No. 19-1964

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

TIM KARTH,
Plaintiff-Appellant

ABRAHAM KISWANI; RICHARD J. ERICKSON; RICHARD B. KING, JR.; TERRELL JACKSON,

Plaintiffs,

v.

KERYX BIOPHARMACEUTICALS, INC., RON BENTSUR, SCOTT A. HOLMES, GREGORY P. MADISON, and JAMES OLIVIERO,
Defendants-Appellees

On Appeal from the
United States District Court, District of Massachusetts
No. 1:16-cv-11745-DJC
Honorable Denise J. Casper, Presiding

APPELLANT'S REPLY BRIEF

Jeffrey C. Block
Jacob A. Walker
Nathaniel Silver
Block & Leviton LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
(617) 398-5600

Counsel for Plaintiff-Appellant

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Preliminary Statement

The District Court's decision denying leave to file the TAC[1] should be reversed. The District Court incorrectly found that Keryx's Risk Disclosures[2] adequately informed investors of the risk of an upcoming supply interruption for sales of Auryxia and of "ongoing manufacturing issues at Norwich," so all prior misrepresentations were cured by these warnings.

First, the Risk Disclosures themselves were misleading and not truthful. Keryx warned that "if any of our suppliers . . . *were to limit* or terminate production . . ." it could impact revenues. Yet, at the time these Risk Disclosures were made, *Norwich was limiting production*. There is no dispute that beginning in early 2016 Norwich was experiencing production problems and was limiting the amount of product it was supplying to Keryx. Indeed, Defendants conceded below that Keryx knew in April 2016 of a possible supply interruption by mid-May 2016 if Norwich did not resolve its manufacturing problems; Norwich had been experiencing production

[1] Abbreviations are consistent with those from Plaintiff's Opening Brief on Appeal.

[2] In its 2015 year-end Form 10-K Keryx disclosed that "[i]f any of our suppliers 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." In its First Quarter Form 10-Q Keryx added the phrase "including the source of Auryxia drug product."

problems for two plus years. The Risk Disclosures therefore did not adequately warn investors of the true facts and cannot be considered curative of any prior misrepresentations or omissions.

Second, the Risk Disclosures never warned investors of the threat of a "supply interruption" or that such a risk was imminent. Instead, it merely warned that if Norwich were to "limit or terminate its production" Keryx "could experience a loss of revenues." Again, Defendants knew that Norwich was limiting production, was experiencing continued production problems and that if those problems continued to persist, a supply interruption would occur. The Risk Disclosures did not adequately warn investors of the true risks that existed at the time they were made.

Third, the Risk Disclosures did not warn of the possibility of an actual supply interruption, but instead of a possible "decline in revenues." For a start-up biotech company, solely reliant on a new artificially created drug compound trying to gain traction with patients, the risk of a complete supply interruption is far more dire than the mere possibility of a decline in revenues. A "decline in revenues" means Keryx might not sell as much product as it expected, not that it might not sell any product at all. Unavailability of a drug

forces doctors and patients to fulfill the need elsewhere, which could (and indeed is highly likely to) damage long-term sales.

Lastly, the Risk Disclosures said nothing of the prior manufacturing issues Keryx's third-party suppliers had experienced over the prior two years. Defendants warned investors that if the third-party suppliers were to experience manufacturing issues, it could hurt Keryx's business, but failed to reveal that the manufacturing issues had occurred and were continuing to occur.

Defendants arguments in support of why the District Court's decision should be sustained are flawed.

First, Defendants disingenuously claim that because Plaintiff did not allege *in the TAC* that the Risk Disclosures were false statements that Plaintiff has waived any such argument on appeal. The Risk Disclosures are Defendants' defense. Defendants relied on them in opposing Plaintiff's motion for leave to amend, arguing that the market was not misled and that these disclosures made full, complete and adequate disclosure. A plaintiff need not be clairvoyant and guess at a defendant's supposed curative disclosures and then plead them as false and misleading statements to assert

on appeal that the alleged curative disclosures are inadequate because they are untrue.

Second, tellingly, Defendants nowhere respond to the point that at the time the Risk Disclosures were made, Norwich *was in fact* limiting its production, thereby conceding the point. These Risk Disclosures were misleading and not curative as a matter of law.

