

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**TIM KARTH,
on behalf of himself and others
similarly situated,**

Plaintiffs,

v.

**KERYX BIOPHARMACEUTICALS, INC.
et al.,**

Defendants.

Civil Action No. 16-11745-DJC

MEMORANDUM AND ORDER

CASPER, J.

September 23, 2019

I. Introduction

Named Plaintiff Tim Karth (“Karth”) has filed this putative class action against Defendants Keryx Biopharmaceuticals, Inc. (“Keryx”), and certain of Keryx’s former and current executives and directors (the “Individual Defendants” and, together with Keryx, “Defendants”) alleging violations of § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder (Count I) and § 20(a) of the Exchange Act (Count II). Karth has moved for class certification. D. 112. Defendants have moved for judgment on the pleadings. D. 96. Karth has additionally moved for leave to file a third amended complaint. D. 115. For the reasons stated below, the Court DENIES Karth’s motion for class certification, D. 112. The Court ALLOWS Defendants’ motion for

judgment on the pleadings, D. 96. The Court DENIES Karth's motion for leave to amend the complaint, D. 115.

II. Standard of Review

A. Class Certification

A class action may be certified only if “(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.” Fed R. Civ. P. 23(a); see In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 18 (1st Cir. 2008). Where, as here, Named Plaintiff has moved to certify a class under Fed. R. Civ. P. 23(b)(3), the Court must also determine whether “questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed R. Civ. P. 23(b)(3); see New Motor Vehicles, 522 F.3d at 18.

“[T]he district court must undertake a ‘rigorous analysis’ to determine whether plaintiffs me[e]t the four threshold requirements of Rule 23(a) (numerosity, commonality, typicality, and adequacy of representation) and Rule 23(b)(3)’s two additional prerequisites.” In re Nexium Antitrust Litig., 777 F.3d 9, 17 (1st Cir. 2015) (quoting Comcast Corp. v. Behrand, 569 U.S. 27, 33 (2013)); see Smilow v. Sw. Bell Mobile Sys., 323 F.3d 32, 38 (1st Cir. 2003). The Named Plaintiff bears the burden of proving that class certification is justified. Makuc v. Am. Honda Motor Co., Inc., 835 F.2d 389, 394 (1st Cir. 1987). When “plaintiffs have made their initial showing, defendants have the burden of producing sufficient evidence to rebut the plaintiff’s showing.” Nexium, 777 F.3d at 27.

B. Judgment on the Pleadings

Rule 12(c) allows a party to move for judgment on the pleadings at any time “[a]fter the pleadings are closed—but early enough not to delay trial.” Fed. R. Civ. P. 12(c). A motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c), is “ordinarily accorded much the same treatment” as a Rule 12(b)(6) motion. Aponte-Torres v. Univ. of P.R., 445 F.3d 50, 54 (1st Cir. 2006). To survive a motion for judgment on the pleadings, therefore, a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Because a motion for judgment on the pleadings “calls for an assessment of the merits of the case at an embryonic stage,” the Court “view[s] the facts contained in the pleadings in the light most favorable to the nonmovant and draw[s] all reasonable inferences therefrom” in their favor. Pérez-Acevedo v. Rivero-Cubano, 520 F.3d 26, 29 (1st Cir. 2008) (citation omitted).

On a Rule 12(c) motion, unlike a Rule 12(b) motion, the Court considers the pleadings as a whole, including the answer. See Aponte-Torres, 445 F.3d at 54-55. Those assertions in the answer that have not been denied and do not conflict with the assertions in the complaint are taken as true. See Santiago v. Bloise, 741 F. Supp. 2d 357, 360 (D. Mass. 2010). In addition, “[t]he court may supplement the facts contained in the pleadings by considering documents fairly incorporated therein and facts susceptible to judicial notice.” R.G. Fin. Corp. v. Vergara-Nuñez, 446 F.3d 178, 182 (1st Cir. 2006).

C. Leave to Amend

Fed. R. Civ. P. 15(a) “mandates that leave to amend is to be ‘freely given when justice so requires’ . . . unless the amendment ‘would be futile, or reward, *inter alia*, undue or intended delay.’” Steir v. Girl Scouts of the USA, 383 F.3d 7, 12 (1st Cir. 2004) (quoting Fed. R. Civ. P.

