produced at the 160L scale at our Framingham facility, and all of our larger scale bulk Myozyme at 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. 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 these steps are 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.

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. For example, since restarting Fabrazyme production at Allston, we have experienced cell growth at lower than expected levels. If we experience such difficulties, we may not be able to produce our products, including new Cerezyme and Fabrazyme, in the expected quantities. In addition, we have also experienced shipment interruptions since restarting Cerezyme and Fabrazyme production and until we re-establish inventories, we may continue experiencing interruptions if there are unanticipated delays in the release of material or if any of the assumptions used for inventory management purposes are incorrect. Finally, until we re-establish inventories, any production interruption for any reason could cause additional shortages of Cerezyme or Fabrazyme.

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. The FDA has approved a treatment IND for Replagal and Shire has submitted a BLA with the FDA for Replagal and been granted “fast track” designation. 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 and the therapies are also available to patients in the European Union through pre-approval access programs. In August 2009, Shire submitted a NDA to the FDA for its therapy and Protalix submitted its NDA in December 2009. The FDA has granted “fast track” designation for both companies’ NDAs and granted orphan drug status for both therapies. Shire’s therapy has received a PDUFA date of February 28, 2010. The FDA has requested additional CMC data from Protalix. Shire has announced that it has accelerated its manufacturing timeline for its therapy by almost 18 months. In December 2009, Protalix and Pfizer entered into an agreement to develop and commercialize Protalix’s therapy.

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 used Replagal or Gaucher patients used 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 our products, which would result in the loss of additional revenue for us. In addition, the institution of treatment guidelines and dose conservation measures during the supply constraint present the risk that physicians and patients will not resume regular treatment levels after the supply constraint has ended.

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. For example, we and certain of our third party suppliers are required to maintain compliance with GMP requirements, and are subject to inspections by the FDA, the EMA and

comparable agencies in other jurisdictions to confirm such compliance. Failure to comply with applicable regulatory requirements could result in regulatory authorities taking actions such as:

- issuing warning letters;
- levying fines and other civil penalties;
- imposing consent decrees;
- 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.

In a Form 483 issued in October 2008, a follow up warning letter issued in February 2009, and a Form 483 issued in November 2009, the FDA has detailed observations from its 2008 and 2009 inspections of our Allston facility considered to be significant deviations from GMP compliance. If the FDA determines that we do not have adequate control over the manufacturing of our products, the FDA could pursue enforcement action, including seeking a consent decree. 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 also may appoint a third party to oversee our manufacturing operations. 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 FDA, the EMA and comparable regulatory agencies worldwide 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, 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 mid-April 2010 and Myozyme has exclusivity in the United States until April 2013, in each case due to its orphan drug status. 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.

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, pharmaceutical and medical device 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.

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;
- delays or 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 pivotal study of hylastan for treatment of patients with osteoarthritis of the knee, hylastan did not meet its primary endpoint. In November 2009, we discontinued development of an advanced phosphate binder because although the advanced phosphate binder met its primary endpoint in its phase 2/3 trial, it did not demonstrate significant improvement in phosphate lowering compared to Renvela. In September 2009, our collaboration partner Osiris, to whom we have made substantial nonrefundable upfront payments, announced that its two phase 3 trials evaluating Prochymal for the treatment of acute GvHD failed to meet their primary endpoints, drawing into question the size of the market that may benefit from use of the product.

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 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, Renvela, Synvisc-One, Fabrazyme, Myozyme, Aldurazyme, Thymoglobulin, Thyrogen, Clolar, alemtuzumab for MS, Mozobil and genetic testing services.

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

- 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;
- 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, more cost effective, or having a more reliable source of supply;
- 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 or risk management activities, including REMS;
- 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 several delays in receiving marketing approval in the United States for alglucosidase alfa produced using a larger scale process, which has adversely impacted our revenues and earnings. We could face additional delays 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 Mozobil, Clolar and alemtuzumab for MS, pursuing marketing approval for our products in new jurisdictions and developing next generation products, such as eliglustat tartrate (formerly Genz-112638). 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 received a complete response letter from the FDA in October 2009 for Clolar's use in adult AML in which the agency recommended that a randomized, controlled clinical study be conducted for label expansion of Clolar in this indication.

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 genetic 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 "*The Cerezyme and Fabrazyme supply constraints resulting from the suspension of production at our Allston facility have created opportunities for our competitors,*" the virus at our Allston facility and associated production interruption have 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 approximately thirty-five countries, including the United States, European Union and Israel, 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. Enzyme replacement therapies in development by Protalix and Shire to treat Gaucher disease are available to patients in the United States under an FDA-approved treatment IND protocol and to patients in the European Union through pre-approval access programs. Both companies have submitted NDAs to the FDA for their therapies.

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 U.S. marketing exclusivity expiring in mid-April 2010, 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. Shire has submitted its BLA for Replagal to the FDA. We also 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. In addition, we are aware of one company pursuing phase 1 clinical studies (after putting a phase 2 study on hold) for a small molecule pharmacologic chaperone treatment for Pompe disease.

Renagel and Renvela compete 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. Generic formulations of PhosLo were launched in the United States in 2008 and 2009. Renagel and Renvela also compete with over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium. Our core patents protecting Renagel and Renvela expire in 2014 in the

United States and in Europe in 2015. However, our Renagel and Renvela patents are the subjects of ANDA filings in the United States by generic drug manufacturers as described in more detail in Part I, Item 3 “Legal Proceedings” of this report and in this Risk Factors section under the heading, “Some of our products may face competition from lower cost generic or follow-on products.”

Current competition for Synvisc/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/Synvisc-One. We believe that single injection products will have a competitive advantage over multiple injection products. Synvisc-One is currently the only single injection viscosupplementation product approved in the United States, but competitors are seeking FDA approval for their single injection products. Furthermore, several companies market products that are not viscosupplementation products but which are designed to relieve the pain associated with osteoarthritis. Synvisc/Synvisc-One will have difficulty competing with competitive products to the extent those 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 B-CLL includes single agent and combination chemotherapy regimens; Rituxan®/MabThera®, which is marketed globally; Treanda®, which is marketed globally; and Arzerra™, which is marketed in the United States and recently received a conditional approval recommendation by the EMA. There are also other therapies under clinical study for the treatment of B-CLL, including lumiliximab and lenalidomide. Competition for Clolar 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.

The examples above are illustrative and not exhaustive. Almost all of our products and services currently 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, demand for our products and services will be significantly limited.

Sales of our products and services are dependent, in large part, on the availability and extent of reimbursement from government health administration authorities, private health insurers and other third party payors. These third party payors may not provide adequate insurance coverage or reimbursement for our products and services, which could reduce demand for our products and services and 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, EMA 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, EMA or other applicable marketing approval.

Efforts by third party payors to reduce costs could decrease demand for our products and services. In the United States, enactment of health reform legislation could adversely affect our revenues through, among other provisions, changes to Part D of Medicare regarding reimbursement for our oral products. 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 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 establish a bundled payment system to reimburse dialysis providers treating ESRD patients. In September 2009, CMS proposed changes to the prospective payment system that would include drugs and biologicals used to treat ESRD patients 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 expected to issue a final rule in 2010 with an anticipated implementation date of January 2011.

Changes to reimbursement rates, including implementation of CMS's proposed bundling rule, could reduce our revenue by causing healthcare providers to be less willing to use our products and services. Although we actively seek to ensure 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 with capacity for Cerezyme and Fabrazyme in Framingham, Massachusetts, expanding our Allston facility, and adding an additional 4000L bioreactor to produce Myozyme at our Belgium facility. We are also expanding our fill-finish capacity in Waterford, Ireland and working with a third party contract manufacturer to transfer fill-finish activities to the contract manufacturer for a portion of our Fabrazyme, Cerezyme and Myozyme production. If we experience a delay in completing these capacity expansions or securing regulatory approval for the new internal capacity or the fill-finish capacity from the contract manufacturer, 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 larger scale bioreactors is a different product than alglucosidase alfa produced in our 160L bioreactors and required us to submit a separate BLA for the larger scale 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.

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, 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 \$793.0 million for the twelve months ended December 31, 2009, representing approximately 18% 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. See *“The Cerezyme and Fabrazyme supply constraints resulting from the suspension of production at our Allston facility have created opportunities for our competitors”* above.

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, including Osiris, PTC and Isis, 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 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.

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 2009, the change in foreign exchange rates had a net unfavorable impact on our revenue.

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 payors, including governments and private insurance plans. As a result of the current volatility in the financial markets, third-party payors 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 several ongoing legal proceedings on which we will continue to expand substantial sums. For example, we have initiated patent infringement litigation against several generic manufacturers. In addition, we are the subject of a consolidated purported securities class action lawsuit and three purported shareholder derivative lawsuits (of which two have been consolidated). We 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 may 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 EMA 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 misconstrued 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 are seeking from our insurers coverage amounting to \$30 million for reimbursement of portions of the costs incurred in connection with the litigation and settlement related to the consolidation of our tracking stocks. 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 twelve months ended December 31, 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 international operations and marketing practices are subject to regulation and scrutiny by the governments of the countries in which we operate as well as the United States government. 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 international 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 criminal or civil sanctions, including substantial monetary penalties.

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 or those patents for which we have license rights, and is successful, a court could declare such 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, Fludara and Mozobil are approved under the provisions of the United States Food, Drug and Cosmetic Act, or FDCA, that render them susceptible to potential competition from generic manufacturers via the 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 innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer 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 brought 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 therapeutic products. We expect this trend to continue and to implicate drug products with even relatively modest revenues.

Renegel/Renvela and Hectorol are subjects of ANDAs containing Paragraph IV certifications. Renegel is the subject of ANDAs submitted by four companies, and Renvela is the subject of ANDAs submitted by two companies, containing Paragraph IV certifications. We have initiated patent litigation against these ANDA applicants. At issue in the lawsuits is U.S. Patent No. 5,667,775, which expires in 2014 (the "775 Patent"). See "Legal Proceedings" in Part I, Item 3 of this report. If we are unsuccessful in these lawsuits, a generic manufacturer may launch its generic product prior to the expiration of the '775 Patent, but not before the expiration in 2013 of our other Orange Book-listed patents covering Renegel and Renvela.

Our Hectorol (doxercalciferol) products (ampule, vial and capsule) are collectively the subject of ANDAs containing Paragraph IV certifications submitted by six companies. We have initiated patent litigation against four of these ANDA applicants. See "Legal Proceedings" in Part I, Item 3 of this report. In all four cases we are pursuing claims with respect to our U.S. Patent No. 5,602,116 related to the use of Hectorol to treat hyperparathyroidism secondary to end-stage renal disease, which expires in 2014 (the "116 Patent"). In one of the four cases, we are also pursuing claims with respect to our U.S. Patent No. 7,148,211 related to the formulation of our Hectorol vial product, which expires in 2023 (the "211 Patent"). Our Hectorol capsule product is labeled for the treatment of secondary hyperparathyroidism in patients with CKD on dialysis and for those patients not on dialysis. In one of the four cases relating to our Hectorol capsule products, the ANDA filer is seeking approval of its generic 0.5µg capsule only for the treatment of patients with CKD who are not on dialysis, thereby attempting to avoid our '116 Patent. If we are unsuccessful in the patent infringement lawsuits that we have chosen to pursue against the ANDA filers, a generic manufacturer may launch its generic product prior to the expiration of our Orange-Book listed patents covering our Hectorol products.

As for the two ANDA applicants against whom litigation was not initiated, they submitted Paragraph IV certifications with respect to only the '211 Patent. Because we did not initiate litigation, the FDA could approve the applicants' generic products upon the later of expiration or invalidation of the '116 Patent or expiration of the 180-day exclusivity, if any, accorded to the first ANDA filer.

We also have two biologic products approved under the FDCA, Cerezyme and Thyrogen. This renders them susceptible to potential competition from follow-on or biosimilar manufacturers via the "505(b)2" pathway of the FDCA. As with an ANDA, the sponsor of a 505(b)2 application is permitted to rely, at least in part, on the safety and efficacy data of the innovator. For that reason, 505(b)(2) applicants may have a shorter time to approval than an applicant filing a New Drug Application.

Other of our products, including Fabrazyme, Aldurazyme, Myozyme, Campath and Leukine (so-called “biotech drugs”) were approved under the Public Health Service Act, or PHSA, which does not currently contain an abbreviated pathway for approval. However, legislation to establish such a pathway is included in the healthcare reform bills passed by both houses of the United States Congress that are pending action. If an abbreviated pathway is established, we could face eventual competition on those products from manufacturers relying, at least in part, on our safety and efficacy data. Such legislation has already been adopted in the European Union.

If an ANDA filer or any biosimilar manufacturer were to receive approval to sell a generic or biosimilar 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 shareholders 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.

Legislative or regulatory changes may adversely impact our business.

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. In addition, we may need to revise our research and development plans if a program or programs no longer are commercially viable. 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, new healthcare legislation or fiscal challenges faced by government health administration authorities. In the United States, enactment of health reform legislation could adversely affect our revenues through, among other provisions, the imposition of fees on certain elements of our businesses, an increase in the Medicaid rebate, and changes to Part D of Medicare that would decrease reimbursement for our oral renal products.

On September 27, 2007, the FDAAA of 2007 was enacted, giving the FDA enhanced authority over products already approved for sale, 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.

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.

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 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 December 31, 2009, we had \$1.05 billion 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:

- expanding and maintaining existing and constructing new manufacturing facilities, including investing significant funds to expand our Allston, Geel, Belgium and Waterford, Ireland facilities and constructing a new manufacturing facility with capacity for Fabrazyme and Cerezyme;
- implementing process improvements and system updates for our biologics manufacturing operations;
- 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, including installation and implementation of a new enterprise resource planning system worldwide;
- contingent payments under business combinations, license and other agreements, including a milestone payment to Synpac once sales of Myozyme reach \$400.0 million, as well as 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.

Since 2008, 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 7A. 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 December 31, 2009, we held a number of financial instruments, including derivative contracts in the form of foreign exchange forward contracts, and investments in marketable securities. We do not hold derivatives or other financial instruments for speculative purposes.

Foreign Exchange Risk

As a result of our worldwide operations, we may face exposure to potential adverse movements in foreign currency exchange rates, primarily to the Euro, British pound and Japanese yen. For example, a hypothetical 10% adverse change in the Euro would have the effect of reducing our 2009 consolidated revenues by approximately \$100 million. Exposures to currency fluctuations that result from sales of our products in foreign markets are partially offset by the impact of currency fluctuations on our international expenses. We use foreign exchange forward contracts to further reduce our exposure to changes in exchange rates, primarily to offset the earnings effect from short-term foreign currency assets and liabilities. We also hold a limited amount of foreign currency denominated equity securities.

As of December 31, 2009, we estimate the potential loss in fair value of our foreign currency contracts and foreign equity holdings that would result from a hypothetical 10% adverse change in exchange rates to be \$4.8 million, as compared to \$26.9 million as of December 31, 2008. The change from the prior period is due to a decrease in our net foreign exchange forward contracts. Since the contracts hedge mainly transactional exchange exposures, most changes in the fair values of the contracts would be offset by changes in the underlying values of the hedged items.

Interest Rate Risk

We are exposed to potential loss due to changes in interest rates. Our principal interest rate exposure is to changes in U.S. interest rates. Instruments with interest rate risk include short- and long-term investments in fixed income securities and a fixed rate capital lease. To estimate the potential loss due to changes in interest rates, we performed a sensitivity analysis using the instantaneous adverse change in interest rates of 100 basis points across the yield curve. On this basis, we estimate the potential loss in fair value to be \$6.5 million as of December 31, 2009, as compared to \$6.2 million as of December 31, 2008.

Equity Price Risk

We hold investments in a limited number of U.S. and European equity securities. We estimated the potential loss in fair value due to a 10% decrease in the equity prices of each marketable security held at December 31, 2009 to be \$15.5 million, as compared to \$16.4 million at December 31, 2008. This estimate assumes no change in foreign exchange rates from quarter-end spot rates.

Item 8. Financial Statements and Supplementary Data

**GENZYME CORPORATION AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Genzyme Corporation:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive income, of cash flows and of stockholders' equity present fairly, in all material respects, the financial position of Genzyme Corporation and its subsidiaries at December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in "Management's Annual Report on Internal Control over Financial Reporting" appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note O. to the consolidated financial statements, the Company changed the manner in which it accounts for unrecognized tax benefits in 2007.

As discussed in Note C. to the consolidated financial statements, the Company changed the manner in which it accounts for business combinations in 2009.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As described in Management's Annual Report On Internal Control Over Financial Reporting, management has excluded the commercial and development rights purchased from Bayer from its assessment of internal controls over financial reporting as of December 31, 2009 because they were acquired by the Company in a purchase business combination during 2009. We have also excluded the acquisition of the commercial and development rights from our audit of internal control over financial reporting. The rights acquired from Bayer are a component of the Company's Hematologic Oncology reporting segment. Total inventories and total revenues related to these rights represent \$47.8 million, or 8%, and \$138.8 million, or 3%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2009.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 26, 2010

GENZYME CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Income
(Amounts in thousands, except per share amounts)

	For the Years Ended December 31,		
	2009	2008	2007
Revenues:			
Net product sales	\$4,076,665	\$4,196,907	\$3,457,778
Net service sales	418,518	366,091	326,326
Research and development revenue	20,342	42,041	29,415
Total revenues	<u>4,515,525</u>	<u>4,605,039</u>	<u>3,813,519</u>
Operating costs and expenses:			
Cost of products sold	1,136,937	913,267	715,504
Cost of services sold	249,139	235,295	211,826
Selling, general and administrative	1,428,596	1,338,190	1,187,184
Research and development	865,257	1,308,330	737,685
Amortization of intangibles	266,305	226,442	201,105
Contingent consideration expense	65,584	—	—
Charge for impaired intangible assets	—	2,036	—
Purchase of in-process research and development	—	—	106,350
Total operating costs and expenses	<u>4,011,818</u>	<u>4,023,560</u>	<u>3,159,654</u>
Operating income	<u>503,707</u>	<u>581,479</u>	<u>653,865</u>
Other income (expenses):			
Equity in income of equity method investments	—	201	7,398
Gain (loss) on investments in equity securities, net	(56)	(3,340)	13,067
Gain on acquisition of business	24,159	—	—
Other	(1,719)	356	3,295
Investment income	17,642	51,260	70,196
Interest expense	—	(4,418)	(12,147)
Total other income	<u>40,026</u>	<u>44,059</u>	<u>81,809</u>
Income before income taxes	<u>543,733</u>	<u>625,538</u>	<u>735,674</u>
Provision for income taxes	<u>(121,433)</u>	<u>(204,457)</u>	<u>(255,481)</u>
Net income	<u>\$ 422,300</u>	<u>\$ 421,081</u>	<u>\$ 480,193</u>
Net income per share:			
Basic	<u>\$ 1.57</u>	<u>\$ 1.57</u>	<u>\$ 1.82</u>
Diluted	<u>\$ 1.54</u>	<u>\$ 1.50</u>	<u>\$ 1.74</u>
Weighted average shares outstanding:			
Basic	<u>268,841</u>	<u>268,490</u>	<u>263,895</u>
Diluted	<u>274,071</u>	<u>285,595</u>	<u>280,767</u>
Comprehensive income (loss), net of tax:			
Net income	<u>\$ 422,300</u>	<u>\$ 421,081</u>	<u>\$ 480,193</u>
Other comprehensive income (loss):			
Foreign currency translation adjustments	67,879	(141,936)	149,425
Loss on affiliate sale of stock, net of tax	—	—	(72)
Pension liability adjustments, net of tax(1)	(14,511)	5,772	1,056
Unrealized gains (losses) on securities, net of tax:			
Unrealized gains (losses) arising during the period, net of tax	(5,799)	5,039	18,050
Reclassification adjustment for gains included in net income, net of tax	(1,622)	(6,742)	(8,586)
Unrealized gains (losses) on securities, net of tax(2)	(7,421)	(1,703)	9,464
Other comprehensive income (loss)	<u>45,947</u>	<u>(137,867)</u>	<u>159,873</u>
Comprehensive income	<u>\$ 468,247</u>	<u>\$ 283,214</u>	<u>\$ 640,066</u>

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

(2) Net of \$4.2 million of tax for the year ended December 31, 2009, \$1.0 million of tax for the year ended December 31, 2008 and \$(5.2) million of tax for the year ended December 31, 2007.

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

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

	December 31,	
	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 742,246	\$ 572,106
Short-term investments	163,630	57,507
Accounts receivable, net	899,731	1,036,940
Inventories	608,022	453,437
Other current assets	210,747	208,040
Deferred tax assets	178,427	188,105
Total current assets	2,802,803	2,516,135
Property, plant and equipment, net	2,809,349	2,306,567
Long-term investments	143,824	344,078
Goodwill	1,403,363	1,401,074
Other intangible assets, net	2,313,262	1,654,698
Deferred tax assets—noncurrent	376,815	269,237
Investments in equity securities	74,438	83,325
Other noncurrent assets	136,870	96,162
Total assets	\$10,060,724	\$8,671,276
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 189,629	\$ 127,869
Accrued expenses	696,223	765,386
Deferred revenue	24,747	13,462
Current portion of contingent consideration obligations	161,365	—
Current portion of long-term debt and capital lease obligations	8,166	7,566
Total current liabilities	1,080,130	914,283
Long-term debt and capital lease obligations	116,434	124,341
Deferred revenue—noncurrent	13,385	13,175
Long-term contingent consideration obligations	853,871	—
Other noncurrent liabilities	313,252	313,484
Total liabilities	2,377,072	1,365,283
Commitments and contingencies (Note N)		
Stockholders' equity:		
Preferred stock, \$0.01 par value	—	—
Common stock, \$0.01 par value	2,657	2,707
Additional paid-in capital	5,688,741	5,779,279
Accumulated earnings	1,670,096	1,247,796
Accumulated other comprehensive income	322,158	276,211
Total stockholders' equity	7,683,652	7,305,993
Total liabilities and stockholders' equity	\$10,060,724	\$8,671,276

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

GENZYME CORPORATION AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(Amounts in thousands)

	For the Years Ended December 31,		
	2009	2008	2007
Cash Flows from Operating Activities:			
Net income	\$ 422,300	\$ 421,081	\$ 480,193
Reconciliation of net income to cash flows from operating activities:			
Depreciation and amortization	456,364	374,664	338,196
Stock-based compensation	204,229	187,596	190,070
Provision for bad debts	18,856	12,983	9,665
Purchase of in-process research and development	—	—	106,350
Contingent consideration expense	65,584	—	—
(Gains) losses on investments in equity securities, net	56	3,340	(13,067)
Gain on acquisition of business	(24,159)	—	—
Deferred income tax benefit	(95,737)	(195,200)	(106,140)
Tax benefit from employee stock-based compensation	15,450	59,868	51,041
Excess tax benefits from stock-based compensation	(3,305)	(18,445)	(13,575)
Other	4,270	3,903	(6,199)
Increase (decrease) in cash from working capital changes (excluding impact of acquired assets and assumed liabilities):			
Accounts receivable	99,374	(137,273)	(105,230)
Inventories	9,976	(4,700)	(15,011)
Other current assets	(1,469)	12,142	(23,897)
Accounts payable, accrued expenses and deferred revenue	7,248	39,216	26,276
Cash flows from operating activities	1,179,037	759,175	918,672
Cash Flows from Investing Activities:			
Purchases of investments	(309,217)	(420,867)	(779,932)
Sales and maturities of investments	402,286	608,994	985,546
Purchases of equity securities	(14,844)	(88,656)	(21,994)
Proceeds from sales of investments in equity securities	10,478	8,594	20,712
Purchases of property, plant and equipment	(661,713)	(597,562)	(412,872)
Distributions from equity method investments	—	4,844	17,100
Acquisitions	(51,336)	(16,561)	(342,456)
Payment of note receivable from Dyax	—	—	7,771
Purchases of other intangible assets	(41,883)	(92,183)	(60,350)
Other	(5,195)	11,857	(4,581)
Cash flows from investing activities	(671,424)	(581,540)	(591,056)

GENZYME CORPORATION AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
(Amounts in thousands)

	<u>For the Years Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Cash Flows from Financing Activities:			
Proceeds from issuance of common stock	100,521	318,753	285,762
Repurchases of our common stock	(413,874)	(143,012)	(231,576)
Excess tax benefits from stock-based compensation	3,305	18,445	13,575
Payments of debt and capital lease obligations	(7,492)	(693,961)	(5,909)
Increase (decrease) in bank overdrafts	896	25,760	(5,910)
Payment of contingent consideration obligation	(26,417)	—	—
Other	6,445	7,772	8,681
Cash flows from financing activities	<u>(336,616)</u>	<u>(466,243)</u>	<u>64,623</u>
Effect of exchange rate changes on cash	(857)	(6,298)	(17,397)
Increase (decrease) in cash and cash equivalents	170,140	(294,906)	374,842
Cash and cash equivalents at beginning of period	572,106	867,012	492,170
Cash and cash equivalents at end of period	<u>\$742,246</u>	<u>\$572,106</u>	<u>\$867,012</u>
Supplemental disclosures of cash flows:			
Cash paid during the year for:			
Interest, net of capitalized interest	\$ —	\$ 1,799	\$ 5,490
Income taxes	\$185,981	\$427,591	\$447,566
Supplemental disclosures of non-cash transactions:			
Strategic Transactions—Note C.			
Property, Plant and Equipment—Note G.			
Capital lease obligation for Genzyme Center—Note L.			
Long-Term Debt—Note L.			