Third, Defendants falsely claim that "plaintiff argued below that allowance of the TAC would not change the outcome of class certification." Def. Br. at 2. In his reply memorandum in support of Class Certification, Plaintiff expressly stated that "If the Court grants Plaintiff leave to file the TAC, Defendants'" arguments as to the lack of a price impact, loss causation and standing became moot. Indeed, Defendants themselves expressly "reserve[d] the right to supplement their class certification opposition should the Court permit any further amendment of the Complaint." JA00780; JA01759. Thus, both parties contemplated that granting leave to file the TAC would fundamentally impact the arguments regarding class certification. Defendants' waiver argument is therefore baseless.

Finally, Defendants' chief argument on appeal is their claim that the only issue in this case is when Defendants knew with certainty that Keryx

would experience a supply interruption of Auryxia. They contend that because Keryx did not conclusively establish that a supply interruption would occur until July 2016, no prior statement is actionable and no Defendant acted with scienter.

But, this is not what Plaintiff alleges. By December 2015, Defendants knew that investors were looking for Keryx to improve sales before they would buy the stock. They also knew that by year-end 2016 Keryx would be "out of cash" and Keryx needed additional financing. Defendants therefore knew that revealing to the market that Keryx was experiencing manufacturing issues with its sole synthetic drug product would not be well received by investors.

So, instead, Defendants concealed the manufacturing problems Keryx was experiencing with Auryxia—which Defendants concede had been ongoing for years. Norwich had repeatedly stopped production of Auryxia and Defendants knew, by mid-April 2016, that if Norwich (which had production issues since 2014, including trouble consistently manufacturing Auryxia – facts about which Defendants were advised as early as 2014) did not fix its problems, a supply interruption would occur by mid-May 2016. Yet, Defendants said nothing of these problems, assured investors that Keryx was "off to a good start," that "the fundamentals of Auryxia continue to remain

strong," and that "With these fundamentals in place . . . we are confident in our ability to achieve our net sales guidance."

In *Tutor Perini* this Court rejected the argument that a risk disclosure cannot be misleading until the precise moment that the risk materializes. If Defendants' view were the law, then all risk disclosures would be meaningless: a company could simply warn that an event might occur, even when the underlying facts leading up to the event were already occurring. Here, Keryx faced a significant risk by April 2016: Norwich was having continued and repeated production problems which could lead to a supply interruption by mid-May 2016; yet Defendants concealed these known facts, white-washed reality and continued to mislead its investors.

This Court should reverse the District Court's decision and remand with instructions that the Risk Disclosures did not adequately warn investors of an impending supply interruption. If the Court goes on to consider whether the TAC states claims for relief—issues not reached by the District Court—it should find that it does state claims for relief.

Argument

I. Keryx's Risk Disclosures Did Not Cure Keryx's Prior Misrepresentations and Omissions About Manufacturing Problems

The District Court relied on Keryx's risk disclosure in its 2016 second quarter Form 10-Q that "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" in finding that investors were adequately warned of the risk of a "supply interruption." The lower court found this disclosure "remedied [any] alleged prior misrepresentations and/or omissions" regarding ongoing manufacturing problems at Norwich and all of Keryx's third-party suppliers. This was in error.

This decision is erroneous for three reasons.

First, the Risk Disclosures were false and misleading as Norwich was in fact limiting its production at the time each Risk Disclosure was made. To be effective, a risk disclosure must warn of a specific risk and here it did not. The Second, Third, Fifth and the D.C. Circuits all find that "cautionary language must be extensive and specific." *Slayton v. Am. Express Co.*, 604 F.3d 758,

772 (2d Cir. 2010) (quoting *Inst. Investors Grp. v. Avaya, Inc.,* 564 F.3d 242, 256 (3d Cir. 2009)). To be effective, "'meaningful' cautions calls for 'substantive' company-specific warnings based on a realistic description of the risks applicable to the particular circumstances, not merely a boilerplate litany of generally applicable risk factors." *Southland Secs. Corp. v. INSpire Ins. Solutions, Inc.,* 365 F.3d 353, 372 (5th Cir. 2004); *see also Lormand v. U.S. Unwired, Inc.,* 565 F.3d 228, 246-47 (5th Cir. 2009) (concluding that cautionary language was not meaningful where the warning was "very vague and general" and did not "disclose the specific risks and their magnitude").[3]

