



**For Immediate Release**

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Media Contact:

Erin Emlock  
(617) 768-6923

Investor Contact:

Patrick Flanigan  
(617) 768-6563

**Genzyme Reports Financial Results for the First Quarter of 2010**

**Provides Update on Product Supply and Consent Decree Terms**

CAMBRIDGE, Mass. – Genzyme Corp. (NASDAQ: GENZ) today reported that first-quarter revenue was \$1.07 billion, compared with \$1.15 billion in the same period last year, reflecting limited shipments of Cerezyme® (imiglucerase for injection) and Fabrazyme® (agalsidase beta) due to product supply constraints.

GAAP net loss was \$114.9 million, or \$0.43 per diluted share, compared with net income of \$195.5 million, or \$0.70 per diluted share, in the first quarter of 2009. GAAP results reflect the impact of the anticipated \$175 million expense associated with the consent decree for the company's Allston manufacturing facility.

Non-GAAP net income was \$99.3 million, or \$0.37 per diluted share, compared with \$227.5 million, or \$0.82 per diluted share, in the same period last year. Non-GAAP net income excludes stock compensation expenses, costs associated with the acquisition of Bayer oncology products and the expense associated with the consent decree.

Genzyme continues to make progress in strengthening the corporation to build shareholder value. The company recently created the position of chief operating officer to establish a sharper focus on commercial execution and appointed Executive Vice President David Meeker to this role; elected Ralph Whitworth, principal and co-founder of Relational Investors LLC, to the company's board of directors to add fresh perspective; launched a search for an additional board member with manufacturing expertise; created new board committees on capital allocation and risk management; advanced manufacturing capacity expansion projects; and reported the publication and presentation of clinical trial data validating the potential of the company's major late-stage development programs.

"As we work to resume sustainable growth, we are focusing on transforming our manufacturing operations, maximizing the potential of our diverse product portfolio, and advancing key pipeline programs, while tightly managing expenses across the corporation," said Henri A. Termeer, Genzyme's chairman and chief executive officer.

**Consent Decree**

Genzyme received a draft consent decree from the FDA regarding its Allston manufacturing plant. The draft provides for an up-front disgorgement of past profits of \$175 million. Because this is a likely outcome, Genzyme booked this expense in the first quarter. In addition, if the Allston fill/finish facility is still operating after deadlines for domestic and exported products, the draft provides for disgorgement of 18.5 percent of revenues from sales of products manufactured and distributed from Allston after those deadlines. Genzyme and the FDA are having discussions regarding appropriate deadlines for moving fill/finish operations, as well as

the details of the disgorgement provisions. Finally, if fill/finish operations are moved from Allston but certain remediation actions relating to overall cGMP compliance are not met by deadlines over the coming years in a remediation plan to be approved by the FDA, the draft provides for a payment of \$15,000 per day per violation until the compliance milestones are met. Genzyme is actively negotiating with the FDA the terms of the consent decree and expects that the negotiations will be completed during the second quarter. After finalization of the consent decree, Genzyme will provide an update, including revised 2010 financial guidance.

## **Product Supply Update**

### Cerezyme

Genzyme achieved its goal of building a small inventory buffer during the first quarter. The current shipping allocation of 50 percent of demand will be extended, however, due to an interruption in operations at the company's Allston facility late in the quarter. The interruption resulted from an unexpected city electrical power failure that compounded issues with the plant's water system, which have been corrected. The facility is fully operational.

Genzyme estimates that it will need to continue the 50 percent shipping allocation for 2-3 months. The company will provide a more precise supply update within a month, after determining whether Cerezyme material that was unfinished when the interruption occurred can be finished, the impact of the pending consent decree on product release timelines and a more accurate assessment of global demand.

### Fabrazyme

Genzyme has made progress in increasing the productivity of the Fabrazyme manufacturing process. The first run of a new working cell bank (WCB) resulted in a 30 percent increase in productivity, and a second run is underway. Genzyme's goal is to increase productivity an additional 30 percent.

Genzyme estimates that it will need to continue the 30 percent shipping allocation through the third quarter. The company will provide a more precise update within a month once additional information is available about the productivity of the new WCB, as well as the timing of regulatory clearance of the new WCB, the impact of the pending consent decree on product release timelines and whether Genzyme is able to finish the small amount of work-in-process Fabrazyme material that was unfinished when the interruption occurred at the Allston plant.

Genzyme will continue to work with minimal levels of inventory for Cerezyme and Fabrazyme until the company's new Framingham manufacturing facility is approved, which is anticipated to take place in late 2011, and any additional manufacturing delays will likely impact supply of these products.