15(a)(2) and Resolution Trust Corp. v. Gold, 30 F.3d 251, 253 (1st Cir. 1994)). Rule 15(a)'s "liberal amendment policy . . . does not mean that leave will be granted in all cases." Acosta-Mestre v. Hilton Int'l of P.R., 156 F.3d 49, 51 (1st Cir. 1998) (quoting 6 Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1487, at 611 (2d ed. 1990)).

III. Factual Background

Keryx sells Auryxia, an FDA-approved drug for the treatment of patients with chronic kidney disease. D. 25 ¶¶ 1, 27. Auryxia is the only drug compound that Keryx has FDA approval to market. D. 25 ¶ 27. The manufacture of Auryxia is a two-step process; production of active pharmaceutical ingredient ("API") and the conversion of API into tablet form as Auryxia. D. 25 ¶¶ 33-34. The company engages a third-party manufacturer to convert the active ingredient in Auryxia into tablet form. D. 25 ¶ 1. It is undisputed that Norwich Pharmaceuticals, Inc. ("Norwich") was the only contract manufacturer approved by the FDA that Keryx engaged for this purpose during the relevant class period. D. 25 ¶ 1, 28, 34.

The Court will not recite all facts previously considered in deciding Defendants' motion to dismiss, see D. 50, but incorporates the entirety of same by reference here. The Court summarizes the timeline of relevant public disclosures, drawn from the operative, first amended complaint, D. 25, which remains the operative complaint,¹ as follows.

In March 2013, in its 10-K form, Keryx disclosed that it would initially rely on a single contract manufacturer to produce Auryxia and then would seek to engage additional contract manufacturers. D. 25 ¶¶ 33, 34. Plaintiffs do not dispute the accuracy of this particular disclosure.

¹ Since the Court considered Defendants' motion to dismiss the first amended complaint, D. 38, at the same time as it considered Karth's motion for leave to file a second amended complaint, D. 43, it considered the allegations in the first amended complaint as well as the allegations in the proposed second amended complaint, but denied that amendment finding such amendment futile. D. 50 at 11.

Id. On May 8, 2013, however, 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 disclosure 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.

As alleged by Karth, Keryx’s material misrepresentations and omissions regarding multiple contract manufacturers for conversion of API into Auryxia drug product was not corrected until August 1, 2016. See D. 25 ¶¶ 7, 10-11, 102. 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 also stated that it was withdrawing its 2016 financial guidance. Id. In an investor conference call the same 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 that day, August 1, 2016, the values of the shares of Keryx’s stock fell by 36%. D. 25 ¶ 101.

Both to challenge class certification and to seek judgment on the pleadings, Defendants now rely upon Keryx’s 2015 10-K, issued on February 26, 2016, and its 10-Q form, dated April 28, 2016, both of which state, in relevant part, “we currently depend on a single supply source for Auryxia drug product.” D. 98-1 at 107, 176, D. 98-2 at 15, 52, 67. The April 28, 2016 10-Q also noted that “[i]f any of our suppliers, including the source of Auryxia drug product, were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations.” D. 98-2 at 15, 52, 67. Both of these public filings were referenced in the still operative first amended complaint, D. 25 ¶¶ 69, 72, 76, and are properly before the Court not only as to class certification but also as to Defendants motion for judgment on the pleadings, even as such statements apparently were not briefed or addressed by either side in connection with Defendants’ motion to dismiss and the Court did not address same in its earlier decision regarding that motion. D. 97 at 6; see D. 39; D. 42; D. 44. As a result of these statements, Defendants allege that Karth, an investor who purchased stock after both such statements, is not an adequate class representative and that the claims of a class that span the period before and after these disclosures do not present typical claims under Fed. R. Civ. P. 23(a) and Defendants are entitled to judgment on the pleadings since Karth cannot satisfy at least two of the essential elements of securities fraud claims. D. 97 at 4-5.

The Court considers Defendants’ arguments as to two bases of the securities fraud claims that survived the earlier motion to dismiss: 1) that it was a material misrepresentation or omission

to suggest that Keryx had more than one manufacturer to convert API into Auryxia drug product in public disclosures between May 8, 2013 and the “cure” of same on August 1, 2016, D. 50 at 9; and 2) the April 2, 2016 Preliminary Schedule 14A was materially misleading as to FDA approval of a second such contract manufacturer when Norwich remained the only such manufacturer for Auryxia drug product. D. 50 at 9-10.²

IV. Procedural History

On August 26, 2016, Plaintiffs initiated this lawsuit, D. 1. On February 27, 2017, Plaintiffs filed the first amended complaint, D. 25. On Defendants’ motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court dismissed one of Karth’s three claims relating to forward-looking statements but allowed the two other claims relating to alleged material misrepresentations and omissions as to multiple contract manufacturers for conversion of API into Auryxia tableted to proceed. D. 50 at 9-10. The Court also denied Karth’s motion to amend his complaint for the second time. Id. at 11.

