# United States Court of Appeals
## For the First Circuit

No. 13-1085

IN RE: GENZYME CORP. SECURITIES LITIGATION,

DEKA INTERNATIONAL S.A. LUXEMBOURG; CITY OF EDINBURGH COUNCIL AS ADMINISTERING AUTHORITY OF THE LOTHIAN PENSION FUND; GOVERNMENT OF GUAM RETIREMENT FUND,

Plaintiffs, Appellants,

VIVIAN OH, individually and on behalf of all other similarly situated; JON RAHN, individually and on behalf of all others similarly situated; GENZYME INSTITUTIONAL INVESTORS,

Plaintiffs,

v.

GENZYME CORPORATION; HENRI A. TERMEER; DAVID P. MEEKER; MICHAEL S. WYZGA; ALLISON LAWTON; MARK R. BAMFORTH; GEOFFREY MCDONOUGH,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. George A. O'Toole, U.S. District Judge]

Before

Torruella, Ripple,[*] and Thompson,
Circuit Judges.

[*] Of the Seventh Circuit, sitting by designation.

Daniel L. Berger, with whom Jay W. Eisenhofer, Diane T. Zilka, Shelly L. Friedland, Grant & Eisenhofer P.A., Avi Josefson, John Rizio-Hamilton, Ann M. Lipton, Bernstein Litowitz Berger & Grossmann LLP, Bryan A. Wood, John H. Sutter and Berman DeValerio, were on brief for plaintiffs-appellants.

John D. Donovan, Jr., with whom Robert G. Jones, Mark D. Vaughn and Ropes & Gray LLP, were on brief for appellee Genzyme Corporation.

Michael T. Marcucci, with whom John D. Hanify and Jones Day, on brief for appellees Termeer, Meeker, Wyzga, Lawton, Bamforth and McDonough.

Richard A. Samp, with whom Cory L. Andrews and Washington Legal Foundation, on brief as amicus curiae.

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June 5, 2014

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**TORRUELLA, Circuit Judge.** This is an appeal from orders of the District Court of Massachusetts granting Defendants-Appellees' motion to dismiss, and subsequently denying Plaintiffs-Appellants' post-judgment motions to amend the complaint. Plaintiffs, a class of investors, brought this securities fraud action against Genzyme Corporation ("Genzyme"), and several company executives (the latter hereinafter collectively referred to as the "individual defendants"). The Consolidated Class Action Complaint ("complaint") charges all defendants with acts constituting securities fraud in violation of Section 10(b) of the Securities Exchange Act, and with violations of Section 20(a) on the part of the individual defendants.

Upon de novo review, we agree with the district court that the complaint fails to meet the exacting pleading standard that securities fraud claims must satisfy. The allegations set forth in the complaint fail to convey a cogent and compelling inference of deceitful intent, or reckless disregard of the truth, on the part of defendants. Scienter has not been pled, and, accordingly, we affirm the district court's order of dismissal.

We also find, not without taking some exception, that the district court did not abuse its discretion in denying plaintiffs' post-judgment motion to amend the complaint.

## I. Background

As this is a review of a motion to dismiss, we recite the facts of the case as alleged in the nonmoving party's complaint, resolving any ambiguities in their favor. Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 5 (1st Cir. 2011).

Genzyme is an international pharmaceutical company engaged in the business of developing and selling biologics. Biologics, as opposed to chemically-synthesized pharmaceuticals, stem from natural sources and are developed through a complex manufacturing process designed to mitigate the ever-present risk of contamination. Companies wishing to market biologics to the general populace must obtain approval from the Food and Drug Administration ("FDA") through a biologics license application ("BLA").

At the time of the conduct at issue in this case, three of Genzyme's main products were biologics related to the treatment of rare metabolic disorders resulting from the absence of certain enzymes (lyosomal storage disease, or "LSD" drugs). Cerezyme, Fabrazyme and Myozyme were developed to treat the rare Gaucher, Fabry, and Pompe diseases, respectively. In 2008, both Cerezyme and Fabrazyme were greater earners than Myozyme, bringing in approximately $1.7 billion in revenue combined. However, Myozyme was an up-and-coming treatment that had recently become the fastest-growing product in Genzyme's history, jumping from $59

million in revenue in 2006 to $296 million in 2008. A substantial reason for the products' success was a complete lack of competition. All three are considered "orphan" drugs under the Orphan Drug Act of 1983, 21 U.S.C. §§ 360aa-ee, which grants limited monopolies to companies that develop drugs to treat rare disorders that might not otherwise be commercially viable for development and production. Genzyme's monopoly of Cerezyme expired in 2001, with Fabrazyme and Myozyme scheduled to expire in 2010 and 2013, respectively.

In April of 2006, the FDA approved Genzyme's BLA for Myozyme manufactured in Genzyme's Framingham, Massachusetts, facility. This version of Myozyme was produced in 160-liter ("160L") bioreactors. However, Genzyme soon realized that production on a small scale would be insufficient to meet market demand. As such, Genzyme developed a manufacturing process for creating Myozyme in a 2000-liter ("2000L") bioreactor in its Allston, Massachusetts facility. To differentiate the two products, Genzyme termed the 2000L Myozyme "Lumizyme." Genzyme was able to obtain quick approval for Lumizyme with European pharmaceutical regulators, but needed to reapply for a new BLA with the FDA for the U.S. market. Genzyme also planned to obtain regulatory approval to develop a 4000-liter ("4000L") version of Myozyme at its plant in Geel, Belgium, for the European market. In the meantime, Myozyme quickly became an unquestionable success for

Genzyme. Analysts considered approval of the Lumizyme BLA to be critical for Genzyme's future earning potential, as it represented a large untapped market for an in-demand product.

