**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF TEXAS**
**AUSTIN DIVISION**

**LINH TRAN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,**

**Plaintiff,**

**-vs-**

**Case No. A-15-CA-01083-SS**

**XBIOTECH INC., JOHN SIMARD, and QUEENA HAN,**

**Defendants.**

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# ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled . Before the Court is Defendants XBiotech Inc., John Simard, and Queena Han's Motion to Dismiss [#37], Lead Plaintiff Kresimir Corak's Response [#38] in opposition, and Defendants' Reply [#39] in support. Having reviewed the documents and the governing law, the Court now enters the following opinion and orders.

## Background[1]

This is a securities fraud class action brought on behalf of all persons who purchased the common stock of Defendant XBiotech Inc. (XBiotech), a biopharmaceutical company, between April 15, 2015 and November 23, 2015 (the Class Period). Lead Plaintiff Kresimir Corak (Plaintiff), on

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[1]The recited facts are taken from Plaintiff's complaint and documents incorporated in the complaint. *See Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1018 & n.1 (5th Cir. 1996) (allowing courts deciding a motion to dismiss in a securities fraud action to consider the complaint, the documents attached to or incorporated in the complaint, and public disclosure documents required by the SEC and actually filed with the SEC but **not** consider other forms of disclosure such as press releases or announcements at shareholder meetings).

behalf of the plaintiff class, alleges that during the Class Period, XBiotech, its CEO, Defendant John Simard (Simard), and its Vice President of Finance and Human Resources, Defendant Queena Han (Han), made a variety of misrepresentations to shareholders in violation of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. Defendants have moved to dismiss, arguing Plaintiff has failed to adequately plead falsity, scienter, loss causation, and a viable claim under § 20(a). Defendants also contend some of the alleged misrepresentations identified by Plaintiff fall within the Private Securities Litigation Reform Act (PSLRA)'s safe harbor, 15 U.S.C § 78u-5(c)(1)(A). As set forth below, the Court agrees with Defendants that Plaintiff has failed to adequately plead scienter. The motion to dismiss is therefore GRANTED, and the Court need not reach Defendants' remaining arguments at this time.

## I. XBiotech and Xilonix

XBiotech is a "clinical-stage biopharmaceutical company engaged in the discovery and development of 'True Human' antibodies," which are intended to treat a variety of diseases. Am. Compl. [#35] ¶ 2. XBiotech devotes the majority of its resources to its lead product candidate "Xilonix," a new drug designed to treat patients with advanced colorectal cancer. *Id.*

In the period before this suit, XBiotech had two clinical trials of Xilonix underway, one in the United States and one in Europe. Defs.' Mot. Dismiss [#37-5] Ex. 5 (Registration Statement) at 56; Defs.' Mot. Dismiss [#3-67] Ex. 6 (Prospectus) at 56.[2] The United States study experienced "significant difficulty identifying colorectal cancer patients," resulting in delay and disruption of the

[2] The Registration Statement and Prospectus are attached to Defendants' motion to dismiss, referred to in Plaintiff's Amended Complaint, and central to Plaintiff's claim. Therefore, the court may consider these documents in assessing the motion to dismiss. *See In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 205 (5th Cir. 2007) ("Because the defendants attached to the contracts to their motions to dismiss, the contracts were referred to in the complaints, and the contracts are central to the plaintiffs' claims, we may consider the terms of the contracts in assessing the motions to dismiss.").

trial. Registration Statement at 56–57; Prospectus at 56–57. The clinical trial in Europe, on the other hand, continued without suspending enrollment. *Id.*

Begun in July 2014, the European study was a Phase III trial to evaluate Xilonix's treatment of symptomatic colorectal cancer (Phase III Trial). Am. Compl. [#35] ¶ 3. Specifically, the trial's primary objective was to evaluate Xilonix's ability to reverse the symptoms of patients with advanced colorectal cancer, including muscle loss, fatigue, appetite loss, and pain, by comparing the experiences of patients treated with Xilonix with those of patients treated with a placebo. *Id.* at ¶ 28. To accomplish this objective, the Phase III Trial sought to recruit at least 276 patients across 40 clinical trial sites in Europe and complete the entire trial in 2015. *Id.*

## II. Management of the Phase III Trial

### A. KCR as the CRO

In order to manage the complexities of such clinical trials, biopharmaceutical companies typically engage contract research organizations (CROs). *Id.* at ¶ 5. The sponsoring biopharmaceutical company retains ultimate regulatory oversight over the clinical trial, but the CRO conducts the drug trial on the ground. *Id.* The selection of a CRO depends on the priorities of the sponsoring company considering criteria such as capability, size, pricing, and reputation. *Id.* at ¶ 35, 37–39.