Karth has now moved for class certification, D. 112, and moved again to amend the complaint, D. 115. Defendants have moved for judgment on the pleadings. D. 96. The Court heard the parties on the pending motions and took the matters under advisement. D. 147.

V. Discussion

² The Court rejects Plaintiff’s argument that the motion for judgment on the pleadings is merely an attempt by Defendants to get the Court to reconsider the motion to dismiss, which was denied in part. This motion is not only brought under Fed. R. Civ. P. 12(c), rather than R. 12(b)(6) which was the basis of the prior motion, but addresses a legal basis not previously addressed or resolved by the Court. See generally D. 50.

A. Class Certification

Karth has proposed the following class for certification as to both his claims: “all persons and entities who purchased or otherwise acquired Keryx securities between May 8, 2013, through August 1, 2016, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.” D. 25 at 56. Karth must meet all the requirements under Rule 23(a) and under Rule 23(b)(1), (2) or (3) to prevail on his class certification motion. See Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 614 (1997).

1. Ascertainability

Before addressing the Rule 23(a) and (b) analysis, the Court must determine “whether the scope of the class . . . is appropriate, *i.e.*, whether it is administratively feasible.” Kent v. SunAmerica Life Ins. Co., 190 F.R.D. 271, 278 (D. Mass. 2000) (citing 7C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1760, 581 (2d ed. 1972)). A class must be determinable by “stable and objective factors” at the outset of a case, *id.*; not every class member must be identified, but the class must be sufficiently ascertainable to permit a court to “decide and declare who will receive notice, who will share in any recovery, and who will be bound by the judgment.” *Id.* (citing Crosby v. Soc. Sec. Admin. of the U.S., 796 F.2d 576, 580 (1st Cir. 1986)). The definition for the proposed class here identifies members by their purchase of Keryx securities during a defined time period. The Court, therefore, concludes that Karth has provided objective criteria for defining the class and has satisfied his initial burden of showing ascertainability.

2. Rule 23(a) Requirements

a) Numerosity

The Court must now determine whether “the class is so numerous that joinder of all members is impracticable.” Fed. R. Civ. P. 23(a)(1). “No minimum number of plaintiffs is required . . . but generally if the named plaintiff demonstrates that the potential number of

plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.” García-Rubiera v. Calderón, 570 F.3d 443, 460 (1st Cir. 2009) (quoting Stewart v. Abraham, 275 F.3d 220, 226-27 (3d Cir. 2001)); see In re Relafen Antitrust Litig., 218 F.R.D. 337, 342 (D. Mass. 2003). Karth contends, and Defendants do not dispute, that he has met his burden with respect to numerosity because during the proposed class period Keryx securities traded at such a high volume that the class necessarily includes at least hundreds of members. D. 113 at 5-6. The Court concludes that the putative class satisfies the numerosity requirement. See, e.g., In re Evergreen Ultra Short Opportunities Fund Sec. Litig., 275 F.R.D. 382, 388 (D. Mass. 2011) (noting that “[a]lthough the number of class members is still unknown, because there are millions of shares outstanding and were millions of transactions during the class period, the Court can reasonably infer that there are at least hundreds, if not thousands of class members”).

b) Commonality

Karth also must demonstrate that “there are questions of law or fact common” to the class. Fed. R. Civ. P. 23(a)(2). Commonality is satisfied where the claims at issue depend upon a “common contention . . . of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.” Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 350 (2011). Karth asserts that the class shares common questions of law and fact, including whether Keryx violated federal securities laws through misrepresentation and/or omission of material facts and the scienter of the Individual Defendants. D. 113 at 6-7. Defendants either do not object to commonality or contend that the proposed class lacks commonality for the same reasons it cannot satisfy the predominance inquiry set forth in Rule 23(b)(3). See D. 133 at 7-17. However, the “predominance criterion is far more demanding . . . than the commonality requirement.” New Motor Vehicles, 522 F.3d at 20 (quoting Amchem, 521 U.S. at 624). Here, the common questions among the class

overcome the commonality requirement's "low bar." New Motor Vehicles, 522 F.3d at 19. The Court concludes that Karth has established commonality as to the proposed class and addresses Defendants' concerns regarding the predominance of common issues or questions affecting individual members in its later analysis of the Rule 23(b)(3) factors.