Across the company's manufacturing operations, programs to expand capacity are on-track. The new Framingham plant is mechanically complete. Pre-operational activities, including cell culture, media preparation, bioreactor validation and staff training, are currently taking place. Engineering and process validation runs are planned for this year. At its Geel, Belgium facility, Genzyme is adding a third bioreactor for the production of Myozyme, and approval is anticipated in mid-2011. The company is also working to transition fill/finish operations out of its Allston facility to its Waterford, Ireland plant and to a contract manufacturer.

## First Quarter Results and Business Updates

### Personalized Genetic Health

Within the Personalized Genetic Health segment (previously called Genetic Diseases) first-quarter sales of Myozyme<sup>®</sup> (alglucosidase alfa) increased 28 percent to \$86.1 million from \$67.4 million in the same period in 2009. First-quarter revenue was down from fourth-quarter 2009 sales, reflecting an \$8 million shipment that was delayed for a release hold at the end of the first quarter. It was subsequently shipped early in the second quarter.

New patients continued to begin treatment with Myozyme during the first quarter. Expansion is ongoing worldwide, and Genzyme plans new regulatory filings in more than 15 countries during 2010. Positive results from the Late-Onset Treatment Study of Myozyme were published last week in the *New England Journal of Medicine*. The trial was conducted to evaluate the safety and efficacy of the treatment in older children and adults with Pompe disease.

A June 17 PDUFA date has been set by the FDA for the marketing application of Lumizyme<sup>™</sup> (alglucosidase alfa) produced at the 4000L scale. Genzyme in December reopened enrollment in the Alglucosidase Alfa Temporary Access Program (ATAP), a U.S. program which provides access to treatment for severely affected adults with Pompe disease prior to commercial approval of Lumizyme. The ATAP program will remain active until commercial approval of Lumizyme. Genzyme is currently providing therapy free of charge to more than 200 patients in the United States.

First-quarter sales of Cerezyme were \$179.1 million compared with \$296.0 million in the first quarter of last year. Cerezyme revenue increased 70 percent from \$105.4 million in the fourth quarter of 2009, reflecting the resumption of product shipments to patients in approximately 100 countries. Sales of Fabrazyme in the first quarter were \$53.2 million, compared with \$122.2 million in the same period last year.

Genzyme's Personalized Genetic Health segment now includes the company's cardiovascular business, enabling this business to build upon its expertise in registry development, reimbursement and patient advocacy. The cardiovascular business includes the mipomersen development program, Cholestagel<sup>®</sup> (colesevelam hydrochloride), and product sales and royalties from Welchol<sup>®</sup> (colesevelam hydrochloride). Genzyme markets Cholestagel in Europe for the treatment of patients with the genetic disease familial hypercholesterolemia (FH), and for statin-intolerant patients. Mipomersen is being developed initially for FH patients with severe hypercholesterolemia.

### Biosurgery

Within the Biosurgery segment, sales of Synvisc<sup>®</sup> (hylan G-F 20) increased 26 percent to \$79.5 million from \$63.2 million in the first quarter of 2009. This growth was driven by Synvisc-One<sup>®</sup> (hylan G-F 20), which was launched in the United States in March 2009 and is the only single-injection viscosupplement approved for the treatment of osteoarthritis knee pain. First-quarter 2010 sales were down from \$95.4 million in the fourth quarter of 2009, reflecting the annual seasonality trend in the viscosupplement market, in which sales typically decline in the first quarter, and peak during the second quarter.

Sales of Sepra<sup>®</sup> products grew 8 percent to \$37.2 million, from \$34.3 million in the same period last year, with growth driven by increasing use of the Seprafilm<sup>®</sup> adhesion barrier in C-section and other gynecologic procedures.

### Renal and Endocrinology

Within this segment, sales of Genzyme's sevelamer therapies, Renvela<sup>®</sup> (sevelamer carbonate) and Renagel<sup>®</sup> (sevelamer hydrochloride), were \$164.6 million, compared with \$170.6 million during the first quarter of 2009. While sevelamer volume grew by 4 percent year over year, Renagel pricing in Brazil and conversion to Renvela in the United States resulted in a decrease in revenue. Genzyme last year lowered the price of Renagel in Brazil to compete with generics marketed in that country. Genzyme had raised the price of Renagel in the United States last year to encourage conversion to Renvela, and revenue reflects the increasing percentage of Renvela sales within total U.S. sevelamer revenue. The U.S. market share for sevelamer grew during the first quarter and is currently 51 percent.

The ongoing launch of Renvela in Europe continues to progress well, with launches in the key markets of France, Spain, Italy and the U.K. planned in the coming months. The U.S. launch of the powder formulation of Renvela is also exceeding expectations.

Sales of Thyrogen<sup>®</sup> (thyrotropin alfa for injection) increased 18 percent to \$45.6 million from \$38.8 million in the first quarter of 2009, driven by increased utilization of the treatment in thyroid remnant ablation procedures.