Here, Keryx's risk disclosure was similar to Harman International's generic warnings that "sales could suffer if the Company failed to 'develop, introduce and achieve market acceptance of new and enhanced products.'" *In re Harman Int'l Indus., Inc. Sec. Litig.,* 791 F.3d 90, 104 (D.C. Cir. 2015). The Court of Appeals there found this warning failed to inform investors that Harman's on-hand inventory actually included a significant amount of obsolete inventory. *Id.* Here, Keryx's Risk Disclosures failed to acknowledge that Norwich "was limiting" its supply of product and that a supply

[3] This Court has cited *Lormand* with approval. *See Tutor Perini Corp. v. Banc of Am. Secs. LLC*, 842 F.3d 71, 91 (1st Cir. 2016).

interruption was imminent. Keryx's Risk Disclosures were "too general and fail[ed] to account for the materialization, rather than abstract possibility, of the important risk posed by" Norwich's production stoppages. *Id.* at 106. Contary to Defendants' contention, just because they were able to temporarily manage Norwich's supply problems does not mean that their alleged cautionary language was adequate.

Second, the Risk Disclosure does not mention the risk of a supply interruption. Therefore, the Risk Disclosures did not adequately warn investors of the true risks facing Keryx at the time. *See Slayton,* 604 F.3d at 772 (warning that "if our portfolio deteriorates, then there will be losses" was too vague and general to properly warn investors that company's bond portfolio was in fact deteriorating in value at the time the risk disclosure was made). Here, warning that, if third-parties do not supply product, "revenues could decline," does not adequately warn that third-parties were, in fact, limiting product supply, Keryx was managing inventories to avoid a supply interruption because of those limitations and if Norwich, which had a history of production stoppages, encountered another stoppage, a supply interruption would occur by mid-May 2016. Defendants, by failing to even address this point, concede its accuracy.

The risk of a "supply interruption" is vastly different for a start-up biotech company for its only drug product than is the risk of a "decline in revenues." When the supply interruption was announced, market analysts noted concern not necessarily with the short-term potential of lost revenue, but the long-term damage to the product due to physicians and patients seeking out alternatives to Auryxia. Patients do not just keep switching back and forth with a critical drug to manage their kidney dialysis. *See* Appellant's Opening Brief ("Opening Br.") at 35.

Defendants erroneously claim that because the Risk Disclosures "are ***not referenced*** anywhere in the 120-page proposed TAC" Plaintiff waived his right to challenge whether the Risk Disclosures were factually untrue and misleading. Def. Br. at 25 (emphasis in original). The Risk Disclosures are Defendants' defense. Plaintiff is not required to guess what disclosures Defendants might assert as a defense and then plead those disclosures as being false in the TAC. Tellingly, Defendants fail to cite any authority for their novel proposition.[4]

[4] Defendants' claim that because they pointed to these Risk Disclosures in their 12(c) motion, Plaintiff should have anticipated that they would also point to them as having properly informed the market of a risk of a supply interruption and ongoing production problems in producing Auryxia. This improperly requires Plaintiff to be clairvoyant.

Their claim that Plaintiff did not challenge the sufficiency of the Risk Disclosures below is belied by their own admissions. In their Opposition to Plaintiff's Motion to Amend, after citing to the April 2016 Risk Disclosure, Defendants concede "Plaintiff alternatively contends this disclosure was inadequate. . .". JA01031. Plus, in the Reply Brief in support of Plaintiff's Motion for leave to Amend, Plaintiff repeatedly argued that Keryx was experiencing manufacturing issues that caused limitations in the supply of product. ("[M]anufacturing issues had already occurred and were continuing to occur" and the "business was being harmed.") JA01721.[5] Where, as here, Plaintiff specifically challenged the sufficiency of the Risk Disclosure and specifically argued that Norwich was experiencing manufacturing issues that clearly showed it was limiting its production at the time the Risk Disclosures