In conjunction with acquisitions completed in 2009 and 2007 (we did not complete any acquisitions in 2008), as described in Note C, “Strategic Transactions,” we assumed the following net liabilities (amounts in thousands):

	<u>For the Years Ended December 31,</u>	
	<u>2009</u>	<u>2007</u>
Net cash paid for acquisitions and acquisition costs	\$ (42,425)	\$(342,456)
Contingent consideration obligations	(964,100)	—
Fair value of assets acquired	1,030,684	226,579
Accrual for dissenting shares	—	(16,128)
Acquired in-process research and development	—	125,500
Gain on acquisition of business	(24,159)	—
Goodwill	—	100,393
Liabilities for exit activities and integration	—	(2,671)
Income taxes payable	—	(72,461)
Net deferred tax assets (liabilities)	—	(8,210)
Net liabilities assumed	<u>\$ —</u>	<u>\$ 10,546</u>

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

GENZYME CORPORATION AND SUBSIDIARIES
Consolidated Statements of Stockholders' Equity
(Amounts in thousands)

	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Accumulated Earnings	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Par Value					
Balance, January 1, 2007	263,026	\$2,630	\$5,106,274	\$(15,057)	\$ 312,659	\$ 254,205	\$5,660,711
Stock issued through stock option and stock purchase plans	6,482	65	285,697	—	—	—	285,762
Tax benefit from stock option exercises	—	—	27,654	—	—	—	27,654
Stock-based compensation	—	—	189,661	—	—	—	189,661
Adoption of provisions of ASC 740, "Income Taxes"	—	—	6,933	—	33,863	—	40,796
Repurchases of our common stock	(3,500)	(35)	(231,541)	—	—	—	(231,576)
Foreign currency translation adjustments	—	—	—	—	—	149,425	149,425
Change in unrealized gains and losses on investments, net of tax	—	—	—	—	—	9,464	9,464
Loss on affiliate sale of stock, net of tax	—	—	—	—	—	(72)	(72)
Pension liability adjustment, net of tax	—	—	—	—	—	1,056	1,056
Other	—	—	476	(613)	—	—	(137)
Net income	—	—	—	—	480,193	—	480,193
Balance, December 31, 2007	266,008	2,660	5,385,154	(15,670)	826,715	414,078	6,612,937
Stock issued through stock option and stock purchase plans	6,682	67	318,686	—	—	—	318,753
Tax benefit from stock option exercises	—	—	31,526	—	—	—	31,526
Stock-based compensation	—	—	187,596	—	—	—	187,596
Repurchases of our common stock	(2,000)	(20)	(142,992)	—	—	—	(143,012)
Conversion of our convertible senior notes	40	—	2,825	—	—	—	2,825
Payments of notes receivable from stockholders	(26)	—	(1,974)	14,609	—	—	12,635
Foreign currency translation adjustments	—	—	—	—	—	(141,936)	(141,936)
Change in unrealized gains and losses on investments, net of tax	—	—	—	—	—	(1,703)	(1,703)
Pension liability adjustment, net of tax	—	—	—	—	—	5,772	5,772
Other	—	—	(68)	(413)	—	—	(481)
Net income	—	—	—	—	421,081	—	421,081
Balance, December 31, 2008	270,704	2,707	5,780,753	(1,474)	1,247,796	276,211	7,305,993
Stock issued through stock option and stock purchase plans	2,516	25	100,496	—	—	—	100,521
Tax benefit from stock option exercises	—	—	16,749	—	—	—	16,749
Stock-based compensation	—	—	204,602	—	—	—	204,602
Repurchases of our common stock	(7,500)	(75)	(413,799)	—	—	—	(413,874)
Payments of notes receivable from stockholders	(1)	—	(60)	1,474	—	—	1,414
Foreign currency translation adjustments	—	—	—	—	—	67,879	67,879
Change in unrealized gains and losses on investments, net of tax	—	—	—	—	—	(7,421)	(7,421)
Pension liability adjustment, net of tax	—	—	—	—	—	(14,511)	(14,511)
Net income	—	—	—	—	422,300	—	422,300
Balance, December 31, 2009	265,719	\$2,657	\$5,688,741	\$ —	\$1,670,096	\$ 322,158	\$7,683,652

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

GENZYME CORPORATION AND SUBSIDIARIES

Notes To Consolidated Financial Statements

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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.

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, Aldurazyme and Elaprase;
- 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 and the Septra line of products; and
- Hematologic Oncology, which develops, manufactures and distributes products for the treatment of cancer and the mobilization of hematopoietic stem cells. This business is also developing a product for the treatment of MS. The unit derives substantially all of its revenue from sales of Clolar, Mozobil, Campath, Fludara and Leukine.

Formerly, we included our MS business unit under the caption "Other." As a result of our acquisition of certain products and development programs from Bayer in the second quarter of 2009, as described under the heading "Strategic Transactions—Acquisition from Bayer," our MS business unit is now material. We have aggregated our Hematologic Oncology reporting segment and MS business unit and now report the activities of these two reporting units 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 genetic testing business unit, which provides testing services for the oncology, prenatal and reproductive markets, are included 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 report our corporate, general and administrative operations and corporate science activities under the caption "Corporate."

We have revised our 2008 and 2007 segment disclosures to conform to our 2009 presentation.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements 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 own less than a 100% 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 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 and losses of these entities. All intercompany accounts and transactions have been eliminated in consolidation.

Dividend Policy

We have never paid a cash dividend on shares of our stock. We currently do not anticipate paying any cash dividends on our stock in the foreseeable future.

Use of Estimates

Under U.S. GAAP, we are required to make certain estimates and assumptions that affect reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in our consolidated financial statements. Our actual results could differ from these estimates.

Cash and Cash Equivalents

We value our cash and cash equivalents at cost plus accrued interest, which we believe approximates their market value. Our cash equivalents consist principally of money market funds at December 31, 2009, but can consist of corporate, government, agency and municipal notes with original maturities of three months or less at any time. We generally invest our cash in investment-grade securities to mitigate risk.

Fair Value Measurements

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.

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

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 foreign exchange forward 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 have unobservable value drivers 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 market values of our fixed income investments using market data from observable and corroborated sources. We also perform the fair value calculations for our derivative and equity securities using market data from observable and corroborated sources. 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.

Investments

We can invest our excess cash balances on a global basis in short-term and long-term marketable debt securities, which can consist of corporate, government, agency and municipal notes. As part of our strategic relationships, we may also invest in equity securities of other biotechnology companies, some of which are currently, or have been in the past, considered related parties. Other investments are accounted for as described below.

We classify all of our:

- marketable equity investments as available-for-sale; and
- investments in marketable debt securities as either held-to-maturity or available-for-sale based on facts and circumstances present at the time we purchase the securities.

As of each balance sheet date presented, we classified all of our investments in debt securities as available-for-sale. We report available-for-sale investments at fair value as of each balance sheet date and include any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses are determined on the specific identification method and are included in investment income. We classify our investments with remaining maturities of twelve months or less as short-term investments exclusive of those categorized

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

as cash equivalents. We classify our investments with remaining maturities of greater than twelve months as long-term investments, unless we expect to sell the investment in less than 1 year. Investments in equity securities for which fair value is not readily determinable or which are subject to trading restrictions for more than one year are carried at cost, subject to review for impairment.

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

Prior to our adoption of this new accounting standard, if any adjustment to fair value reflected a decline in the value of the investment, we considered all available evidence to evaluate the extent to which the decline was "other than temporary" and marked the investment to market through a charge to our statement of operations. Under the new accounting standards, we are required to recognize an other-than-temporary impairment through earnings if we have the intent to sell the debt security or if it is more likely than not that we will be required to sell the debt security before recovery of our amortized cost basis. However, even if we do not expect to sell a debt security, we must evaluate expected cash flows to be received to determine if a credit loss has occurred. In the event of an other than temporary impairment, only the amount associated with the credit loss is recognized in income. The amount of losses relating to other factors, including those resulting from changes in interest rates, are recorded in accumulated other comprehensive income. The adoption of this guidance did not have a material impact on our financial position or results of operations.

For additional information on our investments, please read Note I, "Investments in Marketable Securities and Equity Investments," and Note J, "Equity Method Investments."

Inventories

We value inventories at cost or, if lower, fair value. We determine cost using the first-in, first-out method.

We analyze our inventory levels quarterly and write down to its net realizable value:

- inventory that has become obsolete;
- inventory that has a cost basis in excess of its expected net realizable value;
- inventory in excess of expected requirements; and
- expired inventory.

We capitalize inventory produced for commercial sale, which may result in the capitalization of inventory prior to regulatory approval or prior to approval of a manufacturing facility. In no event is inventory capitalized prior to completion of a phase 3 clinical trial. If a product is not approved for sale or a manufacturing facility does not receive approval, it would likely result in the write off of the inventory and a charge to earnings.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Property, Plant and Equipment

We record property, plant and equipment at cost. When we dispose of these assets, we remove the related cost and accumulated depreciation and amortization from the related accounts on our balance sheet and include any resulting gain or loss in our statement of operations.

We generally compute depreciation using the straight-line method over the estimated useful lives of the assets. We compute economic lives as follows:

- plant and equipment—three to fifteen years;
- furniture and fixtures—five to seven years; and
- buildings—twenty to forty years.

We evaluate the remaining life and recoverability of this equipment periodically based on the appropriate facts and circumstances.

We amortize leasehold improvements and assets under capital leases over their useful life or, if shorter, the term of the applicable lease.

We capitalize certain computer software and software development costs incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are included in property, plant and equipment, net on our consolidated balance sheet and amortized on a straight-line basis over the estimated useful lives of the software, which generally do not exceed 10 years.

For products we expect to commercialize, we capitalize, to construction-in-progress, the costs we incur in validating facilities and equipment. We begin this capitalization when the validation process begins, provided that the product to be manufactured has demonstrated technological feasibility, and end this capitalization when the asset is substantially complete and ready for its intended use. These capitalized costs include incremental labor and direct material, and interest. We depreciate these costs using the straight-line method.

Costs of idle production facilities, including related depreciation, are charged directly to cost of products sold.

Goodwill and Other Intangible Assets

Our intangible assets consist of:

- goodwill;
- purchased technology rights;
- patents, trademarks and trade names;
- license fees;
- distribution rights;
- customer lists;
- covenants not to compete; and

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- IPR&D acquired after January 1, 2009.

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 asset may not be recoverable. We complete our annual impairment test in the third quarter of each year.

We amortize intangible assets using the straight-line method over their estimated useful lives, which range between 1 and 15 years or, using the economic use method if that method results in significantly greater amortization than the straight-line method.

For certain acquired intangible assets, we may be required to make additional payments contingent upon meeting certain sales targets. We record amortization expense for these intangibles based on estimated future sales of the related products and include in the determination of amortization all contingent payments that we believe are probable of being made. We apply this amortization model to our Synvisc distribution rights (acquired from Wyeth), our license agreement with Synpac related to Myozyme patent and technology rights and our technology intangible assets for Fludara related to our acquisition from Bayer. We review the sales forecasts of these products on a quarterly basis and assess the impact changes in the forecasts have on the rate of amortization and the likelihood that contingent payments will be made. Adjustments to amortization expense resulting from changes in estimated sales are reflected prospectively.

Accounting for the Impairment of Long-Lived Assets

We periodically evaluate our long-lived assets for potential impairment. We perform these evaluations whenever events or changes in circumstances suggest that the carrying amount of an asset or group of assets is not recoverable. Indicators of potential impairment include:

- a significant change in the manner in which an asset is used;
- a significant decrease in the market value of an asset;
- a significant adverse change in its business or the industry in which it is sold; and
- a current period operating cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the asset.

If we believe an indicator of potential impairment exists, we test to determine whether impairment recognition criteria have been met. We charge impairments of the long-lived assets to operations if our evaluations indicate that the carrying value of these assets is not recoverable.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Translation of Foreign Currencies

We translate the financial statements of our foreign subsidiaries from local currency into U.S. dollars using:

- the current exchange rate at each balance sheet date for assets and liabilities;
- the average exchange rate prevailing during each period for revenues and expenses; and
- the historical exchange rate for our investments in our foreign subsidiaries.

We consider the local currency for all of our foreign subsidiaries to be the functional currency for that subsidiary. As a result, we include translation adjustments for these subsidiaries in stockholders' equity. We also record in stockholders' equity, exchange gains and losses on intercompany balances that are of a long-term investment nature. Our stockholders' equity includes net cumulative foreign currency translation gains of \$336.9 million at December 31, 2009 and \$263.1 million at December 31, 2008. Gains and losses, net of tax, on all other foreign currency transactions, including gains and losses attributable to foreign exchange forward contracts, are included in SG&A in our results of operations and were a net loss of \$(7.3) million for fiscal year 2009, a net loss of \$(18.3) million for fiscal year 2008 and a net gain of \$5.8 million for fiscal year 2007.

Derivative Instruments

We are required to recognize all derivative instruments as either assets or liabilities in our consolidated balance sheets and measure those instruments at fair value. Subsequent changes in fair value are reflected in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedge relationship and, if it is, the type of hedge relationship.

Defined Benefit Plan Accounting

We are required to recognize the overfunded or underfunded status of any pension or other postretirement plans we may have as a net asset or a net liability on our statement of financial position and to recognize changes in that funded status in the year in which the changes occur as an adjustment to accumulated other comprehensive income in stockholders' equity. Currently, we have defined benefit pension plans for certain of our foreign subsidiaries and a defined benefit postretirement plan for one of our U.S. subsidiaries, which has been frozen since 1995 and is not significant. Actuarial gains and losses, prior service costs or credits, and any remaining transition assets or obligations that have not been recognized for our defined benefit pension plans under previous accounting standards must be recognized in accumulated other comprehensive income, net of tax effects, until they are amortized as a component of net periodic benefit cost. In addition, the measurement date, which is the date at which the benefit obligation and plan assets are measured, is as of our fiscal year end, which is December 31.

Accounting for our defined benefit plans requires management make certain assumptions relating to the following:

- long-term rate of return on plan assets;
- discount rates used to measure future obligations and interest expense;

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- salary scale inflation rates; and
- other assumptions based on the terms of each individual plan.

We obtained actuarial reports to compute the amounts of liabilities and expenses relating to the majority of our plans subject to the assumptions that management selects as of the beginning of the plan year. Management reviews the long-term rate of return, discount, and salary scale inflation on an annual basis and makes modifications to the assumptions based on current rates and trends as appropriate.

Revenue Recognition

We recognize revenue from product sales when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured. For sales to distributors that do not or can not bear the risk of loss, we recognize revenue when the product is sold through to hospitals or other healthcare providers. We recognize revenue from service sales, such as Carticel services and genetic testing services, when we have finished providing the service. We recognize the revenue from the contracts to perform research and development services and selling and marketing services over the term of the applicable contract and as we complete our obligations under that contract. We recognize nonrefundable, upfront license fees over the related performance period or when we have no remaining performance obligations.

Revenue from milestone payments for which we have no continuing performance obligations is recognized upon achievement of the related milestone. When we have continuing performance obligations, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

We evaluate revenue from agreements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting. To recognize a delivered item in a multiple element arrangement, it is required that the delivered items have value to the customer on a stand alone basis, be objective and reliable evidence of fair value of the undelivered items and that delivery or performance is probable and within our control for any delivered items that have a right of return.

We follow the issued guidance in the presentation of revenues and direct costs of revenues. This guidance requires us to assess whether we act as a principal in the transaction or as an agent acting on behalf of others. We record revenue transactions gross in our statements of operations if we are deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

We receive royalties related to the manufacture, sale or use of our products or technologies under license arrangements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the licensee.

We record allowances for product returns, rebates payable to Medicaid, managed care organizations or customers, chargebacks and sales discounts. These allowances are recorded as a

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

reduction to revenue at the time product sales are recorded. These amounts are based on our historical activity, estimates of the amount of product in the distribution channel and the percent of end-users covered by Medicaid or managed care organizations. We record consideration paid to a customer or reseller of our products as a reduction of revenue unless we receive an identifiable and separable benefit for the consideration, and we can reasonably estimate the fair value of the benefit received. If both conditions are met, we record the consideration paid to the customer as an expense.

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers was to deteriorate and result in an impairment of their ability to make payments, additional allowances may be required.

Stock-Based Compensation

All stock-based awards to non-employees are accounted for at their fair value. We periodically grant awards, including stock options, time vesting restricted stock, or RS, or time vesting RSUs, under our employee and director equity plans. We record the estimated fair value of awards granted as stock-based compensation expense in our consolidated statements of operations over the requisite service period, which is generally the vesting period. Where awards are made with non-substantive vesting periods, such as where a portion of the award vests upon retirement eligibility, we estimate and recognize expense based on the period from the grant date to the date on which the employee is retirement eligible.

The fair values of our stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the stock options, including the effect of estimated forfeitures, are then expensed over the options' vesting periods. The fair values of our time vesting restricted stock awards are based on the market value of our stock on the date of grant. Compensation expense for time vesting RSUs are recognized over the applicable service period, adjusted for the effect of estimated forfeitures.

We have an ESPP under which participating employees are allowed to purchase shares of our common stock at a discount. The purchase price of common stock under our ESPP is equal to 85% of the fair market value of Genzyme Stock at the beginning of an enrollment period or the purchase date. The fair value of the discounted purchases made under our ESPP is calculated using the Black-Scholes model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over the purchase period. We apply a graded vesting approach since our ESPP provides for multiple purchase periods and is, in substance, a series of linked awards.

Research and Development

We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred. We also expense the cost of purchased technology in the period of purchase if we believe that the technology has not demonstrated technological feasibility and that it does not have an alternative future use.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes

We use the asset and liability method of accounting for deferred income taxes. We are subject to income taxes in both the United States and numerous foreign jurisdictions; however, our most significant tax jurisdictions are the U.S. federal and states. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. These judgments, estimates and assumptions involve:

- interpreting the tax laws in various jurisdictions in which we operate;
- analyzing changes in tax laws, regulations, and treaties, foreign currency exchange restrictions; and
- estimating our levels of income, expenses and profits in each jurisdiction and the potential impact of that income on the tax liability in any given year.

We operate in many jurisdictions where the tax laws relating to the pricing of transactions between related parties are open to interpretation, which could potentially result in tax authorities asserting additional tax liabilities with no offsetting tax recovery in other countries.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not the tax position will be sustained based on the technical merits of the tax position. The tax benefits recognized in our consolidated financial statements from such a position are measured on the largest amount, using the cumulative probability measure, which is likely to be ultimately realized. If an uncertain tax position does not meet the more likely than not threshold, it will only be recognized in the first period in which the more likely than not threshold is met, the matter is ultimately settled through negotiation or litigation or the statute of limitations for the relevant taxing authority to examine and challenge the matter has expired. See Note O, "Income Taxes," included in this report for more information regarding the impact the recognition of the tax benefit from an uncertain tax position had on our results of operations, financial condition and liquidity.

We continue to recognize interest relating to unrecognized tax benefits within our provision for income taxes but have not recorded any amounts related to potential penalties. The amounts of accrued interest related to unrecognized tax benefits within our provision for income taxes for the years ended December 31, 2009 and 2008 were not significant.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income or loss and all changes in equity from non-shareholder sources, including changes in unrealized gains and losses on investments, foreign currency translation adjustments and liabilities for pension obligations, net of taxes.

Net Income (Loss) Per Share

To calculate base earnings per share, we divide our earnings by the weighted average number of outstanding shares during the applicable period. To calculate diluted earnings per share, we also include in the denominator all potentially dilutive securities outstanding during the applicable period unless inclusion of such securities is anti-dilutive.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF 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 other standard setting bodies. Changes to the ASC are communicated through ASU's. The following table shows FASB ASU's recently issued that could affect our disclosures, and our position for adoption:

<u>Accounting Standards Update</u>	<u>Relevant Requirements of Accounting Standards Update</u>	<u>Issued Date/ Our Effective Dates</u>	<u>Status</u>
<i>ASC 860-20, "Accounting for Transfers of Financial Assets."</i>	Update 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.	We adopted the update as of January 1, 2010. We do not expect the adoption of this pronouncement to have any affect on our consolidated financial statements.
<i>ASC 810-20, "Control of Partnerships and Similar Entities."</i>	Update improves financial reporting by enterprises involved with variable interest entities and 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.	We will adopt this update in the second quarter of 2010. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.
<i>ASU No. 2009-13 "Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force."</i>	Establishes the accounting and reporting guidance for arrangements under which a vendor will perform multiple revenue-generating activities. Specifically, the provisions of this update address how to separate deliverables and how to measure and allocate arrangement consideration to one or more units of accounting.	Issued October 2009. Effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted.	We will adopt the provisions of this update for the first quarter of 2011. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

<u>Accounting Standards Update</u>	<u>Relevant Requirements of Accounting Standards Update</u>	<u>Issued Date/ Our Effective Dates</u>	<u>Status</u>
<i>ASU No. 2009-17 "Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities."</i>	This update consists of amendments to ASC 810, "Consolidation," which change how a company determines when an entity that is insufficiently capitalized or is not controlled through voting should be consolidated. This is based on, among other things, an entity's purpose and design and a company's ability to direct the activities of the entity that most significantly impact the entity's economic performance.	Issued December 2009. Effective the first interim or annual reporting period after December 15, 2009.	We will adopt the provisions of this update for the first quarter of 2010. We do not expect the provisions of this update to have a material impact on our consolidated financial statements.
<i>ASU No. 2010-02 "Accounting and Reporting for Decreases in Ownership of a Subsidiary—a Scope Clarification."</i>	Amends ASC 810-10, "Consolidation," and related guidance within U.S. GAAP to clarify what the scope of the decrease in ownership of subsidiaries does and does not apply to.	Issued January 2010. Effective the first interim or annual reporting period after December 15, 2009.	We will adopt the provisions of this update for the first quarter of 2010. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE A. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

<u>Accounting Standards Update</u>	<u>Relevant Requirements of Accounting Standards Update</u>	<u>Issued Date/ Our Effective Dates</u>	<u>Status</u>
<i>ASU No. 2010-06 "Improving Disclosures about Fair Value Measurements."</i>	Requires new disclosures and clarifies some existing disclosure requirements about fair value measurements codified within ASC 820, "Fair Value Measurements and Disclosures," including significant transfers into and out of Level 1 and Level 2 investments of the fair value hierarchy. Also requires additional information in the roll forward of Level 3 investments including presentation of purchases, sales, issuances, and settlements on a gross basis. Further clarification for existing disclosure requirements provides for the disaggregation of assets and liabilities presented, and the enhancement of disclosures around inputs and valuation techniques.	Issued January 2010. Effective for the first interim or annual reporting period beginning after December 15, 2009, except for the additional information in the roll forward of Level 3 investments. Those disclosures are effective for fiscal years beginning after December 15, 2010, and for interim reporting periods within those fiscal years.	We will adopt the provisions of this update for the first quarter of 2010. We are currently assessing the impact the provisions of this update will have, if any, on our consolidated financial statements.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE B. NET INCOME PER SHARE

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

	<u>For the Years Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Net income	\$422,300	\$421,081	\$480,193
Effect of dilutive securities:			
Interest expense and debt fee amortization, net of tax, related to our 1.25% convertible senior notes	—	6,915	7,543
Net income—diluted	<u>\$422,300</u>	<u>\$427,996</u>	<u>\$487,736</u>
Shares used in computing net income per common share—basic	268,841	268,490	263,895
Effect of dilutive securities(1):			
Shares issuable upon the assumed conversion of our 1.25% convertible senior notes	—	8,851	9,686
Stock options(2)	3,719	7,286	7,039
Restricted stock units	1,501	700	11
Other	10	268	136
Dilutive potential common shares	<u>5,230</u>	<u>17,105</u>	<u>16,872</u>
Shares used in computing net income per common share—diluted(1,2)	<u>274,071</u>	<u>285,595</u>	<u>280,767</u>
Net income per share:			
Basic	<u>\$ 1.57</u>	<u>\$ 1.57</u>	<u>\$ 1.82</u>
Diluted	<u>\$ 1.54</u>	<u>\$ 1.50</u>	<u>\$ 1.74</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. 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 each such period (amounts in thousands):

	<u>For the Years Ended</u> <u>December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Shares of Genzyme Stock issuable upon exercise of outstanding options	<u>18,047</u>	<u>3,816</u>	<u>12,262</u>

NOTE C. 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

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

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:

<u>Element</u>	<u>Prior to January 1, 2009</u>	<u>On or after January 1, 2009</u>
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

We classify nonrefundable fees paid outside of a business combination for the acquisition or licensing of products that have not received regulatory approval and have no future alternative use as research and development expense.

2009:

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,

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

equipment and materials used in manufacturing AAV vectors. We paid Targeted Genetics Corporation a nonrefundable upfront payment of \$3.5 million in September 2009 and an additional \$2.5 million in the fourth quarter of 2009 as certain technology transfer-based milestones were achieved. The remaining \$1.0 million of technology transfer-based milestone payments were paid in January 2010. The purchased assets did not qualify as a business combination and have not reached technological feasibility, nor have alternative future use. Therefore 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 in 2009.

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 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 have primary responsibility for the product's development while Bayer continues to fund development at the levels specified under the previous agreement and participates in a development steering committee. We 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

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

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 \$113.2 million to Bayer, of which \$70.8 million was refundable. The remaining nonrefundable amount of \$42.4 million represents a payment for acquired inventory. A total of \$61.8 million of the refundable amount was received in 2009. As of December 31, 2009, \$8.9 million remains due from Bayer. 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 December 31, 2009, the fair value of the total contingent consideration obligations was \$1.02 billion primarily due to changes in discount periods and management estimates. Accordingly, we recorded contingent consideration expense in our consolidated statements of operations of \$65.6 million in 2009. As of December 31, 2009, we have paid \$36.4 million in contingent consideration payments to Bayer and have received \$10.0 million in funding from Bayer for the development of alemtuzumab for MS since May 29, 2009.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

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 in 2009.

SG&A in our 2009 consolidated statements of operations include approximately \$5 million of acquisition-related costs, primarily legal fees, associated with the Bayer transaction.

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 in March 2009.

2008:

Strategic Alliance with Osiris

In October 2008, we entered into a strategic alliance with Osiris, whereby we obtained an exclusive license to develop and commercialize Prochymal and Chondrogen, mesenchymal stem cell products, outside of the United States and Canada. Osiris will commercialize Prochymal and Chondrogen in the United States and Canada. We paid Osiris a nonrefundable upfront payment of \$75.0 million in November 2008, and a \$55.0 million nonrefundable upfront license fee in July 2009. The results of these programs are primarily included in our immune mediated disease business unit, which are reported under the category "Other" in our segment disclosures.

Osiris will be responsible for completing, at its own expense, all clinical trials of Prochymal for the treatment of GvHD and Crohn's disease, both of which are in phase 3 trials, and clinical trials of

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

Prochymal and Chondrogen through phase 2 for all other indications. Osiris will be responsible for 60% and we will be responsible for 40% of the clinical trial costs for phase 3 and 4 clinical trials of Prochymal (other than for the treatment of GvHD and Crohn's disease) and Chondrogen. Osiris is eligible to receive:

- up to \$500.0 million in development and regulatory milestone payments for all indications of Prochymal and up to \$100.0 million for Chondrogen, unless we elect to opt out of further development of Chondrogen; and
- up to \$250.0 million in sales milestones for all indications of Prochymal and up to \$400.0 million in sales milestones for all indications of Chondrogen for the prevention and treatment of conditions of articulating joints.

Osiris is also eligible to receive tiered royalties from us on sales of Prochymal and Chondrogen outside of the United States and Canada. In September 2009, Osiris announced that its two phase 3 trials evaluating Prochymal for the treatment of acute GvHD failed to meet their primary endpoints.

Strategic Alliance with PTC

On July 15, 2008, we entered into a collaboration agreement with PTC to develop and commercialize ataluren, PTC's novel oral therapy in late-stage development for the treatment of DMD and CF. Under the terms of the agreement, PTC will commercialize ataluren in the United States and Canada, and we will commercialize the treatment in all other countries. In connection with the collaboration agreement, we paid PTC a nonrefundable upfront payment of \$100.0 million, which we recorded as a charge to research and development expense for our Genetic Diseases segment in our consolidated statements of operations during the third quarter of 2008. At its own expense, PTC will conduct and be responsible for the phase 2b trial of ataluren in DMD, the phase 2b trial of ataluren in CF and two proof-of-concept studies in other indications to be determined. Once these four studies have been completed, we and PTC will share research and development costs for ataluren equally. We and PTC will each bear the sales and marketing and other costs associated with the commercialization of ataluren in our respective territories. PTC is eligible to receive up to \$337.0 million in milestone payments as follows:

- up to \$165.0 million in development and approval milestones, the majority of which would be paid upon the receipt of approvals obtained outside of the United States and Canada; and
- up to \$172.0 million in sales milestones, commencing if and when annual net sales for ataluren outside of the United States and Canada reach \$300.0 million and increasing in increments through revenues of \$2.4 billion.

