UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TIM KARTH and ABRAHAM KISWANI,	)	
Plaintiffs,	)	
v.	)	**No. 16-cv-11745-DJC**
KERYX BIOPHARMACEUTICALS, INC., RON BENTSUR, SCOTT A. HOLMES, GREGORY P. MADISON, and JAMES F. OLIVIERO,	)	
Defendants.	)	

MEMORANDUM AND ORDER

CASPER, J. **July 19, 2018**

I. Introduction

Plaintiffs Tim Karth and Abraham Kiswani ("Plaintiffs") bring a suit on behalf of a putative class of shareholders against Keryx Biopharmaceuticals, Inc. ("Keryx") and certain officers of Keryx: Ron Bentsur, Scott A. Holmes, Gregory P. Madison and James. F. Oliviero ("Individual Defendants"). The Defendants have moved to dismiss the Plaintiffs' complaint, D. 38. In addition to opposing the motion, the Plaintiffs have moved for leave to amend their complaint, D. 43. The Court DENIES the Plaintiffs' motion to amend their complaint, D. 43, and ALLOWS in part and DENIES in part the Defendants' motion to dismiss, D. 38.

II. Standard of Review

In evaluating a motion to dismiss, a court must first "isolate and ignore statements in the complaint that simply offer legal labels and conclusions" and then "take the complaint's well-pled

. . . facts as true, drawing all reasonable inferences in the pleader's favor, and see if they plausibly narrate a claim for relief." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012).

III. Factual Background

The following facts are taken from the operative first amended complaint, D. 25, and the Court accepts them as true for the purposes of resolving the Defendants' motion to dismiss. Keryx is a biopharmaceutical company which sells Auryxia, a drug approved for the treatment of hyperphosphatemia, or elevated phosphorus levels, in patients with chronic kidney disease. D. 25 ¶¶ 1, 27. Auryxia is the only compound that Keryx has received FDA approval to market. D. 25 ¶ 27. Keryx is not capable of converting the active pharmaceutical ingredient ("API") of Auryxia into a tablet; rather, it contracts that process to another company. D. 25 ¶ 1. Engaging a new contract manufacturer could be a difficult process as the FDA would have to approve any new contract manufacturer to convert the API into a tablet. D. 25 ¶ 34. In January 2014, Keryx contracted with Norwich Pharmaceuticals, Inc. ("Norwich") as a contract manufacturer to convert the API into a tablet and, until November 2016, did not have another contract manufacturer approved by the FDA to perform that role. D. 25 ¶¶ 1, 28.

In March 2013, in its 10-K form, Keryx disclosed that that it would first rely on a single contract manufacturer to produce Auryxia and then would seek to engage additional contract manufacturers. D. 25 ¶¶ 33, 34. On May 8, 2013, Keryx released a 10-Q form which stated that "[w]e rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully manufacture and test our drug candidate, our business will be harmed." D. 25 ¶ 35. The form contained other references to "third parties" and "manufacturers," including the statement that "[o]ur ability to conduct clinical trials and commercialize our drug candidate will depend on the ability of such third parties" and "issues that may arise in our current transition

to commercial batch sizes with our third party manufacturers [] can lead to delays." Id. This 10-Q form did not specifically indicate that Keryx did not, at the time, have contracts with multiple contract manufacturers. D. 25 ¶ 36.

Keryx made similar statements referencing multiple manufacturers or third parties in its August 2013 10-Q form, its November 2013 10-Q form, its January 2014 Final Prospectus Supplement, its March 2014 10-K form, its May 2014 10-Q form, its June 2014 presentation during the Goldman Sachs Global Healthcare Conference, its August 2014 10-Q form, its November 2014 10-Q form, its January 2015 Prospectus Supplement, its February 2015 10-K, its May 2015 10-Q form, its August 2015 10-Q form, its October 2015 10-Q form and its February 2016 10-K form. D. 25 ¶¶ 37-65, 69-72. Additionally, Keryx provided generally positive forward-looking guidance about the future financial performance of Keryx in communications with the press in February 2016 and April 2016. D. 25 ¶¶ 66-68, 77-78. Specifically, in a press release issued on February 25, 2016, Madison, the Chief Executive Officer of Keryx, stated that "the fundamental of Auryxia are solid" and the press release further noted that Keryx "expect[ed] sales to ramp throughout the year," D. 25 ¶¶ 66-67; Holmes, the Chief Financial Officer of Keryx, stated in a conference call on February 25, 2016 that "[w]e are encouraged with the solid fundamentals we see with Auryxia, given the continued growth in prescriptions," D. 25 ¶ 68; on April 28, 2016, Keryx issued a press release stating that it was "progressing nicely toward achieving our previously stated 2016 full year financial objectives," D. 25 ¶ 77; and on April 28, 2016, Madison stated in a conference call with investors that "the fundamental[s] of Auryxia continue to remain strong" and "we are confident in our ability to achieve our net sales guidance," D. 25 ¶ 78. Finally, in April 2016, Keryx filed a Preliminary Schedule 14A with the SEC, which stated that it was a management

incentive goal to achieve "Regulatory Approval of Additional Contract Manufacturer" and that the management had obtained "100%" performance of that goal in 2015. D. 25 ¶¶ 73-74.