Genzyme initially revealed its plans for the Lumizyme BLA on the first day of the Class Period, October 24, 2007. During a conference call, David Termeer, who served as Genzyme's CEO, told investors that the company had filed an application for a "supplemental" BLA for Lumizyme based off of the company's previously-approved 160L Myozyme BLA.[1] Termeer stated he expected that approval of the supplemental BLA would occur in the first quarter of 2008. He also gave a positive outlook for all three of Genzyme's LSD drugs.

On April 21, 2008, however, the FDA notified Genzyme that a supplemental BLA was insufficient, and it would need to submit a separate BLA for Lumizyme approval. After Genzyme submitted the revised BLA in May, the FDA gave Genzyme a "PDUFA date" of November 29, 2008, as mandated by the Prescription Drug User Fee Act ("PDUFA") of 1992, 21 U.S.C. §§ 379g-h.[2] Termeer continued to

[1] A "supplemental" BLA allows companies to obtain rapid, streamlined approval for drugs that are substantially similar to previously-approved products.

[2] The PDUFA allows the FDA to collect fees for applications, but requires the FDA to set a target date for approval of the application. This target date, however, is not a guarantee of approval nor is it binding on the FDA.

give an optimistic outlook for Lumizyme approval throughout the summer of 2008.

In September of 2008, Genzyme's manufacturing facility in Geel, Belgium, suffered a bioreactor failure. At the time, Genzyme had been working towards approval from European regulators to develop Myozyme at the 4000L scale at Geel. An internal investigation ensued as to the cause of the breakdown, which was unknown at the time. Genzyme did not publicly disclose the bioreactor failure at that time. Notwithstanding these events, in February of 2009, Genzyme secured approval from the European Medicines Agency ("EMEA") to produce Myozyme 4000L at Geel.

In October of 2008, the FDA conducted an inspection of the Allston, Massachusetts plant. The FDA routinely conducts inspections to determine if facilities are complying with Current Good Manufacturing Practices ("CGMP") standards for biologics manufacturers. As a result of the inspection, the FDA noted several variations from CGMP at Allston. The FDA summarized these findings in a Form 483 ("October 2008 Form 483"). The form was sent to Termeer, as it is common protocol for the FDA to present Forms 483 to top management officials. A Form 483 contains advisory language that make clear it lists only "inspectional observations and do[es] not represent a final agency determination regarding your compliance." Genzyme responded to the October 2008 Form 483 on October 31, 2008, with a proposed plan to remedy the

problems by March 31, 2009, though it did not receive an immediate reply from the FDA. The October 2008 Form 483 made no mention of the Lumizyme BLA and it did not otherwise note that the drug's approval process might be jeopardized.

Briefly after receiving the October 2008 Form 483, Genzyme conducted a conference call with market analysts on October 22, 2008. No mention was made of the October 2008 Form 483 or of Genzyme's response. One analyst asked Allison Lawton[3] if anything had been discussed during a recent FDA Advisory Committee meeting that could affect the Lumizyme BLA. Though no defendant mentioned the October 2008 Form 483, Lawton stated that "[i]t was really just a discussion about the biochemical differences [between Myozyme and Lumizyme]" and that the clinical data was "the most important piece." On that note, Senior Vice President Geoffrey McDonough shared the news that the FDA Advisory Committee had confirmed the clinical effectiveness of Lumizyme at the 2000L scale, stating that "the likelihood of approval seems to be more certain." During this conference call, Termeer projected that analysts could expect a return of $4.70 per share in 2009, a figure that assumed approval of Lumizyme in November of 2008. At that

[3] Lawton held numerous positions with Genzyme during the class period, including Head of Regulatory Organization; Senior Vice President of Global Access, Quality Systems & Regulatory Affairs; Senior Vice President of Regulatory Affairs and Corporate Quality Systems; and her current position as Senior Vice President of Global Product Access. Generally speaking, Lawton's responsibilities focused on regulatory compliance.

time, the PDUFA date the FDA had provided Genzyme continued to be November 28, 2008.

Also in November, the Allston plant experienced an episode of bioreactor failure similar to the one experienced at the Geel plant months earlier. These events slowed manufacturing for the company and forced Genzyme to ramp down production of Cerezyme and Fabrazyme at Allston. The company dipped into its supply of Cerezyme, Fabrazyme, and Myozyme to make up for the manufacturing shortage, which left Genzyme vulnerable to a lack of supply that could affect sales if problems continued. Though an investigation of the causes of the equipment failures at Allston and Geel was underway, the bioreactor failures were not disclosed to investors at that time. However, company officials did inform investors that "tight" Myozyme inventories could potentially limit sales unless the company could secure European approval of a 4000L version of Lumizyme for production in Geel, which it would eventually secure a few months later in February of 2009.