PTC is also eligible to receive tiered royalties from sales of ataluren outside of the United States and Canada. The results of our ataluren program are included in the results of our Genetic Diseases segment disclosures.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

Strategic Alliance with Isis

On January 7, 2008, we entered into a strategic alliance with Isis, whereby we obtained an exclusive, worldwide license to develop and commercialize mipomersen, a lipid-lowering drug targeting apolipoprotein B-100, which is currently being developed for the treatment of FH, an inherited disorder that causes exceptionally high levels of LDL-cholesterol. In February 2008, we made a nonrefundable payment to Isis of \$150.0 million, of which \$80.1 million was recorded as an other noncurrent asset on our consolidated balance sheets based on the fair value of the five million shares of Isis common stock we acquired in connection with the transaction. Due to certain trading restrictions, we classify this investment as other noncurrent assets. We allocated the remaining \$69.9 million to the mipomersen license, which we recorded as a charge to research and development expense in our consolidated statements of operations during the first quarter of 2008.

In June 2008, we finalized the terms of our license and collaboration agreement with Isis and paid Isis an additional \$175.0 million upfront nonrefundable license fee. Under the terms of the agreement, Isis will be responsible, at its own expense, for up to \$125.0 million for the development of mipomersen. Thereafter, we and Isis will share development costs for mipomersen equally. The initial funding commitment by Isis and shared development funding would end when the mipomersen program is profitable. In the event the research and development of mipomersen is terminated prior to Isis completing their funding obligation, we are not entitled to any refund of our \$175.0 million upfront payment. Isis is eligible to receive up to \$750.0 million in commercial milestone payments and up to \$825.0 million in development and regulatory milestone payments.

We will be responsible for funding sales and marketing expenses until mipomersen revenues are sufficient to cover such costs. Profits on mipomersen initially will be allocated 70% to us and 30% to Isis. The profit ratio would be adjusted on a sliding scale if and as annual revenues for mipomersen ramp up to \$2.0 billion, at which point we would share profits equally with Isis. The results of our mipomersen program are included in the results of our cardiovascular business unit, which are reported in our Cardiometabolic and Renal segment disclosures.

We account for our investment in Isis common stock on a cost basis due to certain trading restrictions imposed by Isis that prohibit us from selling our holdings of Isis common stock until the earlier of:

- January 7, 2012;
- the first commercial sale of product under our agreement with Isis; or
- termination or reversion of the product license granted to us under the agreement.

As of December 31, 2009, our investment in Isis common stock had a carrying value of \$80.1 million, or \$16.02 per share, and a fair market value of \$55.6 million, or \$11.11 per share. The closing price per share of Isis common stock exhibited volatility in 2009 and has remained below our historical cost since September 1, 2009, with closing prices subsequent to that date ranging from a high of \$15.69 per share to a low of \$9.94 per share. We considered all available evidence in assessing the decline in value of our investment in Isis common stock, including investment analyst reports and Isis's expected results and future outlook, and we believe that the investment can be expected to recover to at least our historical cost. Currently, the average 12-month price estimate for Isis common stock among some analysts is approximately \$16 per share. As a result of our analysis, as of December 31, 2009, we

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

consider the \$24.6 million unrealized loss on our investment in Isis common stock to be a temporary loss. We will continue to review the fair value of our investment in Isis common stock in comparison to our historical cost and in the future, if the decline in value has become "other than temporary," we will write down our investment in Isis common stock to its then current market value and record an impairment charge to our consolidated statements of operations.

2007:

Bioenvision

Effective October 23, 2007, we completed our acquisition of Bioenvision through the culmination of a two-step process consisting of a tender offer completed in July 2007, and a merger approved in October 2007. We paid gross consideration of \$349.9 million in cash, including \$345.4 million for the outstanding shares of Bioenvision common and preferred stock and options to purchase shares of Bioenvision common stock, and approximately \$5 million for acquisition costs. The transaction was accounted for as a business combination and is included in the results of operations of our Hematologic Oncology reporting segment. The acquisition of Bioenvision provided us with the rights to clofarabine outside North America.

In connection with the merger, holders of 2,880,000 shares of Bioenvision common stock, representing less than 5% of the outstanding shares of Bioenvision common stock on an as-converted basis immediately before the merger became effective, submitted written demands for appraisal of their shares and elected not to accept the \$5.60 per share merger consideration. We referred to these holders as dissenters. In September 2008, the appraisal demand was resolved with substantially all of the dissenters for a total of \$16.6 million in cash, consisting of the merger price paid to all other Bioenvision stockholders, plus interest accrued. In total, we paid gross consideration of \$366.5 million in cash, including \$362.0 million for the outstanding shares of Bioenvision common stock and preferred stock and options to purchase shares of Bioenvision common stock.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

The purchase price, including amounts paid for shares of Bioenvision Common Stock and Bioenvision Series A Preferred Stock in July 2007, was allocated to the estimated fair value of the acquired tangible and intangible assets and assumed liabilities as follows (amounts in thousands):

Total purchase price	\$349,941
Cash and cash equivalents	\$ 45,186
Accounts receivable	5,537
Inventory	1,684
Other current assets	5,130
Goodwill	85,269
Other intangible assets	172,441
In-process research and development	106,350
Equity in net loss of pre-acquisition ownership	21,101
Other noncurrent assets	624
Assumed liabilities:	
Income taxes payable	(72,461)
Deferred tax liabilities	(7,829)
Liabilities for exit activities and integration	(2,671)
Other liabilities	(10,420)
Allocated purchase price	<u>\$349,941</u>

IPR&D

The following table sets forth the significant IPR&D projects for the companies and assets we acquired between January 1, 2006 and December 31, 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	\$445.3	alemtuzumab for MS—US	16%	2012
		187.6	alemtuzumab for MS—ex-US	16%	2013
		<u>\$632.9(1)</u>			
Bioenvision (2007)	\$ 349.9	<u>\$125.5(2)</u>	Clolar(3)	17%	2010-2016(4)
AnorMED (2006)	\$ 589.2	<u>\$526.8(2)</u>	Mozobil (stem cell transplant)(5)	15%	2016

- (1) Capitalized as an indefinite-lived intangible asset.
- (2) Expensed on acquisition date.
- (3) Clolar is approved for the treatment of relapsed and refractory pediatric ALL. The IPR&D projects for Clolar 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.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE C. STRATEGIC TRANSACTIONS (Continued)

- (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 tumor sensitization.

Pro Forma Financial Summary (Unaudited)

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 acquisitions been consummated on those dates, or of the future operations of the combined entities. Material nonrecurring charges related to these acquisitions, such as a gain on acquisition of business of \$24.2 million, are included in the pro forma financial summaries of the periods presented (amounts in thousands, except per share amounts):

We did not complete any acquisitions in 2008. The following table provides our pro forma summary for the years ended December 31, 2009 and 2008 (amounts in thousands, except per share amounts):

	<u>2009</u>	<u>2008</u>
Total revenues	\$4,615,674	\$4,869,349
Net income	<u>\$ 359,489</u>	<u>\$ 272,504</u>
Net income (loss) per share:		
Basic	<u>\$ 1.34</u>	<u>\$ 1.01</u>
Diluted	<u>\$ 1.31</u>	<u>\$ 0.98</u>
Weighted average shares outstanding:		
Basic	<u>268,841</u>	<u>268,490</u>
Diluted	<u>274,071</u>	<u>285,595</u>

NOTE D. DERIVATIVE FINANCIAL INSTRUMENTS

We periodically enter into foreign exchange forward contracts, all of which have a maturity of less than three years. These contracts have not been designated as hedges and accordingly, unrealized gains or losses on these contracts are reported in current earnings. The net notional settlement value of foreign exchange forward contracts outstanding was \$139.1 million at December 31, 2009, \$349.5 million at December 31, 2008 and \$347.1 million at December 31, 2007.

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 December 31, 2009 and December 31, 2008 had maturities of 1 to 2 months. We report these contracts on a net basis. Net asset derivatives are included in other current assets and net liability derivatives are included in accrued expenses in our consolidated balance sheets.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE D. DERIVATIVE FINANCIAL INSTRUMENTS (Continued)

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

<u>As of:</u>	<u>Unrealized Gain/Loss on Foreign Exchange Forward Contracts</u>			
	<u>Gross</u>		<u>As Reported</u>	
	<u>Asset Derivatives</u>	<u>Liability Derivatives</u>	<u>Asset Derivatives</u>	<u>Liability Derivatives</u>
	<u>Other current assets</u>	<u>Accrued expenses</u>	<u>Other current assets</u>	<u>Accrued expenses</u>
December 31, 2009	\$9,834	\$5,550	\$4,284	\$ —
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 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 periods presented (amounts in thousands):

<u>Derivative Instrument</u>	<u>Statement of Operations Location</u>	<u>Net (Gain)/Loss Reported</u>		
		<u>2009</u>	<u>2008</u>	<u>2007</u>
		Foreign exchange forward contracts	SG&A	\$23,620

NOTE E. ACCOUNTS RECEIVABLE

Our trade receivables primarily represent amounts due from distributors, healthcare service providers, and companies and institutions engaged in research, development or production of pharmaceutical and biopharmaceutical products. We perform credit evaluations of our customers on an ongoing basis and generally do not require collateral. Accounts receivable are booked net of certain allowances for bad debts, chargebacks and prompt pay discounts. The allowances were \$69.9 million at December 31, 2009 and \$40.4 million at December 31, 2008.

NOTE F. INVENTORIES

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
	<u>(Amounts in thousands)</u>	
Raw materials	\$123,434	\$ 96,986
Work-in-process	288,653	141,094
Finished goods	195,935	215,357
Total	<u>\$608,022</u>	<u>\$453,437</u>

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE F. INVENTORIES (Continued)

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. We recorded a total of \$43.5 million of charges to cost of products sold in our consolidated statements of operations in 2009 for the amortization of inventory step-up for these products.

In June 2009, we 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 \$45.5 million in 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 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 \$11 million in 2009.

NOTE G. PROPERTY, PLANT AND EQUIPMENT

	December 31,	
	2009	2008
	(Amounts in thousands)	
Plant and equipment	\$ 1,403,719	\$ 879,933
Land and buildings	1,239,721	1,006,140
Leasehold improvements	270,003	246,468
Furniture and fixtures	74,023	63,241
Construction in progress	899,687	1,015,497
	3,887,153	3,211,279
Less accumulated depreciation	(1,077,804)	(904,712)
Property, plant and equipment, net	\$ 2,809,349	\$ 2,306,567

Our total depreciation expense was \$190.1 million in 2009, \$148.4 million in 2008 and \$137.1 million in 2007.

Our property, plant and equipment includes the following amounts for assets subject to capital leases (amounts in thousands):

	December 31, 2009
Building—Corporate headquarters in Cambridge, Massachusetts	\$131,031
Less accumulated depreciation	(55,429)
Assets subject to capital leases, net	\$ 75,602

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE G. PROPERTY, PLANT AND EQUIPMENT (Continued)

We capitalize costs we have incurred in validating manufacturing equipment and facilities for products which have reached technological feasibility in plant and equipment. Capitalized validation costs, net of accumulated depreciation, were \$19.4 million at December 31, 2009 and \$32.9 million at December 31, 2008.

Net capitalized software costs, which are included in plant and equipment, totaled \$44.1 million at December 31, 2009 and \$25.8 million at December 31, 2008. Capitalized software development costs, a component of construction in progress, were \$155.2 million at December 31, 2009 and \$89.8 million at December 31, 2008.

We have capitalized the following amounts of interest costs (amounts in millions):

<u>For the Years Ended December 31,</u>		
<u>2009</u>	<u>2008</u>	<u>2007</u>
\$12.3	\$19.0	\$14.5

As of December 31, 2009, the estimated remaining cost to complete our assets under construction is approximately \$900 million.

Under certain lease agreements for our worldwide facilities, we are contractually obligated to return leased space to its original condition upon termination of the lease agreement. At the inception of a lease with such conditions, we record an asset retirement obligation liability and a corresponding capital asset in an amount equal to the estimated fair value of the obligation. In subsequent periods, for each such lease, we record interest expense to accrete the asset retirement obligation liability to full value and depreciate each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. Our asset retirement obligations were not significant as of December 31, 2009 or 2008.

NOTE H. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill

Formerly, we included our MS business unit under the caption "Other." As a result of our 2009 acquisition of certain products and development programs from Bayer, our MS business unit is now material. We have aggregated our Hematologic Oncology reporting segment and MS business unit and now report the activities of these two reporting units under the caption "Hematologic Oncology." As a result of this change, goodwill of \$318.1 million was transferred from "Other" to the Hematologic Oncology reporting segment. Prior year balances were revised to conform to our 2009 presentation.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE H. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

The following table contains the change in our goodwill during the years ended December 31, 2008 and 2009 (amounts in thousands):

	Genetic Diseases	Cardiometabolic and Renal	Biosurgery	Hematologic Oncology	Other	Total
Goodwill	\$339,563	\$319,882	\$ 110,377	\$640,160	\$ 315,883	\$1,725,865
Accumulated impairment losses(1)	—	—	(102,792)	—	(219,245)	(322,037)
Balance as of December 31, 2007	339,563	319,882	7,585	640,160	96,638	1,403,828
Net exchange differences arising during the period	—	—	—	—	(2,731)	(2,731)
Other changes in carrying amounts during the period	—	—	(1)	(22)	—	(23)
Balance as of December 31, 2008	339,563	319,882	7,584	640,138	93,907	1,401,074
Net exchange differences arising during the period	—	—	—	—	1,925	1,925
Other changes in carrying amounts during the period	—	—	—	—	364	364
Balance as of December 31, 2009	<u>\$339,563</u>	<u>\$319,882</u>	<u>\$ 7,584</u>	<u>\$640,138</u>	<u>\$ 96,196</u>	<u>\$1,403,363</u>
Goodwill	\$339,563	\$319,882	\$ 110,376	\$640,138	\$ 315,441	\$1,725,400
Accumulated impairment losses(1)	—	—	(102,792)	—	(219,245)	(322,037)
Balance as of December 31, 2009	<u>\$339,563</u>	<u>\$319,882</u>	<u>\$ 7,584</u>	<u>\$640,138</u>	<u>\$ 96,196</u>	<u>\$1,403,363</u>

(1) Accumulated impairment losses include:

- a \$102.8 million pre-tax charge recorded in 2003 to write off the goodwill of our Biosurgery reporting segment's orthopaedics reporting unit; and
- a \$219.2 million pre-tax charge recorded in 2006 to write off the goodwill of our genetic testing reporting unit.

We are required to perform impairment tests related to our goodwill annually, which we perform in the third quarter of each year, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For 2009, 2008 and 2007, we completed the required annual impairment tests for our \$1.4 billion of goodwill that had been recorded as of September 30, 2009 and 2008 and \$1.3 billion of goodwill that had been recorded as of September 30, 2007 and determined that no impairment charges were required. In December 2008, we filed an IND for our advanced phosphate binder, Genz-644470. However, in November 2009, we discontinued this program because the results of a phase 2/3 clinical study of the advanced phosphate binder did not demonstrate significant improvement in phosphate lowering compared to Renvela. Upon discontinuation of this program, we updated the annual goodwill impairment test that had been performed for our renal reporting unit in the third quarter of 2009. We determined that the fair value of our renal reporting unit continued to exceed its carrying value, and, therefore, no impairment charge was required as a result of the termination of our advanced phosphate binder program.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE H. 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 December 31, 2009			As of December 31, 2008		
	Gross Other Intangible Assets	Accumulated Amortization	Net Other Intangible Assets	Gross Other Intangible Assets	Accumulated Amortization	Net Other Intangible Assets
Finite-lived other intangible assets:						
Technology(1)	\$2,180,232	\$ (877,611)	\$1,302,621	\$1,919,074	\$ (692,235)	\$1,226,839
Distribution rights(2)	440,521	(227,726)	212,795	399,768	(170,892)	228,876
Patents	188,651	(131,898)	56,753	194,560	(121,763)	72,797
License fees	98,647	(47,052)	51,595	98,123	(39,824)	58,299
Customer lists	87,423	(43,822)	43,601	83,729	(34,271)	49,458
Trademarks	60,608	(47,623)	12,985	60,556	(42,194)	18,362
Other	—	—	—	2,039	(1,972)	67
Total finite-lived other intangible assets	3,056,082	(1,375,732)	1,680,350	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>\$3,688,994</u>	<u>\$(1,375,732)</u>	<u>\$2,313,262</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 \$41.9 million in 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, \$287.5 million of the maximum amount payable under the agreement has been paid. We anticipate completing the contingent royalty payments to Wyeth during 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 \$445.3 million related to the development of the product for sale in the United States and \$187.6 million for the development of the product for sale outside of the United States.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE H. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

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

As of December 31, 2009, the estimated future amortization expense for our finite-lived other intangible assets for the five succeeding fiscal years and thereafter is as follows (amounts in thousands):

<u>Year Ended December 31,</u>	<u>Estimated Amortization Expense(1)(2)</u>
2010	\$ 312,076
2011	304,138
2012	229,408
2013	150,452
2014	118,310
Thereafter	372,186

(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 Consolidated Financial Statements (Continued)

NOTE I. INVESTMENTS IN MARKETABLE SECURITIES AND EQUITY INVESTMENTS

Fair Value Measurements

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

<u>Description</u>	<u>Balance as of December 31, 2009</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Fixed income investments(1):				
Cash equivalents:				
Money market funds/other	\$ 603,109	\$603,109	\$ —	\$ —
Short-term investments:				
U.S. Treasury notes	41,040	41,040	—	—
Non U.S. Governmental notes	4,114	—	4,114	—
U.S. Government agency notes	56,810	—	56,810	—
Corporate notes—global	54,825	—	54,825	—
Commercial paper	6,841	—	6,841	—
Total	<u>163,630</u>	<u>41,040</u>	<u>122,590</u>	<u>—</u>
Long-term investments:				
U.S. Treasury notes	29,793	29,793	—	—
Non U.S. Governmental notes	4,873	—	4,873	—
U.S. Government agency notes	28,015	—	28,015	—
Corporate notes—global	81,143	—	81,143	—
Total	<u>143,824</u>	<u>29,793</u>	<u>114,031</u>	<u>—</u>
Total fixed income investments	<u>910,563</u>	<u>673,942</u>	<u>236,621</u>	<u>—</u>
Equity holdings(1):				
Publicly-traded equity securities	40,380	40,380	—	—
Derivatives:				
Foreign exchange forward contracts	4,284	—	4,284	—
Contingent liabilities(2):				
Contingent consideration obligations	(1,015,236)	—	—	(1,015,236)
Total assets (liabilities) at fair value	<u>\$ (60,009)</u>	<u>\$714,322</u>	<u>\$240,905</u>	<u>\$(1,015,236)</u>

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE I. INVESTMENTS IN MARKETABLE SECURITIES AND EQUITY INVESTMENTS
(Continued)

<u>Description</u>	<u>Balance as of December 31, 2008</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
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. Government agency notes	10,328	—	10,328	—
Corporate notes—global	39,674	—	39,674	—
Total	<u>57,507</u>	<u>7,505</u>	<u>50,002</u>	<u>—</u>
Long-term investments:				
U.S. Treasury notes	75,040	75,040	—	—
Non U.S. Governmental notes	7,322	—	7,322	—
U.S. Government agency notes	121,707	—	121,707	—
Corporate notes—global	140,009	—	140,009	—
Total	<u>344,078</u>	<u>75,040</u>	<u>269,038</u>	<u>—</u>
Total fixed income investments	<u>759,265</u>	<u>440,225</u>	<u>319,040</u>	<u>—</u>
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	<u>\$814,427</u>	<u>\$496,821</u>	<u>\$317,606</u>	<u>\$—</u>

- (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.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE I. INVESTMENTS IN MARKETABLE SECURITIES AND EQUITY INVESTMENTS
(Continued)

Changes in the fair value of the our Level 3 contingent consideration obligations during the year ended December 31, 2009 were as follows (amounts in thousands):

Contingent consideration obligations related to acquisition from Bayer in May 2009	\$ (964,100)
Payments	36,403
Contingent consideration expense	(65,584)
R&D reimbursement received	(9,987)
Effect of foreign currency adjustment	(11,968)
Fair value at December 31, 2009	<u><u>\$ (1,015,236)</u></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.

Marketable Securities:

	December 31,			
	2009		2008	
	Cost	Market Value	Cost	Market Value
	(Amounts in thousands)			
Cash equivalents:				
Money market funds/other	\$603,109	\$603,109	\$357,680	\$357,680
Short-term investments:				
Corporate notes	61,620	62,508	41,457	39,674
U.S. Government agencies	54,815	55,968	10,260	10,328
Non U.S. Government notes	4,037	4,114	—	—
U.S. Treasury notes	40,135	41,040	7,281	7,505
	<u>160,607</u>	<u>163,630</u>	<u>58,998</u>	<u>57,507</u>
Long-term investments:				
Corporate notes	80,011	81,143	143,674	140,009
U.S. Government agencies	27,292	28,015	117,143	121,707
Non U.S. Government notes	4,765	4,873	7,277	7,322
U.S. Treasury notes	29,751	29,793	71,110	75,040
	<u>141,819</u>	<u>143,824</u>	<u>339,204</u>	<u>344,078</u>
Total cash equivalents, short- and long-term investments	<u>\$905,535</u>	<u>\$910,563</u>	<u>\$755,882</u>	<u>\$759,265</u>
Investments in equity securities	<u>\$ 62,221</u>	<u>\$ 74,438</u>	<u>\$ 57,777</u>	<u>\$ 83,325</u>

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE I. INVESTMENTS IN MARKETABLE SECURITIES AND EQUITY INVESTMENTS
(Continued)

The following table contains information regarding the range of contractual maturities of our cash equivalents and short- and long-term investments (amounts in thousands):

	December 31,			
	2009		2008	
	Cost	Market Value	Cost	Market Value
Within 1 year	\$763,716	\$766,739	\$416,678	\$415,187
1-2 years	134,498	136,334	323,196	328,588
2-10 years	7,321	7,490	16,008	15,490
	\$905,535	\$910,563	\$755,882	\$759,265

Investments in Equity Securities

The following table shows the investments in equity securities of unconsolidated entities as of December 31, 2009 and 2008 (amounts in thousands):

	December 31, 2009			December 31, 2008		
	Adjusted Cost	Market Value	Unrealized Gain/(Loss)	Adjusted Cost	Market Value	Unrealized Gain/(Loss)
Publicly-held companies(1)(2):						
Dyax	\$12,173	\$11,399	\$ (774)	\$17,992	\$18,090	\$ 98
ABIOMED	11,332	18,737	7,405	12,185	37,893	25,708
EXACT Sciences	4,470	10,170	5,700	—	—	—
Other	188	74	(114)	871	613	(258)
Total publicly-held companies	28,163	40,380	12,217	31,048	56,596	25,548
Private equity funds	16,755	16,755	—	18,684	18,684	—
Privately-held companies(3)	17,303	17,303	—	8,045	8,045	—
Total	\$62,221	\$74,438	\$12,217	\$57,777	\$83,325	\$25,548

- (1) Marketable equity securities that have readily determinable market values are stated at market value.
- (2) On January 7, 2008, as part of our strategic alliance with Isis, we acquired five million shares of Isis common stock. Due to certain trading restrictions, we classify this investment, which had a carrying value of \$80.1 million at December 31, 2009, as an other noncurrent asset. Our relationship with Isis is described in Note C., "Strategic Transactions," to these consolidated financial statements.
- (3) Equity securities without readily determinable market values and for which we do not exercise significant influence are stated at cost and are periodically reviewed for impairment.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE I. INVESTMENTS IN MARKETABLE SECURITIES AND EQUITY INVESTMENTS
(Continued)

Unrealized Gains and Losses on Marketable Securities and Equity Investments

We record unrealized holding gains and losses, net of tax, related to our investments in marketable securities and equity investments, to the extent they are determined to be temporary, in stockholders' equity. The following table sets forth the gross amounts recorded (amounts in millions):

	December 31,	
	2009	2008
Unrealized holding gains	\$18.3	\$35.1
Unrealized holding losses	\$ 1.1	\$ 6.3

We also collaborate with or provide services to certain of the companies in which we hold or have held equity investments, including Dyax.

NOTE J. EQUITY METHOD INVESTMENTS

Our equity method investments are included in other noncurrent assets in our consolidated balance sheets and were not significant at both December 31, 2009 and 2008.

The following tables describe:

- our portion of the net income (loss) of each equity method investment for the periods presented, which we have recorded as income (charges) to equity in income (loss) of equity method investments in our consolidated statements of operations (amounts in millions); and
- total net income (loss) of each equity method investment for the periods presented (amounts in millions).

<u>Equity Method Investment</u>	Our Portion of the Net Income (Loss) of Our Equity Method Investments			Total Income (Loss) of Our Equity Method Investments		
	2009	2008	2007	2009	2008	2007
BioMarin/Genzyme LLC	\$—	\$ —	\$ 30.1	\$—	\$ —	\$60.2
Bioenvision(1)	—	—	(21.1)	—	—	(9.6)
Other	—	0.2	(1.6)	—	0.4	(9.4)
Totals	\$—	\$0.2	\$ 7.4	\$—	\$0.4	\$41.2

(1) For the period from July 10, 2007 through October 22, 2007, we accounted for our initial investment in Bioenvision common stock under the equity method of accounting. We completed the acquisition of Bioenvision effective October 23, 2007.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE J. EQUITY METHOD INVESTMENTS (Continued)

Condensed financial information for our equity method investees, excluding Bioenvision, is summarized below in aggregate (amounts in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Revenue	\$—	\$ —	\$124,203
Gross profit	—	—	97,092
Operating expenses	—	326	(46,656)
Net income	8	370	50,866
		December 31,	
		2009	2008
Current assets		\$1,593	\$1,585
Noncurrent assets		—	—
Current liabilities		351	351
Noncurrent liabilities		—	—

BioMarin/Genzyme LLC

Through December 31, 2007, our portion of the net income of BioMarin/Genzyme LLC was included in equity in income of equity method investments in our consolidated statements of operations. Effective January 1, 2008, we restructured the relationship regarding the manufacturing and commercialization of Aldurazyme by entering into several new agreements. BioMarin/Genzyme LLC no longer engages in commercial activities related to Aldurazyme and solely:

- holds the intellectual property relating to Aldurazyme and other collaboration products; and
- engages in research and development activities that are mutually selected and funded by BioMarin and us, the costs of which are shared equally.

Under the restructured relationship, BioMarin/Genzyme LLC licensed all intellectual property relating to Aldurazyme and other collaboration products on a royalty-free basis to BioMarin and us. BioMarin holds the manufacturing rights and we hold the global marketing rights. We pay BioMarin a tiered payment ranging from 39.5% to 50% of worldwide net product sales of Aldurazyme.

