United States District Court
District of Massachusetts

Shih,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 24-12068-NMG**
	)	
Amylyx Pharmaceuticals, Inc. et al.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM & ORDER

GORTON, J.

This is a putative securities class action brought pursuant to the Securities Exchange Act of 1934 ("Exchange Act") on behalf of individuals who purchased or otherwise acquired the common stock of Amylyx Pharmaceuticals, Inc. ("Amylyx") between November 11, 2022, and November 8, 2023, ("the Class Period"). Now before the Court is defendants' motion to dismiss the amended complaint.

I. Background

A. The Parties

Defendant Amylyx is a commercial-stage biotechnology company that specializes in the discovery and development of treatments for amyotrophic lateral sclerosis ("ALS"), otherwise knowns as "Lou Gerhig's Disease," and other neurodegenerative

diseases. Defendants Joshua B. Cohen ("Cohen") and Justin B. Klee ("Klee") are co-founders and co-Chief Executive Officers ("Co-CEOs") of Amylyx. Defendant James M. Frates ("Frates") was Amylyx's Chief Financial Officer ("CFO") at all relevant times. Defendant Margaret Olinger ("Olinger") was Amylyx's Chief Commercial Officer ("CCO") at all relevant times (collectively, "defendants").

The lead plaintiff, who purports to represent the class in this action, is Oliver Shih ("plaintiff" or "Shih"). He acquired Amylyx securities during the Class period.

B. Facts

"AMX0035" or "Relyvrio" is a drug produced by Amylyx and used for the treatment of ALS in adults. Typically, drugs that require approval from the Food and Drug Administration ("FDA") need to pass three challenging clinical trials called "phases" before they become commercially available. Due to the unmet need in the market for an effective ALS treatment, the FDA approved Relyvrio for commercial use while it was still undergoing its Phase III trial. The FDA approved Relyvrio for commercial use in September, 2022, and the drug went on the market the following month. The Phase III trial was to assess whether the drug was effective as compared to a placebo and Amylyx executives announced that they would withdraw the drug from the market if the data was not positive.

Defendants reported a strong market launch. During the 2022 Q4 earnings call in March, 2023, almost five months into the launch, defendants reported that 1,300 patients were taking Relyvrio at the end of 2022. While they assured investors that the uptick in demand had continued and that there was "still significant opportunity for growth," defendants also advised that they did not know how long the initial "bolus" (meaning the surge in demand for a new drug) would last. The individual defendants stated several times that they foresaw a long "runway ahead of [them]."

These sentiments continued during the 2023 Q1 earnings call in May, 2023. Defendants reported that there were roughly 3,000 patients taking Relyvrio as of March 31, 2023, and that strong demand was "driving near term profitability ahead of [their] expectations." The individual defendants made statements that they were

> well-positioned to build a profitable financially strong organization for the long term [and that they] still [had] plenty of room for growth [in net patient subscribers and that they saw] an opportunity for broader and deeper uptake of key ALS centers.

When asked if management could provide any details on the duration of treatment, defendants responded that it was too early to tell and that patients had not been on therapy long enough to provide clarification.

During the Q2 2023 earnings call in August, 2023, Defendants reported that there were 3,800 patients nationwide taking Relyvrio as of June 30, 2023. They continued to make similar statements related to the success of the drug and its opportunities for growth. When asked about any discontinuations, defendants responded that their metrics reported net patients on therapy, which was therefore inclusive of any discontinuations, and that it was still a little early to identify long-term trends.

On November 9, 2023, defendants issued a press release reporting that a slowdown in new subscribers and an increase in discontinuations had resulted in a failure to meet anticipated Q3 2023 earnings. Defendants admitted that only 60% of patients remained in treatment after six months and corporate share value fell more than 30% in response to that news. In March, 2024, defendants reported that the drug had failed to produce meaningful results in its Phase III trials. Share price fell another 80% and shortly thereafter defendants announced that they would withdraw Relyvrio from the market.

C. Procedural History

In February, 2024, Oliver Shih, individually and on behalf of all others similarly situated, filed the Complaint alleging claims under Sections 10(b) and 20(a) of the Exchange Act, 15

U.S.C. §§78t(a)-(b), and SEC Rule 10b-5, 17 C.F.R. §240.10b-5. Shih filed an amended complaint on June 24, 2024.