On August 1, 2016, Keryx released a press release indicating that it was halting the distribution of Auryxia until at least October 2016 due to a production issue with its contract manufacturer. D. 25 ¶ 80. In that press release, it stated that it was withdrawing its 2016 financial guidance. D. 25 ¶ 80. In a conference call that day, Keryx acknowledged that it only had one contract manufacturer and stated that "[i]n [the] past few months," it had been "experiencing difficulties" in the manufacturing process. D. 25 ¶ 81. Over the course of the day on August 1, the values of the shares of Keryx's stock fell by 36%. D. 25 ¶ 101.

Plaintiffs have filed a proposed second amended complaint, in which they add the following factual allegations. Keryx operated at a loss in 2013, 2014, 2015, and 2016. D. 43-3 ¶¶ 100-103. Keryx was cash-constrained during that period and raised capital twice. D. 43-3 ¶ 104. On September 13, 2016, at a presentation at a conference, Madison stated that Norwich had "all of a sudden began to have trouble converting [API] into finished drug product" and that, until that time, it "had been producing commercial product for us for almost two years without any type of incident." D. 43-3 ¶ 93. On September 27, 2016, Holmes stated at a conference that Norwich was Keryx's first contract manufacturer and that a second contract manufacturer would soon be brought online. D. 43-3 ¶ 94. On November 9, 2016, Keryx released a public statement that its "second contract manufacturer is successfully producing Auryxia." D. 43-3 ¶ 96. The Court considers the allegations in the proposed second amended complaint, D. 43, in addition to the allegations in the operative first amended complaint, D. 25, to evaluate whether the claim would survive a motion to dismiss even with the allegations in the second amended complaint and thus whether the proposed amendments would be futile.

IV. Procedural History

On August 26, 2016, Plaintiffs filed their complaint, D. 1. On February 27, 2017, Plaintiffs filed the first amended complaint, D. 25. The Defendants have now moved to dismiss, D. 38, and the Plaintiffs have moved for leave to amend the first amended complaint, D. 43. The Court heard argument on both motions, D. 48, and took the motions under advisement.

V. Discussion

The Plaintiffs bring claims against the Defendants under Section 10(b) of the Securities Exchange Act and, relatedly, Rule 10b-5. They also bring claims against the Individual Defendants under Section 20(a) of the Securities Exchange Act.

To state a claim under Section 10(b) and Rule 10b-5, Plaintiffs must plead "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds, 568 U.S. 455, 460–61 (2013) (citation omitted). The Defendants first challenge the first of these elements: whether the Defendants made a material misrepresentation or omission. "To establish a material misrepresentation or omission, [the plaintiff] must show 'that defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.'" Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447, 454 (1st Cir. 2017) (quoting Geffon v. Micrion Corp., 249 F.3d 29, 34 (1st Cir. 2001)). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor." Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 135 S. Ct. 1318, 1327 (2015). The allegations in the complaint must also meet the "heightened pleading requirements" imposed on private securities litigation. Miss. Pub. Empls. Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008). "[W]hen alleging that a defendant

made a material misrepresentation or omission, a complaint must 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" Id. (quoting 15 U.S.C. § 78u–4(b)(1)). The heightened pleading standard in the context of the element of scienter requires that the complaint "plead facts giving rise to a strong inference of scienter." Id. at 86.

The Plaintiffs contend that the Defendants made three types of false or misleading statements: first, the Defendants repeatedly referred in public filings to contract manufacturers or third parties in the plural, rather than the singular, even though during that period Keryx had only contracted with one firm to convert the API into tablets; second, that the Defendants indicated in an April 2016 public filing that the goal of obtaining FDA approval for a second contract manufacturer had been completed, even though, during that period, Norwich was the only firm converting the API into tablets; and third, that the Defendants continued to provide positive forward guidance in February 2016 and April 2016 despite being aware at the time of production problems at Norwich. D. 42 at 10, 20, 21. The additional allegations the Plaintiffs seek to add in the second amended complaint, D. 43, relate only to this third theory.