As a result of the restructuring of our relationship with BioMarin/Genzyme LLC, effective January 1, 2008, we began consolidating the results of BioMarin/Genzyme LLC. Upon consolidation of BioMarin/Genzyme LLC, we recorded the assets and liabilities of the joint venture in our consolidated balance sheets at fair value. The value of the intellectual property of the joint venture of approximately \$480.5 million was recorded as an intangible asset in our consolidated balance sheets. The consolidation also included a corresponding noncurrent liability for the same amount which represented the encumbered value of the intellectual property which had been out licensed to us and BioMarin for no consideration. The intangible asset and noncurrent liability are being amortized over a period of 20 years. We recorded BioMarin's portion of the joint venture's losses, the amount of which was not significant for the years ended December 31, 2009 and 2008, as minority interest in our consolidated statements of operations.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE K. ACCRUED EXPENSES

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
	(Amounts in thousands)	
Compensation	\$213,686	\$232,363
Rebates	134,002	132,905
Bank overdraft	45,918	45,022
License fees	98	65,188
Royalties	63,502	56,501
Other	239,017	233,407
Total	<u>\$696,223</u>	<u>\$765,386</u>

NOTE L. LONG-TERM DEBT AND LEASES

Long-Term Debt, Capital Lease Obligations and Convertible Debt

Our long-term debt, capital lease obligations and convertible debt consist of the following (amounts in thousands):

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Notes payable	\$ 5,847	\$ 6,916
Revolving credit facility maturing in July 2011	—	—
Mortgage payable	17,509	17,957
Capital lease obligations	101,244	107,034
Long-term debt, capital lease obligations and convertible debt, including current portion	124,600	131,907
Less current portion	(8,166)	(7,566)
Noncurrent portion	<u>\$116,434</u>	<u>\$124,341</u>

Over the next five years and thereafter, we will be required to repay the following principal amounts of our long-term debt (excluding capital leases) (amounts in millions):

<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>After 2014</u>
\$1.6	\$1.6	\$1.7	\$1.8	\$1.8	\$14.9

Notes Payable

We assumed a \$10.0 million note payable in July 2005 in connection with our acquisition of Equal Diagnostics. This note bears interest at 3.86% and is payable to three former shareholders of Equal Diagnostics over eight years in equal annual installments of \$1.3 million.

Revolving Credit Facility

In July 2006, we entered into our revolving credit facility. The proceeds of loans under our 2006 revolving credit facility can be used to finance working capital needs and for general corporate

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE L. LONG-TERM DEBT AND LEASES (Continued)

purposes. We may request that our 2006 revolving credit facility be increased at any time by up to an additional \$350.0 million in the aggregate, subject to the agreement of the lending banks, as long as no default or event of default has occurred or is continuing and certain other customary conditions are satisfied. Borrowings under our 2006 revolving credit facility will bear interest at various rates depending on the type of loan. We are required to pay a facility fee of between 7 to 20 basis points based on the aggregate commitments under our 2006 revolving credit facility, and in certain circumstances a utilization fee of 10 basis points as follows:

- revolving loans denominated in U.S. dollars or a foreign currency (other than Euros) bear interest at a variable rate equal to LIBOR for loans in U.S. dollars and a comparable index rate for foreign currency loans, plus an applicable margin;

As of December 31, 2009, we had approximately \$17 million of outstanding standby letters of credit issued against this facility and no borrowings, resulting in approximately \$333 million of available credit under our 2006 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 December 31, 2009 we were in compliance with these covenants.

Mortgage Payable

In July 2008, we purchased land and a manufacturing facility we formerly leased in Framingham, Massachusetts, for an aggregate purchase price of \$38.9 million, including fees. We paid \$20.8 million in cash and assumed the remaining \$18.1 million in principal outstanding under the existing mortgage for the facility, which bears interest at 5.57% annually and is due in May 2020.

Capital Leases

We have non-cancelable capital lease obligations related to certain machinery and equipment, administrative offices and our corporate headquarters.

Our capital lease obligation related to our corporate headquarters in Cambridge, Massachusetts requires us to make monthly payments of \$1.3 million, which will be adjusted to \$1.6 million in August 2013. We have recorded the value of the building and related obligations of \$131.0 million in our consolidated balance sheets at the date of inception. The term of the lease is fifteen years and may be extended at our option for two successive ten-year periods.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE L. LONG-TERM DEBT AND LEASES (Continued)

Over the next five years and thereafter, we will be required to pay the following amounts under our non-cancelable capital leases (amounts in millions):

2010	\$ 15.4
2011	15.4
2012	15.5
2013	16.9
2014	18.9
Thereafter	67.5
Total lease payments	149.6
Less: interest	(48.4)
Total principal payments	101.2
Less current portion	(6.4)
Total	<u>\$ 94.8</u>

Operating Leases

We lease facilities and personal property under non-cancelable operating leases with terms in excess of one year. Our total expense under operating leases was (amounts in millions):

<u>For the Years Ended December 31,</u>		
<u>2009</u>	<u>2008</u>	<u>2007</u>
\$81.8	\$75.2	\$74.3

Over the next five years and thereafter, we will be required to pay the following amounts under non-cancelable operating leases (amounts in millions):

<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>After 2014</u>	<u>Total</u>
\$79.9	\$69.3	\$52.6	\$33.9	\$27.5	\$151.0	\$414.2

NOTE M. STOCKHOLDERS' EQUITY

Preferred Stock

<u>Series</u>	<u>At December 31, 2008 and 2009</u>		
	<u>Authorized</u>	<u>Issued</u>	<u>Outstanding</u>
Series A Junior Participating, \$0.01 par value	3,000,000	—	—
Undesignated	7,000,000	—	—
	<u>10,000,000</u>	—	—

Our charter permits us to issue shares of preferred stock at any time in one or more series. Our board of directors will establish the preferences, voting powers, qualifications, and special or relative rights or privileges of any series of preferred stock before it is issued.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

Common Stock

The following table describes the number of authorized and outstanding shares of our common stock at December 31, 2009 and 2008:

Series	Authorized	Outstanding at December 31,	
		2009	2008
Genzyme Stock, \$0.01 par value	690,000,000	265,696,834	270,704,169

Directors' Deferred Compensation Plan

Each member of our board of directors who is not also one of our employees may defer receipt of all or a portion of the cash compensation payable to him or her as a director and receive either cash or stock in the future. Under this plan, the director may defer his or her compensation until his or her services as a director cease or until another date specified by the director.

Under a deferral agreement, a participant indicates the percentage of deferred compensation to allocate to cash and stock, upon which a cash deferral account and a stock deferral account are established. The cash account bears interest at the rate paid on 90-day Treasury bills with interest accruing quarterly. The stock account is for amounts invested in hypothetical shares of Genzyme Stock. These amounts are converted into hypothetical shares quarterly at the average closing price of Genzyme Stock for all trading days during the quarter.

Distributions are paid in a lump sum or in annual installments for up to five years. Payments begin the year following a director's termination of service or, subject to certain restrictions, in a year elected by the participant. As of December 31, 2009, five of the eight eligible directors had established accounts under this plan, and three of these directors are currently deferring their compensation. We have reserved 105,962 shares of Genzyme Stock to cover distributions credited to stock accounts under the plan. We had not made any stock distributions under this plan as of December 31, 2009. As of December 31, 2009, we have made cash distributions totaling \$69,492 to one director under the terms of his deferral agreement.

Stock Repurchase Program

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.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

During the year ended December 31, 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. 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

Equity Plans

The purpose of each of our equity plans is to attract, retain and motivate our key employees, consultants and directors. Awards granted under these plans can be either incentive stock options, or ISOs, nonstatutory stock options, or NSOs, RS or RSUs, as specified in the individual plans. Shares issued under all of our plans are funded through the issuance of new shares. The following table contains information about our equity plans:

Plan Name	Group Eligible	Type of Award Granted	As of December 31, 2009		
			Awards Reserved for Issuance	Awards Outstanding	Awards Available for Grant
2004 Equity Incentive Plan(1) . . .	All key employees and consultants	ISO/NSO/RS/RSU	35,052,286	29,721,887	5,330,399
2001 Equity Incentive Plan(1) . . .	All key employees and consultants	ISO/NSO	6,773,548	6,749,303	24,245
2007 Director Equity Plan(2) . . .	Non-employee board members	NSO/RS/RSU	775,891	661,983	113,908
Assumed Options(3)			77,779	77,779	—
			<u>42,679,504</u>	<u>37,210,952</u>	<u>5,468,552</u>

- (1) The exercise price of option grants may not be less than the fair market value of Genzyme Stock at the date of grant. Option grants have a maximum term of ten years and RSUs generally have cliff vesting in three years. The compensation committee of our board of directors, or its delegates as applicable, determines the terms and conditions of each award, including who among eligible persons will receive awards, the form of payment of the exercise price of stock options, the number of shares granted, the vesting schedule and the terms of exercise or release.
- (2) Options and RSUs are automatically granted on the date of our annual shareholders meeting or at a director's initial appointment to the board. Options have an exercise price equal to the fair market value of Genzyme Stock on the date of grant and expire ten years after the initial grant date. Options and RSUs vest on the date of the next annual shareholders meeting following the date of grant.
- (3) Consists of options we assumed through our acquisitions.

In 2009, 2008 and 2007, we accounted for options granted to our employees and directors using the Black-Scholes valuation model to measure stock option expense at the date of grant. All stock option grants have an exercise price equal to the fair market value of Genzyme Stock on the date of grant and generally have a 10-year term and vest in increments, generally over four years from the date of grant, although we may grant options with different vesting terms from time to time. Upon termination of employment other than by death, disability or change of control, unvested options are cancelled, and any unexercised vested options will expire three months after the employee's termination date. Excluding our directors who are not employees, when an employee meets a retirement eligibility age of 60 with at least five years of service, upon termination (except for cause) the employee's options

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

automatically become fully vested and will expire three years after the employee's termination date or on the original expiration date set at the time the options were granted, whichever is earlier. When a director leaves the board, unvested options are cancelled and any unexercised vested options will expire at the end of their term. We recognize stock-based compensation expense for each grant on a straight-line basis over the employee's or director's requisite service period, generally the vesting period of the award. Additionally, stock-based compensation expense related to stock options includes an estimate for pre-vesting forfeitures. We recognize stock-based compensation expense immediately for awards granted to retirement eligible employees or over the period from the grant date to the date retirement eligibility is achieved, if that is expected to occur during the nominal vesting period. For stock-based compensation expense recognition purposes only, grants to retirement eligible employees prior to January 1, 2006 are not subject to accelerated vesting and expense is recognized over the nominal vesting period.

We award time vesting RSUs to employees that generally vest no sooner than one-third per year over three years on the anniversary of the date of grant if the employee has reached the retirement eligibility threshold, or upon the third anniversary of the date of grant, provided the employee remains continuously employed with us. Shares of Genzyme Stock will be delivered to the employee upon vesting, subject to payment of applicable withholding taxes. Time vesting RSUs awarded to our directors for service on our board of directors vest on the date of the next annual meeting of shareholders following the date of grant, provided that the director continues to serve on our board of directors through the vesting date. Shares of Genzyme Stock will be delivered to the director upon vesting. The fair value of all time vesting RSUs is based on the market value of Genzyme Stock on the date of grant. We recognize compensation expense for our RSUs, including the effect of forfeitures, over the applicable service period.

ESPP

Our 2009 ESPP was approved by shareholders in May 2009, and succeeds our 1999 ESPP. The ESPP allows employees to purchase our stock at a discount. Under this plan, the purchase price per share of Genzyme Stock is 85% of the lower of the fair market value of Genzyme Stock at the beginning of an enrollment period or on the applicable purchase date. Employees working at least 20 hours per week may elect to participate in our ESPP during specified open enrollment periods, which occur twice each year shortly before the start of each new enrollment period. New enrollment periods begin on the first trading day of January and July and each enrollment period lasts two years. Employee contributions for each enrollment period are automatically used to purchase stock on behalf of each participating employee on eight pre-determined purchase dates during the two-year enrollment period, which occur once every three months, in January, April, July and October. We place limitations on the total number of shares of stock that employees can purchase under the plan in a given year.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

Stock-Based Compensation Expense, Net of Estimated Forfeitures

We recorded the following amounts of pre-tax stock-based compensation expense, net of estimated forfeitures, and related tax benefits for the years ended December 31, 2009, 2008 and 2007 (amounts in thousands, except per share amounts):

	For the Years Ended December 31,		
	2009	2008	2007
Pre-tax stock-based compensation expense, net of estimated forfeitures	\$(204,115)	\$(186,973)	\$(189,950)
Less: tax benefit of stock options	53,434	56,740	58,148
Stock-based compensation expense, net of tax	<u>\$(150,681)</u>	<u>\$(130,233)</u>	<u>\$(131,802)</u>
Per basic and diluted share	<u>\$ (0.56)</u>	<u>\$ (0.49)</u>	<u>\$ (0.50)</u>

(1) We capitalized \$16.4 million in 2009, \$13.9 million in 2008 and \$13.5 million in 2007, of stock-based compensation expense to inventory, all of which is attributable to participating employees that support our manufacturing operations. We amortize stock-based compensation expense capitalized to inventory based on inventory turns.

At December 31, 2009, there was approximately \$238 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 two years.

Valuation Assumptions for Stock Option Plans and ESPP

We use the Black-Scholes option valuation model to determine the amount of employee stock-based compensation expense to recognize in our consolidated statements of operations. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted average assumptions used are as follows:

	For the Years Ended December 31,		
	2009	2008	2007
Risk-free interest rate	2%	2%	4%
Dividend yield	0%	0%	0%
Expected option life (in years)—directors	7	7	7
Expected option life (in years)—officers	6	6	6
Expected option life (in years)—other senior managers	5	5	4
Expected option life (in years)—all other employees	4	4	4
Volatility-stock options	32%	27%	28%
Volatility-ESPP	42%	27%	23%

The risk-free interest rate is based on the U.S. Treasury yield curve in effect on the date of grant. The dividend yield percentage is zero because we do not currently pay dividends nor intend to do so during the expected option life. We used historical data from exercises of our stock options and other factors to estimate the expected option life (in years), or term, of the share-based payments granted.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

We determined the volatility rate for our stock options based on the expected term of the equity award granted. We determine separate volatility rates for each enrollment under our ESPP based on the period from the commencement date of each enrollment to each applicable purchase date. Stock option expense in future periods will be based upon the Black-Scholes values determined at the date of each grant or the date of each purchase under our ESPP.

Stock Option Plan Activity

The following table contains information regarding our stock option activity for the year ended December 31, 2009:

	Shares Under Option	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	31,850,152	\$55.39		
Granted	2,099,955	\$58.61		
Exercised	(1,368,273)	\$33.18		
Forfeited and cancelled	(484,246)	\$87.16		
Outstanding at December 31, 2009	<u>32,097,588</u>	\$56.09	5.37	\$76,034,685
Vested and expected to vest at December 31, 2009	<u>31,977,058</u>	\$56.07	5.36	\$76,034,685
Exercisable at December 31, 2009	<u>25,655,170</u>	\$54.41	4.71	\$76,034,685

The following table contains information regarding the pre-tax intrinsic value of our stock options and the weighted average grant date fair value per share of stock granted under our stock option plans for the periods presented (amounts in thousands, except per share amounts):

	For the Years Ended December 31,		
	2009	2008	2007
Pre-tax intrinsic value of options exercised	\$36,421	\$176,048	\$153,772
Weighted average grant date fair value per share of stock granted under our stock option plans	\$ 18.80	\$ 19.24	\$ 19.39

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE M. STOCKHOLDERS' EQUITY (Continued)

Time Vesting RSU Activity

The following table contains information regarding our time vesting RSUs for the year ended December 31, 2009:

	Shares Under Award	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	2,985,925	\$65.87	1.89	
Granted	2,352,820	\$58.64		
Vested and issued	(80,123)			
Forfeited and cancelled	(145,258)	\$63.18		
Outstanding at December 31, 2009	<u>5,113,364</u>	\$62.56	1.53	\$250,605,970
Vested and expected to vest at December 31, 2009	<u>4,959,699</u>		1.51	\$243,074,826
Cumulative shares issued at December 31, 2009	<u>90,599</u>			

ESPP Activity

The following table contains information regarding our ESPP activity for the years ended December 31, 2008 and 2009:

Shares available and issued:

Available for purchase as of December 31, 2007	1,445,791
Shares purchased by employees	(936,105)
Available for purchase as of December 31, 2008	509,686
Additional shares authorized	3,000,000
Adjustment—shares from our 2001 ESPP plan	9,909
Shares purchased by employees	(1,067,192)
Available for purchase as of December 31, 2009	<u>2,452,403</u>

NOTE N. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

Federal Securities Litigation

In July 2009 and August 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 lawsuits is premised upon allegations that we made materially false and misleading statements and omissions by

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE N. COMMITMENTS AND CONTINGENCIES (Continued)

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 GMP. The plaintiffs seek unspecified damages and reimbursement of costs, including attorneys' and experts' fees. In November 2009, the lawsuits were consolidated and a lead plaintiff appointed. We intend to defend this lawsuit vigorously.

Shareholder Demand Letters

Since August 2009, we have received nine letters from shareholders demanding that our board of directors take action on our behalf of Genzyme Corporation to remedy alleged breaches of fiduciary duty by our directors and certain executive officers. The demand letters are primarily premised on allegations regarding our disclosures to shareholders with respect to manufacturing issues and compliance with GMP and our processes and decisions related to manufacturing at our Allston facility. Several of the letters also assert that certain of our executive 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 behalf of Genzyme Corporation 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 the benefit of Genzyme Corporation. The special committee's investigation is ongoing.

Shareholder Derivative Actions

In December 2009, two actions were filed by shareholders derivatively for Genzyme's benefit in the U.S. District Court for the District of Massachusetts against our board of directors and certain of our executive officers after a ninety day period following their respective demand letters had elapsed (the "District Court Actions"). In January 2010, a derivative action was filed in Massachusetts Superior Court by a shareholder who has not issued a demand letter (the "January State Court Action"). In February 2010, a derivative action was filed in Massachusetts Superior Court by a shareholder after a ninety day period following the shareholder's demand letter had elapsed. The derivative actions in general are based on allegations that our directors and certain executive officers breached their fiduciary duties by causing Genzyme to make purportedly false and misleading or inadequate disclosures of information regarding manufacturing issues, compliance with GMP, ability to meet product demand, expected revenue growth, and approval of Lumizyme. The actions also allege that certain of our directors and executive officers took advantage of their knowledge of material non-public information about Genzyme to illegally sell stock they personally held in Genzyme. The plaintiffs generally seek, among other things, judgment in favor of Genzyme for the amount of damages sustained by Genzyme as a result of the alleged breaches of fiduciary duty, disgorgement to Genzyme of proceeds that certain of our directors and executive officers received from sales of Genzyme stock and all proceeds derived from their service as directors or executives of Genzyme, and reimbursement of plaintiffs' costs, including attorneys' and experts' fees. The plaintiffs in the District Court Actions have agreed to a joint stipulation consolidating and staying these cases until our board of directors has had sufficient time to exercise its duties and complete an appropriate investigation, which is ongoing. We have filed a motion to dismiss, or in the alternative, stay the January State Court Action. We intend to defend these lawsuits vigorously.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE N. COMMITMENTS AND CONTINGENCIES (Continued)

Fabrazyme Patent Litigation

In October 2009, Shelbyzyme LLC filed a complaint against us in the U.S. District Court for the District of Delaware alleging infringement of U.S. patent 7,011,831 by “making, using, selling and promoting a method for the treatment of” Fabry disease. The ‘831 patent, which is directed to a method for treating Fabry disease, was issued in March 2006 and expired in March 2009. The plaintiffs seek damages for past infringement, including treble damages for alleged willful infringement and reimbursement of costs, including attorney’s fees. We intend to defend this lawsuit vigorously.

Other Matters

We are party to a legal action brought by Kayat pending before the District Court in Nicosia, Cyprus. Kayat alleges that we breached a 1996 distribution agreement under which we granted Kayat the right to distribute melatonin tablets in the Ukraine, primarily by not providing products or by providing non-conforming products. Kayat further claims that due to the alleged breach, it suffered lost profits that Kayat claims it would have received under agreements it alleges it had entered into with subdistributors. Kayat also alleges common law fraud and violations of Mass. Gen. L. c. 93A and RICO. Kayat filed its suit on August 8, 2002 and a trial began in Cyprus in December 2009. Kayat seeks damages for its legal claims and for expenses it claims it has incurred, including legal fees and advertising, promotion and other out-of-pocket expenses. We believe we acted appropriately in all regards, including properly terminating the agreement when we decided to exit the melatonin business, and we intend to defend this lawsuit vigorously.

We are not able to predict the outcome of the lawsuits and matters described above or estimate the amount or range of any possible loss we might incur if we do not prevail in final, non-appealable determination of these matters. Therefore, we have not accrued any amounts in connection with the lawsuits and matters described above.

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. In November 2009, we paid \$6.0 million to Abbott for a full release of any indemnification obligations we might have had under the agreement between Wyntek and Abbott, which was recorded as a charge to SG&A in our consolidated statements of operations for 2009.

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

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE N. COMMITMENTS AND CONTINGENCIES (Continued)

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 have appealed this judgment.

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 the ultimate resolution of any of these existing matters would have a material adverse effect on our consolidated financial position or results of operations.

NOTE O. INCOME TAXES

Our income (loss) before income taxes and the related income tax provisions are as follows (amounts in thousands):

	<u>For the Years Ended December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Income (loss) before income taxes:			
Domestic	\$ 218,744	\$ 655,550	\$ 753,987
Foreign	324,989	(30,012)	(18,313)
Total	<u>\$ 543,733</u>	<u>\$ 625,538</u>	<u>\$ 735,674</u>
Currently payable:			
Federal	\$ 135,699	\$ 347,100	\$ 313,136
State	14,736	26,212	19,498
Foreign	66,709	26,345	28,986
Total	<u>217,144</u>	<u>399,657</u>	<u>361,620</u>
Deferred:			
Federal	(111,133)	(153,183)	(75,931)
State	(23,005)	(13,588)	(10,311)
Foreign	38,427	(28,429)	(19,897)
Total	<u>(95,711)</u>	<u>(195,200)</u>	<u>(106,139)</u>
Provision for income taxes	<u>\$ 121,433</u>	<u>\$ 204,457</u>	<u>\$ 255,481</u>

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE O. INCOME TAXES (Continued)

Our provisions for income taxes were at rates other than the U.S. federal statutory tax rate for the following reasons:

	For the Years Ended December 31,		
	2009	2008	2007
Tax provision at U.S. statutory rate	35.0%	35.0%	35.0%
Domestic manufacturing benefits	(4.3)	(2.1)	(0.5)
Legal settlements	—	—	3.0
Audit settlements	—	(1.3)	0.5
Stock compensation	2.2	1.5	1.3
Tax credits	(5.5)	(3.9)	(3.5)
Foreign rate differential	(3.2)	1.4	(2.1)
Other	(1.9)	2.1	1.0
Effective tax rate	<u>22.3%</u>	<u>32.7%</u>	<u>34.7%</u>

Our effective tax rate for 2009 was impacted by:

- non-deductible stock-based compensation expenses totaling \$33.5 million;
- the tax benefits related to tax credits of \$30.0 million; and
- domestic manufacturing benefits of \$23.5 million.

Our effective tax rate for 2008 was impacted by:

- non-deductible stock compensation expenses of \$34.0 million in 2008; and
- \$5.1 million of tax benefits recorded to our income tax provision reflecting the resolution of various issues related to the settlement of IRS audits for the tax years 2004 to 2005. In conjunction with those settlements, we reduced our tax reserves by \$4.9 million and recorded current and deferred tax benefits for the remaining portion of the settlement amounts.

Our effective tax rate for 2007 was impacted by:

- the charge for IPR&D of \$106.4 million recorded in October 2007 in connection with our acquisition of Bioenvision, of which \$100.3 million was deductible and taxed at rates other than the U.S. statutory income tax rate and \$6.1 million was non-deductible;
- non-deductible stock compensation expenses of \$32.0 million in 2007;
- a non-deductible charge of \$64.0 million for the settlement of the Biosurgery tracking stock suit in August 2007; and

In addition, our overall tax rate has changed significantly due to fluctuations in our income before taxes, which was \$543.7 million in 2009, \$625.5 million in 2008, and \$735.7 million in 2007.

Effective January 1, 2007, we recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the tax position. The tax benefits recognized in our consolidated

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE O. INCOME TAXES (Continued)

financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

As of December 31, 2009, we had \$41.3 million of total gross unrecognized tax benefits, of which approximately \$40 million represents the amount of unrecognized tax benefits that, if recognized, would favorably affect our effective income tax rate in future periods. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (amounts in thousands):

Balance as of December 31, 2006	\$ 36,515
Additions to tax provisions related to the current year	9,634
Additions to tax provisions related to the prior years	829
Reduction for tax provisions of prior years	<u>(5,155)</u>
Balance as of December 31, 2007	41,823
Additions to tax provisions related to the current year	8,445
Additions to tax provisions related to the prior years	10,029
Reduction for tax provisions of prior years	<u>(8,232)</u>
Balance as of December 31, 2008	52,065
Additions to tax provisions related to the current year	6,501
Additions to tax provisions related to prior years	3,403
Reduction for tax provisions of prior years	<u>(22,139)</u>
Balance as of December 31, 2009	<u>\$ 39,830</u>

We continue to recognize interest and penalties related to unrecognized tax benefits, which are not significant, within our provision for income taxes.

The components of net deferred tax assets (liabilities) are described in the following table (amounts in thousands):

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 1,649	\$ 49,587
Tax credits	22,163	18,831
Inventory	85,511	75,314
Depreciable assets	8,433	3,331
Stock-based compensation	183,395	133,847
Intangible amortization	133,172	75,051
Reserves, accruals and other	<u>120,388</u>	<u>103,887</u>
Total deferred tax assets	554,711	459,848
Deferred tax liabilities:		
Realized and unrealized capital (gains) losses	531	<u>(2,506)</u>
Net deferred tax assets	<u>\$555,242</u>	<u>\$457,342</u>

Our ability to realize the benefit of the net deferred tax assets is dependent on our generating sufficient taxable income. While it is not assured, we believe that it is more likely than not that we will

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE O. INCOME TAXES (Continued)

be able to realize all of our net deferred tax assets. The amount we can realize, however, could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

At December 31, 2009, we had for U.S. income tax purposes, no significant net operating loss carryforwards and tax credit carryforwards of \$22.2 million, primarily for state income tax purposes. The tax credits begin expiring after 2021.

We are currently under IRS audit for the tax years 2006 and 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 within the next twelve months by approximately \$13 million as a result of the resolution of tax examinations. 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.

NOTE P. BENEFIT PLANS

Defined Contribution Plans

We have two defined contribution plans:

- the Genzyme Corporation 401(k) Plan, which we refer to as the 401(k) Plan; and
- the Biomatrix, Inc. Retirement Plan, which we refer to as the Biomatrix Plan.

The 401(k) Plan was established effective January 1, 1988 to provide a long-range program of systematic savings for eligible employees. Employees of Genzyme Corporation as well as our wholly-owned subsidiaries in the United States are eligible to participate in the 401(k) Plan. For 2009, eligible employees could elect, through salary reduction agreements, to have up to 60% or a maximum of \$16,500 of their eligible compensation contributed on a pre-tax basis to the 401(k) Plan. We made bi-weekly matching contributions to the 401(k) Plan equal to 100% of the first 6% of the 401(k) Plan participant's eligible earnings that are contributed as pre-tax contributions.