c) Typicality and Adequacy

As to the typicality requirement, Karth also must show that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "The representative plaintiff satisfies the typicality requirement when its injuries arise from the same events or course of conduct as do the injuries of the class and when plaintiff's claims and those of the class are based on the same legal theory." In re Credit Suisse–AOL Sec. Litig., 253 F.R.D. 17, 23 (D. Mass. 2008) (citation omitted).

As to adequacy of the class representative, pursuant to Rule 23(a)(4), the Court considers whether "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This factor requires Karth to establish an absence of potential conflict and an assurance of vigorous prosecution. See Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985). The class representative must be part of the class, possess the same interest and suffer the same injury as class members. See Amchem, 521 U.S. at 625-26. "[P]erfect symmetry of interest is not required and not every discrepancy among the interests of class members renders a putative class action untenable." Matamoros v. Starbucks Corp., 699 F.3d 129, 138 (1st Cir. 2012). Rather, the inquiry "serves to uncover conflicts of interest between named parties and the class they seek to represent," Amchem, 521 U.S. at 625, and focuses on conflicts that are "fundamental to the suit and that go to the heart of the litigation," Matamoros, 699 F.3d at 138 (quoting 1 William B. Rubenstein, Newberg on Class Actions § 3:58 (5th ed. 2012)).

“[S]peculative conflict should be disregarded at the class certification stage.” Natchitoches Parish Hosp. Serv. Dist. v. Tyco Int’l, Ltd., 247 F.R.D. 253, 265 (D. Mass. 2008) (citation omitted).

The Court considers these separate Rule 23(a) factors together because Defendants challenge Karth’s adequacy as the class representative because, in part, his claims are not typical of the proposed class he seeks to represent. Karth contends that his claims are typical of the class because he, like all proposed class members, purchased Keryx shares within the proposed class period between May 8, 2013 and August 1, 2016 and seeks recovery for damages suffered as a result of the alleged inflation of the market price he paid for those shares by the allegedly materially false statements and omissions of material facts by Defendants. D. 113 at 7-8. Likewise, Karth says that his “interests are perfectly aligned with the remainder of the class.” Id. at 8. Defendants argue that Karth is not a suitable representative of the class because he purchased Keryx shares on behalf of a trust in July 2016. Defendants maintain that Karth’s status as representative of an allegedly defunct trust renders his claims susceptible to “unique defenses that would divert attention from the common claims of the class.” Swack v. Credit Suisse First Bos., 230 F.R.D. 250, 260 (D. Mass. 2005). D. 133 at 18. Defendants further argue that the timing of Karth’s purchase, in July 2016, renders him unsuitable because Defendants claim they disclosed Keryx’s reliance on a single manufacturer in February and April 2016 thus putting Karth potentially at odds with those members of the putative class who purchased prior to the alleged February and April 2016 disclosures and/or removing him from the class entirely. Id.

(1) Karth’s purchase of shares as a trustee does not make him an inadequate representative.

Defendants initially challenged Karth’s standing to be a plaintiff at all here given Karth’s own statement that the trust had been dissolved before the filing of the complaint. D. 133 at 24; D. 142 at ¶ 1. Further investigation by Karth, produced to Defendants, however, showed that the

trust was never dissolved. D. 142 at ¶ 3. The trustee argument thus appears to reflect an initial misunderstanding, now corrected, of the trust's status and, at most, harmless error in Karth's initial failure to identify himself as having purchased Keryx shares in his role as a trustee. See D. 141 at 31.