That same month, the FDA informed Genzyme that it considered aspects of its application to be a major amendment to its earlier Lumizyme BLA, and that it would take more time to review the changes. Accordingly, the FDA set a new PDUFA date of February 28, 2009. Genzyme promptly disclosed this information to investors, stated that it expected Lumizyme to be approved by the

new PDUFA date, and that this news would not affect the projected earnings of $4.70 per share for 2009.

Over the next several months, the defendants maintained that Lumizyme would be approved and the company was in a good position to meet increasing demand for Cerezyme and Fabrazyme. During one conference call with analysts, an investor asked for more information about "incomplete process validation runs" at the 4000L plant in Geel. These runs were affected by the bioreactor failures, the cause for which was unknown at the time. McDonough stated that "the way to think about that is part of the normal development process that we would undergo for any new facility." European authorities approved 4000L Myozyme for manufacture in Geel shortly thereafter in February of 2009.

Having received no response from the FDA as to its proposed remedies to the October 2008 Form 483, Genzyme submitted a supplemental response to the FDA on February 23, 2009. Four days later, the FDA replied with a Formal Warning Letter ("February Warning Letter"), as well as a Complete Response Letter, both addressed to Termeer and later published on the FDA website. The Complete Response Letter stated that the FDA would withhold approval of Lumizyme until the issues in the February Warning Letter were addressed. The February Warning Letter reiterated many of the issues that were contained in the October 2008 Form 483, while also critiquing Genzyme's proposed remedies as insufficient.

On March 2, 2009, Genzyme issued a press release disclosing both the February Warning Letter and the Complete Response Letter. Genzyme also disclosed the October 2008 Form 483 for the first time. That same day, Genzyme filed the company's Form 10-K for 2008, which stated that the February Warning Letter reiterated many of the problems first identified in the October 2008 Form 483, and that approval of Lumizyme was conditioned on resolution of these issues.

Genzyme held a conference call that same afternoon, during which Termeer notified investors that Lumizyme would not be approved by the expected PDUFA date of February 28, 2009. While making these disclosures, Genzyme maintained that it would be able to address all of the issues the FDA had raised and that it would obtain approval of Lumizyme several months down the road. A contemporaneous press release quoted Termeer as saying that the issues could be resolved "within three to six months" and that the company was "confident that the products produced at the Allston facility continue to meet the highest quality and safety standards." During the conference call, Lawton stated that Genzyme was confident that they could respond in full to the February Warning Letter by the end of the week. Senior Vice President of Corporate Operations and Pharmaceuticals Mark Bamforth told investors that the issues raised by the February Warning Letter would not have an impact on Genzyme's ability to produce drugs

manufactured at Allston, including Cerezyme and Fabrazyme. In light of the news, Genzyme adjusted its projections to account for a six-month delay in Lumizyme approval, predicting a 12-cent per share drop and a $60 million decrease in Myozyme revenue.

Not surprisingly, the market reacted negatively to this news. JP Morgan commented that "we remain troubled at the lack of disclosure of the Form 483 issuance last fall, since we believe investors would have been more cautious on near-term Myozyme approval." Some also criticized Genzyme for issuing a press release after trading closed on Monday despite receiving the letter on Friday, and some suspected that a four percent drop in Genzyme stock on Friday could be attributed to early leakage of the letters. After the March 2, 2009 disclosures, Genzyme's shares fell by $4.04, or approximately seven percent.

On March 24, 2009, Genzyme's 2008 Annual Report anticipated Lumizyme approval in mid-2009. On April 22, 2009, Genzyme reported its earnings for the first quarter of 2009, with Myozyme sales falling more than $20 million below estimates. Genzyme again attributed this to "tight" Myozyme supply, but did not disclose the bioreactor problems in Geel or Allston. That same day, Lawton told investors that the Lumizyme BLA was on schedule and said that "at this point we've actually resolved all of any outstanding items with [the] FDA."

The FDA reinspected the Allston plant in mid-May of 2009, but did not issue any warnings or advisory materials at that time. After this inspection, Genzyme adjusted its timeline for the Lumizyme BLA approval and resubmitted its BLA to the FDA. The company acknowledged that a PDUFA was likely six months away, but was optimistic that the FDA would work with them to expedite approval.

On June 16, 2009, Genzyme detected a third bioreactor failure event, the second such outbreak in Allston. This time, Genzyme publicly announced the bioreactor failure, and acknowledged that it had suffered two such events in Allston and Geel in late 2008. Genzyme explained that internal investigations had recently shown the failures were due to the outbreak of a rare virus, Vesivirus 2117. In order to sanitize the plant, Genzyme halted all production of Cerezyme and Fabrazyme in Allston. As Genzyme had already begun selling off its Cerezyme and Fabrazyme inventory in order to increase Allston production of Myozyme, this led to further supply constraints on these drugs.

Genzyme denied to investors that the Vesivirus 2117 contaminations were linked to the CGMP issues identified by the FDA, stating that the FDA had signed off on plant conditions during their May 2009 re-inspection. Termeer stated that no formal letter signing off on the plant had been received, but Lawton said that while they had no written communication, they had positive verbal

communication from the FDA inspectors. While Genzyme stated it had not yet identified the source of the viral outbreaks, it believed the virus was related to the raw materials used in the biologics. The company also predicted it would not need another inspection and that Lumizyme was on track for November 2009 approval, or possibly earlier.