SG&A includes the following charges related to the 401(k) Plan, representing our matching contributions incurred in each year:

- \$33.8 million in 2009;
- \$33.6 million in 2008; and
- \$25.0 million in 2007.

Effective December 31, 2000, the Biomatrix Plan was frozen and the participants in this plan became eligible to participate in the 401(k) Plan.

Defined Benefit Plans

We have defined benefit pension plans for certain employees in countries outside the United States and a defined benefit post-retirement plan for one of our U.S. subsidiaries, which has been frozen since 1995 and is not significant. These plans are funded in accordance with requirements of the appropriate regulatory bodies governing each plan.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE P. BENEFIT PLANS (Continued)

The following table sets forth the funded status and the amounts recognized for our defined benefit pension plans outside the United States (amounts in thousands):

	December 31,	
	2009	2008
Change in benefit obligation:		
Projected benefit obligation, beginning of year	\$ 65,322	\$ 97,608
Service cost	4,471	6,313
Interest cost	4,642	5,468
Plan participants' contributions	2,024	2,073
Actuarial (gain)/loss	24,687	(21,372)
Foreign currency exchange rate changes	8,658	(23,150)
Benefits paid	(1,444)	(1,618)
Projected benefit obligation, end of year	\$108,360	\$ 65,322
Change in plan assets:		
Fair value of plan assets, beginning of year	\$ 43,755	\$ 72,387
Return on plan assets	10,145	(16,155)
Employer contribution	4,380	4,486
Plan participants' contributions	2,024	2,073
Foreign currency exchange rate changes	6,053	(17,640)
Benefits paid	(1,246)	(1,396)
Fair value of plan assets, end of year	\$ 65,111	\$ 43,755
Funded status at end of year	\$(43,249)	\$(21,567)

Amounts recognized in our consolidated balance sheets consist of (amounts in thousands):

	December 31,	
	2009	2008
Accrued expenses	\$ (1,973)	\$ (1,234)
Other noncurrent liabilities	(41,276)	(20,333)
Net amount recognized	\$(43,249)	\$(21,567)

The amounts recognized in accumulated other comprehensive income (loss) for our U.K. Pension Plan were (amounts in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Net actuarial gains	\$34,076	\$20,631	\$22,187
Net prior service costs	—	—	—

The amounts recognized or not yet recognized in accumulated other comprehensive income (loss) by our other pension plans were not significant for the years ended December 31, 2009, 2008 or 2007. The

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE P. BENEFIT PLANS (Continued)

estimated amounts that will be amortized from accumulated other comprehensive income (loss) at December 31, 2009 into net pre-tax periodic pension costs in 2010 are also not significant.

The weighted average assumptions used in determining related obligations of pension benefit plans are shown below:

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Weighted average assumptions:		
Discount rate	5.67%	6.42%
Rate of compensation increase	4.62%	4.12%

For the year ended December 31, 2009, the discount rate used to determine the benefit obligations for our plans was based on highly rated long-term bond indices and yield curves that match the duration of each plan's benefit obligations. The bond indices and yield curve analyses include only bonds rated Aa or higher from reputable rating agencies. The discount rate represents the average of the discount rates for each plan weighted by plan liabilities as of December 31, 2009. The discount rate reflects the rate at which the pension benefits could be effectively settled.

The weighted average assumptions used to determine the net pension expense are shown below:

	<u>December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Weighted average assumptions:			
Discount rate	6.43%	5.78%	5.12%
Rate of return on assets	7.64%	7.61%	7.67%
Rate of compensation increase	4.15%	4.81%	4.44%

The components of net pension expense are as follows (amounts in thousands):

	<u>December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Service cost	\$ 4,471	\$ 6,313	\$ 6,436
Interest cost	4,642	5,468	5,063
Expected return on plan assets	(4,034)	(5,607)	(3,411)
Amortization and deferral of actuarial gain (loss)	761	827	(456)
Net pension expense	<u>\$ 5,840</u>	<u>\$ 7,001</u>	<u>\$ 7,632</u>

The projected benefit obligation, accumulated benefit obligation, and fair value of plan assets for pension plans with accumulated benefit obligations in excess of plan assets are as follows (amounts in thousands):

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
Projected benefit obligation	\$108,360	\$65,322
Accumulated benefit obligation	99,079	56,462
Fair value of plan assets	65,111	43,755

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE P. BENEFIT PLANS (Continued)

In December 2009, we adopted the provisions of new guidance related to expanded disclosure requirements for assets held in employer's defined benefit pensions or other post retirement plans, including employers' investment strategies, major categories of plan assets, concentrations of risk within plan assets and the valuation techniques used to measure fair value of plan assets.

At December 31, 2009 and 2008, plan assets for our foreign defined pension benefit plans consist primarily of the assets of our U.K. Pension Plan. All of the U.K. Pension Plan assets are invested in nine mutual funds, which are designated as Level 2 investments as of December 31, 2009. Defined pension benefit plan assets for our other foreign subsidiaries as of December 31, 2009 and 2008 were not significant.

The investment objective of our U.K. Pension Plan is to maximize the overall return from investment income and capital appreciation without resorting to a high risk investment strategy. The plan has no employer-related investments. Our U.K. Pension Plan retains professional investment managers that invest plan assets primarily in equity securities, bonds, property, and cash and other investments, which is consistent with the plan's liability profile.

The U.K. Pension Plan's benchmark allocation strategy is 55% U.K. equities, 20% overseas equities, 15% bonds and 10% real estate.

The actual weighted average asset allocations for our U.K. Pension Plan are as follows:

	December 31,	
	2009	2008
U.K. equity securities	56%	56%
Other overseas equity securities	21%	25%
Bonds	9%	11%
Real estate	8%	4%
Other	6%	4%
Total	<u>100%</u>	<u>100%</u>

The assumption made for the expected return on assets is based on the benchmark allocation strategy for our U.K. Pension Plan. Returns for individual asset categories are derived from market yields at the effective date, together with, in the case of equity-type assets, allowance for the additional future return expected from such assets compared to fixed interest investments.

Contributions

We expect to contribute approximately \$9 million to our U.K. Pension Plan in 2010.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE P. BENEFIT PLANS (Continued)

Estimated Future Benefit Payments

We expect to pay the following benefit payments for our defined pension benefit plans outside the United States, which reflect expected future service, as appropriate (amounts in thousands):

	Estimated Future Benefit Payments
2010	\$ 2,045
2011	1,908
2012	2,176
2013	2,388
2014	2,855
2015-2019	20,987
Total	<u>\$32,359</u>

NOTE Q. 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 A., "Summary of Significant Accounting Policies—Description of Business," to these consolidated financial statements. In addition, we now aggregate our Hematologic Oncology reporting segment and MS business unit under the caption "Hematologic Oncology." The activities of our MS reporting unit were formerly reported under the caption "Other." We have revised our 2008 and 2007 segment disclosures to conform to our 2009 presentation.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE Q. SEGMENT INFORMATION (Continued)

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

	For the Years Ended December 31,		
	2009	2008	2007
Revenues:			
Genetic Diseases(1,3)	\$1,774,544	\$2,226,692	\$1,767,538
Cardiometabolic and Renal	1,011,338	956,183	833,268
Biosurgery	561,815	491,100	426,647
Hematologic Oncology(2)	300,434	139,047	88,528
Other	865,396	790,756	695,923
Corporate	1,998	1,261	1,615
Total	<u>\$4,515,525</u>	<u>\$4,605,039</u>	<u>\$3,813,519</u>
Depreciation and amortization expense:			
Genetic Diseases	\$ 54,512	\$ 46,683	\$ 40,379
Cardiometabolic and Renal	84,487	83,309	83,454
Biosurgery	87,007	76,327	71,512
Hematologic Oncology(2)	78,491	42,708	23,728
Other	63,966	59,347	60,803
Corporate	87,901	66,290	58,320
Total	<u>\$ 456,364</u>	<u>\$ 374,664</u>	<u>\$ 338,196</u>
Equity in income (loss) of equity method investments:			
Genetic Diseases	\$ —	\$ 300	\$ 30,110
Cardiometabolic and Renal	—	(115)	(852)
Biosurgery	—	—	—
Hematologic Oncology	—	—	(21,101)
Other	—	—	(45)
Corporate	—	16	(714)
Total	<u>\$ —</u>	<u>\$ 201</u>	<u>\$ 7,398</u>
Income (loss) before income taxes:			
Genetic Diseases(1,3)	\$ 899,940	\$1,339,073	\$1,177,477
Cardiometabolic and Renal(4)	435,154	138,923	280,345
Biosurgery	149,062	99,553	60,082
Hematologic Oncology(2)	(214,752)	(143,717)	(223,322)
Other(5,6)	97,377	(86,787)	29,766
Corporate(7)	(823,048)	(721,507)	(588,674)
Total	<u>\$ 543,733</u>	<u>\$ 625,538</u>	<u>\$ 735,674</u>

(1) Effective January 1, 2008, instead of sharing all costs and profits of Aldurazyme equally, we began to record all sales of Aldurazyme and began paying BioMarin a tiered payment ranging from

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE Q. SEGMENT INFORMATION (Continued)

approximately 39.5% to 50% of worldwide net product sales of Aldurazyme. Revenue for our Genetic Diseases reporting segment includes Aldurazyme revenue of \$155.1 million for 2009 and \$151.7 million for 2008.

- (2) The results of operations of acquired companies are included in segment results beginning on the date of acquisition. Significant acquisitions impacting our Hematologic Oncology segment results above are:

<u>Acquisition</u>	<u>Date Acquired</u>
Acquisition from Bayer	May 29, 2009
Bioenvision	October 23, 2007

Includes:

- \$65.6 million of contingent consideration expenses recorded in 2009 related to the increase in fair value of the contingent consideration obligations recorded as a result of our acquisition from Bayer; and
 - \$125.5 million of IPR&D charges recorded in 2007 related to our acquisition of Bioenvision.
- (3) Includes:
- the impact of supply constraints for Cerezyme and Fabrazyme due to the temporary suspension of production at our Allston facility in June 2009;
 - a charge of \$100.0 million recorded in July 2008 as a nonrefundable upfront license fee payment to PTC related to our collaboration agreement to develop and commercialize ataluren for the treatment of genetic diseases caused by nonsense mutations, including DMD, CF and hemophilia; and
 - a charge of \$25.0 million recorded in June 2007 for an upfront payment made to Ceregene in connection with a collaboration agreement for the development and commercialization of CERE-120, a gene therapy product for the treatment of Parkinson's disease.
- (4) Includes a charge of \$175.0 million recorded in June 2008 and a charge of \$69.9 million recorded in February 2008 as license fee payments to Isis for exclusive, worldwide rights to mipomersen.
- (5) Includes charges of \$130.0 million recorded in October 2008 for amounts accrued or paid to Osiris for nonrefundable upfront license fees related to our collaboration to develop and commercialize Prochymal and Chondrogen.
- (6) 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.
- (7) Loss before income taxes for Corporate includes our corporate, general and administrative and corporate science activities, all of the stock-based compensation expenses, as well as net gains on investments in equity securities, interest income, interest expense and other income and expense items that we do not specifically allocate to a particular reporting segment. Loss before income taxes for Corporate includes a charge of \$64.0 million in 2007 for the settlement of the litigation related to the consolidation of our former tracking stocks.

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE Q. SEGMENT INFORMATION (Continued)

Segment Assets

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

	December 31,		
	2009	2008	2007
Segment Assets(1):			
Genetic Diseases(2)	\$ 1,494,263	\$1,520,586	\$1,147,256
Cardiometabolic and Renal	1,289,965	1,366,970	1,523,296
Biosurgery	509,064	497,813	458,239
Hematologic Oncology(3)	1,950,425	1,024,674	1,052,346
Other(4)	900,790	773,058	727,727
Corporate(3,4)	3,916,217	3,488,175	3,405,511
Total	<u>\$10,060,724</u>	<u>\$8,671,276</u>	<u>\$8,314,375</u>

- (1) Assets for our four reporting segments and Other include primarily accounts receivable, inventory and certain fixed and intangible assets, including goodwill.
- (2) Effective January 1, 2008, in connection with the restructuring of BioMarin/Genzyme LLC, we licensed certain rights to commercialize Aldurazyme from the joint venture, and began consolidating the results of the joint venture at fair value. As of December 31, 2009, other intangible assets, net includes \$240.2 million for the fair value of the joint venture's manufacturing and commercialization rights to Aldurazyme, offset by \$(24.0) million of related amortization. Other noncurrent liabilities as of December 31, 2009, includes \$216.2 million of additional net liabilities related to the fair value of these rights.
- (3) 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 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):

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

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE Q. SEGMENT INFORMATION (Continued)

In October 2007, we acquired Bioenvision for net consideration of \$304.7 million. Total assets for the acquisition as of October 23, 2007, the date of acquisition, include (amounts in millions):

	<u>Amount</u>	<u>Business Segment</u>
Cash and cash equivalents	\$ 45.2	Corporate
Goodwill and other intangible assets	257.7	Hematologic Oncology
Other tangible assets	13.0	Hematologic Oncology
Total	<u>\$315.9</u>	

- (4) Includes the assets related to our corporate, general and administrative operations, and corporate science activities that we do not allocate to a particular segment, including cash, cash equivalents, short- and long-term investments in debt securities, net property, plant and equipment and deferred tax assets.

Segment assets for Corporate consist of the following (amounts in thousands):

	<u>December 31,</u>		
	<u>2009</u>	<u>2008</u>	<u>2007</u>
Cash, cash equivalents, short- and long-term investments in debt securities	\$1,049,700	\$ 973,691	\$1,460,394
Deferred tax assets, net	555,242	457,342	260,005
Property, plant & equipment, net	1,787,054	1,524,442	1,240,992
Investments in equity securities	74,438	83,325	89,181
Other	449,783	449,375	354,939
Total	<u>\$3,916,217</u>	<u>\$3,488,175</u>	<u>\$3,405,511</u>

Geographic Information

We operate in the healthcare industry and we manufacture and market our products primarily in the United States and Europe. Our principal manufacturing facilities are located in the United States,

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE Q. SEGMENT INFORMATION (Continued)

England, Republic of Ireland, France and Belgium. The following tables contain certain financial information by geographic area (amounts in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Revenues:			
United States	\$2,375,523	\$2,259,086	\$1,996,764
Europe	1,388,415	1,587,318	1,238,360
Other	751,587	758,635	578,395
Total	<u>\$4,515,525</u>	<u>\$4,605,039</u>	<u>\$3,813,519</u>
	December 31,		
	2009	2008	2007
Long-lived assets:			
United States	\$1,646,588	\$1,374,708	\$1,067,918
Europe	1,350,139	1,099,916	1,044,901
Other	23,928	11,429	11,644
Total	<u>\$3,020,655</u>	<u>\$2,486,053</u>	<u>\$2,124,463</u>

Our results of operations are dependent on sales of Cerezyme. Sales of this product represented 18% of our total revenue in 2009, 27% of our total revenue in 2008 and 30% of our total revenue in 2007. We manufacture Cerezyme at our Allston facility and perform certain fill-finish activities at our facility in Waterford, Ireland. We sell this product directly to physicians, hospitals and treatment centers as well as through unaffiliated distributors. Distributor sales of Cerezyme represented 15% of Cerezyme revenue in 2009, 15% in 2008 and 17% in 2007. We believe that our credit risk associated with trade receivables is mitigated as a result of the fact that this product is sold to a large number of customers over a broad geographic area.

Sales of Renagel/Renvela, including sales of bulk sevelamer, represented 16% of our total revenue in 2009, 14% of our total revenue in 2008 and 16% of total revenue in 2007. A substantial portion of the sales of Renagel/Renvela are to wholesale distributors.

NOTE R. QUARTERLY RESULTS (Unaudited)

	1st Quarter 2009	2nd Quarter 2009	3rd Quarter 2009	4th Quarter 2009
	(Amounts in thousands, except per share amounts)			
Total revenues	\$1,148,871	\$1,228,510	\$1,057,514	\$1,080,630
Gross profit(1)	842,931	870,595	696,715	698,866
Net income(2)	195,486	187,574	15,995	23,245
Net income per share:				
Basic	\$ 0.72	\$ 0.69	\$ 0.06	\$ 0.09
Diluted	\$ 0.70	\$ 0.68	\$ 0.06	\$ 0.09

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE R. QUARTERLY RESULTS (Unaudited) (Continued)

	1st Quarter 2008	2nd Quarter 2008	3rd Quarter 2008	4th Quarter 2008
	(Amounts in thousands, except per share amounts)			
Total revenues	\$1,100,061	\$1,171,134	\$1,160,284	\$1,173,560
Gross profit(3)	819,819	862,093	865,674	866,850
Net income(4)	145,271	69,564	119,596	86,650
Net income per share:				
Basic	\$ 0.54	\$ 0.26	\$ 0.44	\$ 0.32
Diluted	\$ 0.52	\$ 0.25	\$ 0.42	\$ 0.31

(1) Includes:

- for the first quarter of 2009, a \$9.2 million pre-tax charge (\$7.2 million after tax) for the write off of Myozyme inventory costs related to incomplete production runs at our Belgium facility;
- for the second quarter of 2009, a \$24.1 million pre-tax charge (\$17.9 million after tax) for the initial costs related to the remediation of our Allston facility and the write off of the Cerezyme work-in-process material;
- for the third quarter of 2009, a \$23.7 million pre-tax charge (\$19.5 million after tax) for costs related to the remediation of our Allston facility; and
- for the fourth quarter of 2009, a \$20.9 million pre-tax charge (\$15.2 million after tax) for manufacturing-related costs, including \$10.1 million related to the remediation of our Allston facility and approximately \$11 million of other manufacturing-related charges.

(2) Includes:

- for the first quarter of 2009, an \$18.2 million pre-tax charge (\$11.6 million after tax) for the acquisition of intellectual property from EXACT Sciences;
- for the second quarter of 2009, a \$24.2 pre-tax gain (\$17.6 million after tax) on acquisition of business related to our acquisition from Bayer; and
- for the third quarter of 2009, a \$7.0 million pre-tax charge (\$5.4 million after tax) for the acquisition of intellectual property from Targeted Genetics.

(3) Includes:

- for the fourth quarter of 2008, an \$18.1 million pre-tax charge (\$13.4 million after tax) for the write off of inventory associated with terminated production runs and validation costs associated with our Belgium facility that were incorrectly capitalized from January to September 2008.

(4) Includes:

- for the first quarter of 2008, a \$69.9 million pre-tax charge (\$56.5 million after tax) for a license fee we paid to Isis;
- for the second quarter of 2008, a \$175.0 million pre-tax charge (\$141.3 million after tax) for an additional license fee paid to Isis;

GENZYME CORPORATION AND SUBSIDIARIES
Notes To Consolidated Financial Statements (Continued)

NOTE R. QUARTERLY RESULTS (Unaudited) (Continued)

- for the third quarter of 2008, a \$100.0 million pre-tax charge (\$91.3 million after tax) for a license fee we paid to PTC and \$14.3 million of pre-tax charges (\$10.6 million after tax) for net losses on investments in equity securities; and
- for the fourth quarter of 2008, a \$130.0 million pre-tax charge (\$82.5 million after tax) for amounts accrued and paid to Osiris for a license fee and a \$16.0 million pre-tax charge (\$11.1 million after tax) for the license or purchase of certain intellectual property and technology relating to transactions with two third parties.

NOTE S. VALUATION AND QUALIFYING ACCOUNTS

The following table provides information about our valuation and qualifying accounts for the years ended December 31, 2009, 2008 and 2007:

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance at End of Period</u>
		<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts</u>		
Year ended December 31, 2009:					
Accounts receivable allowances	\$ 40,375,000	\$18,705,000	\$ 58,152,000	\$ 47,338,000	\$ 69,894,000
Rebates	\$132,905,000	\$ —	\$235,671,000	\$234,574,000	\$134,002,000
Year ended December 31, 2008:					
Accounts receivable allowances	\$ 40,287,000	\$12,933,000	\$ 14,071,000	\$ 26,916,000	\$ 40,375,000
Rebates	\$ 90,437,000	\$ —	\$203,333,000	\$160,865,000	\$132,905,000
Year ended December 31, 2007:					
Accounts receivable allowances	\$ 52,563,000	\$ 9,664,000	\$ 10,964,000	\$ 32,904,000	\$ 40,287,000
Rebates	\$ 62,166,000	\$ —	\$149,967,000	\$121,696,000	\$ 90,437,000

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of December 31, 2009, we evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2009.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2009.

We have excluded the acquisition of the commercial and development rights we received from Bayer from our assessment of internal controls over financial reporting as of December 31, 2009, because we acquired these rights in a purchase business combination during 2009. The rights acquired from Bayer are a component of our Hematologic Oncology reporting segment. Total inventories and total revenues related to these rights represent 8% and 3%, respectively, of our consolidated inventories and our consolidated revenues as of December 31, 2009.

The effectiveness of our internal controls over financial reporting as of December 31, 2009 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report set forth under the heading “Report of Independent Registered Public Accounting Firm,” which is included in Part II, Item 8 of this Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a Corporate Code of Conduct, which applies to our directors and all of our employees, including our principal executive officer, principal financial officer, principal accounting officer and controller. A copy of our Code of Conduct is posted on our website, www.genzyme.com, under the “Corporate Governance—Our Commitment” section of the site. We intend to make all required disclosures concerning amendments to, or waivers from, this code in the Corporate Governance section of our website. Information contained on our website is not part of this document or the documents incorporated by reference into this document.

Certain information regarding our executive officers is set forth at the end of Part I of this Form 10-K under the heading, “Executive Officers of the Registrant.” The other information required by this item is incorporated by reference from our Proxy Statement for our 2010 Annual Meeting of Shareholders.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from our Proxy Statement for our 2010 Annual Meeting of Shareholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference from our Proxy Statement for our 2010 Annual Meeting of Shareholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from our Proxy Statement for our 2010 Annual Meeting of Shareholders.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference from our Proxy Statement for our 2010 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1). Financial Statements

We are incorporating the following financial statements (and related notes) of Genzyme Corporation and Subsidiaries into this section by reference from Part II, Item 8., “Financial Statements and Supplementary Data,” of this Form 10-K:

	Page
Report of Independent Registered Public Accounting Firm	115
Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2009, 2008 and 2007	117
Consolidated Balance Sheets as of December 31, 2009 and 2008	118
Consolidated Statements of Cash Flows for the Years Ended December 31, 2009, 2008 and 2007	119
Consolidated Statements of Stockholders’ Equity for the Years Ended December 31, 2009, 2008 and 2007	121
Notes to Consolidated Financial Statements	122

(a)(2). Financial Statement Schedules

Schedules are omitted because they are not applicable, or not required, or because the information is included in our consolidated financial statements or notes thereto.

(b). Exhibits

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	Lease, dated April 30, 1990, for 64 Sidney Street, Cambridge, Massachusetts between BioSurface Technology, Inc. and Forest City 64 Sidney Street, Inc. Filed as Exhibit 10.22 to BioSurface’s Registration Statement on Form S-1 (File No. 33-55874).
*10.1.1	Amendment to Lease, dated September 11, 1995, to the Lease Agreement dated April 30, 1990 by and between Forest City 64 Sidney Street, Inc. and Genzyme. Filed as Exhibit 10.1.1 to Genzyme’s Form 10-K for 2003.
*10.1.2	Second Amendment to Lease, dated March 1, 1996, to the Lease Agreement dated April 30, 1990 by and between Forest City 64 Sidney Street, Inc. and Genzyme. Filed as Exhibit 10.1.2 to Genzyme’s Form 10-K for 2003.
*10.1.3	Letter Amendment, dated December 30, 1999, to the Lease Agreement dated April 30, 1990, by and between Forest City 64 Sidney Street, Inc. and Genzyme. Filed as Exhibit 10.1.3 to Genzyme’s Form 10-K for 2003.

EXHIBIT NO.	DESCRIPTION
*10.1.4	Fourth Amendment to Lease, dated March 23, 2001, to the Lease Agreement dated April 30, 1990, by and between Forest City 64 Sidney Street, Inc. and Genzyme. Filed as Exhibit 10.1.4 to Genzyme's Form 10-K for 2003.
*10.1.5	Lease Agreement dated November 30, 2005, by and between Forest City 64 Sidney Street, Inc. and Genzyme. Filed as Exhibit 10.1.5 to Genzyme's Form 10-K for 2006.
*10.2	Lease, dated June 1, 1992, for land at Allston Landing, Allston, Massachusetts, between Allston Landing Limited Partnership and the Massachusetts Turnpike Authority. Filed as Exhibit 10.9 to Genzyme's Form 10-K for 1993.
*10.2.1	First Amendment to Lease, dated July 26, 1995, to Lease dated June 1, 1992, between Allston Landing Limited Partnership and the Massachusetts Turnpike Authority. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended June 30, 2005.
*10.2.2	Second Amendment to Lease, dated December 22, 1997, to Lease dated June 1, 1992, between Allston Landing Limited Partnership and the Massachusetts Turnpike Authority. Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended June 30, 2005.
*10.3	Commercial Lease, dated December 24, 1998, by and between Aventis Pasteur SA and Imtix-SangStat S.A.S. for Building C5 located at Marcy L'Etoile, Lyon, France. Filed as Exhibit 10.4 to Genzyme's Form 10-K for 2003.
*10.3.1	Amendment to Commercial Lease, dated September 30, 2000, to the Lease dated December 24, 1998, by and between Aventis Pasteur SA and Imtix-SangStat S.A.S. Filed as Exhibit 10.4.1 to Genzyme's Form 10-K for 2003.
*10.4	Lease, dated August 28, 2000, for Building D, Cambridge Research Park, Cambridge, Massachusetts, between Genzyme and Kendall Square LLC. Filed as Exhibit 10.4 to Genzyme's Form 10-K for 2005.
*10.4.1	First Amendment to Lease, dated August 1, 2003, to the Lease dated August 28, 2000, by and between Genzyme and Kendall Square LLC. Filed as Exhibit 10.5.1 to Genzyme's Form 10-K for 2004.
*10.5	Underlease of 50 Gibson Drive, Kings Hill Business Park, West Malling, Kent, U.K., dated January 19, 2001, by and among Genzyme Limited, Liberty Property Limited Partnership and Kings Hill Estate Management Company Limited. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2005.
*10.5.1	Deed of Variation of Underlease dated January 19, 2001, and Agreement for Lease, each dated August 22, 2005, by and between Genzyme Limited and Kent City Council (successors to Liberty Property Limited Partnership). Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended September 30, 2005.
*10.6	Lease, dated September 3, 1990, for the land located at the Industrial Development Authority Industrial Park, County Waterford, Ireland (comprised in folio 4917 & 324IF County Waterford), by and between the Industrial Development Authority and Bausch & Lomb Ireland. Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended September 30, 2001.
*10.7	Contract for Sale, dated June 25, 2001, for the premises located at the Industrial Development Authority Industrial Park, County Waterford, Ireland, (comprised in folio 4141L County Waterford) by and between Luxottica Ireland Limited and Genzyme Ireland Limited (f/k/a Gosfend Limited). Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2001.