The Defendants contend that the first two types of statements were not false or misleading, because the phrase "contract manufacturer" refers not only to the entity that converts the API into tablets but also to the manufacturer of the API itself, such that it was accurate for Keryx to state that it worked with multiple contract manufacturers and that it did obtain FDA approval for a second contract manufacturer in 2015. D. 39 at 6. The Defendants also contend that the Plaintiffs have not adequately alleged scienter with respect to the third type of statement because the Plaintiffs do not allege that the Defendants knew the positive statements they were making to be false. D. 39 at 20.

A. Statements in the Plural Form

The Court turns to the May 2013 10-Q form, which the Plaintiffs allege contained the first of the false or misleading statements of the first type made by Defendants. The heading of the relevant section of the filing states that Keryx relies "on third parties to manufacture and analytically test our drug candidate." D. 40-3 at 24. The fact that the heading references both manufacture and testing undermines the Plaintiffs' contention that the entire section is about the conversion of the API into tablets, rather than the manufacturing process overall. The relevant section also states that Keryx's "ability to conduct clinical trials and commercialize our drug candidate will depend on the ability of such third parties to manufacture our drug candidate on a large scale at a competitive cost and in accordance with . . . regulatory requirements." Id. That sentence similarly does not specify that there are multiple manufacturers for the step of manufacturing that involves converting the API into tablets. The section later states that "[c]ontract manufacturers often encounter difficulties in scaling up production, including problems involving raw materials supplies . . . These risks become more acute as we scale up for commercial quantities, where a reliable source of raw material supplies becomes critical to commercial success. For example, given the large quantity of materials required for [API] production, . . . we will need to ensure an adequate supply of starting materials." Id. This statement indicates that the section discusses not just the conversion of the API into tablets, but also the production of the API from raw materials. The statement also discloses that "the loss of any of our drug substance or drug product manufacturers would result in significant additional costs and delays," again indicating that the disclosure pertains to both creating the API and converting the API into tablets. Id. at 25. The filing also states that "some of the third parties we employ in the manufacturing process are single source providers," D. 25 ¶ 51, which is consistent with the Defendants' view that the use of the plural in the filing did not imply that there were multiple manufacturers for any given step.

The same or very similar language also appears in the filings by Keryx in August 2013, D. 25 ¶ 37, November 2013, D. 25 ¶ 39, January 2014, D. 25 ¶ 41, March 2014, D. 25 ¶ 43, May 2014, D. 25 ¶ 51, August 2014, D. 25 ¶ 54, November 2014, D. 25 ¶ 56, January 2015, D. 25 ¶ 58, February 2015, D. 25 ¶ 60, May 2015, D. 25 ¶ 62, August 2015, D. 25 ¶ 64, October 2015, D. 25 ¶ 65, and February 2016, D. 25 ¶ 71.

The Plaintiffs respond that the statements are misleading in light of the fact that the March 2013 statement disclosed the fact that there was a single contract manufacturer converting the API into tablets and that the statements at issue omit that disclosure, which could lead a reasonable investor to infer a change in the underlying situation. D. 42 at 15. The Plaintiffs also point out that, in the statement filed in November 2014, Keryx disclosed that certain risks "become more acute as we scale up for commercial quantities, where a reliable source of active pharmaceutical ingredient ("API") and a qualified contract manufacturer become critical to commercial success." D. 25 ¶ 56. That language also appears in the filings released by Keryx in January 2015, D. 25 ¶ 58, February 2015, D. 25 ¶ 60, May 2015, D. 25 ¶ 62, August 2015, D. 25 ¶ 64, October 2015, D. 25 ¶ 65, and February 2016, D. 25 ¶ 71. This additional language indicates that there is a distinction between a "reliable source of [API]" and "a qualified contract manufacturer," and, accordingly, that if the term "qualified contract manufacturer" does not include the source of API, the use of the plural term "manufacturers" is misleading.

The "disclosure required by the securities law is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers." Lucia v. Prospect St. High Income Portfolio, Inc., 36 F.3d 170, 175 (1st Cir. 1994) (quoting McMahan v. Wherehouse Entertainment, Inc., 900 F.2d 576, 579 (2d Cir. 1990)). "Some statements, although literally accurate, can become, through their context and manner of presentation, devices which

mislead investors." Id. Furthermore, "[i]f . . . a company chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth." Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987) (quoting Grossman v. Waste Management, Inc., 589 F. Supp. 395, 409 (N.D. Ill. 1984)) (alteration in original). The Plaintiffs have adequately alleged that a reasonable investor could have concluded from the removal of the disclosure that appeared in the March 2013 filing regarding the single contract manufacturer to convert the API into tablets and from the ambiguous language in the subsequent filings regarding the number of contract manufacturers that Keryx had engaged multiple contract manufacturers to convert the API into tablets when in fact Keryx had not, rendering the statements in the subsequent filings misleading.