Genzyme released its second quarter earnings statements on July 22, 2009. Due to the shutdown of the Allston plant, Genzyme adjusted its projections for the year downward considerably. A press release accompanying the earnings statement revealed Genzyme's plans for 4000L Myozyme/Lumizyme in the United States for the first time. On a conference call, Termeer explained that in order to "simplify operations in Allston" and dedicate all of the reactors to Cerezyme and Fabrazyme, the company would not be pursuing commercial sales of 2000L Lumizyme in the United States. Rather, the company hoped to obtain BLA approval of 2000L Lumizyme, and then file a supplemental BLA for 4000L Lumizyme manufactured in Geel. During the call, McDonough conceded that even if 2000L Lumizyme was approved in November of 2009, approval of a supplemental BLA would take at least four additional months, meaning commercial sales of Lumizyme in the U.S. would not take place until at least 2010. Following this news, Genzyme's shares dropped approximately eight percent.

On July 27, 2009, the FDA sent a letter to Genzyme, stating that it planned to reinspect the plant due to Genzyme's inadequate response to several of its concerns. According to the FDA, Genzyme had yet to validate the cryoshippers -- special equipment designed to transport biological material in a frozen state -- despite earlier promises to do so. Similarly, Genzyme had failed to implement promised maintenance procedures. Genzyme disclosed the letter to the public on July 31, 2009 and received a negative response from the market. Shares fell an additional 7.75 percent following the disclosure.

Meanwhile, the shortage of Cerezyme and Fabrazyme caused regulators to take action. The FDA reached out to several of Genzyme's competitors for help addressing the shortage of these drugs in July of 2009. The FDA fast-tracked approval for drugs manufactured by Genzyme competitor Shire in an effort to treat Gaucher and Fabry diseases. In August of 2009, Genzyme admitted that the continuing shortage of Cerezyme and Fabrazyme meant that those drugs were in danger of losing their lucrative "orphan" monopoly.

On August 14, 2009, Termeer, Lawton, Bamforth and Executive Vice President David Meeker wrote a private, undisclosed letter to the FDA addressing the organization's recent concerns. The letter acknowledged "systemic causes" for the problems in Allston and stated that "[w]e plan to make fundamental systemic and

cultural changes as appropriate." The letter further recognized that "the viral investigation . . . . must be completed in the context of the broader compliance remediation activities." The letter also acknowledged the FDA's most recent observations and proposed new remedies to address the concerns. Publicly, Genzyme continued to project Lumizyme approval in November of 2009.

On the final day of the Class Period, November 13, 2009, several events transpired. First, Genzyme and the FDA issued a public notice to healthcare providers, explaining that vials of Cerezyme, Fabrazyme, and Myozyme were discovered to have been contaminated with foreign particles, such as steel and non-latex rubber. The notice warned that ingesting such particles could have serious negative health effects on patients.

That same day, the FDA sent a second Form 483 ("November 2009 Form 483") to Termeer, as well as a second Complete Response Letter, once again suspending the Lumizyme BLA. The November 2009 Form 483 noted numerous CGMP violations, including several problems that had been first pointed out in the October 2008 Form 483. Genzyme disclosed the form shortly after these events were made public; Genzyme's shares dropped sharply once again, declining more than seven percent.

In the post-class period, defendants held a conference call to address the issues stemming from the November 2009 Form 483 and the denial of the Lumizyme BLA. The conference call revealed

that many of the issues relating to the contaminated drugs were related to the plant's fill/finish capabilities, the process in which vials are filled and then sealed. During the call, Termeer traced many of the issues in Allston back to 2006, when the company decided to add Myozyme production lines on top of existing lines for Cerezyme and Fabrazyme. The resulting inventory shortage that occurred for Cerezyme and Fabrazyme "clearly can never happen again," Termeer stated. During that same call, Meeker conceded that the problems related to fill/finish were the result of old equipment in the Allston facility and that the company had been aware of the problems, stating that the problem was "not new" and "these were elements that we obviously knew about." Shortly thereafter, Genzyme announced it would shut down the Allston plant, abandon pursuit of a 2000L Lumizyme BLA, and move forward with attempting to receive approval for 4000L Lumizyme manufactured in Geel.

The end of the road approached as the FDA filed a complaint in federal court on May 24, 2010 to permanently enjoin Genzyme from committing violations of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 310-399f. As a result, the FDA and Genzyme entered into a consent decree requiring Genzyme to pay $175 million in fines, transfer certain operations out of Allston, and undertake a comprehensive remediation plan under the supervision of independent experts.

The plaintiffs, on behalf of all purchasers of Genzyme stock during the relevant time period, filed their complaint in this action on March 1, 2010, suing Genzyme Corporation, Termeer, Meeker, Lawton, McDonough, Bamforth and Chief Financial Officer Michael Wygza. The complaint alleges that the defendants violated the Securities Exchange Act by making false or misleading statements to investors in connection to the Allston plant and the Lumizyme BLA approval process.

The defendants filed a motion to dismiss the complaint for failure to state a claim upon which relief could be granted, and the district court dismissed the complaint on March 30, 2012. While the court found that "plaintiffs' theory is plausible, and perhaps even reasonable," the allegations in the complaint were "too speculative to give rise to a strong inference of scienter" under the heightened pleading standards of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b). As the dismissal of the complaint was with prejudice, the plaintiffs moved for relief from judgment and for leave to amend the complaint. The district court denied both motions on December 21, 2012, finding that any new evidence plaintiffs wished to present could have been presented earlier. This appeal followed.