(2) *Even assuming arguendo Karth would otherwise be an adequate representative for this class, he is not given the timing of his purchases and nature of his claims.*

The timing of Karth's purchase, however, presents a problematic issue with respect to defining the class period because of the existence of the February and April 2016 disclosures. Karth characterizes the February and April 2016 disclosures as identical to the disclosures about "single source suppliers" the Court analyzed in connection with the motion to dismiss. D. 101 at 2-3, 5-7, 9-11. In deciding the motion to dismiss, however, the Court looked at the shift in disclosures from the March 2013 statement that there was a single contract manufacturer for Auryxia drug product to the later disclosures, from May 2013 through February 2016, which read, for instance, "some of the third parties we employ in the manufacturing process are single source providers," and held that the later in time disclosures were potentially misleading for their ambiguity as to the number of contract manufacturers Keryx was employing. See D. 50 at 8-9. The disclosures Defendants now have brought to the Court's attention are distinct from the disclosures analyzed in connection with the motion to dismiss because they are not ambiguous. The February and April 2016 disclosures, particularly the April disclosure, match the specificity of the March 2013 statement in that all three disclose the fact that Keryx utilized a single source for Auryxia drug product, *i.e.*, Auryxia tablets, as well as the attendant risks. In March 2013, Keryx wrote in its Form 10-K that "[u]ntil such time [as it engages a back-up supplier] we expect that we will rely on a single contract manufacturer to produce [Auryxia]." D. 25 at ¶ 34. The two

public disclosures by Keryx in filings with the SEC in February and April of 2016 read, “[w]e currently depend on a single supply source for Auryxia drug product.” D. 98-1 at 107, 176, D. 98-2 at 15, 52, 67. The April 2016 disclosure further stated, “[i]f any of our suppliers, including the source of Auryxia drug product, were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations,” D. 98-2 at 15, 52, 67, precisely the issue Karth points to as precipitating the drop in share price in August 2016.

Karth’s argument that the February and April 2016 disclosures do no more than muddy the waters and “left investors to guess which disclosures were accurate” is, therefore, unavailing. D. 141 at 21. In its ruling on the motion to dismiss, the Court wrote that “a reasonable investor could have concluded . . . from the ambiguous language . . . 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.” D. 50 at 9. The February and April 2016 disclosures resolve the ambiguity that may have misled the market by stating there was a single supplier for Auryxia drug product. Additionally, they do so in the same forum, SEC filings, as the potentially misleading disclosures. Karth advances additional arguments that the specific language used in the February and April 2016 disclosures, specifically the terms drug product and drug substance, was not clear. “Drug product” is a term defined by the FDA as “[a] finished dosage form.” See Gustavsen v. Alcon Labs., Inc., 903 F.3d 1, 13 (1st Cir. 2018) (citing 69 Fed. Reg. at 18,739); see also 21 C.F.R. § 314.3 (defining “drug product” as “a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients”). It is undisputed that Auryxia tablets were the only “drug product,” as

defined by the FDA, that Keryx manufactured (through its contract with Norwich) during the relevant time period. D. 25 at ¶ 1. At the hearing on the motions, counsel for Karth pointed to an email, referenced in the proposed amended complaint, D. 115-1 at ¶ 116, from a Keryx director, John Butler, in which Butler noted that “retail” investors may not know the difference between drug substance and drug product. D. 150 at 50-51. At this point, however, both parties have embraced the notion that Keryx shares trade in an “efficient market,” i.e. a market that “is said to digest or impound news into the stock price in a matter of minutes.” D. 97 at 10 (citing Erica P. John Fund, Inc. v. Haliburton Co., 309 F.R.D. 251, 269 (N.D. Tex. 2015)); D. 101 at 13 n. 1. This principle, known as the Basic presumption, states that “the market price of shares traded on well-developed markets reflects all publicly available information, and, hence, any material misrepresentations.” Basic Inc. v. Levinson, 485 U.S. 224, 246 (1988). Whether the February and April 2016 disclosures were in footnotes or not is inapposite where parties do not dispute that such information was publicly disclosed or the timing of same. See D. 107 at 4-5.

As courts have noted, “[w]hether a particular announcement . . . actually cured a prior misrepresentation is, of course, a sensitive issue to rule on at this early stage of the proceedings, because it comes so close to assessing the ultimate merits in the case.” In re Fed. Nat. Mortg. Ass'n Sec., Derivative & "ERISA" Litig., 247 F.R.D. 32, 39 (D.D.C. 2008). In instances where there is “no substantial doubt as to the curative effect” of the later-in-time announcement, however, courts “will simply define the class period accordingly” without risk of improperly wading into the merits at the class certification stage. Id. As in Hayes v. MagnaChip Semiconductor Corp., No. 14-CV-01160-JST, 2016 WL 7406418, at *1 (N.D. Cal. Dec. 22, 2016) and Fed. Nat. Mortg. Ass'n Sec., this is not “a situation where the [subsequent] disclosure merely hinted at the existence of the problems and that the market barely reacted to a half-hearted disclosure.” In re Fed. Nat.