The Defendants also contend that because they did not know at the time these filings were made that Norwich's production would be suspended, the statements could not be false or misleading, because the Plaintiffs' claim is essentially one that the Defendants should have foreseen the problems with Norwich's production. D. 39 at 17-18. The complaint, however, adequately alleges that the Defendants understood both that it was important to investors for Keryx to establish multiple vendor relationships to convert the API into tablets and that Keryx had not yet done so. The Plaintiffs do not allege that the Defendants should have known ahead of time that their failure to do so would manifest in an interruption in the production of tablets, but rather that the Defendants were aware that the purported misrepresentation would have been important to investors.

As to the second element of the claims, scienter, the Defendants further contend that the Plaintiffs have not adequately alleged that any particular defendant acted with scienter in making the alleged misrepresentations at issue. D. 39 at 22. But its arguments in support of that contention reduce to the claim that the statements made in the filings were not false or misleading, which the

Court rejects for the reasons described above. The Court thus DENIES the Defendants' motion to dismiss with respect to these statements.

B. Disclosure Regarding "Regulatory Approval of Additional Contract Manufacturer"

The Defendants contend that the April 2016 Preliminary Schedule 14A that disclosed that the goal "Regulatory Approval of Additional Contract Manufacturer" had "100% performance" in 2015 was not false or misleading because the phrase "additional contract manufacturer" could have referred to a API manufacturer. D. 39 at 19 n. 14. Thus, the Defendants argue, the statement was not false or misleading. But, as discussed above, in a February 2016 filing – just two months before the filing at issue -- Keryx drew a distinction between a "reliable source of [API]" and "a qualified contract manufacturer." D. 25 ¶ 71. In that context, and the context of the other statements made by Keryx discussed above, the Plaintiffs have adequately alleged that a reasonable investor could have been misled by the April 2016 Preliminary Schedule 14A. The Court thus DENIES the Defendants' motion to dismiss with respect to this statement.

C. Forward-Looking Statements

Finally, the Defendants contend that the Plaintiffs have not adequately alleged that the Defendants knew that the forward-looking statements by the Defendants regarding the strength of Auryxia and the sales forecast would turn out to be incorrect. D. 39 at 20. The Plaintiffs base this theory on two statements: first, Madison's statement at an August 1, 2016 conference call that "in [the] past few months, we began experiencing difficulties converting [API] to finish[ed] drug product," D. 25 ¶ 81, and second, Madison's statement during a September 13, 2016 conference call that "Norwich has been producing commercial product for almost two years without any type of incident." D. 43-3 ¶ 93.

The Plaintiffs contend that because "Norwich began conversion of the API in January 2014," the problems must have arisen in January 2016 – before the forward-looking statements were made. D. 42 at 21. However, the Plaintiffs offer no support for their contention that Norwich began converting API in January 2014. Rather, the Plaintiffs allege only that Keryx executed the contract with Norwich in January 2014 – but there is no basis on which to infer that Norwich began converting API the same month that the contract was executed. Thus, even considering the statement that the Plaintiffs seek to add to their complaint, the complaint does not adequately allege that any of the Defendants who made the forward-looking statements at issue were aware at the time of the production problems at Norwich. The Court thus ALLOWS the Defendants' motion to dismiss with respect to these statements.

D. Plaintiffs' Motion to Amend Complaint

A party may amend a complaint with the court's leave, which the court "should freely give" when "justice so requires." Fed. R. Civ. P. Rule 15(a)(2). Leave to amend may be "denied for several reasons, including undue delay, bad faith, dilatory motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment." Hagerty ex rel. United States v. Cyberonics, Inc., 844 F.3d 26, 34 (1st Cir. 2016) (citation omitted).

The Plaintiffs seek leave to amend their complaint to include various statements made by Keryx after the class period. Notwithstanding the "liberal" standard for adjudicating motions to amend, ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 56 (1st Cir. 2008), the Court DENIES leave to amend, on the basis that amendment would be futile, for the reasons discussed above.

VI. Conclusion

For the foregoing reasons, the Court DENIES the Plaintiffs' motion to amend their complaint, D. 43, and ALLOWS the Defendants' motion to dismiss, D. 38, with respect to the February 2016 and April 2016 forward-looking statements and DENIES the Defendants' motion

to dismiss, D. 38, with respect to the allegations regarding multiple contract manufacturers or a second contract manufacturer.

So Ordered.

/s/ Denise J. Casper
United States District Judge