XBiotech selected Kiecana Clinical Research (KCR) to manage Xilonix's Phase III Trial. *Id.* at ¶ 40. KCR is a small company sometimes hired by pharmaceutical companies to serve as a CRO but more frequently as a site management organization (SMO). *Id.* at ¶ 41. Compared to CROs, which generally take responsibility for protocol design, data management, and statistical analysis,

SMOs are typically only charged with tasks such as patient recruitment and testing protocol administration. *Id.*

KCR advertises itself as "a reliable alternative to top tier CROs, delivering the all important flexibility." *Id.* at ¶ 43. According to at least one pharmaceutical industry source reviewing CROs, however, KCR is not deemed to be one of the top ten CROs within the industry. *Id.* at ¶ 42. And while KCR previously attempted to expand its global presence into the United States, it has cut back on those ambitions and laid off most of its U.S.-based staff. *Id.* at ¶ 41.

**B. Enrollment Data**

Between Phase III Trial's commencement in July 2014 and March 3, 2015, approximately 122 patients were enrolled across the study sites. *Id.* at ¶ 7. KCR encountered several difficulties enrolling its desired 276 patients: First, the vacation policies of certain countries where the trial was being conducted contributed to a "slower -than-expected enrollment during the study's early months." *Id.* at ¶ 46. Second, because the patient population was "extremely sick," a large number of patients were not physically healthy enough to continue with the study after the initial screening. *Id.*

In alleging Defendants made misleading statements concerning the enrollment data and the timeline for the Phase III Trial, Plaintiff points to Defendants' familiarity with the enrollment data. Two confidential sources, former employee I (FE1) and former employee II (FE2), claim Defendants had real time access to Phase III Trial's patient data.[3] These witnesses indicated XBiotech had a

[3] FE1 was the Vice President of Clinical Operations at XBiotech from June 2014 to February 2015. FE1 oversaw the clinical trials for Xilonix, coordinated with KCR, and reported on the progress of the Phase III Trial. Am. Compl. [#35] at 9 n.6. FE2 was the Director of Clinical Operations at XBiotech from June 2012 to March 2016. FE2 managed the budgets for clinical sites, internal operations, and interactions with CRO employees. *Id.* at 11 n.8.

study team including both confidential witnesses, two project managers, the Director of Biostatistics, the Director of Data Management, and the Medical Director. Am. Compl. [#35] ¶ 47. According to FE2, the study team received updates from KCR "at least twice per month" and sometimes "weekly when there was lots of activity." *Id.* ¶ 48.

While neither Simard nor Han were on the study team, FE1 claims FE1 personally emailed patient data to Simard "on a regular basis." *Id.* ¶ 50. FE1 also notes Simard "received weekly spreadsheets tracking actual enrollment versus projections" and had access to the electronic enrollment data *Id.* ¶¶ 47–48, 50. Additionally, FE2 claims the Clinical Operations department held "enrollment meetings" on a "regular basis" and XBiotech held "governance calls," in which Simard participated on a "regular basis." *Id.* ¶ 49.

According the Complaint, "FE1 considered" XBiotech's timeline for Phase III "'absolutely unrealistic,' if not virtually impossible" without increasing the number of study sites. *Id.* ¶ 52. "During weekly meetings held in Defendant Simard's office," FE1 claims FE1 and other XBiotech employees advised Simard the goals for enrollment and completion of the study were unrealistic without additional study sites. *Id.* ¶ 48. FE1 further recalls "Defendant Simard continually micromanaged KCR's administration of the study" but could not remedy the enrollment problems because of his lack of experience. *Id.* ¶ 45.