EXHIBIT NO.	DESCRIPTION
*10.8	Deed of Transfer, dated July 2, 2001, between Luxottica Ireland Limited and Genzyme Ireland Limited, related to the Lease dated September 3, 1990 for the premises located at the Industrial Development Authority Industrial Park, County Waterford, Ireland (comprised in folio 4141L County Waterford). Filed as Exhibit 10.3 to Genzyme's Form 10-Q for the quarter ended September 30, 2001.
*10.9	Contract for Sale, dated August 2, 2001, for the land located at the Industrial Development Authority Industrial Park, County Waterford, Ireland (comprised in folio 4917 County Waterford), by and between the Industrial Development Authority and Genzyme Ireland Limited. Filed as Exhibit 10.4 to Genzyme's Form 10-Q for the quarter ended September 30, 2001.
*10.10	Lease, dated August 24, 2001, for the land located at the Industrial Development Authority Industrial Park, County Waterford, Ireland (comprised in folio 4917 County Waterford) by the Industrial Development Authority and Genzyme Ireland Limited. Filed as Exhibit 10.5 to Genzyme's Form 10-Q for the quarter ended September 30, 2001.
*10.11	1997 Equity Incentive Plan, as amended. Filed as Exhibit 10.12 to Genzyme's Form 10-K for 2006.
*10.12	1998 Director Stock Option Plan, as amended. Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended June 30, 2006.
*10.12.1	Form of Non-Statutory Stock Option for grants under Genzyme's 1998 Director Stock Option Plan. Filed as Exhibit 10.5 to Genzyme's Form 10-Q for the quarter ended June 30, 2005.
*10.12.2	2007 Director Equity Plan, as amended. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2009.
*10.12.3	Form of Non-Statutory Stock Option Agreement for grants under Genzyme's 2007 Director Equity Plan. Filed as Exhibit 10.3 to Genzyme's Form 10-Q for the quarter ended June 30, 2008.
*10.12.4	Form of Restricted Stock Unit Award Agreement for grants under Genzyme's 2007 Director Equity Plan. Filed as Exhibit 10.4 to Genzyme's Form 10-Q for the quarter ended June 30, 2008.
*10.13	2001 Equity Incentive Plan, as amended. Filed as Exhibit 10.14 to Genzyme's 10-K for 2006.
*10.13.1	Forms of Non-Statutory Stock Option Agreement for grants to executive officers under Genzyme's 2001 Equity Incentive Plan. Filed as Exhibit 10.5 to Genzyme's Form 10-Q for the quarter ended June 30, 2008.
*10.13.2	Forms of Incentive Stock Option Agreement for grants to executive officers under Genzyme's 2001 Equity Incentive Plan. Filed as Exhibit 10.6 to Genzyme's Form 10-Q for the quarter ended June 30, 2008.
*10.14	2004 Equity Incentive Plan, as amended. Filed as Appendix B to Genzyme's Proxy Statement on Schedule 14A filed April 13, 2009 for the 2009 Annual Meeting of Shareholders.
*10.14.1	Forms of Incentive Stock Option Agreement for grants to executive officers under Genzyme's 2004 Equity Incentive Plan. Filed as Exhibit 10.14.1 to Genzyme's Form 10-K for 2008.

EXHIBIT NO.	DESCRIPTION
*10.14.2	Forms of Nonstatutory Stock Option Agreement for grants to executive officers under Genzyme's 2004 Equity Incentive Plan. Filed as Exhibit 10.14.2 to Genzyme's Form 10-K for 2008.
*10.14.3	Forms of Restricted Stock Unit Award Agreement for grants to executive officers under Genzyme's 2004 Equity Incentive Plan. Filed as Exhibit 10.3 to Genzyme's Form 10-Q for the quarter ended March 31, 2008.
*10.15	Genzyme 2010 Senior Executive Long-Term Incentive Program. Described in Genzyme's Form 8-K filed January 28, 2010.
*10.16	1996 Directors' Deferred Compensation Plan, as amended. Filed as Exhibit 10.16 to Genzyme's Form 10-K for 2008.
*10.17	Amended and Restated Executive Employment Agreement effective as of December 31, 2008 between Genzyme Corporation and Henri A. Termeer. Filed as Exhibit 10.2 to Genzyme's Form 8-K filed December 5, 2008.
*10.18	Amended and Restated Executive Employment Agreement effective as of December 31, 2008 between Genzyme Corporation and Peter Wirth. Filed as Exhibit 10.3 to Genzyme's Form 8-K filed December 5, 2008.
*10.19	Form of Indemnification Agreement between Genzyme and its executive officers. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2004.
*10.20	Form of Severance Agreement between Genzyme and its executive officers. Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended September 30, 2007.
*10.21	Genzyme Senior Executive Annual Cash Incentive Program. Filed as Exhibit 10.1 to Genzyme's Form 8-K filed December 5, 2008.
*10.21.1	Genzyme 2010 Senior Executive Annual Cash Incentive Program. Described in Genzyme's Form 8-K filed January 28, 2010.
*10.22	Amended and Restated Collaboration Agreement, effective as of January 1, 2008, among Genzyme, BioMarin and BioMarin/Genzyme LLC. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended March 31, 2008.**
*10.22.1	Manufacturing, Marketing and Sales Agreement among Genzyme, BioMarin and BioMarin/Genzyme LLC, effective as of January 1, 2008. Filed as Exhibit 10.2 to Genzyme's Form 10-Q for the quarter ended March 31, 2008.**
*10.23	Supply Agreement, dated January 24, 2006, by and between Cambrex Charles City, Inc. and Genzyme. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2006.**
*10.24	Contract Manufacturing Agreement dated September 14, 2001, as amended, between GelTex and The Dow Chemical Company. Filed as Exhibit 10.35 to Genzyme's Form 10-K for 2002.**
*10.24.1	Second Amendment, dated October 9, 2002, to Contract Manufacturing Agreement dated September 14, 2001, between GelTex and The Dow Chemical Company. Filed as Exhibit 10.34.1 to Genzyme's Form 10-K for 2003.**
*10.24.2	Third Amendment, dated December 8, 2003, to Contract Manufacturing Agreement dated September 14, 2001, between GelTex and The Dow Chemical Company. Filed as Exhibit 10.34.2 to Genzyme's Form 10-K for 2003.**

EXHIBIT NO.	DESCRIPTION
*10.24.3	Fourth Amendment, dated July 1, 2004, to Contract Manufacturing Agreement dated September 14, 2001, between GelTex and The Dow Chemical Company. Filed as Exhibit 10.29.3 to Genzyme's Form 10-K for 2004.**
*10.24.4	Amended and Restated Contract Manufacturing Agreement signed as of December 15, 2006, between Genzyme (as successor to GelTex) and The Dow Chemical Company. Filed with Genzyme's Form 8-K filed on December 21, 2006.**
*10.25	Credit Agreement, dated July 14, 2006, among Genzyme and those of its subsidiaries party thereto, the lenders listed therein, JPMorgan Chase Bank, N.A., as administrative agent, Bank of America, N.A., as syndication agent, ABN AMRO Bank N.V., Citizens Bank of Massachusetts and Wachovia Bank, National Association, as co-documentation agents. Filed with Genzyme's Form 8-K filed on July 19, 2006.
*10.26	North American Termination and Transition Agreement, dated November 3, 2004, by and between Genzyme and Wyeth. Filed as Exhibit 10.31 to Genzyme's Form 10-K for 2004.**
*10.27	Purchase and Supply Agreement, effective as of January 1, 2005, by and between Genzyme and Invitrogen Corporation. Filed as Exhibit 10.3 to Genzyme's Form 10-Q for the quarter ended June 30, 2005.**
*10.27.1	Amendment No. 2 effective as of January 1, 2007 to Purchase and Supply Agreement, effective as of January 1, 2005, by and between Genzyme and Invitrogen Corporation. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended June 30, 2007.**
*10.27.2	Amended and Restated Contract Purchase and Supply Agreement between Invitrogen Corporation and Genzyme effective December 31, 2007. Filed as Exhibit 10.1 to Genzyme's Form 10-Q for the quarter ended September 30, 2007.**
*10.28	License and Co-Development Agreement between Genzyme and Isis Pharmaceuticals, Inc. dated June 24, 2008. Filed as Exhibit 10.7 to Genzyme's Form 10-Q for the quarter ended June 30, 2008.**
10.29	Technology Transfer and Supply Agreement between Genzyme and Hospira Worldwide, Inc. effective December 31, 2009. Filed herewith.**
*10.30	Agreement dated January 6, 2010 between Genzyme, Relational Investors LLC, Ralph V. Whitworth and the other parties identified therein. Filed as Exhibit 99.1 to Genzyme's Form 8-K filed on January 7, 2010.
21	Subsidiaries of Genzyme. Filed herewith.
23	Consent of PricewaterhouseCoopers LLP. 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.

EXHIBIT NO.	DESCRIPTION
99	Financial statements and notes thereto of BioMarin/Genzyme LLC for the year ended December 31, 2007. Filed 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.DEF	XBRL Taxonomy Extension Definition Linkbase Document. 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-K, 10-Q, 8-K, 8-A, or Schedule 14A of Genzyme Corporation were filed under Commission File No. 0-14680.

** Confidential treatment has been requested or granted for the deleted portions of Exhibits 10.22 through 10.24.4 and 10.26 through 10.29.

EXECUTIVE COMPENSATION PLANS AND ARRANGEMENTS

Exhibits 10.11 through 10.21.1 above are management contracts or compensatory arrangements in which our executive officers or directors participate.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENZYME CORPORATION

Dated: February 26, 2010

By: /s/ MICHAEL S. WYZGA

Michael S. Wyzga
*Executive Vice President, Finance And Chief
Financial Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ HENRI A. TERMEER</u> Henri A. Termeer	Director and Principal Executive Officer	February 26, 2010
<u>/s/ MICHAEL S. WYZGA</u> Michael S. Wyzga	Principal Financial Officer	February 26, 2010
<u>/s/ JASON A. AMELLO</u> Jason A. Amello	Corporate Controller and Principal Accounting Officer	February 26, 2010
<u>/s/ DOUGLAS A. BERTHIAUME</u> Douglas A. Berthiaume	Director	February 26, 2010
<u>/s/ GAIL K. BOUDREAUX</u> Gail K. Boudreaux	Director	February 26, 2010
<u>/s/ ROBERT J. CARPENTER</u> Robert J. Carpenter	Director	February 26, 2010
<u>/s/ CHARLES L. COONEY</u> Charles L. Cooney	Director	February 26, 2010

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ VICTOR J. DZAU</u> Victor J. Dzau	Director	February 26, 2010
<u>/s/ CONNIE MACK III</u> Connie Mack III	Director	February 26, 2010
<u>/s/ RICHARD F. SYRON</u> Richard F. Syron	Director	February 26, 2010
<u>/s/ ROBERT J. BERTOLINI</u> Robert J. Bertolini	Director	February 26, 2010

1. The first part of the document discusses the importance of maintaining accurate records of all transactions. This is essential for ensuring the integrity of the financial statements and for providing a clear audit trail. The records should be kept up-to-date and should be easily accessible to all relevant parties.

2. The second part of the document outlines the various methods used to collect and analyze data. These methods include interviews, surveys, and focus groups. Each method has its own strengths and weaknesses, and it is important to choose the most appropriate method for the specific research objectives.

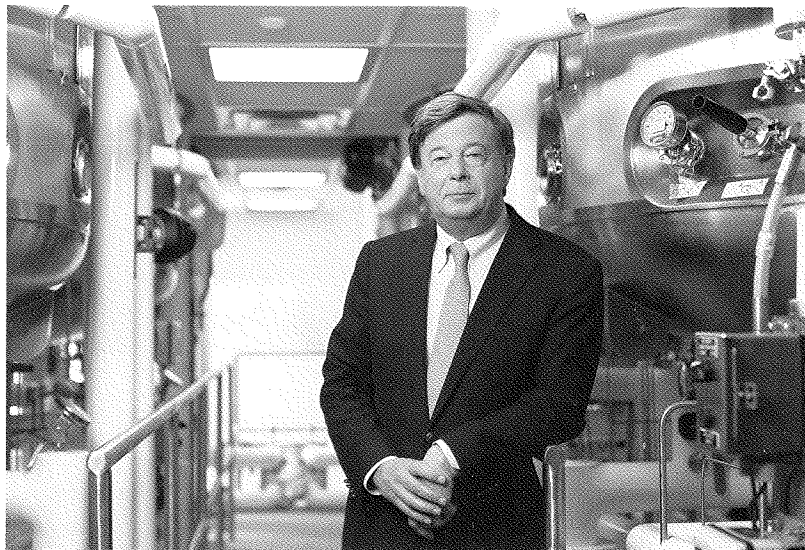
3. The third part of the document describes the process of data analysis. This involves identifying patterns and trends in the data, and then interpreting these findings in the context of the research objectives. It is important to be objective and unbiased in this process, and to avoid drawing conclusions that are not supported by the data.

4. The final part of the document discusses the importance of reporting the results of the research. This involves presenting the findings in a clear and concise manner, and providing a detailed explanation of the methods used and the limitations of the study. It is important to be transparent and honest in this process, and to provide a clear and accurate picture of the research findings.

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APR 27 2010

Washington, DC
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Henri A. Termeer

Chairman, President and Chief Executive Officer

Photographed in the company's new Framingham, Mass., biologics manufacturing facility, which will provide redundant capacity for the production of Cerezyme and Fabrazyme.

- Beyond Mozobil, we continued to execute our strategy for expanding our presence in oncology, where we see a large opportunity to contribute given the need for new medicines, the well-defined disease areas and the increasingly personalized approaches to treatment that combine therapeutics and diagnostics. Our revenue growth in 2009 reflects the integration of Fludara and Leukine, two oncology products acquired from Bayer, as well as Campath revenue, which we now record.
- Renvela was launched in the EU for patients with chronic kidney disease in June, helping to bolster a stable, profitable sevelamer franchise.

This productivity demonstrates the impact of our long-term strategy to build the company both through acquisitions and internal research and development. Our acquisition of U.S. marketing rights to Synvisc from Wyeth in 2005, and our subsequent investment in the product's clinical development, led to the launch of Synvisc-One. Our acquisition of AnorMed in 2006 brought us Mozobil, and we are building our oncology franchise on products acquired from Ilex Oncology, such as Clolar. These newer products are strengthening and diversifying a portfolio based on internally developed treatments, including Cerezyme, Fabrazyme and Myozyme.

Building Trust with Patients and Physicians

We are making investments across all areas of our Genetic Diseases business to maintain our leadership in this field. These investments include expanding our sales force to provide greater support to our customers; building our product pipeline so that we can continue to advance innovative treatment alternatives; and adding manufacturing capacity to ensure a reliable product supply.

We were deeply encouraged that more than 85 percent of Gaucher patients restarted Cerezyme treatment immediately after we reintroduced the product at the beginning of this year. We are resupplying Cerezyme to patients in more than 100 countries and taking steps to make this process as smooth and predictable as possible for both patients and physicians.

We are seeking to increase the productivity of the Fabrazyme manufacturing process through a new working cell bank, so that we can have a sufficient supply to enable full dosing for patients on Fabrazyme this year.

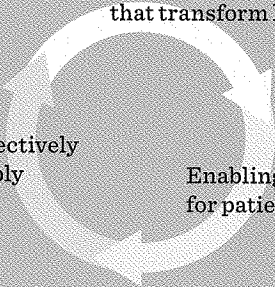
Late last year, we reached agreement with the FDA on a regulatory pathway for Lumizyme produced at the 4000L bioreactor scale, and our action date is June 17. This product is made in our Geel, Belgium, manufacturing plant, which was approved by European and other regulatory authorities last year.

Business Strategy

Discovering novel therapies that transform lives

Operating effectively and sustainably

Enabling access for patients



During 2009, Genzyme accelerated efforts to improve its global processes and practices, a key element of ongoing initiatives to build the company for the next level of growth. People – both new and longtime Genzyme employees – are critical to these efforts.

Scott Canute, the new President of Global Manufacturing and Corporate Operations, was one of a number of highly respected, experienced professionals who joined Genzyme in 2009 and early 2010. Scott comes to the company having served as global manufacturing head at Eli Lilly & Company.

The majority of markets have transitioned to the 4000L product, which is known as Myozyme outside the United States. All Myozyme bulk production now occurs at the Geel plant, and we are currently expanding capacity at the facility to support the product's long-term growth.

Transforming Manufacturing Operations

To strengthen our global manufacturing operations and bring them up to world-class standards, we are implementing a plan to reduce risk, increase capacity and renew the organization.

To mitigate risk, we are implementing a comprehensive effort designed to enhance our quality systems, while we continue to improve our operational performance at our Allston Landing plant. To increase capacity, we are pushing forward with expansion projects that will result in a quadrupling of our biologics manufacturing capacity from 2004 levels by 2012. To renew the organization, we have hired new senior leaders and made significant management changes.

Pursuing Excellence

We have taken actions that strengthen our board of directors, improve our corporate governance and prepare for future growth.

We added fresh perspective to our board with the election of Robert Bertolini, a former Executive Vice President and

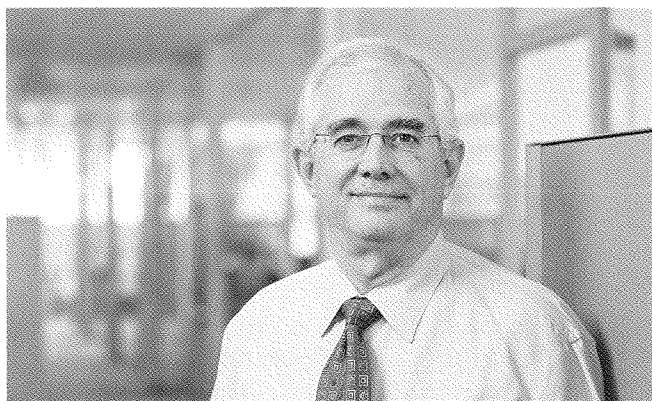
Chief Financial Officer of Schering-Plough Corp. We further strengthened the role of the board's independent directors, including expanding the role of our lead independent director, Robert Carpenter.

Our board took significant action to address corporate performance by implementing new annual and long-term incentive plans for senior executives. These innovative plans align incentive compensation with a broader set of measures of company performance. We believe that these measures appropriately reflect the factors most important to the creation of shareholder value: revenue growth, capital efficiency/profitability and key business objectives. The plans provide greater transparency to our shareholders regarding executive compensation decisions.

In early 2009, we initiated the Business Excellence Initiative, a comprehensive effort to enhance decision-making and improve operational processes to prepare for expected future growth. Our goal is to build alignment and introduce new performance metrics across all functions of the business, including manufacturing, sales and R&D, to create the capacity for growth.

Products for our Future

We achieved a number of important milestones across our late-stage clinical development programs that confirm the potential of the products in our pipeline.



Ron Branning, an industry veteran specializing in product and device quality, joined Genzyme as Senior Vice President of Global Product Quality. Ron, formerly with Gilead Sciences and Genentech, is an expert in the development of world-class quality and regulatory compliance practices.



Pamela Williamson brings many years of experience to her new role as Senior Vice President and Global Head of Regulatory Affairs and Corporate Quality Compliance. Prior to joining the Genzyme team, Pamela was Vice President of Regulatory Affairs and Quality Assurance at Serono, Inc.

- We completed enrollment ahead of schedule in two phase 3 studies of alemtuzumab in multiple sclerosis, which based on four-year data from the phase 2 study holds the potential to fundamentally change the standard-of-care for this disease. This program is our largest development effort, and phase 3 results are expected next year.
- We saw encouraging two-year follow-up data from the phase 2 study of our investigational oral therapy for patients with Gaucher disease, eliglustat tartrate, formerly called Genz-112638. This oral option has the potential to transform the Gaucher treatment experience by offering patients and physicians more flexibility to individualize therapy for optimal management of the disease. We are currently enrolling patients in two global, multi-center, phase 3 trials of eliglustat tartrate.
- With Isis Pharmaceuticals, we reported positive results from two phase 3 studies of mipomersen for patients with homozygous and heterozygous familial hypercholesterolemia. We expect data from two additional phase 3 studies in mid-2010.

Our Commitment to Patients and Performance

I am proud of Genzyme's accomplishments during 2009, especially the way we managed a significant set of challenges. Across the organization, our employees performed well under pressure, taking constructive action that moved us into recovery

mode in 2010. The Allston staff worked with great energy and commitment to remediate and resume production of Cerezyme and Fabrazyme. Genzyme field representatives are connecting with patients and physicians to both listen and inform them of options.

To ensure that the most vulnerable patients were treated first, we established a set of guiding principles that articulated clear, patient-focused priorities. These included distributing our limited supplies in all countries with equal consideration to commercial patients and free drug programs.

Genzyme is made up of a group of people who have learned from our experience and are focused on delivering value to patients and our shareholders. We are aligned around our commitment to patients and motivated to ensure they have access to the medicine they need. I am confident that we will emerge from 2009 a stronger company and resume our tremendous track record of performance for investors. In 2010, we will continue to execute our plan for growth. Our future is bright, and we appreciate your support.

Sincerely,

Henri A. Termeer
March 4, 2010

Financial highlights 2009

Revenue Growth

In 2009, Genzyme achieved revenue of \$4.5 billion, which was impacted by a supply interruption for Cerezyme and Fabryzyme. Excluding the Genetic Diseases segment, revenues from the other businesses grew 15% from 2008 levels.

Product Launches

We had successful launches of three products across our businesses: Mozobil globally for stem cell mobilization; Synvisc-One in the U.S. for osteoarthritic knee pain; and Renvela in Europe for patients with chronic kidney disease.

Efficient Cash Utilization

Cash flow from operating activities was approximately \$1.2 billion in 2009. We purchased \$414 million in Genzyme stock and invested \$662 million in capital expenditures to further build capacity for our key products. We ended the year with \$1.0 billion in cash.

Pipeline Progress

We completed a phase 3 mipomersen trial for hoFH. In addition, we completed enrollment in the phase 3 alemtuzumab program for multiple sclerosis and launched a phase 3 program with eliglustat tartrate for Gaucher disease type 1.

(in thousands, except per share data)

	2009	2008	2007	2006	2005
SUMMARY OF OPERATIONS					
Revenues	\$ 4,515,525	\$ 4,605,039	\$ 3,813,519	\$ 3,187,013	\$ 2,734,842
Product and service gross margin	3,109,107	3,414,436	2,856,774	2,433,856	2,082,030
Operating income (loss)	503,707	581,479	653,865	(190,509)	600,862
Net income (loss)	422,300	421,081	480,193	(16,797)	441,489
Earnings per share (diluted)	\$ 1.54	\$ 1.50	\$ 1.74	\$ (0.06)	\$ 1.65

FINANCIAL POSITION

Cash and investments	\$ 1,049,700	\$ 973,691	\$ 1,460,394	\$ 1,285,604	\$ 1,089,102
Working capital	1,722,673	1,601,852	1,137,904	1,338,062	1,114,976
Total assets	10,060,724	8,671,276	8,314,375	7,191,188	6,878,865
Long-term obligations	1,296,942	451,000	217,511	879,038	1,178,975
Stockholders' equity	\$ 7,683,652	\$ 7,305,993	\$ 6,612,937	\$ 5,660,711	\$ 5,149,867

¹ GAAP TO NON-GAAP RECONCILIATION

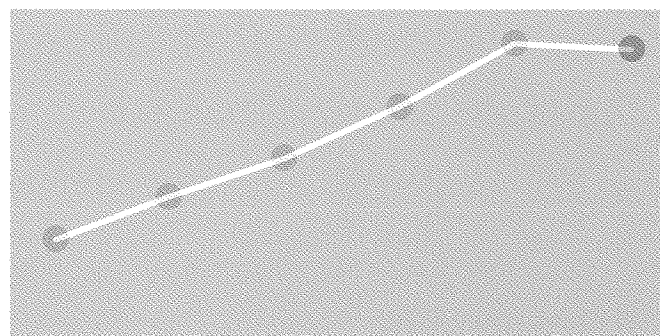
(in millions, except per share data. All amounts except weighted average shares are net of tax)

	2009	2008	2007	2006	2005	2004
GAAP net income (loss)	\$422.3	\$421.1	\$480.2	\$(16.8)	\$441.5	\$86.5
Acquisition-related expense	48.5	0.0	109.7	404.3	22.2	254.5
Stock compensation expense	150.7	130.2	131.8	142.2	0.0	0.0
Non-GAAP net income	\$621.5	\$551.3	\$721.7	\$529.7	\$463.7	\$341.0
Adjustment for diluted effect of convertible debt	0.0	7.0	7.5	7.5	7.5	0.0
Adjusted Non-GAAP net income for purposes of calculating Non-GAAP earnings per share	\$621.5	\$558.3	\$729.2	\$537.2	\$471.2	\$341.0
Weighted average shares outstanding — diluted	274.1	285.6	280.8	268.0	272.2	234.3
Non-GAAP earnings per share — diluted*	\$2.27	\$1.95	\$2.60	\$2.00	\$1.74	\$1.47

*Non-GAAP earnings per share may not calculate due to rounding.

Revenue
(in millions)

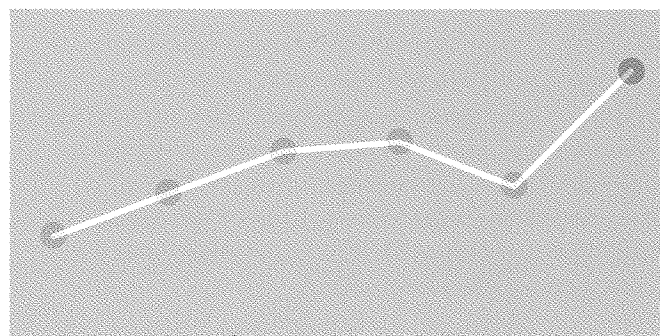
\$ 5,000
\$ 4,500
\$ 4,000
\$ 3,500
\$ 3,000
\$ 2,500
\$ 2,000
\$ 1,500
\$ 1,000



2004 2005 2006 2007 2008 2009

Cash Flow from Operating Activities
(in millions)

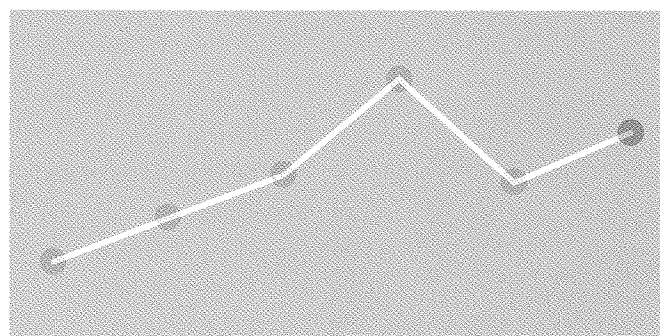
\$ 1,400
\$ 1,200
\$ 1,000
\$ 800
\$ 600
\$ 400
\$ 200



2004 2005 2006 2007 2008 2009

Non-GAAP Earnings per Share¹

\$ 3.0
\$ 2.0
\$ 1.0



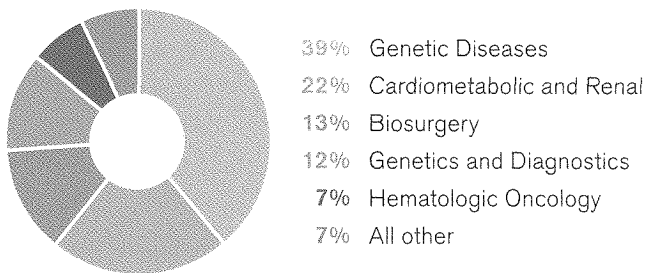
2004 2005 2006 2007 2008 2009

A strong core. Our purpose has always been to make a life-changing difference for patients with serious diseases through truly innovative therapies, market and scientific leadership and global reach. Providing access to these therapies is our strength.