Mortg. Ass'n Sec., 247 F.R.D. at 39. Instead, “there was nothing equivocal” about Keryx’s April 28, 2016 disclosure that Keryx had a single manufacturer for its drug product. Id. A plausible class period can therefore extend no further than April 28, 2016.³ See, e.g. Hayes, 2016 WL 7406418, at *8 (noting that “[a] number of district courts have declined to extend the class period in a securities case beyond the date of [curative] disclosures” and collecting cases).

Karth, who purchased shares in July 2016, therefore, purchased Keryx shares in a markedly different disclosure environment than other proposed class members who purchased shares as early as May 8, 2013. Such a different position is “fundamental to the suit” and “go[es] to the heart of the litigation,” namely, Karth not being a member of a sustainable class. See, e.g., Basic, 485 U.S. at 248–49 (noting that “if, despite petitioners’ allegedly fraudulent attempt to manipulate market price, news of the merger discussions credibly entered the market and dissipated the effects of the misstatements, those who traded . . . after the corrective statements would have no direct or indirect connection with the fraud”). This disparity creates a conflict between Karth and prospective class members, see Vargas v. Spirit Delivery & Distrib. Servs., 245 F. Supp. 3d 268, 288 (D. Mass. 2017), that threatens to “overbalance the common interests of the class members as a whole,” Matamoros, 699 F.3d at 138. The Court, therefore, concludes Karth is not a suitable named plaintiff for reasons of atypicality and inadequacy.

After the voluntary dismissal by named plaintiff Abraham Kiswani in April 2019, D. 104, Karth has become the sole Named Plaintiff remaining in the case. Having found that the timing of Karth’s purchase makes his claims atypical from those of a majority of proposed class members and removes his standing to bring the claims on behalf of the proposed class, see City of Bristol

³ Even if a class period could be shortened to this “curative” date, it is not clear that securities fraud claims would survive for such a class given the issues of reliance and loss causation addressed below.

Pension Fund v. Vertex Pharm. Inc., 12 F. Supp. 3d 225, 235 (D. Mass. 2014) (noting “a plaintiff who purchased after a corrective disclosure was made would have no standing, because relying on the earlier misrepresentation would no longer be reasonable in light of the new information”), and thus that Karth is an inadequate class representative, the Court declines to certify the proposed class given the lack of a named plaintiff.⁴ See 1 William B. Rubenstein, Newberg on Class Actions § 2:5 (5th ed. 2012) (noting that “[i]n a class action suit with multiple claims, at least one named class representative must have standing with respect to each claim”).

Due to the Court’s conclusion as to adequacy and typicality, the Court need not proceed to address the Rule 23(b)(3) requirements of predominance and superiority, but does so here in the interest of completeness.

3. *Rule 23(b)(3) Superiority*

A putative class seeking certification under Rule 23(b)(3) also bears the burden of showing that a class action “is superior to other available methods for fairly and efficiently adjudicating the controversy,” Fed. R. Civ. P. 23(b)(3). Nexium, 777 F.3d at 18. The Court considers four factors within the superiority inquiry: 1) the individual interests in controlling the prosecution of separate actions; 2) any existing litigation already begun by class members; 3) the advantages or disadvantages of litigating the claims in the forum; and 4) any particular difficulties in managing the class action. Fed. R. Civ. P. 23(b)(3). The Court considers the alternatives to a class action, conscious that “[t]he policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for an individual to bring a solo action

⁴ At the hearing on the motions, Karth’s counsel agreed that if the February and April 2016 disclosures were curative, Karth “clearly . . . would have purchased after there’s a cure of the information” and added that he was “not sure anybody would be able to bring a claim.” D. 150 at 15.

prosecuting his or her rights.” Amchem, 521 U.S. at 617 (quoting Mace v. Van Ru Credit Corp., 109 F.3d 338, 344 (1997)) (internal quotation marks omitted). The superiority inquiry thus ensures that litigation by class action will “achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results.” Id. (quoting Advisory Committee’s Notes on Fed. R. Civ. P. 23).

The first two factors weigh in favor of a class action given the lack of any record of particularized interest in directing the litigation from any individual and the lack of existing litigation concerning the same controversy. As to the latter two factors, the fact that Keryx is headquartered in Massachusetts is an advantage to this forum and there are no particular difficulties presented by the management of this class action. Defendants also do not challenge the superiority of a class action as a method of adjudicating the class claims here. A class action would be superior to litigation of individual claims by the multitudinous individual investors who purchased Keryx shares during the shortened class period.