## II. Discussion

### A. The order of dismissal

As with any motion to dismiss, our analysis centers on the complaint, and we accept all well-pleaded factual allegations as true and draw all a reasonable inferences in favor of the plaintiff. Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011). In order to survive a motion to dismiss, the complaint must plead sufficient facts to render the plaintiff's entitlement to relief plausible, and not merely possible. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007). As to allegations of fraud in particular, Federal Rule of Civil Procedure Rule 9(b) requires plaintiffs to plead the circumstances of fraud with heightened specificity. Hill, 638 F.3d at 55.

To state a claim for securities fraud under Section 10(b), a plaintiff must allege: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005). A complaint alleging violations of Section 10(b) must plead facts giving rise to a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). Scienter may be pled by "showing that defendants either 'consciously intended to defraud, or that they acted with a high degree of recklessness.'" Miss. Pub. Emps. Ret. Sys. v. Bos.

Scientific Corp., 523 F.3d 75, 85 (1st Cir. 2008)(internal citation omitted). An inference of scienter is "strong" only if it is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007). "[W]here there are equally strong inferences for and against scienter, Tellabs now awards the draw to the plaintiff." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 59 (1st Cir. 2008).

The 140 page complaint, though seemingly an attempt at artful pleading, is an ill organized and convoluted collection of 364 paragraphs. The events are not alleged chronologically, and the happenings that plaintiffs allege were concealed, as well as the statements alleged to be misleading, are often not clearly paired to related events, dates, characters or a time-line. Not without considerable difficulty, we have endeavored to organize the allegations of fraud into three main categories. We first discuss the circumstances surrounding the alleged concealment of the October 2008 Form 483. We then discuss the purported non-disclosure of the viral outbreaks at the Allston and Geel plants. Finally, we address the defendants's allegedly misleading assertions of Lumizyme's timely approval and disingenuous revenue and performance projections.

**1. October 2008 Form 483**

As to the October 2008 Form 483, plaintiffs essentially contend that defendants concealed the form with fraudulent intent. This theory fails for several reasons, not the least persuasive of which is the fact that defendants ultimately disclosed the form not long after its relevance became apparent to Genzyme.

After the FDA carried out its inspection of the Allston plant sometime between late September and early October 2008, it issued the October 2008 Form 483 to CEO Termeer. The form detailed several observations regarding potential compliance problems with CGMPs. The FDA did not postpone the PDUFA date for Lumizyme of November 29, 2009 by way of the October 2008 Form 483, nor did the form otherwise state that the Lumizyme BLA had been compromised.

Shortly thereafter, on October 22, 2008, Genzyme issued a press release, and held a conference call with analysts regarding the general state of affairs at the company. During the conference call, executives generally touted positive projections for Genzyme. As to approval of the Lumizyme BLA in particular, CEO Termeer referenced the recent decision by an FDA advisory committee approving the therapy, and stated that they were "working very hard with the FDA to get everything done at that time, [the as of yet PDUFA date of November 29, 2008] that still needs to be done." Asked by an analyst if anything had been discussed during the "closed manufacturing session" that might affect BLA approval for

Lumizyme, Lawton replied that the discussion mainly centered on the differences in the scale of production between Myozyme and Lumizyme, and on the clinical data on Lumizyme; an FDA advisory panel had recently vouched for the clinical effectiveness of Lumizyme. Neither Lawton nor any other defendant made any mention of the October 2008 Form 483 at that time.

Towards the end of November, the FDA informed Genzyme that the Lumizyme BLA was substantially distinct from the Myozyme BLA, and that it would require more time to review the application. The PDUFA date was extended to February 28, 2009. Genzyme promptly disclosed the new PDUFA date to investors, but not the earlier receipt of the October 2008 Form 483.

Defendants would not make any mention of the October 2008 Form 483 until March 2, 2009, shortly after receipt of the February Warning Letter and the first Complete Response Letter, both of which addressed some of the observations in the October 2008 Form 483. All three documents were disclosed simultaneously, that same day.

We first note that Section 10(b) does not create an affirmative duty to disclose. In re Bos. Scientific Corp. Sec. Lit., 686 F.3d 21, 27 (1st Cir. 2012). A duty to disclose information earlier omitted arises only when affirmative statements were made and the speaker "fail[ed] to reveal those facts that are

needed so that what was revealed would not be so incomplete as to mislead." Id.

The facts alleged here quite nicely track this proposition. Though the October 2008 Form 483 was not disclosed by Genzyme at the time it was issued by the FDA, it was disclosed roughly four months later upon Genzyme's receipt of the February Warning Letter and the first Complete Response Letter, which formalized some of the October 2008 Form 483's observations. It was these latter two communications that crystalized the relevance of the October 2008 Form 483 to defendants earlier positive statements regarding Lumizyme's approval. This rings particularly true given the advisory language that accompanies all Forms 483, to the effect that the circumstances noted therein are merely observational in nature, and do not represent the FDA's final word.[4] That it was not disclosed at an earlier time that plaintiffs' would have preferred, does not amount to a breach of the duty to disclose, if there ever was one. ACA Fin. Guar. Corp., 512 F.3d at 61.