### Hematology and Oncology

Within this segment, revenue from Mozobil<sup>®</sup> (plerixafor injection) grew 75 percent to \$18.9 million from \$10.8 million in the first quarter last year. Mozobil was launched in the United States in January 2009 and in Europe in August 2009, and additional worldwide launches are ongoing. First-quarter growth in this segment was also driven by sales of Clolar<sup>®</sup> (clofarabine injection), which increased 36 percent to \$24.7 million from \$18.2 million in the same period a year ago, with significant volume growth seen in all major markets.

Sales of Thymoglobulin<sup>®</sup> (anti-thymocyte globulin, rabbit), which is now being included in this segment, were \$52.9 million, compared with \$50.7 million in the first quarter of 2009, due primarily to increased sales in Asia.

Results from several clinical trials have been submitted for presentation at the June American Society of Clinical Oncology meeting, including results of a phase 3 trial of Leukine<sup>®</sup> (sargramostim) in melanoma, Leukine data in prostate cancer, and Clolar data in myelodysplastic syndromes, non-Hodgkins lymphoma, and acute myeloid leukemia.

### Other Revenue

Other revenue – which now includes the company's Genetics, Diagnostics, and Pharmaceuticals businesses – was \$135.9 million in the first quarter of 2010.

### **Operating Expenses**

Genzyme's GAAP SG&A was \$553.3 million, including the \$175 million consent decree expense, compared with \$317.9 million in the first quarter of 2009. Non-GAAP SG&A was

\$352.8 million compared with \$294.1 million in the same period last year. The increase was lower than anticipated, reflecting strong expense controls across the company. The company's GAAP R&D was \$220.9 million compared with \$206.9 million in last year's first quarter; non-GAAP R&D was \$206.5 million compared with \$193.4 million in the first quarter of 2009. Last year's R&D included \$18 million of expense associated with the Exact Sciences transaction. Amortization expense was \$71 million compared with \$57.6 million in the same period last year, due primarily to the Bayer transaction.

### **Late-Stage R&D Programs**

Genzyme made excellent progress during the first quarter across its late-stage pipeline:

- Four-year follow-up data from Genzyme's completed phase 2 trial of alemtuzumab in multiple sclerosis patients were presented at last week's American Academy of Neurology meeting. Results of the four-year review found that an estimated 71 percent of alemtuzumab-treated patients remain free of clinically active disease as much as three years after most patients received their last course of the investigational therapy. Two phase 3 studies are ongoing, and results are expected next year.
- Enrollment is underway in two global, multi-center, phase 3 trials of eliglustat tartrate, Genzyme's investigational oral therapy for patients with Gaucher disease type 1. There are currently a total of 30 active sites for these trials, with additional sites preparing to begin enrollment. Results of the phase 2 trial of eliglustat tartrate are expected to be published in the journal *Blood* next month. This therapy has the potential to transform the treatment experience for patients by providing a daily oral capsule option instead of bi-weekly infusions lasting several hours or more.
- Genzyme and Isis Pharmaceuticals Inc. in February reported positive results from the second phase 3 study of mipomersen, in patients with heterozygous familial hypercholesterolemia (FH). Phase 3 data in patients with homozygous FH were published last month in *The Lancet*. The companies expect data from two additional phase 3 studies in mid-2010; one involves patients with severe hypercholesterolemia and the other includes hypercholesterolemic patients at high risk for coronary heart disease.

### **About Genzyme**

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 12,000 employees in locations spanning the globe and 2009 revenues of \$4.5 billion.

With many established products and services helping patients in approximately 100 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune disease, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need.

Genzyme's press releases and other company information are available at [www.genzyme.com](http://www.genzyme.com) and by calling Genzyme's investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

### **Important Information**

Genzyme, its directors, and the other individuals identified in its preliminary proxy statement filed with the SEC on April 16, 2010, may be deemed to be participants in the solicitation of proxies from Genzyme's shareholders in connection with the company's 2010 annual meeting of shareholders. Information about the directors and other individuals and their interests can be found in the preliminary proxy statement, a copy of which is available at the SEC's web site at [www.sec.gov](http://www.sec.gov).

Genzyme shareholders are advised to read carefully the company's definitive proxy statement relating to the company's 2010 annual meeting of shareholders and any other relevant documents filed by the company with the SEC, when they become available, before making any voting or investment decision, because they will contain important information. The definitive proxy statement and other reports, when available, can be obtained free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov) or from Genzyme at [www.genzyme.com](http://www.genzyme.com). A copy of the company's definitive proxy statement will also be available for free by writing to Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142. In addition, copies of the proxy materials may be requested from our proxy solicitor, Innisfree M&A Incorporated, 501 Madison Avenue, 20th Floor, New York, NY 10022, (212) 750-5833.