[5] Plaintiff further argued that: "Keryx's risk factors spoke in hypothetical terms at a time when Defendants knew with certainty that the risks described were already occurring." JA01725; "Indeed, in March 2016 Norwich began a five-week production halt [. . .]. ¶¶ 113-14. This production halt led directly to the supply interruption announced on August 1, 2016." JA01731. "[W]hen Madison made his statements on April 28, 2016, omitting to disclose that Norwich was in the midst of a production stoppage, Keryx had only one-month of supply on-hand, that achieving the forecast was based on Norwich fully resolving all "manufacturing deviations" and producing the largest amount of Auryxia bottles it had ever produced to date and that if Norwich could not resolve the manufacturing issues a supply interruption would occur in May 2016, would have altered the total mix of information rendering the omitted facts material." JA01731.

were made, this Court should not find that Plaintiff waived his right to argue this point on appeal. Waiver is appropriate only where the issues were "adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation," *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990), or where the issue raised on appeal is wholly "alien to the record[.]" *United States v. Kobrosky,* 711 F.2d 449, 457 (1st Cir. 1983). Neither situation is applicable here and waiver is therefore unjustified.

Waiver is also unwarranted because the District Court addressed the issue. *Fidelity Co-op. Bank v. Nova Cas. Co.*, 726 F.3d 31, 39 (1st Cir. 2013) ("The issue is not waived on appeal as it was an issue directly passed on *sua sponte* by the court below."). To be sure, the District Court explicitly addressed Plaintiff's arguments that the February and April 2016 Risk Disclosures were misleading:

> 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.

JA00870.[6] Thus, Plaintiff not only "pressed" the issue—the District Court also "passed upon" it. *See Fidelity*, 726 F.3d at 39 (rejecting waiver argument premised on plaintiff's alleged failure to raise issue below where "the district court addressed and passed on the issue directly," and plaintiff "did in fact raise the issue in the court below when it filed its motion for reconsideration following the district court's granting of summary judgment[.]").[7]

Third, the Risk Disclosures nowhere mention anything about the prior production problems at Norwich and Keryx's other third-party suppliers. Defendants concede that "both Norwich and Keryx's third-party API suppliers encountered various manufacturing issues" from "December 2014 until August 1, 2016." Def. Br. at 4. The Risk Disclosures cannot be read to

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[6] *See also* JA00860 (rejecting Plaintiff's arguments that the disclosures were misleading and finding that "[t]he February and April 2016 disclosures resolve the ambiguity that may have misled the market[.]")

[7] *United States v. Slade*, 980 F.2d 27 (1st Cir. 1992), cited by Defendants (Def. Br. at 26) is inapposite. *Slade* involved a criminal appeal of the denial of a motion for a new trial premised on newly discovered evidence. *Slade*, 980 F.2d at 29. This Court explained that "[f]ollowing the district court's denial of her motion for a new trial, [defendant] apparently reassessed the field, decided her old argument was lame, and now seeks to ride a fresh mount in a new direction." *Id.* at 30. This Court held defendant "waived the argument that she pressed below and, therefore cannot be heard to complain about the district court's rejection of that argument. By the same token, she is estopped from pursuing at this late date a newly emergent argument never presented to the lower court." *Id.* at 32.

have alerted investors to these prior problems as they say nothing about any production issues at any third-party supplier.

Accordingly, the Risk Disclosures did not adequately warn investors of a supply interruption and of prior manufacturing issues at Keryx's third-party suppliers; the District Court's decision should be reversed.

II. The District Court Incorrectly Found There Was No Loss Causation and Plaintiff Has Not Waived His Right To So Argue

Because the District Court incorrectly found the Risk Disclosures adequately informed the market that a supply interruption could occur, the finding that Plaintiff could not establish reliance or loss causation due to the timing of his purchase of Keryx stock was also in error.

Defendants recognize this error, arguing only that if the Risk Disclosures adequately informed investors that a supply interruption was imminent, then the materialization of the warned of risk could not have caused the August 1, 2016 stock drop. Def. Br. at 27. Since the Risk Disclosures were inadequate, loss causation is properly pled and Plaintiff has standing to bring the claims.