Diverse portfolio

Genzyme pioneered the treatment of rare genetic diseases with Ceredase in 1991, which was quickly followed by a second-generation product, Cerezyme, in 1994. Since 2002, Genzyme has steadily built a highly diversified portfolio of products to reduce risk and reliance on one therapy. Genzyme products range from a few mature, well-established therapies to new treatments still in launch phase—with the vast majority early in their growth.

Percent of revenue by business group



Market leaders

Genzyme has 12 number one products across its broad portfolio, each of which represents the standard of care in its respective medical area. This is a direct result of Genzyme's strategic focus on developing and marketing first-in-class, life-changing therapies—our answer to some of medicine's most difficult problems in genetic diseases, hematologic cancers, renal disease, organ transplantation, osteoarthritis of the knee and other areas.

Twelve number one products

- Cerezyme®
imiglucerase for injection
- Myozyme®
aglucosidase alfa
- Fabrazyme®
agalsidase beta
- Aldurazyme®
laronidase
- Renvela®
sevelamer carbonate
- Synvisc-One®
hylan G-F 20
- Thymoglobulin®
anti-thymocyte globulin (rabbit)
- Thyrogen®
thyrotropin alfa for injection
- Clolar®
clofarabine injection
- Carticel®
autologous cultured chondrocytes
- Seprafilm®
adhesion barrier
- Epicel®
cultured epidermal autografts

Global presence

Genzyme considers the world our discovery engine and our market. It is our responsibility to provide access to patients around the world, regardless of ability to pay. Product manufacturing, R&D, sales and regulatory affairs take place around the world. Our international presence fosters a strong understanding of the diverse healthcare systems and patient needs unique to each region.

Strategic global expansion

We have operations in over
100 countries

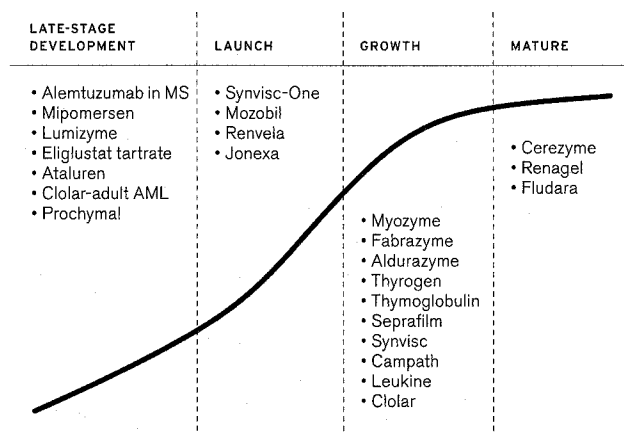
20 Genzyme products
are available to the international market

Well-balanced global sales
~50% ex-U.S.

Growth potential

Genzyme has leveraged unique and powerful scientific expertise to build a robust late-stage pipeline of novel therapies that could redefine patient care in their disease areas. From multiple sclerosis to severe hypercholesterolemia, our late-stage pipeline holds significant, long-term promise for the company and patients.

Balanced product life cycle will drive future growth



Building capacity. From 2004 to 2012, we will increase bioreactor capacity needed to manufacture our enzyme replacement therapies fourfold through an investment of more than \$1 billion.

To strengthen our global manufacturing operations and to attain world-class standards, we are implementing a comprehensive plan to reduce risk, increase capacity and renew the organization.

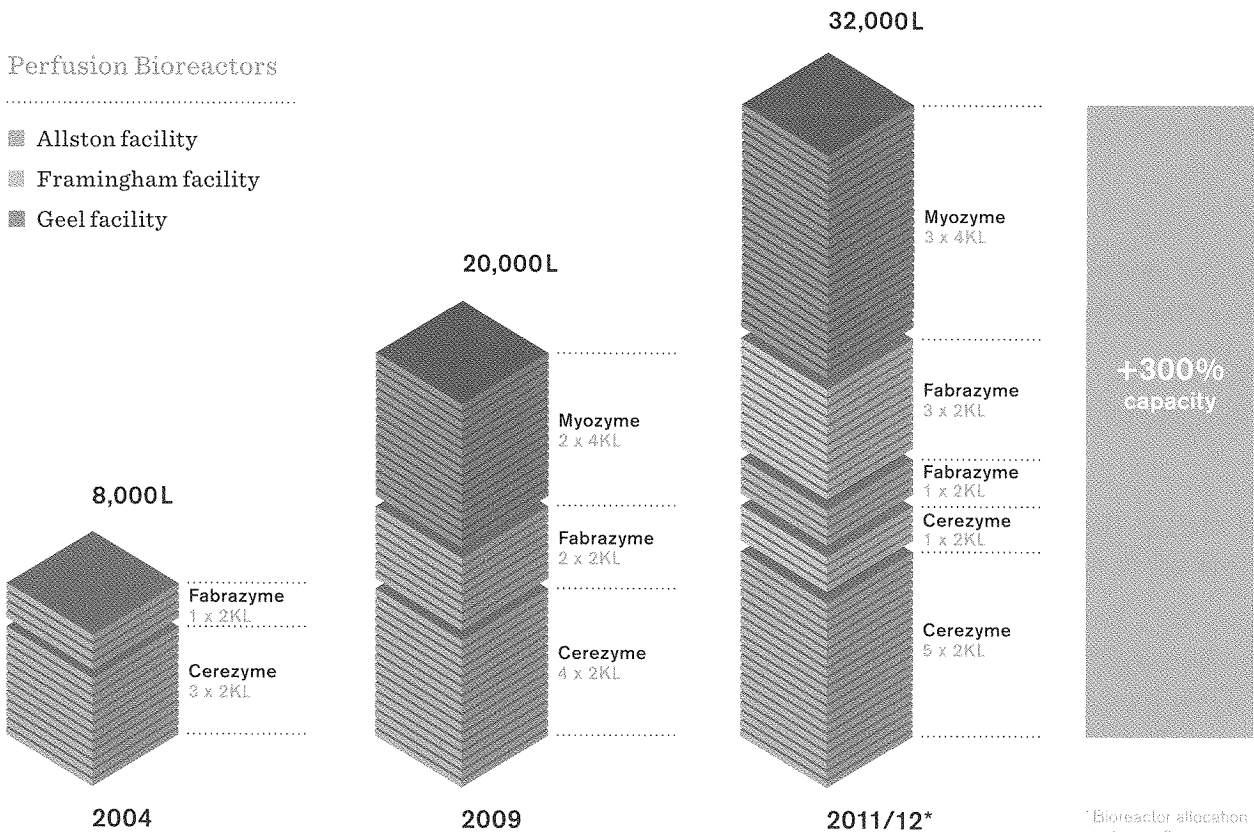
To increase capacity, we moved forward with several expansion projects including the addition of a third 4000L scale bioreactor at our Geel, Belgium, facility for the production of Myozyme; a new facility in Framingham, Mass., providing redundant capacity for Cerezyme and Fabrazyme production; and additional fill/finish capacity in Waterford, Ireland.

Increasing Manufacturing Capacity

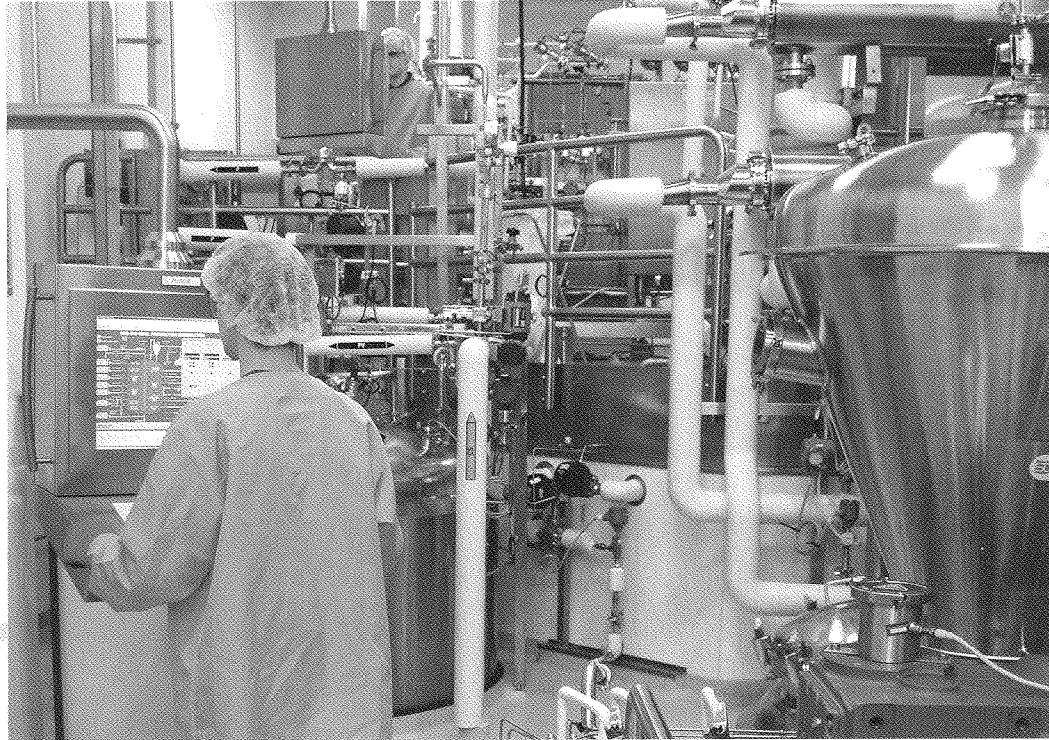
4x from 2004 to 2012

Perfusion Bioreactors

- Allston facility
- Framingham facility
- Geel facility



* Bioreactor allocation between Cerezyme and Fabrazyme subject to change.



Bioreactors in Geel, Belgium



Paula O'Donnell, Director, Bulk Manufacturing, Allston



Fill/Finish operations in Waterford, Ireland

The new 4000L reactor in Geel is expected to be online in 2011, and we anticipate approval for commercial production at the Framingham facility next year.

We are also actively evaluating additional sources of capacity to support longer-term Myozyme/Lumizyme growth, and have engaged in contracting relationships to provide additional fill/finish capacity.

To mitigate risk, the company is moving rapidly to incorporate manufacturing innovations and systems that reduce risks to products. Programs have been designed to evaluate and implement risk reduction strategies such as irradiation of serum as well as the potential elimination of serum from therapeutic protein processes.

To renew the organization, we have recruited new manufacturing and quality leaders, and relocated the senior manager who oversaw the development of our Geel plant to run the Allston facility.

Committed to patients and performance. Genzyme is making a difference for people with life-threatening, difficult-to-treat diseases. This commitment drove positive results across the majority of our businesses in 2009, validating our strategy over the past decade of building a diverse, global company.

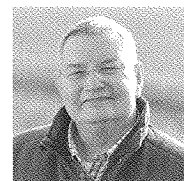
Genetic Diseases

We made substantial progress supplying Myozyme to patients, overcoming Cerezyme and Fabrazyme shortfalls and developing next-generation therapies.



Hematologic Oncology

New product launches and products acquired from Bayer defined a highly successful year.



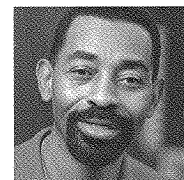
Cardiometabolic and Renal

Regulatory approvals for sevelamer products for the treatment of chronic kidney disease in Europe drove solid results.



Biosurgery

We saw the rapid market adoption of Synvisc-One, the only FDA-approved, single-injection viscosupplement for knee pain caused by osteoarthritis.



Genetics and Diagnostics

Both businesses had strong years, growing revenues while increasingly collaborating with other Genzyme businesses to advance targeted therapeutics.





Xanadu Caban

Fabrazyme patient, Sutton, Mass., USA

Xanadu is passionate about Fabry diagnosis and the education of physicians on the unique signs and symptoms that help patients through early diagnosis. She enjoys an active lifestyle and balances the thrill of raising a two-year-old daughter with maintaining a small farm with two horses.

Genzyme's **Genetic Diseases** segment continues to expand on its leadership position as a pioneer and provider of innovative solutions for genetic diseases.

MARKETED PRODUCTS

Cerezyme®

imiglucerase
enzyme

Myozyme®

alglucosidase alfa

Fabrazyme®

agalsidase braf

Aldurazyme®

hurleridase

IN THE PIPELINE

Eliglustat tartrate

oral therapy for
Gaucher disease

Neo-GAA

oral agalsidase
Fabry disease
treatment

Ataluren

oral therapy for
cystic fibrosis

Genzyme has long been a leader in the development of targeted therapies for genetic diseases. We are making substantial investments to ensure that our medicines provide the best possible outcomes for the greatest number of people worldwide.

Cerezyme, the gold-standard therapy for Gaucher disease, posted solid first-half sales in 2009 and is seeing strong demand following resumed shipments. During the year, we began pivotal trials for the oral drug eliglustat tartrate. Based on positive phase 2 data, this therapy could become a significant treatment alternative for Gaucher disease. It combines convenience with the efficacy seen in enzyme replacement therapy across all endpoints, including bone disease.

Fabrazyme, Genzyme's market-leading treatment for Fabry disease, was showing steady growth before the supply interruption. We began shipping again in January 2010 and have made changes to improve production.

We expect both Cerezyme and Fabrazyme to perform well in the face of increased competition anticipated in 2010. Fabrazyme has already demonstrated its ability to grow in a competitive marketplace, while Cerezyme's clinical and safety benefits are well-established in the patient and physician communities.

Myozyme (alglucosidase alfa), the only approved treatment for Pompe disease, grew 10 percent around the world in 2009, supported by the approval outside of the United States to produce this key therapy in the larger 4000L bioreactors at our Geel, Belgium, facility. Genzyme also resubmitted a BLA for alglucosidase alfa produced at the 4000L scale in the United States and received a June 17, 2010, PDUFA date from the FDA. To provide this lifesaving therapy to U.S. patients prior to approval, Genzyme has expanded the Alglucosidase Alfa Temporary Access Program (ATAP).

We also continue to innovate on behalf of Pompe patients and are in early-stage development of neo-GAA, a potential next-generation enzyme replacement therapy for Pompe disease.

Aldurazyme, the only approved therapy for patients with mucopolysaccharidosis I, posted strong year-over-year growth as we improve our ability to identify patients with this disease and meet their needs.

We have also advanced gene therapy in Parkinson's disease, and have begun a phase 1 trial in age-related macular degeneration (AMD). In addition, ataluren, a truly novel approach to therapy with potential in many genetic diseases, is in development for cystic fibrosis and hemophilia caused by nonsense mutation.

Genzyme's **Hematologic Oncology** segment comprises a growing portfolio of innovative therapies for the treatment of blood cancers, as well as important immune system-modifying drugs for transplant.

MARKETED PRODUCTS

Mozobil®
plerixafor
injection

Campath®/
MabCampath®
alemtuzumab

Clolar®/Evotra®
clofarabine
injection

Leukine®
sargramostim

Fludara®
fludarabine
phosphate

Thymoglobulin®
anti-thymocyte
globulin (rabbit)

IN THE PIPELINE

Mozobil
tumor
chemosensitizer

Thymoglobulin
myelodysplastic
syndromes

Clolar
acute ALL

Genzyme's Hematologic Oncology segment delivered strong growth in 2009 as it expanded its leadership positions both in blood cancers and solid organ transplant. In the treatment of hematological malignancies, we have assembled a portfolio of innovative products and services that address a continuum of care, from diagnosis to therapy and follow-up.

Mozobil, our first-in-class product for stem cell mobilization, was launched in the U.S. and EU in 2009 and has experienced rapid adoption and exceeded sales guidance in 2009. We expect Mozobil to continue to expand in front-line mobilization for stem cell transplantation driven by clinical and economic benefits to patients, physicians and transplant centers. We are also making progress on a potential new and larger indication, with multiple trials in tumor sensitization for certain blood cancers advancing in 2009.

We continued an aggressive strategy to develop Clolar, which has become the standard of care in pediatric acute lymphoblastic leukemia (ALL). Genzyme's phase 3 clinical trial evaluating Clolar in relapsed and refractory adult acute myeloid leukemia (AML) was fully enrolled ahead of schedule. We are looking at additional indications that include an oral formulation in myelodysplastic syndromes as a conditioning agent for blood stem cell transplant procedures.

In 2009, we acquired the full marketing and development rights to Campath, the first FDA-approved humanized monoclonal antibody for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). In September, Genzyme announced that a combination regimen of Campath plus Fludara met its primary endpoint in a phase 3 trial for relapsed or refractory B-CLL. If approved, it could provide physicians with an important new approach to treating this incurable disease.

We also added Fludara and Leukine during 2009, which doubled our portfolio of blood cancer therapies. The acquisition of these products significantly expanded our global reach in oncology and accelerated growth of our infrastructure to support the adoption of our key drivers, Mozobil and Clolar.

Thymoglobulin, Genzyme's therapy for the treatment of acute kidney transplant rejection and hematologic disorders, achieved strong sales growth in 2009. We are also continuing to build awareness of Thymoglobulin for aplastic anemia in markets outside the United States.

We have an active pipeline of new oncology agents, including a novel topoisomerase-1 inhibitor, which entered phase 1 clinical trials. Our product differs structurally and should provide a broader therapeutic index over the two topoisomerase-1 inhibitors currently marketed, which generate over \$1 billion in annual sales. We are also encouraged by phase 3 trial data for Leukine in melanoma.



Alasdair Mackay Mozobil patient, Edinburgh, Scotland

Doctors diagnosed Alasdair with multiple myeloma in 1998. He relapsed in 2008 and was the first patient in the U.K. to receive Mozobil. After two stem cell harvests, he received a transplant in Nov. 2008. He is now enjoying time with his family in retirement.



Carmen Müller Renvela patient, Gebesee, Germany

Carmen refuses to let kidney disease slow her down. This mother of two first began dialysis in 1992. She received a kidney transplant two years later, which failed in 2007. Back on dialysis and a Renvela patient, Carmen enjoys ninepins and choir while she waits for a new transplant.

Genzyme's **Cardiometabolic and Renal** business brings a comprehensive approach to significant disease areas that creates important scientific and commercial synergies.

MARKETED PRODUCTS

Renvela® urofollin® injection	Renage® urofollin® injection	Hectorol® urofollin® injection	Cholestagel® atorvastatin hydrochloride	Thyrogen® thyrotropin alfa injection
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IN TEST PIPELINE

Mipomersen Mipomersen injection	TSH thyrotropin injection	GC1008 GC1008 injection
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The Cardiometabolic and Renal segment achieved significant success in 2009, led by further expansion of its sevelamer franchise, growing demand for Thyrogen and the steady clinical trial advancement of mipomersen, a potentially life-changing therapy for patients with certain types of severe hypercholesterolemia.

In mid-June 2009, Genzyme received European Commission approval of Renvela for patients with chronic kidney disease (CKD), including those not on dialysis, significantly increasing the number of patients who could benefit from this therapy. Renvela is the first phosphate binder approved in Europe for patients not on dialysis, and the approval covered both the tablet and powder formulations. We are expanding the availability of Renvela country by country, with 2009 launches in Germany, Greece, the Netherlands and Portugal, and plans for the U.K., France, Spain and Italy in 2010.

Genzyme received U.S. approval for Renvela in the powder formulation in the latter half of 2009. We believe powder is an important alternative for patients who have difficulty swallowing tablets and see significant potential globally for this product.

Thyrogen is Genzyme's adjunctive therapeutic for thyroid cancer, approved for thyroid cancer remnant ablation and follow-up testing. Thyrogen continued to grow at a double-digit rate in 2009, with a similar outlook for 2010, driven by

increased use in ablation procedures. A new formulation of our recombinant TSH (thyroid stimulating hormone) continues to show potential in multinodular goiter. Genzyme presented proof-of-concept data suggesting improved radioiodine uptake in 2009 and is planning a phase 3 study in 2010.

Cholestagel, Genzyme's first marketed lipid-lowering product, met its primary endpoint in a post-marketing study in 2009. Marketing Cholestagel in Europe provides an opportunity to develop relationships with cardiovascular thought leaders, patients and provider associations that will support the launch of mipomersen, an investigational therapy for patients who have high cholesterol and do not respond adequately to standard treatments.

Together with partner Isis, Genzyme has made great progress in the development of mipomersen. We presented positive mipomersen phase 3 data in patients with homozygous familial hypercholesterolemia (hoFH) at the American Heart Association annual meeting in 2009 and saw similar results in a phase 3 trial in heterozygous familial hypercholesterolemia (heFH). We plan to file for approval of mipomersen for hoFH and, potentially, severe hypercholesterolemia, during the first half of 2011. Two phase 3 studies are ongoing in high-risk patients and those with severe hypercholesterolemia; we expect data in mid-2010.

Genzyme's Biosurgery segment focuses on highly innovative, life-changing therapies and technologies.

MARKETED PRODUCTS

Synvisc®,
Synvisc-One®
hyaluronic acid

Carticel®
arthroplasty and
osteonecrosis

Seprafilm®
adhesions

Epicel®
arthroplasty
autograft

Jonexa™
arthroplasty

MACI®
arthroplasty and
osteonecrosis

IN THE PIPELINE

DMOAD
osteoarthritis disease
modifier

Sepraspray®
arthroplasty
adhesions

MACI
arthroplasty
osteonecrosis

The Biosurgery business achieved solid growth in 2009, led by Synvisc-One, the only single-injection viscosupplement available for osteoarthritis (OA) knee pain in the United States. Following FDA approval in February 2009, a successful U.S. launch drove rapid adoption and growth that exceeded expectations. Less than a year after its introduction, Synvisc-One represents more than half of Synvisc products' total U.S. sales and leads the category in market share.

In addition to strengthening the company's competitive position, Synvisc-One has the potential to expand the viscosupplement market for treatment of OA knee pain. As a single-injection product, Synvisc-One provides patient convenience, and with fewer injections, could lead to increased compliance and reduction of injection-related adverse events.

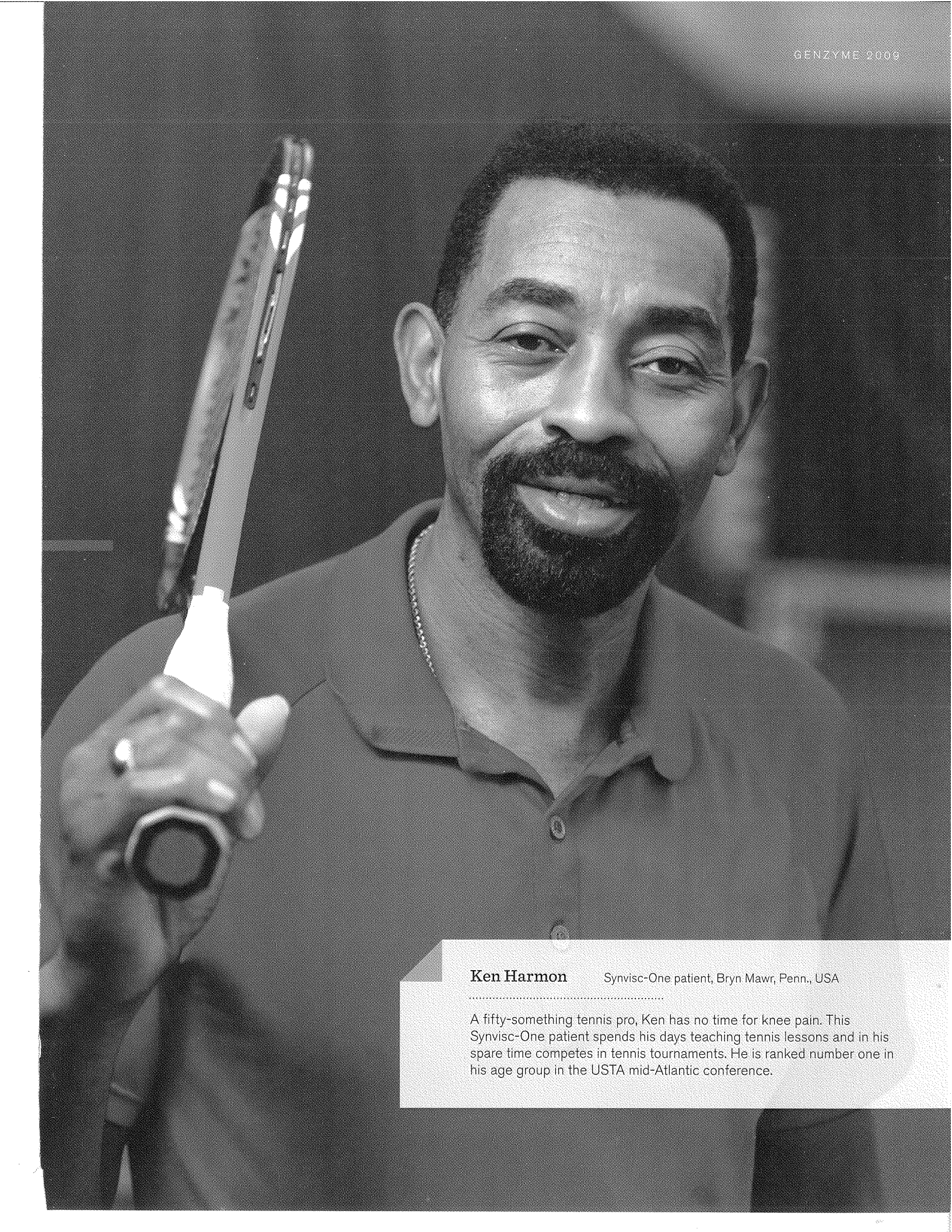
We continued our efforts to build support for viscosupplements, and the Genzyme franchise outside of the United States. Synvisc-One is performing well in France and the United Kingdom, where reimbursement is available, as well as in Canada, Mexico and Germany which are self-pay markets. Synvisc-One is also off to a strong start in India after its launch there in 2009.

Expansion plans include a potential role for Synvisc-One as an element of disease management models in chronic conditions such as diabetes, cardiovascular diseases and obesity. We are also initiating a clinical study to test the potential of Synvisc products to modify the rate of cartilage loss.

Jonexa (hylastan) is an effective, high-quality product that addresses patient need in market segments where patients, for financial reasons, may not have had access to a single-injection viscosupplement. Launched in the first half of 2010 outside the United States, Jonexa will provide a quality alternative for patients in Italy, Turkey, Poland and Hong Kong, widening access worldwide to viscosupplement treatment for osteoarthritis knee pain.

The Sepra line of anti-adhesion products for abdominal and pelvic surgery continued to grow at a double-digit rate in 2009. Expansion opportunities include Seprafilm in gynecologic procedures and development of Sepraspray for laparoscopic procedures.

Carticel and MACI are cell-based treatments for the repair of articular cartilage injuries in the knee. In 2009, we enrolled patients in a clinical trial for MACI. This trial is intended to meet new European regulations, and the data generated could form the basis for global registration.