In September, 2024, defendants filed the present Motion to Dismiss for failure to state a claim pursuant to Fed.R.Civ.P. 9(b) and 12(b)(6) as well as the Private Securities Litigation Reform Act, 15 U.S.C. §§78u-4 and 78u-5 ("the PSLRA").

II. Motion to Dismiss

In their motion to dismiss, defendants argue that they have made no actionable misstatements or omissions. Specifically, they assert that their disclosures of "net subscribers" were inherently inclusive of discontinuations. Moreover, they posit that most of the challenged statements were protected by the PSLRA safe harbor or amounted to corporate puffery. Defendants also contend that plaintiffs have pled neither scienter nor loss causation in the amended complaint.

A. Legal Standard

To survive a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the plaintiff must state a claim for relief that is actionable as a matter of law and plausible on its face. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

The PSLRA imposes a heightened pleading requirement on claims under Section 10(b), requiring plaintiffs to specify each allegedly misleading statement as well the reasons why the statement is misleading. See Miss. Pub. Emps.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008). Furthermore, Fed.R.Civ.P. (9)(b) requires that plaintiffs plead the circumstances of the fraud with particularity. Zhou v. Desktop Metal, Inc., 120 F.4th 278, 287 (1st Cir. 2024).

B. Application

i. Material Misrepresentations or Omissions

Defendants claim that their statements fall into three distinct and non-actionable categories: statements of interest or demand, corporate puffery and forward-looking statements.

a. Statements of Interest or Demand

Many of the alleged fraudulent statements made by defendants relate to the initial interest and demand for Relyvrio. Plaintiffs claim that defendants knew the initial bolus had ended just months after launch and that the net number of new subscribers was declining despite telling the public that they did not know how long the bolus would last.

The Court agrees with defendants that such claims are without merit. Throughout 2023, defendants updated the public on the company's belief regarding the bolus. During the Q4 2022 earnings call in March, 2023, defendants reported that they did

not know when the initial bolus would end. During the next earnings call in May, 2023, defendants stated that, while the situation was about the same, they had begun to see the number of net new patients decline. During those calls defendants adequately conveyed their ambivalence. They informed investors that they did not know how long the surge would last and noted the decrease in net new patients. The facts as alleged are insufficient to show that defendants misled the public with respect to the bolus.

b. Corporate Puffery

This Circuit routinely regards statements of corporate puffery, that is, undefined statements of optimism and future prospects, as non-actionable. See In re Biogen, 193 F. Supp. 3d 5, 41 (D. Mass. 2016). Defendants argue that many of the challenged statements amount to just that.

The Court agrees that several of the challenged statements are non-actionable corporate puffery. Statements regarding "encouragement," a "strong start," executives being "thrilled," etc., are statements of cautious optimism about the future of the company and are therefore not actionable.

c. Forward-looking Statements

Under the safe harbor provision of the PSLRA, a defendant may not be held liable for a forward-looking statement that was 1) identified as forward looking, 2) accompanied by meaningful

cautionary statements and 3) made without actual knowledge that the statement was false or misleading. 15 U.S.C. §78u-5(c)(1).

Plaintiffs claim that defendants' forward-looking statements related to future growth opportunities were misleading because of the high, unreported discontinuation rate. Specifically, plaintiffs allege that a previous Regional Business Director employed by defendants reported that, at the peak of the bolus, over 9,000 patients had been prescribed Relyvrio. Plaintiffs contend that, when compared to the reported number of net subscribers, the number of total prescriptions indicates a high volume of discontinuations such that the projected growth metrics were misleading. Defendants respond that the reported net-subscriber rate was inclusive of discontinuations and that, furthermore, such forward-looking statements are protected under the PSLRA safe-harbor provision.

This Court finds that plaintiffs have adequately alleged material misrepresentations with respect to forward-looking statements made in May and August, 2023, that discuss growth opportunities within the ALS community. First, during the Q1 2023 earnings call in May, 2023, defendants reported that there were 3,000 net Relyvrio subscribers which amounted to over 10% of the 29,000 patients living with ALS at the time. Defendants then commented that there was more to do with respect to the "1000s of people" living with ALS in the country. Such

statements suggested that defendants foresaw tremendous growth potential with respect to the remaining ALS population.