Defendants also erroneously contend that Plaintiff argued below that nothing in the TAC would change the outcome of class certification, so he "failed to preserve this issue[.]" Def. Br. at 55. Defendants are wrong. The

out-of-context quote relied on by Defendants assumed the TAC was granted. Indeed, Plaintiff expressly preserved this issue informing the District Court that "If the Court grants Plaintiff leave to file the TAC, Defendants'" arguments on many of the points they raised will become moot. JA00780. Defendants' argument violates the rules of logic: that Plaintiff said that granting permission to file the TAC would also allow the Court to grant class certification does not mean that Plaintiff conceded that failing to grant permission to file the TAC would also doom class certification.

Second, Defendants' argument relies on taking quotes out of context. The relevant portion of Plaintiff's motion to amend, of which Defendants cite only the italicized portion, states:

> while the amendment adds allegations of additional false statements and material omissions, as well as allegations about Defendants' scienter in making those statements, it does not change the alleged Class Period, and still concerns the same general subject matter of the operative complaint. The alleged corrective disclosure has not changed. E.g., TAC ¶¶ 115, 258, 259. As such, there is no prejudice to Defendants in allowing the amendment, *which does not fundamentally change the nature of the case at bar.*[8]

Defendants' waiver argument is meritless.

[8] JA00878.

III. The TAC Otherwise States A Claim

While this Court need not go any further to address the errors in the District Court's decision, Defendants' arguments that the TAC otherwise fails to state a claim (on grounds not addressed by the District Court) are also without merit.

A. The TAC Adequately Pleads Scienter

The TAC contains the gold standard of scienter evidence: internal documents that contradict public statements made by Defendants.[9] Defendants concede that complaints with "clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware they were withholding vital information . . ." satisfy the standard for pleading scienter. Def. Br. at 48 (citing *In re Boston Scientific Corp. Sec. Litig.*,

[9] Defendants rely on *Glassman v. Computervision Corp.*, 90 F.3d 617 (1st Cir. 1996) to suggest that Plaintiff's TAC should be subject to an even further heightened standard that the PSLRA imposes because substantial discovery had been completed in the case. Def. Br. at 49. But this case is nothing like *Computervision*, where "full discovery" had been completed. 90 F.3d at 628. Here, Defendants did not produce discovery relating to their 2016 Auryxia sales forecasts (JA00378), only one deposition had been taken, and discovery deadlines were extended during the pendency of Defendants' Motion for Judgment on the Pleadings, Plaintiff's Motion for Class Certification and Plaintiff's Motion for Leave to File the TAC. ECF No. 149. While it is true that some discovery allowed Plaintiff to plead internal documents, it is a far cry from the complete record in *Computervision*.

686 F.3d 21, 31 (1st Cir. 2012). Indeed, that "defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002).[10]

Ignoring the well-pled allegations of internal documents and discussions that directly contradicted Defendants' public statements,[11] Defendants instead argue that scienter cannot be inferred because "the manufacturing issues experienced by Norwich had ***never*** prevented Keryx from meeting demand for its product." Def. Br. at 50 (emphasis in original). This suggests that Defendants could only be found to have acted with scienter if the statements at issue were made ***after*** a supply interruption occurred. This

[10] Defendants take issue with Plaintiff's citation to *Serabian v. Amoskeag Bank Shares, Inc.*, 24 F.3d 357, 365 (1st Cir. 1994), claiming that it was "abrogated by the PSLRA." Def. Br. at 48, n.17 (citing *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196-97 (1st Cir. 1999)). But *Greebel* makes clear that the PSLRA "d[id] not alter the pre-existing definition of scienter adopted by this circuit," and even *Greebel* relies on *Serabian*: "In *Serabian* this court held that it was error to dismiss a . . . complaint that alleged sufficient facts to draw 'an inference that the [defendant] knew, or should have known, that its public statements were inconsistent with the actual conditions then being reported to [it].' We understand *Serabian* to have used 'should have known' in the reckless disregard sense. *Greebel*, 194 F.3d at 199. Plaintiff does not suggest by citing to *Serabian* that the PSLRA's strong inference standard does not apply here.

[11] *See* Opening Br. at 52-57.

is not the law. Defendants knowingly concealed the ongoing, serious production problems from investors while knowing the risk of a supply interruption. For example, the TAC pleads that Defendants knew in April 2016 that Norwich was in the midst of a 5-week production stoppage, supply of Auryxia was constrained, and Keryx was internally warning that a supply interruption would occur if nothing changed. Opening Br. at 56, JA00991-92 ¶246. These facts were contrary to Defendants' statements to investors at the time, thus supporting a strong inference of scienter. *See Aldridge*, 284 F.3d at 83.