## III. The Alleged Misrepresentations & Omissions

The statements Plaintiff identifies as misleading are drawn from XBiotech's Registration Statement and Prospectus and incorporated into SEC 10-Q forms disclosing and discussing XBiotech's financial results for every quarter during the Class Period. The alleged misrepresentations and omissions can be divided into two overarching categories: (1) the risks facing

XBiotech and (2) the timeline for completion of the Phase III Trial. In general, Plaintiff alleges Defendants failed to accurately and fully disclose the specific risks affecting XBiotech and the Phase III Trial. Am. Compl. [#35] ¶¶ 55, 59, 61. Plaintiff further alleges, in light of the enrollment problems outlined above, Defendants falsely represented the Phase III Trial would be completed by mid-2015. *Id.* ¶ 57. The specific alleged misrepresentations identified by Plaintiff are set forth below as briefly as possible with additional context from the statements themselves.

**A. SEC Registration Statement & Prospectus**

In preparation for its initial public offering (IPO), XBiotech filed a Registration Statement and Prospectus with the United States Securities and Exchange Commission (SEC) on February 2, 2015. *Id.* at ¶ 7. After three subsequent amendments, the SEC declared XBiotech's Registration effective on April 15, 2015. *Id.* The SEC similarly deemed XBiotech's Prospectus effective on April 16, 2015. *Id.*

**i. Risks**

In disclosing the "Risk Factors" in its Registration Statement and Prospectus, XBiotech devoted 22 pages to discussing the variety of risks and uncertainties that could harm XBiotech and its investors. Registration Statement at 9–30; Prospectus at 9–30. In a section entitled "Risks Related to our Business," XBiotech stated:

> We are highly dependent on our Chief Executive Officer. Our future success depends in significant part on the continued service of our Chief Executive Officer, John Simard. Mr. Simard is critical to the strategic direction and overall management of our Company as well as our research and development process. Although we have an employment agreement with Mr. Simard, it has no specific duration. The loss of Mr. Simard could adversely affect our business, financial condition and operating results.

*Id.* ¶ 54. Plaintiff alleges this statement about the risks associated with XBiotech's dependency on its CEO were misleading because Defendants failed to disclose CEO John Simard "did not have any experience with oversight of a large, global clinical trial like the Phase III Trial." *Id.* ¶ 55.

In the same "Risk Factors" section, XBiotech also stated:

> ***If we are unable to enroll subjects in clinical trials, we will be unable to complete these trials on a timely basis.***
>
> Patient enrollment, a significant factor in the time of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrollment subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drugs being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on Clinical Research Organizations (CROs) and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we may have agreements governing their committed activities, we have limited influence over their actual performance. We may experience delays in enrolling subjects in our trials and may not be able to enroll sufficient subjects to complete the trials.

*Id.* ¶ 58, 60 (quoting Registration Statement at 13 and Prospectus at 13). According to Plaintiff, because XBiotech oversaw KCR's performance of the Phase III Trial and Simard exercised "material influence" over that performance, Defendants' statement that XBiotech only exercised "limited influence" was false and misleading. *Id.* ¶ 59. Plaintiff also alleges Defendants' assertion about CROs, by only addressing general or hypothetical risks that CROs might fail to complete trials, is misleading; it did not include the risk KCR specifically could fail to conduct the Phase III Trial properly in light of its smaller size and reputation. *Id.* Likewise, Plaintiff also alleges the above statement is misleading because it did not disclose the delays in patient enrollment KCR and XBiotech had already realized in the administration of the Phase III Trial. *Id.* ¶ 61.

### ii. Phase III Trial Timeline

In both the Registration Statement and the Prospectus, XBiotech also described its "Current Clinical Investigation Activity," informing potential investors about the two clinical trials for Xilonix. *Id.* ¶ 56. For the United States study, XBiotech disclosed the delays the trial had experienced due to enrollment difficulties. Registration Statement at 56–57; Prospectus at 56–57. Concerning the Phase III Trial in Europe, XBiotech stated:

> The study, which started in July 2014, will enroll at least 276 patients and is expected to be completed by mid-2015. As of March 3, 2015 about 122 patients had been enrolled. If the study endpoints are satisfactorily achieved, we expect to submit a registration package to the EMA and possible other foreign regulatory agencies.

Am. Compl. [#35] ¶ 3 (quoting Registration Statement at 56 and Prospectus at 56).