[4] The parties debate the state of the law as to the materiality of Forms 483. Because we find the complaint does not sufficiently plead scienter, we need not reach this particular question. We note however, the Eight Circuit's view that Forms 483 in general, as is the case with any other purported evidence, may or may not be material depending on the circumstances of each case. See Pub. Pension Fund Gr. v. KV Pharm. Co., 679 F.3d 972, 983 (8th Cir. 2012).

More importantly, and fatal to this theory of the complaint, the allegations regarding the October 2008 Form 483 fall well short of pleading a strong inference of scienter. Dearborn Heights Act 345 Pol. & Fir. Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011)("A plaintiff must allege facts that make an inference of scienter 'more than merely plausible or reasonable -- it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent'")(internal citation omitted). At the time of the issuance of the October 2008 Form 483, the PDUFA date of November 29, 2008 had been left unchanged. Furthermore, also around that same time an FDA advisory committee vouched for the clinical effectiveness of Lumizyme therapy, indeed a crucial step in the approval process. Though it is possible that defendants acted with scienter under these circumstances, the inference of the requisite intent to defraud is certainly not cogent or compelling. Id. It is more likely that defendants made no mention of the October 2008 Form 483, because, given the observational nature of such forms, the fact that it made no mention of the Lumizyme approval process, and more importantly, given other significant factors that pointed to Lumizyme approval -- recent endorsement from the FDA advisory committee, and a steady PDUFA date -- they likely believed Genzyme continued to be on the path towards Lumizyme approval. Tellabs, 551 U.S. at 324 ("A complaint will survive, we hold, only if a reasonable person would

deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.").

Finally, the fact the Genzyme promptly disclosed the extended PDUFA date -- which was extended in late November for reasons unrelated to the October 2008 Form 483 -- and that the October 2008 Form 483 was disclosed only a few months later, in early March of 2009, along with a full and prompt disclosure of the February Warning Letter and the first Complete Response Letter, further undercut any inference of fraudulent intent on the part of defendants. See In re The First Marblehead Corp. Sec. Lit., 639 F. Supp. 2d 145, 163 (D. Mass. 2009)(finding that corporation's related informative disclosures negate inference of scienter).

**2. Bioreactor failures and viral contamination events**

Plaintiffs' claim that defendants' failure to contemporaneously disclose the bioreactor failure events at its Geel and Allston facility, while simultaneously insisting on the expected approval of the Lumizyme BLA, is also indicative of scienter. As with the alleged non-disclosure of the October 2008 Form 483, these allegations also fail to amount to a strong inference of fraudulent intent.

Genzyme initially came across a bioreactor run failure at its Geel plant in September of 2008. The cause of the bioreactor run failure was unknown at the time. Accordingly, Genzyme launched an investigation into the matter. Later, in October of 2008,

another bioreactor failure event occurred, this time at the Allston plant. A second bioreactor failure event occurred at the Allston plant sometime in late May of 2009, the third such event for Genzyme. Shortly thereafter, Genzyme publicly disclosed the bioreactor failures, the cause of which it had only recently discovered upon conclusion of a months-long investigation, and informed investors that the culprit was the rare Vesivirus 2117.

Plaintiffs claim that defendants concealed the viral contamination events with deceitful intent, as they knew, purportedly, that these issues would hamper approval of the Lumizyme BLA. For a number of reasons, this theory fails as well.

As an initial matter, the bioreactor run failures at the Geel plant bore no relation to FDA approval of the Lumizyme BLA for production at the Allston plant. Information regarding that event is, therefore, immaterial to Lumizyme's BLA approval at Allston. Hill, 638 F.3d at 57 ("[I]nformation is material only if its disclosure would alter the total mix of facts available to the investor and if there is a substantial likelihood that a reasonable shareholder would consider it important to the investment decision.") (internal quotations and citations omitted). Furthermore, the EMEA issued a press release in January of 2009 noting that the manufacturing difficulties at Geel were being investigated by the company. Thus, the problems at Geel were not quite a mystery.

As to the specific circumstances regarding any of the three bioreactor run failures at either plant, and as with the October 2008 Form 483, defendants had no affirmative duty to disclose them. In re Bos. Scientific, 686 F.3d at 27. This is particularly so considering that -- even reading the complaint in the light most favorable to the plaintiffs -- the cause of these events was unknown to defendants, and would remain a mystery for several months while an investigation was underway. Furthermore, at no point before Genzyme disclosed the results of its internal investigation did the FDA give any indication that the bioreactor run failures would hinder approval of the Lumizyme BLA.

Also, throughout the period while the investigation was underway, Genzyme kept the market informed by way of several press releases that supply of Myozyme would remain constrained until EMEA gave approval of Lumizyme production at the Geel facility. When the EMEA approved Geel for production of Lumizyme, Genzyme nonetheless continued to inform the market of their diminishing supply of all of their LSD therapeutics, as production slowed because of the bioreactor failures. Genzyme's constant reports to that effect continued until it informed investors of the second bioreactor run failure at Allston, shortly after conclusion of their investigation, when the cause of these events was ascertained.