Similarly, the TAC further pleads internal documents showing that Keryx was experiencing significant manufacturing problems and Defendants were aware of these problems, all while presenting these manufacturing problems to investors as merely hypothetical. Opening Br. at 54-55, JA000894-914, JA00989 ¶¶43-47, 50-53, 57-58, 64-89, 242. The TAC also alleges that while Defendants were informing the Board that it was a high priority for Keryx to find another tablet supplier, it told investors that its single supplier was sufficient for commercial success. JA00917, JA00980, JA00982 ¶¶99, 213, 221. In short, the TAC pleads significant direct evidence

that Defendants knew that the statements they made to investors were false or omitted to disclose material facts.

Defendants' reliance on *Zafgen* and *MEMC Elec. Materials, Inc.* is misplaced. In *Zafgen*, unlike here, defendants disclosed two "serious" adverse events, but scienter was found lacking for failing to disclose two "superficial" adverse events, which the Court found "took on the bulk of their significance only after" a patient in a drug trial died. *Brennan v. Zafgen, Inc.*, 853 F.3d 606, 617-18 (1st Cir. 2017). But the disclosures here are not about "superficial" events that only became important later; the TAC charges Defendants with failing to disclose existential manufacturing problems and production delays, not every minor manufacturing issue Keryx experienced. *Zafgen* is wholly inapposite.

Similarly, *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023 (8th Cir. 2011) involved a company that missed quarterly revenue guidance by two percent, in part because of an undisclosed manufacturing problem. *Id.* at 1026. Defendants cherry-pick language about the lack of an alleged "personal[] benefit" in *MEMC* to suggest that no complaint can survive a motion to dismiss where a personal benefit is not alleged. Def Br. at 53. But in *MEMC*, two additional factors cut against a

finding of scienter: the alleged omission resulted only in a minor 2% earnings miss, and the company had previously issued specific warnings about running low on manufacturing supplies from time to time. 641 F.3d at 1025, 1030. Neither of those minimizing factors are present here.[12]

While the TAC also alleges Defendants' motive,[13] such allegations are not necessary to plead scienter where Defendants are charged with publishing

[12] Defendants also argue that scienter is undermined because Keryx did not seek expedited FDA approval for a second manufacturer until July 2016. Def. Br. at 50-51. Defendants improperly raise this argument for the first time on appeal. *See United States v. Nee*, 261 F.3d 79, 86 (1st Cir. 2001) (waiver rule designed to prevent "sandbagging."). Regardless, the TAC contradicts the argument. The TAC pleads facts showing that Keryx's attepts to get FDA approval for this second manufacturer were plagued by delays. JA00914-15, JA00985-87 ¶¶90-93, ¶¶232, 234, 236, 239. The fair inference is that Keryx had been unsuccessful in its prior attempts to get the second manufacturer approved. JA00910-12 ¶¶83-85 ("the overall appearance would be to the FDA that we do not have our process under control.").

[13] Defendants' attempts to minimize the allegations of motive—which they admit are not even necessary to find scienter pled—are unavailing. Def. Br. at 51-52. Defendants claim that the TAC pleads only the "usual concern by executives to improve financial results," Def. Br. at 52 (citing *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 41 (1st Cir. 2017). Not so. The TAC specifically pleads that Defendants knew both that Keryx investors were taking a skeptical, wait-and-see approach to the company before investing, that that Keryx would need additional financing or would only have about 90 days of operating cash by year end 2016. JA00915-916 ¶¶94-97. These allegations go beyond the "revenue generation" motive described in *Corban*. Nor is this case like *Slayton*, 604 F.3d at 777 (Def. Br. at 52). There, unlike here, defendants took only a short time to make an informed disclosure to investors about an adverse event.

statements "when they knew facts suggesting the statements were inaccurate or misleadingly incomplete[.]" *Aldridge*, 284 F.3d at 83. *See also Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc.*, 778 F.3d 228, 241 (1st Cir. 2015) ("There is no set pattern of facts to establish scienter; it is a case-by-case inquiry.")