Second, during the Q2 2023 earnings call in August, 2023, defendants reported that there were 3,800 net Relyvrio subscribers as of June 30, 2023. When asked about discontinuation rates and new subscriptions versus refill numbers, defendants repeated their forward-looking statements with regard to growth opportunities. In response to one such question, defendant Klee reiterated that there were 3,800 current subscribers, which "means that there's many, many more people that we'd like to help as well." Defendants reported that there was an opportunity for growth among the major ALS centers already prescribing Relyvrio, and that management believed there was a "really large untapped opportunity for growth" outside of those centers.

Taking all well-pled factual allegations as true, 9,000 patients had been prescribed Relyvrio by the time of the peak of the bolus. Assuming that was sometime between the end of March, 2023 (3,000 net subscribers) and the end of June, 2023 (3,800 net subscribers), more than 5,000 of the total 9,000 subscribers had discontinued treatment. This represents a discontinuation rate of over 50% and indicates that there was significantly less potential for new subscribers. The omission of this data could

therefore be found to have rendered defendants' assertions regarding Relyvrio's growth potential materially misleading.

Accordingly, the Court finds that the amended complaint adequately states a claim with respect to statements made between May and August, 2023, related to Relyvrio's growth potential.

ii. Scienter

Defendants also argue that plaintiffs have failed to raise a strong inference of scienter. To state a claim under the PSLRA, plaintiffs must plead with particularity facts that give rise to a strong inference of scienter. 15 U.S.C. §78u-4(b)(2)(A). That requires raising an inference that defendants acted with either 1) a conscious intent to deceive or 2) a high degree of recklessness. City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 757 (1st Cir. 2011). For such an inference to be strong, a reasonable person would have to find it at least as compelling as any opposing inference that could be drawn from the same facts. Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151, 158 (1st Cir. 2019).

Plaintiffs have met this burden with respect to the growth statements made between May and August, 2023. They assert that a former Regional Business Director employed by defendants at the relevant time reported that 9,000 patients had been prescribed Relyvrio by the peak of the bolus. Because the net

subscriber metric was inclusive of all discontinuations, defendants would have been aware of those negative indications when calculating and reporting that metric.

Defendants respond that allegations of such employee knowledge are insufficient to show scienter. Indeed, employees' opinions about what management knew are insufficient to establish an intent to deceive. In re Bos. Sci. Corp. Sec. Litig., 646 F. Supp. 3d 249, 285 (D. Mass. 2022). Plaintiffs, however, have pled that the particular employee oversaw the company's entire West Coast business operation and was responsible for 25% of the company's revenue. It is plausible that such an employee would know what management knew with respect to the market status of their product. Plaintiffs also pled that defendants were tracking discontinuations in real time, which would establish that management had direct knowledge of the high number of discontinuations. Such facts, if proven, are sufficient to establish a strong inference of scienter.

iii. Loss Causation

Finally, defendants assert that plaintiffs have failed to allege loss causation. Under the PSLRA, plaintiffs must allege a causal connection between the alleged misrepresentation and the eventual drop in share price. Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 237 (1st Cir. 2013). That is often shown by a corrective disclosure of previously withheld

information followed by a decrease in stock price (so long as other possible explanations are eliminated). Id. Bad news without a direct connection to the alleged misleading statements is insufficient. Coyne v. Metabolix, Inc., 943 F. Supp. 2d 259, 273 (D. Mass. 2013).

Plaintiffs have met this pleading requirement as well. The amended complaint alleges that in November, 2023, defendants disclosed an increase in discontinuations. During the subsequent earnings call defendants stated that only 60% of patients remained on the treatment after six months. By announcing that high discontinuation rate, such statements were corrective disclosures of the alleged previous misrepresentations regarding future growth potential. Amylyx's stock price fell more than 30% following those disclosures, which is sufficient to show loss causation.

ORDER

For the forgoing reasons, defendants' motion to dismiss (Docket No. 48) is **DENIED.**

So ordered.

Nathaniel M. Gorton
Senior United States District Judge

Dated: September 30, 2025