4. *Rule 23(b)(3) Predominance*

Rule 23(b)(3) requires the Court to find that “the questions of law or fact common to class members predominate over any questions affecting only individual members.” Fed. R. Civ. P. 23(b)(3). The focus of the predominance inquiry is “whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” Amchem, 521 U.S. at 623. When conducting a Rule 23(b)(3) analysis, the Court must determine whether there is “reason to think that [individualized] questions will overwhelm common ones and render class certification inappropriate.” Halliburton Co. v. Erica P. John Fund Inc., 573 U.S. 258, 276 (2014). This requires a district court to “formulate some prediction as to how specific issues will play out in

order to determine whether common or individual issues predominate in a given case.” Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 298 (1st Cir. 2000).

Given that the class definition for the full period through August 1, 2016 cannot be sustained, Defendants’ arguments as to price impact and Plaintiff’s damages model no longer apply with full force. It is not clear that the predominance factor could be met here, particularly as to the class presently proposed. Given the proposed class period—stock purchases from May 8, 2013 through August 1, 2016—which spans non-ambiguous public disclosures as to the single contract manufacturer for Auryxia drug product in February and April 2016, the Court cannot say that questions of law or fact common to this class predominate over any questions affecting individual members, particularly as to reliance and loss causation.

For all of these reasons, the Court DENIES the motion to certify the proposed class. Accordingly, what remains are Karth’s individual claims against Defendants, which the Court turns to now.

B. Defendants’ Motion for Judgment on the Pleadings

Thus the Court turns to Defendants’ motion for judgment on the pleadings, D. 96, against Karth’s individual claims against Defendants for violations of §10(b) of the Exchange Act and Rule 10b-5 against all Defendants and violations of §20(a) of the Exchange Act against the Individual Defendants. Both of Karth’s claims to survive the Court’s order on the motion to dismiss, D. 50, are premised on the same set of alleged facts, namely that: 1) Keryx, through material misrepresentations and/or omissions misled investors about the number of its third-party manufacturers of Auryxia drug product even though there was, at all relevant times to this matter, only one manufacturer of Auryxia tablets; and 2) when Keryx revealed that it only had a single manufacturer for Auryxia tablets in August of 2016 and that the single manufacturer was

experiencing issues that impacted the availability of Auryxia for sale, the market responded with a significant price drop in Keryx shares. The sole theory of liability to survive the earlier motion to dismiss ruling was that Keryx's statements from May 2013 forward may have misled investors as to how many drug product manufacturers were producing Auryxia tablets. D. 50 at 7-10. Defendants argue that the February and April 2016 disclosures break the link between the alleged misstatements to Karth and the drop in share price in August 2016, thereby robbing Karth's claims of the only alleged loss causation Plaintiff suffered as a result of the alleged misstatements and defeating the two remaining claims. Also, since only Karth's individual claims remain with no class having been certified, Karth's claims also fail because he has not plausibly alleged material reliance upon misrepresentations and/or omissions. D. 97 at 10.

As the Court stated in its ruling on Defendants' motion to dismiss, D. 50, 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). "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.

Emples. 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.

Karth contends that Defendants’ arguments amount to a “truth on the market defense,” for which they have failed to meet their burden. D. 101 at 8-10, 11-14. A truth on the market defense, as explained by Karth, “requires a defendant to establish that the allegedly misrepresented information was already fully reflected in the market so that the stock price already reflected the misrepresented facts.” D. 101 at 11. A truth on the market defense posits that despite any alleged misrepresentation the market already knows the truth of the matter. See, e.g., In re Credit Suisse-AOL Sec. Litig., 465 F. Supp. 2d 34, 51 (D. Mass. 2006). In raising this defense, a party rebuts the allegation that the alleged misrepresentations were material by providing evidence that the market did not “believe” the alleged misrepresentation due to other available information, usually from a third party. See, e.g., In re Apple Computer Sec. Litig., 886 F.2d 1109, 1115 (9th Cir. 1989) (finding that press scrutiny and disbelief of positive statements was sufficient to form basis of truth on the market defense). The fact that the corrective information usually comes from a third party is why the “degree of intensity and credibility sufficient to counter-balance effectively any misleading information” is an important part of the truth on the market analysis. See In re Credit Suisse-AOL, 465 F. Supp. at 51. Here, the issue is not the ability of the new information to counterbalance the misleading information, but non-ambiguous language that breaks the causal link between allegedly misleading information as to multiple contract manufacturers and reliance