Earlier in the same section, XBiotech also reported Phase III Trial's "sites are located in a number of different European Union member states, and the addition of sites in Russia is expected soon." Registration Statement at 56; Prospectus at 56. In addition, a few pages before the section quoted by Plaintiff, XBiotech outlined its strategy for Xilonix. Registration Statement at 50; Prospectus at 50. XBiotech disclosed that it was "projecting" to complete the European "Phase III enrollment in the second-half of 2015" and submit its registration package to the European regulatory authority "in the fourth quarter of 2015." *Id.*

Plaintiff alleges Defendants misrepresented the Phase III Trial timeline despite knowing such a timeline was unrealistic. Am. Compl. [#35] ¶ 57.

## B. SEC 10-Q Forms

In May, August, and November, XBiotech filed quarterly reports on Form 10-Q with the SEC for the periods ending March 31, 2015, June 30, 2015, and September 30, 2015, respectively. Am.

Compl. [#35] ¶¶ 62, 64, 66. Each of these 10-Q Forms "incorporates by reference the risk disclosures made in the Company's Registration Statement and Prospectus." *Id.*

## IV. The Alleged Corrective Disclosures

Plaintiff alleges Defendants' corrective disclosures occurred through a July 28, 2015 press release and associated earnings conference and through a November 23, 2015 press release. *See id.* ¶¶ 68–71.[4] During the earnings conference on July 28, 2015, Simard stated the Phase III Trial "is expected to be completed towards the end of this year," and "enrollment is a little less than what we would like it to be at this juncture." *Id.* ¶ 68 (citing Defs.' Mot. Dismiss [#37-3] Ex. 13 at 4). Simard also stated "My expectation was to have enrollment complete sometime this summer. We may now see enrollment carry on into September but our timeline to have a readout by yearend should not be affected." Ex. 13 at 4. Following the July 28, 2015 alleged corrective disclosure, XBiotech's share price declined from $20.00 on the morning of July 28 to $18.51 at close on July 30. Am. Compl. [#35] ¶ 70.

A few months later, the November 23, 2015 press release reported "25 patients dropped off study prior to receiving any dosing with drug or placebo," "14 patients erroneously received either placebo or study drug," and "33 patients completed the study but failed to receive scheduled DEXA scans, properly complete EORTC evaluation, or both." Am. Compl. [#35] ¶ 71. According to the press release, 72 patients from the Phase III Trial were compromised and "oversampling was not performed to accommodate [such] data loss." *Id.* Significantly, the press release noted "the study will

[4] The July 28, 2015 press release is attached to Defendants' motion to dismiss at Exhibit 14. Defs.' Mot. Dismiss [#37-14] Ex. 14. The associated earning conference is Defendants' Exhibit 13 and the November 23, 205 press release is Exhibit 18. Defs' Mot. Dismiss [#37-13] Ex. 13; Defs' Mot. Dismiss [#37-18] Ex. 18.

have reduced statistical power to demonstrate the proposed effect." *Id.* The press release also reported Simard's statements, "These findings relating to the execution of the study [are] disappointing. We anticipate another 10 days to complete ongoing analysis of patient sample and data. At such time, we will provide an update of our findings." Ex. 18 at 1. After the November press release, Biotech stock fell $4.50 per share to close at $8.75 per share on November 24th. Am. Compl. [#35] ¶ 72.

## IV. Plaintiff's Scienter Allegations

According to Plaintiff, Defendants knew or recklessly disregarded the potential the statements describing risks affecting XBiotech and the timeline for the Phase III Trial were materially false and misleading at the time they were made. *Id.* ¶¶ 89, 91–92.

For the alleged misleading statements about CROs, Plaintiff alleges Defendants knew the selection of KCR "went against conventional wisdom" because KCR was a small company, was not regarded as a "top" CRO, had failed in its effort to expand to the U.S., had historically operated as an SMO, and its employees had limited training. *Id.* ¶¶ 6, 59. Specifically, Plaintiff alleges"Defendants knew or recklessly disregarded the potential impact that their CRO selection could have upon the administration of the Phase III Trial." *Id.* ¶ 6.