B. Statements About Keryx's Strong Fundamentals Are Actionable

Defendants argue that certain statements are not actionable because they are (a) forward-looking, (b) non-actionable statements of opinion, and (c) puffery. None of these arguments have merit.[14]

For the reasons described above, to the extent any of the challenged statements were forward looking, Keryx's inadequate risk disclosures failed to provide the required "meaningful cautionary statements identifying important factors that could cause actual results to differ materially." Def. Br. at 44 (quoting 15 U.S.C. § 78u-5(c)(1)(A)(i)). What is more, the statements about Keryx having "solid fundamentals," being "off to a good start," and having "all the pieces in place" are by definition not forward looking, even if they appeared in a section entitled "Financial Forecasts." Def. Br. at 44-45.

[14] Even if they did, dismissing these allegations would not dispose of the entire case pled in the TAC, which includes the additional allegations of false statements about Keryx's risk disclosures discussed in detail above.

Each of these statements is about the then-existing state of affairs, not about the future. Opening Br. at 47-52.

Defendants reach to the 11th Circuit to argue that a statement that a company would "continue to provide strong servicing results" was forward looking even though it "implicitly communicate[s] information about the present." Def. Br. at 45 (quoting *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1329 (11th Cir. 2019)). But this position—to the extent it even applies to the statements at issue, which have no obvious forward-looking component—is directly contradicted by First Circuit law. *In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 213 (1st Cir. 2005) ("[t]he mere fact that a statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward looking aspects of the statement.")

Defendants are also wrong that the statements are non-actionable opinions under *Omnicare*. *First*, as *Omnicare* acknowledges, even opinion statements can "contain embedded statements of fact[.]" *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 185 (2015). *Second*, *Omnicare* makes clear that even statements of pure opinion are actionable where they "convey facts about how the speaker has formed the

opinion[,]" and "if the real facts are otherwise, but not provided, the opinion statement will mislead its audience." *Id.* at 188. That is precisely what has happened here. Defendants' statements about the fundamentals of Auryxia being solid, being off to a good start, and having all the pieces in place omitted to disclose (a) the consistent production problems at Norwich, (b) the risk that if the production problems were not solved, a supply interruption could occur, and (c) that supply itself was "constrained" as of March 2016. Opening Br. at 49-52.

Finally, Defendants are wrong that their statements are inactionable puffery.[15] Def. Br. at 45. Defendants cite *Shaw* for the general proposition that vague, loosely optimistic statements are not actionable. Def. Br. at 45. But the challenged statements here go beyond the "expressions of optimism" and "predict[ions of] growth" discussed in *Shaw*. *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1218 (1st Cir. 1996). In the context made, Defendants' claim that Keryx's fundamentals were solid, and that the company had "all the pieces in place," communicated concrete (and false) facts about the existing state of

[15] Besides, Defendants did not argue that any challenged statements were puffery below, and have thus waived the argument. *See* JA01001-36 (no discussion of puffery); *Campos-Orrego v. Rivera*, 175 F.3d 89, 95 (1st Cir. 1999).

Auryxia, given the manufacturing problems Keryx was experiencing. Those statements go well beyond the statement that things are "going reasonably well" made in reaction to disappointing earnings dismissed as puffery in *Shaw*. *Id.* at 1219.

Conclusion

Appellant respectfully requests this case be remanded for the District Court to consider whether the TAC pleads valid claims for relief, with instructions that the Risk Disclosures did not cure any potentially prior misleading statements, and were misleading themselves.

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Respectfully submitted,

/s/ Jeffrey C. Block

Jeffrey C. Block
Jacob A. Walker
Nathaniel Silver
Block & Leviton LLP
260 Franklin Street, Suite 1860
Boston, MA 02110
(617) 398-5600

Counsel for Plaintiff-Appellant

Certificate of Service

I hereby certify that on May 19, 2020, I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that all parties or their counsel of record are registered as ECF Filers and will be served through the CM/ECF system.

/s/ Jeffrey C. Block
Jeffrey C. Block

Certificate of Compliance

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 32(a)(7)(B) because it contains 5,254 words, as determined by the word-count function of Microsoft Word, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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/s/ Jeffrey C. Block
Jeffrey C. Block