Ken Harmon

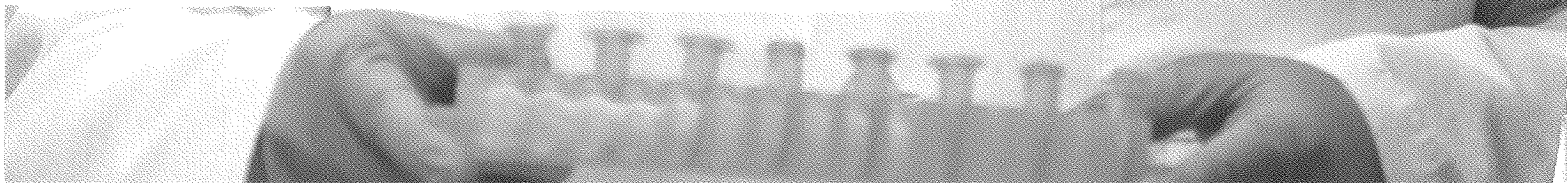
Synvisc-One patient, Bryn Mawr, Penn., USA

.....
A fifty-something tennis pro, Ken has no time for knee pain. This Synvisc-One patient spends his days teaching tennis lessons and in his spare time competes in tennis tournaments. He is ranked number one in his age group in the USTA mid-Atlantic conference.



Velda Pomales Sr. Quality Control Analyst, Framingham, Mass., USA

Velda is part of the Quality Control team at Genzyme that performs analyses on our Clinical Chemistry platforms for multiple test methods, including HDL/LDL cholesterol reagents. Genzyme is a global leader in HDL/LDL diagnostic testing, with approximately 68 percent of the market.



Our Genetics and Diagnostics businesses support a number of key therapeutic areas and are playing an increasingly important role in personalized medicine.

MARKETED PRODUCTS

Reproductive testing

Oncology testing

Rapid tests

Clinical chemistry reagents

IN THE PIPELINE

KIM-1

kidney injury marker

HbA1c

diabetes

FISH

diagnostic testing

Pro. beta.2a.

comparative genomic hybridization (aCGH)

Genzyme Genetics is focused on the development and marketing of highly complex and specialized tests that allow patients and physicians to make important healthcare decisions. With its highly valued and growing reproductive and oncology test menus, more than 600 managed care contracts, and the largest genetic counselor network in the U.S., Genetics saw increasing sales in 2009.

In its reproductive business, Genetics launched a postnatal array comparative genomic hybridization (aCGH) test in 2009, providing more precise technology for identifying abnormalities in infants. Planning is underway to offer a prenatal array CGH test. With the acquisition of intellectual property from EXACT Sciences in early 2009, Genzyme is currently working on development of the next generation of noninvasive prenatal tests. We also launched an award-winning Web site called mytestingoptions.com that includes video presentations from counselors to support patient education.

In oncology, we introduced a digital technology offering called iScope™, which creates a digital slide of patient tissue samples for diagnosis of cancers anywhere in the world. Genetics also received CAP15189™ ISO accreditation for quality in its Phoenix, Ariz., laboratory.

Genzyme's Diagnostics business, with a unique and growing portfolio of products in important disease areas, also had strong sales performance. This growth was driven by product demand and expanded relationships with clinical laboratories and diagnostic manufacturers worldwide for point-of-care rapid tests, formulated reagents and raw materials.

We also expanded our companion diagnostics/personalized medicine program. Utilizing our core research strengths, Diagnostics has begun to develop a position in personalized medicine by advancing companion diagnostics for Genzyme-specific and non-company therapeutics.

Diagnostics is supporting growth in the company's businesses through product development tailored to their specific disease areas. We are making progress with novel biomarkers and companion diagnostics in MS, transplant, chronic kidney disease, acute kidney injury, Fabry disease and Genzyme Genetics.

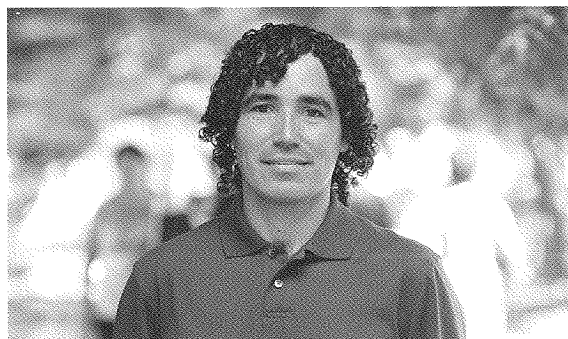
Pursuing the next therapeutic breakthroughs. Our commitment to patients and performance remains strong. Throughout 2009, we continued our investments to advance important, potentially breakthrough treatments in the pipeline, including several in late-stage development.



Promising multiple sclerosis treatment moving forward

We completed phase 3 enrollment ahead of schedule and published four-year data that continue to show durable treatment benefit.

*Janna Wright, Pleasant Hill, Calif., USA
Alemtuzumab in MS patient*



Potential oral Gaucher treatment

Eliglustat tartrate, our oral candidate for Gaucher disease, could become a significant treatment alternative.

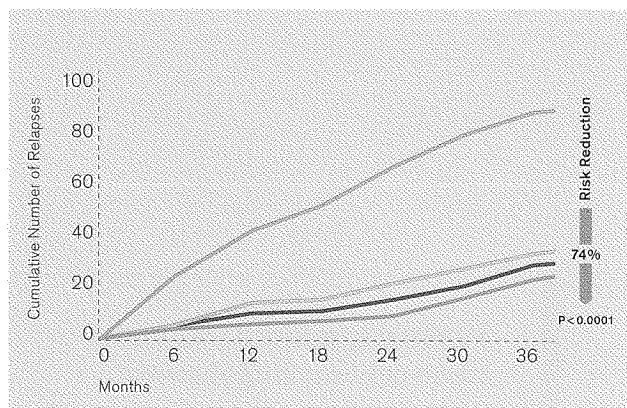
*Pablo Villar, Buenos Aires, Argentina
Eliglustat tartrate patient*



Advancing promising therapy for severe hypercholesterolemia

Two phase 3 trials of mipomersen met their primary endpoints, supporting the promise of this therapeutic option.

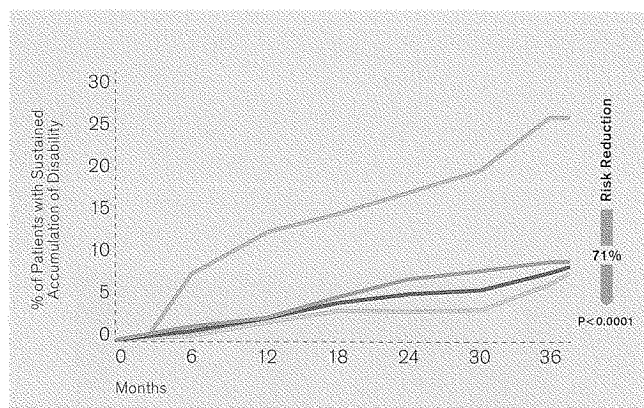
*Thomas Lipp, Munich, Germany
familial hypercholesterolemia patient*



Alemtuzumab vs. Interferon Beta-1a in Early Multiple Sclerosis
Reduced Risk of Relapse

IFNB-1A SC Alemtuzumab 12mg/day Alemtuzumab 24mg/day Alemtuzumab Pooled

N Engl J Med 2008;359:1786. Original Article.



Alemtuzumab vs. Interferon Beta-1a in Early Multiple Sclerosis
Reduced Risk of Acquiring Fixed Disability

IFNB-1A SC Alemtuzumab 12mg/day Alemtuzumab 24mg/day Alemtuzumab Pooled

N Engl J Med 2008;359:1786. Original Article.

A truly novel treatment for multiple sclerosis

Genzyme made excellent progress in advancing alemtuzumab in multiple sclerosis, with enrollment of its two pivotal phase 3 trials completed ahead of schedule and data expected next year.

Long-term follow-up data from our phase 2 study continue to show durable treatment benefit. Alemtuzumab's dosing and mechanism of action differs fundamentally from current MS treatments. Existing therapies require up to daily injections and, in some cases, chronically suppress the immune system. Administered in once-yearly infusions, alemtuzumab appears to eliminate the cells attacking the central nervous system, while allowing the immune system to reconstitute. In addition, neurotropic benefits were observed in our phase 2 study, with some recovery of neurological function.

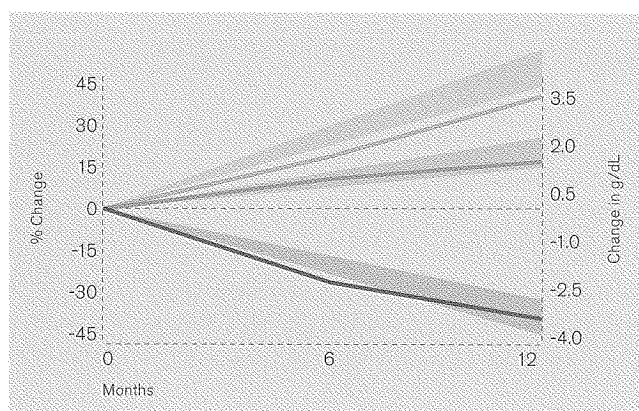
Genzyme researchers are also developing a second-generation molecule targeting safety and efficacy.

Potential next-generation Gaucher therapy

In 2009, Genzyme announced that its phase 2 clinical trial of eliglustat tartrate, our oral Gaucher therapy in development, met its primary endpoint and presented results that suggest it could become a significant treatment alternative for patients with this disease. Data showed strong effects on the blood system and organs, which could indicate a meaningful alternative to enzyme replacement infusions. The trial data also suggested early and robust positive impact on bone disease.

Enrollment is proceeding in two global, multi-center phase 3 trials. The first is a study for adult patients with Gaucher disease type 1 designed to compare eliglustat tartrate with Cerezyme. The second trial is a study of confirmed Gaucher patients who have been untreated for nine months or more.

An oral drug with comparable efficacy and improved effect on bone disease could be a competitive advantage. Even more important, an oral Gaucher therapy would dramatically enhance Genzyme's ability to meet the needs of more patients in large, developing markets where the lack of healthcare systems makes it difficult to deliver a protein therapy.

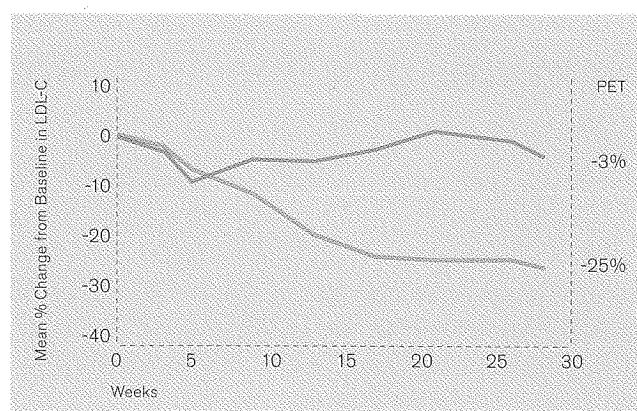


Eliglustat Tartrate

Phase 2 Data Comparable to Range of Observed CZ Outcomes

••• Platelets ••• Hemoglobin ••• Spleen Cerezyme Range

2008 Registry Data: Grabowski et al. (1995)



Placebo vs. Mipomersen in Phase 3 hoFH Study
Mipomersen Significantly Reduced LDL-C Levels

••• Placebo ••• Mipomersen

PET, primary efficacy time point, 2 weeks after final dose

The Lancet, Volume 375, Issue 9719, Pages 998-1006, 20 March 2010

Addressing unmet need in severe hypercholesterolemia

Mipomersen, being developed in collaboration with Isis Pharmaceuticals, is a potential first-in-class inhibitor of the body's ability to synthesize apoB, the carrier of bad cholesterol (LDL). Mipomersen is the only drug candidate currently targeting apoB in high-risk hypercholesterolemia trials.

Our first phase 3 trial met its primary endpoint in homozygous familial hypercholesterolemia (hoFH). In this study, a 25 percent average reduction in LDL levels was observed, which could represent a profound impact in this difficult-to-treat patient population.

The second phase 3 trial is examining heterozygous familial hypercholesterolemia (heFH), a larger patient population. We reported positive phase 3 data for heFH in the first quarter of 2010; we expect data from two additional late-stage studies of mipomersen in mid-2010. Genzyme anticipates filing for marketing approval of mipomersen to treat hoFH and potentially severe hypercholesterolemia in the first half of 2011.

First-in-class potential in genetic diseases

In 2009, Genzyme advanced its collaboration with PTC Therapeutics to develop ataluren, a novel approach focused on the treatment of genetic diseases associated with so-called nonsense mutations. Ataluren allows for normal protein development by reading over specific errors in genetic code. We launched a pivotal trial in nonsense mutation cystic fibrosis in 2009, with data expected in the second half of 2012; a phase 2a study in hemophilia is currently underway. Nonsense mutations cause disease in 5 to 15 percent of patients in many genetic diseases.

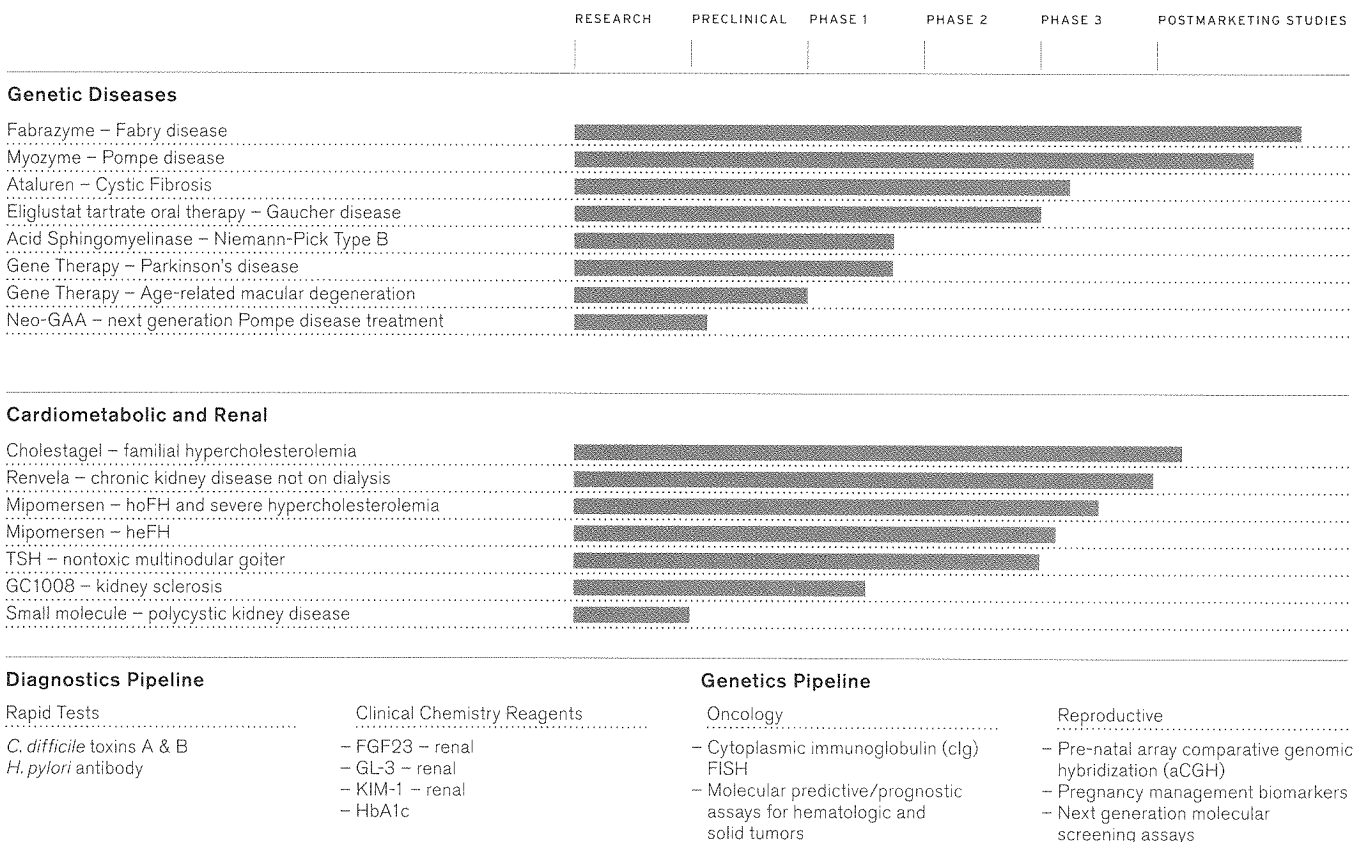
Other late-stage programs

There are many promising programs in Genzyme's late-stage research pipeline. Among the new indications of successfully marketed Genzyme products currently being explored are Clolar for adult acute myeloid leukemia and Leukine for melanoma. We are also exploring additional indications for marketed products such as Thymoglobulin and Thyrogen.

Genzyme pipeline: Long-term promise.

Genzyme is committed to the discovery and development of therapies with strong patient value, including many in early- and mid-stage development that could drive growth a decade or more from now. For instance, early clinical data from a phase 1/2 trial suggest that Mozobil in combination with chemotherapy may have a therapeutic impact on leukemic cells protected in the bone marrow.

Even as Myozyme is in early commercialization, we are developing neo-GAA, potentially the next-generation enzyme replacement therapy for Pompe disease. In the gene therapy area, a phase 1 clinical trial is now underway for neovascular age-related macular degeneration. Unlike current treatments, which require monthly injections to inhibit VEG-F (a protein associated with blood vessel production), the Genzyme gene therapy approach would inhibit production of VEG-F in the eye over extended periods following a single injection.



We are rapidly advancing our phase 2 trial of oral Clolar for myelodysplastic syndromes. Genzyme researchers also began a phase 1 trial of Topo-1, a novel topoisomerase inhibitor for treatment of solid tumors.

GC1008 is a fully humanized monoclonal antibody that suppresses TGF-beta, an enzyme implicated in a number of serious diseases. To date, we have completed three phase 1 trials: kidney sclerosis, idiopathic fibrosis and malignant melanoma. We initiated a phase 2 trial in kidney sclerosis in 2009.



Sustainable care, supporting our communities.
We are dedicated to providing our medicines to those who need them, regardless of ability to pay; we are passionate about supporting the communities in which we live and work, while minimizing our impact on the environment.

Charitable drug programs

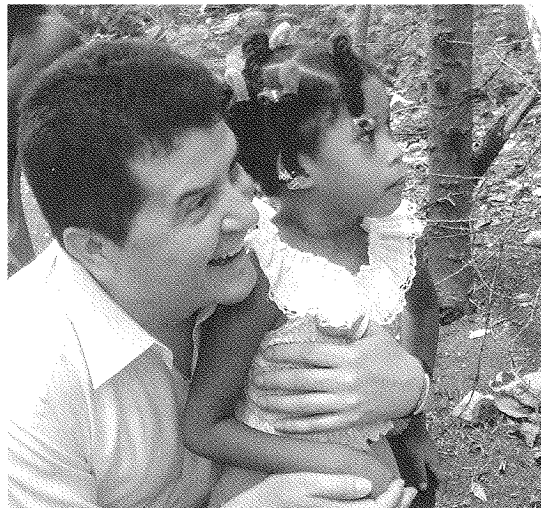
Since 1999, the Gaucher Initiative, our partnership with the humanitarian organization Project HOPE, has provided free access to Cerezyme for patients with Gaucher disease around the world. During the Cerezyme and Fabrazyme supply interruption in 2009, we also sought to protect the most vulnerable patients by providing newly produced product to those in greatest need regardless of their ability to pay. We have established similar programs across the globe for our genetic disease therapies and other products, particularly cancer and kidney disease therapies. Since 2007, Genzyme has also ensured that severely affected adults with Pompe disease in the United States have access to treatment prior to commercial approval of the drug.

In 2006, Genzyme founded the Humanitarian Assistance for Neglected Diseases (HAND) initiative to participate in the development of new therapies for diseases that represent important unmet needs with little commercial potential. Since that time, we have partnered with numerous governments and other organizations to focus on novel solutions for Chagas disease and malaria. Through our partnership with Medicines for Malaria Venture and the Broad Institute, new, potential anti-malaria compounds have been identified.

Committed to our community and our world

In the current environment of economic challenge, Genzyme programs to support the communities where we live and work are more important than ever. For a number of years, Genzyme has been included in the Dow Jones Sustainability World Index for economic, environmental and social performance, recognizing our programs to support health and science education, responsible environmental practices and contributions to local community organizations and employee volunteerism.

Genzyme develops and funds innovative science education programs that serve students, teachers, schools and community groups worldwide. We also fund community-based, nonprofit organizations dedicated to health-related issues, from food banks to cancer patient support programs. Genzyme employees volunteer time and talent to a wide variety of important causes, expressing through action a very personal commitment to our communities. Our commitment to the environment is reflected by the number of Genzyme facilities (4) that have received U.S. Green Building Council LEED® certification, recognizing green architectural design over the past six years. Beyond goals to reduce corporate carbon emission, the company guides each employee on how to continuously improve the company's environmental performance.



Large photo: Malaria remains one of the world's most devastating diseases. It is responsible for over a million deaths annually, primarily children under the age of five. Africa and Southeast Asia share 95 percent of all cases. Through a public-private partnership, Genzyme is making progress against this neglected disease. Researchers are identifying novel candidates that are active against the most frequently encountered malaria parasites.

Inset photo: 5-year-old Carolyne de la Cruz was diagnosed with Gaucher disease type 1 in 2006. She is the only known Gaucher patient in the Dominican Republic. Jhon Cuervo (pictured with Carolyne), Genzyme General Manager for Venezuela, Central America and the Caribbean, has ensured through the Gaucher Initiative that Carolyne is provided Cerezyme at no charge until a long-term solution can be found.

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*Corporate Controller;
 Chief Accounting Officer*

John P. Butler
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Scott Canute
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Zoltan Csimma
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Sandford D. Smith
Executive Vice President

Gail F. Sullivan
Treasurer

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*Executive Vice President,
 Secretary*

Michael S. Wyzga
*Executive Vice President,
 Chief Financial Officer*

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 H. Lee Moffitt Cancer and Research
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 Committees: Nominating/Governance
 (Chair) and Audit*

Richard F. Syron, Ph.D.*
*Adjunct Professor of Finance,
 Boston College
 Committees: Audit and
 Nominating/Governance*

*Independent Directors

STOCK MARKET INFORMATION

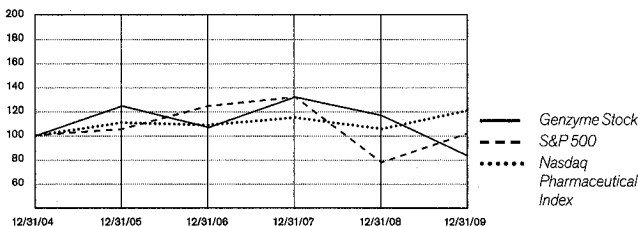
Our common stock, which we refer to as Genzyme Stock, is traded on The Nasdaq Stock Market, Inc. ("NASDAQ®") system under the symbol "GENZ". As of February 17, 2010, there were 3,169 stockholders of record of Genzyme Stock. The following table sets forth, for the periods indicated, the high and low sale price of Genzyme Stock as reported by NASDAQ.

	2009		2008	
	HIGH	LOW	HIGH	LOW
GENZYME STOCK				
First Quarter	\$73.75	\$50.05	\$ 82.08	\$67.38
Second Quarter	63.47	50.83	76.76	65.21
Third Quarter	58.43	47.09	83.97	67.00
Fourth Quarter	57.27	47.55	81.16	57.61

We have never paid any cash dividends on any series of our common stock, and we do not anticipate paying cash dividends in the foreseeable future.

GENZYME STOCK PERFORMANCE

The graph below compares the five-year cumulative total shareholder returns for our common stock to that of the S&P 500 Composite Index and the NASDAQ® Pharmaceutical Index. The cumulative returns are based on a \$100 investment on January 1, 2004, with all dividends being reinvested. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock. Information used in the graph was obtained from Standard and Poor's and the Nasdaq Global Select Stock Market®, sources we believe to be reliable, but we are not responsible for errors or omissions in such information.



SHAREHOLDER INFORMATION

Corporate Headquarters
Genzyme Corporation
500 Kendall Street
Cambridge, Massachusetts 02142

Registrar and Transfer Agent
American Stock Transfer and
Trust Company, Inc.
59 Maiden Lane
New York, New York 10038
(212) 936-5100

The Transfer Agent is responsible for handling shareholder questions regarding lost stock certificates, address changes, and changes of ownership or name in which shares are held.

Independent Accountants
PricewaterhouseCoopers LLP
Boston, Massachusetts

SEC Form 10-K

A copy of Genzyme Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission is available free of charge upon request to:

Corporate Communications,
Genzyme Corporation,
500 Kendall Street, Cambridge,
Massachusetts 02142.

FOR MORE INFORMATION

Genzyme's Investor
Information Line
1-800-905-4369 (North America)
(703) 797-1866 (elsewhere)
The information line provides
recorded messages and a fax-on-
demand feature for news releases.

Genzyme on the Internet
<http://www.genzyme.com>
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This report is printed on paper certified by Green E and manufactured with non-polluting wind energy. Mohawk 50/10 contains 15% Post Consumer Waste and is FSC-certified.

This report contains forward-looking statements regarding our business plans and strategies, including, without limitation, our: plans and estimated timetables to increase bulk and fill/finish manufacturing capacity for our enzyme replacement therapies; plans reducing potential manufacturing risks; expectations for performance of Fabrazyme and Cerezyme and Fabrazyme supply; plans and estimated timetables for receipt of regulatory decisions and launching of existing products for use in new indications, territories or formulations, including Mozobil, Renvela, Synvisc-One, and the Septra line of products, and assessment of the market potential of such therapies; and plans and estimated timetables for new and next-generation clinical trials, filings, regulatory decisions and launches, including alemtuzumab for MS, eliglustat tartrate, mipomersen, and statuloren, and assessment of the market potential for such therapies. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those forecasted. These risks and uncertainties include, among others, that: production of Fabrazyme and Cerezyme does not continue as planned due to any reason, including bacterial or viral contamination, mechanical failures, cell growth at lower than expected levels, fill/finish issues or regulatory issues; we are unable to obtain and maintain regulatory approvals for our products and manufacturing facilities; we or our collaboration partners are not able to successfully complete clinical development and obtain regulatory approvals of our product candidates within the anticipated timeframes and for anticipated indications; we are unable to expand the use of current products or successfully develop next generation ones; we are unable to manufacture products and product candidates in a timely and cost effective manner and in sufficient quantities to meet demand; we are unable to effectively compete against alternative treatments and maintain or grow market share for our products; reimbursement for our products is unavailable or available at lower levels than anticipated; we are unable to maintain and enforce our intellectual property rights or secure necessary intellectual property rights from third parties; and the risks and uncertainties described in our reports filed with the SEC under the Securities Exchange Act of 1934, including the factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2009. We caution investors not to place substantial reliance on the forward-looking statements contained in this report. These statements speak only as of March 22, 2010, and we undertake no obligation to update or revise the statements. Reconciliation of any non-GAAP number can be found under the Investors section of our website at www.genzyme.com.

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genzyme

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