

Genzyme books 1Q loss on gov't manufacturing fine

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Cambridge, Mass.

Genzyme Corp. said Wednesday it fell to a first-quarter loss as sales declined and the biotech drugmaker set aside \$175 million to pay a government fine related to manufacturing problems at its Allston, Mass., plant.

Viral contamination and other problems at the Allston plant forced Genzyme to shut down production for about three months in 2009. Later in the year, the FDA discovered particles of trash in some of the company's drugs. Genzyme still not resumed full production of its drugs Cerezyme and Fabrazyme, which treat rare hereditary illnesses.

The \$175 million payment will go to the U.S. Treasury, the company said.

Genzyme is moving production out of the Allston, Mass., plant and into a new facility in Framingham. That process is about half finished, and the company is in talks with the Food and Drug Administration about when the move will be complete.

If the Allston facility is still operating after the agency's deadline, Genzyme will have to pay 18.5 percent of revenue it received from selling products made there. Furthermore, if Genzyme fails to comply with manufacturing standards over the next few years, it will have to pay \$15,000 per day until it is compliant.

Genzyme said it built up a small inventory of Cerezyme during the quarter, but could only ship enough of the drug to meet 50 percent of worldwide demand. In addition to its past problems, operations were affected in the first quarter by a city power outage, which compounded problems with the plant's water system. As a result, Cerezyme revenue dropped 39 percent in the first quarter to \$179.4 million and Fabrazyme revenue fell 56 percent to \$53.2 million.

Going forward, Genzyme said that for the next two to three months, it still will only be able to ship enough Cerezyme to meet 50 percent of global demand. The Cambridge, Mass., company also won't be able to ship more than 30 percent of Fabrazyme demand through the third quarter, which will continue to depress sales. The company's new Framingham manufacturing plant isn't expected to be approved until late 2011.

Cerezyme is a treatment for Gaucher disease, an enzyme disorder that can cause liver and neurological problems. Fabrazyme treats Fabry disease, which is caused by the buildup of a particular type of fat in the body's cells.

Combined with the \$175 million that Genzyme expects to have to pay the government, the reduced sales pushed the company to a first-quarter loss of \$114.9 million, or 43 cents per share. That's down from a year-ago profit of \$195.5 million, or 70 cents per share. Excluding one-time costs, the company said it would have earned 37 cents per share in the latest period.

Overall revenue fell 6 percent to \$1.07 billion from \$1.15 billion. The company said sales of its drug Myozyme rose 28 percent to \$86.1 million. Myozyme is a treatment for Pompe disease, a rare disorder that interferes with muscle development and can cause deadly respiratory problems.

Still, adjusted earnings topped analysts' average estimate of 33 cents per share, excluding one-time items. Revenue had been expected to come in slightly higher at \$1.14 billion.

Genzyme said it will update its annual guidance after its agreement with the FDA is complete.

In afternoon trading, shares rose 69 cents to \$54.41.