Throughout this period, Genzyme also timely and promptly disclosed the revised PDUFA date handed down by the FDA in November of 2008, the February Warning Letter and the first Complete Response Letter. Plaintiffs provide no support for the proposition that defendants knew all along the cause of the bioreactor failures. They ultimately rest support for an inference of scienter on failure to disclose circumstances at Genzyme facilities that were, at best, only partially known to defendants. However, Genzyme's efforts to keep the market informed of tightening product supplies, and of relevant and important exchanges it held with the FDA, coupled with the fact that the results of the investigation were relatively promptly disclosed, run counter to any inference of scienter. In re First Marblehead, 639 F. Supp. 2d at 163 (D. Mass. 2009).

Moreover, and again, as a general matter, a corporation cannot be expected to inform the market of any and all developments that might possibly affect stock value. In re Boston Scientific, 686 F.3d at 27 ("[C]ompanies do not have to disclose immediately all information that might conceivably affect stock prices . . . ."). This general principle is particularly relevant here, where the defendants did not immediately know the cause of the first two bioreactor run failures at Geel and Allston. Bioreactor failures can indeed come about for different reasons. Accordingly, on these facts, it was proper for Genzyme to open an

inquiry into the matter, and to wait for a complete picture to become apparent before making any formal announcements. See N.J. Carpenters Pen. & Ann. Funds v. Biogen IDEC Inc., 537 F.3d 35, 45 (1st Cir. 2008); see also Higginbotham v. Baxter Int'l. Inc., 495 F.3d 753, 761 (7th Cir. 2007) ("Managers cannot tell lies but are entitled to investigate for a reasonable time, until they have a full story to reveal."). Under these circumstances, where Genzyme kept the market apprised of supply shortages, we are not compelled to infer that defendants acted with fraudulent intent by taking the time to investigate, and discover, what was essentially unknown to them.

**3. Assurances of Lumizyme approval and projections**

Plaintiffs' also assert, though more generally, that defendants deceived the market by repeatedly assuring investors and analysts alike that the BLA for Lumizyme would be approved in a timely fashion. To the extent that defendants' statements were positive yet generally qualified, were accompanied by disclosures of relevant exchanges with the FDA, and generally tracked the PDUFA dates set by the FDA, we find these general statements were not misleading.

The FDA initially set a PDUFA date for the Lumizyme BLA of November 29, 2008. During the October 22, 2008 conference call, defendants touted Lumizyme's recent advances with the FDA at the clinical trial stage. McDonough in particular mentioned they

expected the FDA to take action by the PDUFA date, and that the likelihood of approval "seemed" to be "taking a more solid shape." Termeer remarked that they were "working very hard with the FDA to get everything done" by the PDUFA date. These are hardly categorical statements, and were well within the expectations set by the PDUFA date. Furthermore, lest we forget, the October 2008 Form 483 made no mention of any risk to Lumizyme approval, and, again, the therapy's clinical effectiveness had been recently backed by an FDA advisory committee.

Late in November of 2008, the FDA informed Genzyme that the Lumizyme BLA would require more time for review, as certain aspects of the current application were significantly different from the earlier supplemental one. The FDA issued a new PDUFA date of February 28, 2009, and until that time, Genzyme's public communications conveyed the general message that Lumizyme was on track for approval at that date. Considering the February 2009 PDUFA date was early in the year, Genzyme maintained that it did not expect this delay to affect revenue projections for 2009.

Upon receipt of the February Warning Letter and the first Complete Response Letter, Genzyme relayed to investors that, by way of these communications, the FDA had cautioned that Lumizyme approval would not occur until the problems identified by the FDA were resolved. Though defendants employed rather rosy language to express optimism that Genzyme would eventually be able to appease

the FDA, their statements as to when the Lumizyme approval would come about were far from categorical, and they were clear that approval would be months away.

From that point forward, throughout most of 2009, all of Genzyme's communications regarding the approval process were generally optimistic, yet forward looking and certainly not categorical. Genzyme projected the company's belief that the problems related to the Lumizyme BLA were being addressed, and the expectation that Lumizyme approval would come about at some point later in 2009. Genzyme's communications were accompanied, and supplemented, by full and prompt disclosure of all relevant communications from the FDA, and periodic submissions to the SEC, as well as revised earnings projections.

On June 16, 2009, Genzyme announced the second bioreactor run failure at Allston, and as a result of its investigation, explained the cause for that failure and the earlier October 2008 event. Investors were made aware that the Allston plant would halt production while the plant was sanitized in order to purge the viral contamination. Genzyme also announced that performance projections, as well as product supplies, would obviously be negatively affected.

On July 27, 2009, the FDA informed Genzyme it would reinspect the Allston plant. Genzyme disclosed the upcoming investigation in a July 31, 2009 press release.

On November 13, 2009, the last day of the class period, the FDA issued Genzyme another Form 483 ("November 2009 Form 483"), and a second Complete Response Letter, this time withholding approval of Lumizyme. Genzyme announced receipt of both documents only several days later, and hosted a conference call announcing that, due to another viral outbreak, it would have to shut down Allston once again. Genzyme again made clear that these events would negatively impact earnings.