This press release contains forwarding-looking statements regarding Genzyme's financial outlook and business plans including, without limitation: its expectations regarding the terms of the consent decree being negotiated with the FDA and when those negotiations are expected to be completed; its expectations regarding the duration and amount of the continuing allocations of Cerezyme and Fabrazyme; its assessment of the factors that will influence those allocations; its expectation of receipt of regulatory approvals of the new Fabrazyme working cell bank and the timing thereof; its expectation that its new Framingham manufacturing facility will be approved in late 2011; its expectation that a third Myozyme bioreactor in its Geel facility will be approved in mid-2011; its expectation that results from its two phase 3 studies of alemtuzumab in MS patients will be available next year; its assessment that eliglustat tartrate has the potential to transform the treatment for patients; its expectation that data from two phase 3 studies of mipomersen will be available in mid-2010; and its expectation that Renvela will be launched in key European markets in the coming months. These statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, among others: that the final terms of the consent decree differ from the terms described in this release or that the negotiations with the FDA around the consent decree take longer than anticipated; that the allocations of Fabrazyme and Cerezyme need to last longer than expected or need to be more severe than expected for any reason, including that Genzyme is unable to finish work-in-process material that was in production when operations at Allston were interrupted, that third party oversight under a consent decree results in delays in product releases, that Genzyme's demand forecasts and estimates are inaccurate, or that productivity of the new Fabrazyme working cell bank does not increase as anticipated or that regulatory approval does not proceed as anticipated; that production of Fabrazyme and Cerezyme does not continue as planned due to any reason, including bacterial or viral contamination, equipment failures, cell growth at lower than expected levels, fill-finish inefficiencies, power outages, human error or regulatory issues; that Genzyme cannot obtain on expected timetables or maintain regulatory approvals for its products and manufacturing facilities, including its Allston manufacturing facility, its new Framingham facility, and a third Myozyme bioreactor in its Geel

facility; that Genzyme is unable to successfully transition its fill/finish operations out of its Allston facility to its Waterford, Ireland plant and to a contract manufacturer on planned timelines; that Genzyme is not able to successfully complete clinical development and obtain regulatory approvals of its product candidates within anticipated timeframes and for anticipated indications, including eliglustat tartrate, alemtuzumab-MS and mipomersen for any reason, including trial results that are not as favorable as expected and safety profiles that reduce the potential target population; and the risks and uncertainties described in Genzyme's SEC reports filed under the Securities Exchange Act of 1934, including the factors discussed under the caption "Risk Factors" in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of Genzyme's Annual Report on Form 10-K for the year ended December 31, 2009. Genzyme cautions investors not to place substantial reliance on the forward-looking statements contained in this press release. These statements speak only as of April 21, 2010 and Genzyme undertakes no obligation to update or revise them.

Genzyme<sup>®</sup>, Cerezyme<sup>®</sup>, Fabrazyme<sup>®</sup>, Myozyme<sup>®</sup>, Cholestage<sup>®</sup>, Synvisc<sup>®</sup>, Synvisc-One<sup>®</sup>, Septra<sup>®</sup>, Septrafilm<sup>®</sup>, Renvela<sup>®</sup>, Renagel<sup>®</sup>, Thyrogen<sup>®</sup>, Mozobil<sup>®</sup> and Thymoglobulin<sup>®</sup> are registered trademarks and Lumizyme<sup>™</sup> is a trademark of Genzyme Corporation or its subsidiaries. Leukine<sup>®</sup> is a registered trademark licensed to Genzyme Corporation. Welchol<sup>®</sup> is a registered trademark of Daiichi Sankyo, Inc. All rights reserved.

#### Conference Call Information

Genzyme will host a conference call today at 11 a.m. Eastern. To participate in the call, please dial 773-799-3828 and refer to pass code "Genzyme." A replay of this call will be available by dialing 203-369-0536. This call will also be Webcast live on the investor events section of [www.genzyme.com](http://www.genzyme.com). Replays of the call and the Webcast will be available until midnight on April 28, 2010.

#### Upcoming Events

On May 6, 2010, Genzyme will hold its annual Analyst and Investor Day starting at 1 p.m. Eastern, which will be webcast live on the investor events section of [www.genzyme.com](http://www.genzyme.com)

On July 21, 2010, Genzyme will report its financial results for the second quarter of 2010. There will be a conference call at 11 a.m. Eastern. To participate in the call, please dial 773-799-3828 and refer to pass code "Genzyme." A replay of this call will be available by dialing 402-998-1512. This call will also be Webcast live on the investor events section of [www.genzyme.com](http://www.genzyme.com). Replays of the call and the Webcast will be available until midnight on July 28, 2010.

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