Concerning XBiotech's statements on the Phase III Trial timeline, Plaintiff does not allege direct proof of scienter on the part of Simard or Han but instead argues circumstantial evidence supports a strong inference of scienter. Plaintiff alleges Defendants knew or recklessly disregarded the "wealth of daily and weekly patient enrollment data" and "guidance and warnings provided by senior Company employees," specifically FE1, indicating achieving the patient enrollment target within the stated time frame was "absolutely unrealistic." *Id.* ¶ 72. Plaintiff also argues, because the

Phase III Trial's enrollment problems were so obvious, Defendants must have been aware the mid-2015 timeline was unrealistic, especially in light of the importance of Xilonix to XBiotech. *Id.* ¶¶ 17, 26, 48–50. Finally, Plaintiff argues that XBiotech's small size provides another basis for inferring that Defendants were aware the mid-2015 timeline the Phase III Trial was misleading. *See* Registration Statement at 21; Prospectus at 21 (stating XBiotech only had 56 employees).

Plaintiff also cites XBiotech's IPO as establishing scienter. *Id.* ¶ 81. In the Prospectus, XBiotech stated that it expected to use "approximately $30 million" from the net proceeds of the IPO to complete the two Xilonix trials. *Id.* ¶ 81. The IPO netted XBiotech approximately $70.9 million. *Id.* ¶ 81.

## Analysis

### I. Legal Standard

### A. Motion to Dismiss—Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A motion under Federal Rule of Civil Procedure 12(b)(6) asks a court to dismiss a complaint for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). To survive a motion to dismiss, the plaintiff must plead sufficient facts to state a claim for relief that is facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 566 U.S. at 678. Although a plaintiff's factual allegations need not establish that the defendant is probably liable, they must establish more than a "sheer possibility" a defendant has acted unlawfully.

*Id.* Determining plausibility is a "context-specific task," and must be performed in light of a court's "judicial experience and common sense." *Id.* at 679.

In deciding a motion to dismiss under Rule 12(b)(6), a court generally accepts as true all factual allegations contained within the complaint. *Leatherman v. Tarrant Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993). However, a court is not bound to accept legal conclusions couched as factual allegations. *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Although all reasonable inferences will be resolved in favor of the plaintiff, the plaintiff must plead "specific facts, not mere conclusory allegations." *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994). In deciding a motion to dismiss, courts "must consider"the complaint, as well as other sources such as documents incorporated into the complaint by reference and matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

**B. Securities Exchange Act § 10(b) Pleading Requirements**

Section 10(b) of the Securities Exchange Act of 1934 empowers the SEC to promulgate rules to prevent manipulative or deceptive practices in the sale or purchase of securities. 15 U.S.C. § 78j(b). Under this grant of authority, the SEC issued Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

Both Federal Rule of Civil Procedure 9(b) and the PSLRA impose a heightened pleading requirement on § 10(b) claims. FED. R. CIV. P. 9(b); 15 U.S.C. § 78u-4(b). Rule 9(b) requires plaintiffs alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). In order to avoid dismissal under Rule 9(b) for lack of particularity, the Fifth Circuit has held a plaintiff must:

(1) specify each statement alleged to have been misleading, i.e., contended to be fraudulent;

(2) identify the speaker;

(3) state where and when the statement was made;

(4) plead with particularity the contents of the false representations;

(5) plead with particularity what the person making the misrepresentation obtained thereby; and

(6) explain the reason or reasons why the statement is misleading, i.e., why the statement is fraudulent.

*Rosenzweig*, 332 F.3d at 866.

The PSLRA was enacted in response to an increase in securities fraud lawsuits perceived as frivolous. *Newby v. Enron Corp.*, 338 F.3d 467, 471 (5th Cir. 2003). Consequently, the PSLRA enhanced the pleading standard for private securities fraud actions in two ways. *Ind. Elec. Workers' Pension Tr. Fund IBEW v. Shaw Group, Inc.*, 537 F.3d 527, 533 (5th Cir. 2008). First, in any such action alleging the defendant made an untrue statement of material fact or a misleading omission:

> [T]he complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b). Second, for claims under which the plaintiff must prove a particular state of mind to recover, as is the case here:

> [T]he complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind.

*Id.* (emphasis added).Section 10(b) claims are subject to both of these pleading requirements of the PSLRA. *Cent. Laborers' Pension Fund v. Integrated Elec. Servs. Inc.*, 497 F.3d 546, 550 (5th Cir. 2007).