The bulk of the statements plaintiffs claim were misleading, were mere forward-looking projections that are not actionable Section 10(b) transgressions. See In re Stone & Webster, 414 F.3d at 195; Greeble v. FTP Software, Inc., 194 F.3d 185, 201 (1st Cir. 1999) ("The safe harbor . . . . shelters forward-looking statements that are accompanied by meaningful cautionary statements . . . . [and] precludes liability for a forward-looking statement unless the maker of the statement had actual knowledge it was false or misleading."). Defendants' statements, though optimistic, expressed belief and not certainty, and were accompanied by either cautionary language or further qualifying information. In re Stone & Webster, 414 F.3d at 195 (holding that forward-looking statements are not fraudulent even if later found to be inaccurate, when they are accompanied by meaningful cautionary statements identifying information that may cause results to differ materially from statements).

In sum, as the district court noted, plaintiffs' account is plausible. However, their allegations do not muster sufficient strength to meet the formidable pleading standard set by Congress for securities fraud claims under Section 10(b). The element of materiality is wanting as to some allegations, as is the element of falsity as to others. But more importantly, the complaint as a whole, as well as the allegations individually, fail to compel a strong inference of scienter on the part of defendants.[5]

**B. The order denying post-judgment leave to amend**

Plaintiffs' challenge to the district court's denial of their motion to amend the complaint is, in a way, two-fold. Plaintiffs first contend that the court erred in dismissing the complaint with prejudice, particularly considering that the district court recognized their claims were plausible. Plaintiffs also challenge the district court's order denying their post judgment efforts to amend the complaint.

A Rule 15(a) motion to amend pleadings is ordinarily granted freely. See Fed. R. Civ. P. 15(a)(2). However, once judgment has been entered, the district court is without power to entertain any amendments unless the judgment is set aside. Fisher v. Kadant, 589 F.3d 505, 508-09 (1st Cir. 2009). A motion to alter or amend a judgment may be granted under Rule 59 only if the movant

[5] As plaintiffs' claims under Section 20(a) are contingent on those under Section 10(b), we need go no further.

demonstrates that an intervening change in controlling law, a clear legal error, or newly discovered evidence warrants modification of the judgment. Soto-Padró v. Pub. Bldgs. Auth., 675 F.3d 1, 9 (1st Cir. 2012). We review a district court's denial of a motion to alter judgment for abuse of discretion. Markel Am. Ins. Co. v. Díaz-Santiago, 674 F.3d 21, 32 (1st Cir. 2012); ACA Fin. Guar. Corp., 512 F.3d at 55 ("Review of the denial of [a] Rule 59(e) motion is for 'manifest abuse of discretion.'") (quoting Council of Ins. Agents & Brokers v. Juarbe-Jiménez, 443 F.3d 103, 111 (1st Cir. 2006)).

We construe plaintiffs' two-pronged attack as a single challenge -- that the district court should have either altered the judgment so as to enter a dismissal without prejudice, or should have granted relief from judgment and allowed the submission of an amended complaint. Though we are somewhat concerned with the district court's order on this front, we ultimately find that it did not abuse its discretion in denying plaintiffs Rule 59 relief.

Plaintiffs sought post-judgment leave to amend the complaint before the district court, arguing that after filing the complaint they had continued conducting interviews with Genzyme employees who provided information that further strengthened their case. They contend that these witnesses yielded valuable new information to support new allegations that would bolster the inference that defendants acted with fraudulent intent throughout

the class period, and that they should be allowed to amend the complaint to include these new allegations.

However, plaintiffs admit that most of this purportedly new evidence was available to them well before the order of dismissal. Indeed, many of the interviews were conducted after the filing of the complaint, and continued after briefings on the motion to dismiss had subsided. But most had concluded before the district court dismissed the complaint on March 30, 2012, two years after the complaint had been filed. Accordingly, we agree with the district court that this was not newly discovered, or previously unavailable evidence, which is the only kind that would warrant relief from judgment under Rule 59. United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 127 (1st Cir. 2013); Marie v. Allied Home Mortg. Corp., 402 F.3d 1, 7 n.2 (1st Cir. 2005). We thus find the district court did not abuse its discretion in denying plaintiffs' Rule 59 motion.

We pause to note our discomfort with the district court's choice to dismiss the complaint with prejudice. The district court granted relief in the form petitioned for by defendants, and it is certainly within the bounds of the district court's discretion to dismiss with prejudice. However, as we have done in the past, we again make clear that the PSLRA has not modified the liberal amendment policy of Rule 15(a). ACA Fin. Guar. Corp., 512 F.3d at 56. More to the point, we emphatically reiterate that the PSLRA

does not require that orders of dismissal be with prejudice. Id. (quoting Belizan v. Hershon, 434 F.3d 579, 583-84 (D.C. Cir. 2006) ("[H]ad the Congress wished to make dismissal with prejudice the norm, and to that extent supercede the ordinary application of Rule 15(a), we would expect the text of the PSLRA so to provide.")). This is particularly so in light of the fact that the PSLRA is a tool designed to curb vexatious litigation, not a mechanism for denying bona fide claimants their day in court. Tellabs, 551 U.S. at 320. The latter right is one that Congress specifically sought to preserve. Hill, 638 F.3d at 54. Courts must be mindful of the will of Congress, and not merely in part. And our duty to guarantee access to the courts, is equally paramount.

## **III. Conclusion**

We find the complaint fails to marshal sufficient allegations to meet the required pleading standard for securities fraud claims. We find it is particularly wanting on the element of scienter.

We also find the district court did not abuse it's discretion in denying plaintiffs relief from judgment. Accordingly, we affirm the judgment of the district court.

**AFFIRMED.**