on same and resulting loss causation when such misrepresentation was allegedly cured on August 1, 2016. That is, the newly presented disclosures do not render the disclosures the Court analyzed on the motion to dismiss immaterial; rather, they bring to light a lack of a necessary causal link between the earlier misstatements prior to February 2016 and any claimed economic loss by Karth. Such missing link is fatal to Karth's claims. See, e.g., Miller Inv. Tr. v. Morgan Stanley & Co., LLC, 308 F. Supp. 3d 411, 449 (D. Mass. 2018) (dismissing securities fraud claim because plaintiff "has not adequately pled loss causation"); In re Polaroid Corp. Sec. Litig., 134 F. Supp. 2d 176, 189 (D. Mass. 2001) (dismissing securities fraud claims because "the Complaint fails to allege adequate loss causation").

As previously stated, Karth must show a material misrepresentation or omission, scienter, a connection between the misrepresentation or omission and the purchase of a security, reliance upon the misrepresentation or omission, economic loss and loss causation. Amgen, 568 U.S. at 460-461. Both of Karth's remaining claims rely on the premise that once the market learned in August 2016 that Keryx had a single manufacturer of Auryxia tablets along with the attendant increased risk of a failure to "meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand," the market reacted with a sharp drop in Keryx's share price. The disclosure to the market of those key facts nearly six months prior to the subsequent market reaction breaks the causal chain for purposes of Karth's fraud on the market theory. Cf. Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 342-347 (2005) (holding plaintiff alleging securities fraud must show causal link between alleged fraud and economic loss occurring at time of sale of securities to survive motion to dismiss). Karth is similarly unable to plausibly allege reliance because his July 2016 purchase of Keryx shares came after the curative disclosures in February and April 2016. See City of Bristol, 12 F. Supp. 3d at 235 (noting "a plaintiff who purchased after

a corrective disclosure was made would have no standing, because relying on the earlier misrepresentation would no longer be reasonable in light of the new information”).

Moreover, it would be futile to amend as to loss causation or reliance where there has been no suggestion that there was any stock drop after either earlier disclosure, but only later on August 1, 2016. See D. 107 at 6. Accordingly, the Court grants judgment to Defendants on both counts.

C. Karth’s Motion to Amend the 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 court denies the motion for leave to amend on futility grounds.

First, the alleged amendment does not cure the deficiencies as to loss causation and reliance as to the lone remaining plaintiff, Karth. As Karth notes in his motion for leave to amend, the proposed amended complaint “still concerns the same general subject matter of the operative complaint” and “[t]he alleged corrective disclosure [on August 1, 2016] has not changed.” D. 115 at 5. The new alleged facts in the proposed amended complaint merely bolster Karth’s claims as to Keryx’s misrepresentations and omissions surrounding the number of contract manufacturers for Auryxia drug product. See D. 115-1 at ¶¶ 99, 230, 239.

Second, to the extent that Karth seeks to present new legal theories, specifically with respect to disclosures of risks from manufacturing interruptions, see D. 115 at 3; D. 115-1 at ¶¶ 43-47, 50-53, 56-58, 67-69, 81-86, 100-101, 104-108, 11-114, it would be futile to amend because the April 2016 disclosure functions as a curative disclosure for that theory as well. The April 28,

2016 10-Q noted that “[i]f any of our suppliers, including the source of Auryxia drug product, were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations.” D. 98-2 at 15, 52, 67. The warned-of risk of supply interruption, and resulting adverse impact on revenue, was realized in late July 2016 leading to the stock price drop in August 2016, but the February and April 2016 disclosures had already remedied the alleged prior misrepresentations and/or omissions. Karth’s theory as to ongoing manufacturing issues at Norwich thus suffers the same infirmities with respect to loss causation and reliance as his theory as to the number of contract manufacturers and further amendment would be futile.

VI. Conclusion

For the foregoing reasons, the Court DENIES Karth’s motion for class certification, D. 112, and dismisses all class claims against Defendants. The Court ALLOWS Defendants’ motion for judgment on the pleadings, D. 96, and dismisses Karth’s remaining individual claims against Defendants. The Court DENIES Karth’s motion for leave to amend the complaint, D. 115.

So Ordered.

/s/ Denise J. Casper
United States District Judge