## II. Application

The Fifth Circuit has held the elements of a claim under § 10(b) are: (1) a misrepresentation or omission; (2) of a material fact; (3) in connection with the purchase or sale of a security; (4) scienter by the defendant; (5) justifiable reliance by the plaintiff; (6) damages; and (7) proximate cause. *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 865 (5th Cir. 2003).

Defendants' motion to dismiss alleges Plaintiff's Amended Complaint fails to satisfy the PSLRA's heightened pleading requirements for four reasons: first, because the complaint fails to plead facts indicating the challenged statements were false when made; second, because it fails to plead facts giving rise to a strong inference of scienter; third, because it fails to plead loss causation; and fourth, because it fails to plead a viable claim under § 20(a). Because the Court agrees with Defendants that Plaintiff has failed to plead facts giving rise to a strong inference of scienter, Plaintiff's complaint must be dismissed. The Court declines to reach Defendants' remaining arguments at this time.

### A. Scienter Requirements

To establish scienter, a plaintiff must show the defendant intended to deceive, defraud, or manipulate, or that the defendant acted with severe recklessness. *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 251 (5th Cir. 2009). Severe recklessness is defined by an "extreme departure from the standard of ordinary care," and "is limited to highly unreasonable omissions or misrepresentations that involve not merely simple or even inexcusable negligence." *Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Diodes, Inc.*, 810 F.3d 951, 957 (5th Cir. 2016) (citing *Owens v. Jastrow*, 789 F.3d 529, 537 (5th Cir. 2015)). Severe recklessness only exists where there was a danger of misleading buyers or sellers which was either known to the defendant or was so obvious the defendant must have been aware of it. *Id.*

The United States Supreme Court has outlined a framework for courts to use in analyzing motions to dismiss § 10(b) complaints for failing to establish a strong inference of scienter. First, as in any other motion to dismiss, the court accepts all factual allegations in the complaint as true. *Tellabs*, 551 U.S. at 322–23. Second, the court considers the entire complaint, other sources typically examined in a 12(b)(6) motion, sources incorporated by reference into the complaint, and matters of which a court may take judicial notice. *Id.* Third, in determining whether the pleaded facts give rise to a strong inference of scienter, as required by the PSLRA, a court should consider all of the facts alleged, taken collectively, and should also take into account plausible opposing inferences. *Id.* The inference of scienter need not be irrefutable, nor even the most compelling of all competing inferences, but must be strong in light of other inferences. *Id.* at 324. Ultimately, to create an inference of scienter, "the allegations in the complaint must be 'cogent and compelling,' not simply 'reasonable,' or 'permissible.'" *Local 731*, 810 F.3d at 957 (quoting *Tellabs*, 551 U.S. at 323).

Building on the framework provided the United States Supreme Court, the Fifth Circuit has stated "allegations of motive and opportunity standing alone" are not enough to establish scienter, but such circumstantial evidence may "meaningfully enhance the strength of the inference of scienter." *Ind. Elec.*, 537 F.3d at 533. The Fifth Circuit has also rejected the group pleading approach to scienter, which would allow a plaintiff to prove state of mind through the collective knowledge of all the corporation's officers and employees. *Id.* Instead, a court looks only to the state of mind of the corporate officials who made or issued the alleged misleading statement to determine if a complaint sufficiently pleads scienter. *Id.*

As a threshold matter, the Court considers Plaintiff's allegation Defendants were motivated to make the alleged misleading statements collectively by a desire to inflate XBiotech's stock price to raise capital for the company through the IPO. The Fifth Circuit has held "[t]he desire to raise capital in the normal course of business does not support a strong inference of scienter because virtually all corporate insiders share this goal." *Owens*, 789 F.3d at 539 (citing *Abrams v. Baker Hughes*, 292 F.3d 424, 434 (5th Cir. 2002)). Thus, the Court considers the motive to raise capital through XBiotech's IPO as supporting a weak inference of scienter, if supporting any inference at all.

The Court now reviews Plaintiff's allegations of scienter for each allegedly misleading statement or omission in light of the Plaintiff's obligation to state with particularity facts giving rise to a strong inference of scienter.

**B. Failure to Disclose CEO's Inexperience**

Without deciding if Defendants' nondisclosure of Simard's inexperience managing a large, global clinical trial was an omission of material fact, the Court examines the allegations regarding

Defendants' state of mind for this omission. After scouring the less-than-organized complaint, the Court finds Plaintiff fails to allege any facts supporting the claim Defendants acted with scienter in not disclosing Simard's lack of experience. In fact, Plaintiff never even specifically addresses Simard or Han's state of mind in failing to disclose Simard's allegedly insufficient experience. Instead, Plaintiff relies on general conclusory allegations sprinkled throughout the complaint stating Defendants either knew of material omissions and intended to deceive investors or acted with reckless disregard for the truth. As conclusory allegations are not enough to prop up a complaint in light of a motion to dismiss, the complaint fails to sufficiently plead scienter for Defendants' omission of the purported shortcoming in Simard's experience. *See Tuchman*, 14 F.3d at 1067.

**C. Statements Regarding CROs**

Similarly, Plaintiff provides no facts that Defendants intended to deceive, manipulate, or defraud investors with respect to XBiotech's disclosures discussing its relationships with CROs. Rather, Plaintiff implies Defendants were severely reckless because Defendants knew the selection of KCR "went against conventional wisdom." In sum, the complaint's description of Defendants' reasons for selecting KCR and the nature of XBiotech's relationship with KCR criticizes XBiotech's management of the Phase III Trial, not Defendants' state of mind in making misleading statements. Allegations of mismanagement, even gross mismanagement, do not establish a strong inference of scienter. *Goldstein v. MCI WorldCom*, 340 F.3d 238, 254 (5th Cir. 2003) (finding the complaint's allegations of mismanagement of the company's accounts receivable to be insufficient to establisha strong inference of scienter). Accordingly, Plaintiff's allegations concerning the CRO disclosures do not meet the PLSRA's strict requirements for pleading scienter.

**D. Statements Concerning the Phase III Trial and Patient Enrollment**

Unlike the previous two sets of statements, Plaintiff has provided some facts alleging scienter for the statements about the Phase III Trial and its enrollment. In evaluating such facts, the Court weighs both the inferences for and against scienter as a complaint will only survive if the inference of scienter is "at least as compelling as any opposing inference one could draw from the facts alleged." *See Tellabs*, 551 U.S. at 324. The Court finds the inference of scienter is outweighed by opposing inferences.

Plaintiff alleges Defendants' disregard of enrollment data and warnings provided by senior company employees, the importance of Xilonix to XBiotech, the small size of XBiotech, and the motive to inflate the value of stock for the IPO all create a strong inference of scienter. But as discussed above, motive to raise capital in the normal course of business provides a weak, if any, inference of scienter. *Owens*, 789 F.3d at 539. Plaintiff's other allegations rely on confidential witness statements and XBiotech's circumstances, i.e. that XBiotech is a small company with one important product. Most significantly, Plaintiff repeatedly emphasizes Defendants' continued use of the Phase III Trial timeline despite FE1's warning the timeline was unrealistic without more study sites. Yet, Plaintiff does not contradict, or even acknowledge, XBiotech's stated intention to add more study sites in Russia, an indication Defendants believed they had addressed FE1's concerns.

Essentially, Plaintiff's allegations of scienter boil down to a claim Defendants either knew or should have been aware of the danger of misleading investors about the timeline for the Phase III Trial in light of the enrollment data and the nature of XBiotech's business. But Plaintiff points to no specific report or data available at the time of the alleged misstatements that contradicted those statements. "An unsupported general claim" about the existence of reports or data revealing information contradictory to a defendant's statements is insufficient to survive a motion to dismiss.

*See Abrams*, 292 F.3d at 432 (finding the plaintiffs' pleading insufficient to demonstrate scienter where plaintiffs alleged individual defendants received daily, weekly, and monthly financial reports that appraised them of the company's financial status). "Such allegations must have corroborating details regarding the contents of allegedly contrary reports, their authors, and recipients." *Id.*

On the other hand, Defendants' transparency cuts against the inference of scienter. Defendants did not attempt to hide Phase III Trial's enrollment numbers. Instead, Defendants provided investors with specific enrollment numbers in the Registration Statement and Prospectus, numbers which Plaintiff does not allege were incorrect. Moreover, as the Defendants initially filed the Registration statement and Prospectus in February 2015, the March 5, 2015 enrollment numbers show Defendants even updated the enrollment numbers as they amended their SEC filings. Defendants also disclosed information on the disruption of the United States study due to enrollment problems and provided investors with the July and November press releases adjusting the "anticipated" Phase III Trial timeline. Reading these statements together suggests that Defendants endeavored to be transparent and sought to avoid misleading investors.

Additional characteristics of the Registration Statement and Prospectus further negate the inference of scienter. While the section of the Registration Statement and Prospectus Plaintiff references as misleading cites mid-2015 as the "expected" goal for completing the Phase III Trial, XBiotech also notes it was "projecting" to complete "Phase III enrollment in the second-half of 2015" and submit its registration package to the European regulatory authority "in the fourth quarter of 2015." The conflicting timelines in the two sections of the Registration and Prospectus suggest negligence or indefiniteness—plausible nonculpable explanations—rather than scienter. Conflicting timelines aside, both sections referencing the timeline use words emphasizing uncertainty. Words

like "expected" and "projecting" indicate Defendants attempted to warn investors the Phase III Trial timeline estimates were imprecise and might be incorrect.

The transparency of the timeline statements themselves provide immediate evidence signaling Defendants did not act with scienter while Plaintiff provides limited facts to support a weak inference of scienter. Thus, the Court finds the inference against scienter more compelling than any inference of scienter.

The Fifth Circuit's decision in *Owens,* 789 F. 3d 529 supports the Court's analysis here. In *Owens*, investors brought federal securities law claims against a company's officers, alleging the officers made false and misleading statements about the company's assets.789 F. 3d at 533. The plaintiffs pled the officers all knew the company was undercapitalized and were motivated to issue misleading statements by a desire to raise more capital. *Id.* at 538. The plaintiffs also argued the officers were aware of "red flags," which should have alerted them to problems in the company's asset valuation. *Id.* at 540. However, the defendants disclosed those same red flags, which included numbers indicating the company's valuation was incorrect, to investors. *Id.* at 540–41. Defendants also conveyed to investors that the company's valuation was "difficult" and involved "uncertainty." *Id.* at 541. Weighing the knowledge of the defendant officers, the motive allegations, and defendants' transparency attempts, even together with *other* scienter allegations, the Fifth Circuit ruled the plaintiffs did not raise a strong inference of scienter. *Id.* at 546.

Here, as in *Owens*, Defendants' knowledge of a problem, desire to raise funds, and awareness of red flags fall short of a strong inference of scienter. Like the officers in *Owens*, Defendants disclosed to investors the same red flag enrollment numbers Plaintiff alleges should have warned Defendants of the inability to meet the mid-2015 timeline; Defendants also provided an accurate

update of the enrollment count to investors, informed investors another Xilonix trial had been disrupted due to enrollment problems, warned about the possibility of enrollment problems, and cautioned that the timeline was only the "expected" date for events. Hence, like the complaint filed in *Owens*, the complaint filed by Plaintiff in this case fails to show a strong inference of scienter.

Plaintiff relies on *In re Netsolve, Inc. Sec. Litig.*, 185 F. Supp. 2d 684 (W.D. Tex. 2001) to argue the Court should find the complaint here does give rise to a strong inference of scienter. But *Netsolve* does not resuscitate Plaintiff's complaint. The misleading statements discussed in *Netsolve* concerned the omission of historical data and trends, not a projected timeline formed before data disclosed to investors even materialized. 185 F. Supp. 2d at 697 (discussing the omission of financial results revealing declining sales to the defendant's primary customer and a significant loss of other customers). Also, the plaintiffs in *Netsolve* alleged the defendants sold their shares following inflation of the stock price, an allegation not present here. *Id.*

Viewed holistically, Plaintiff's allegations do not present a strong inference of scienter against any Defendant "at least as compelling as any opposing inference of nonfraudulent intent." *See Tellabs,* 551 U.S. at 314. Plaintiff has therefore failed to carry its pleading burden under the PSLRA.

**Conclusion**

In sum, the Plaintiff does not allege sufficient facts to generate a strong inference of scienter. First, the complaint does not include facts supporting the claim Defendants acted with scienter in failing to disclosing Simard's lack of experience. Second, as to Defendants' omission of the specific risks concerning KCR, Plaintiff only alleges Defendants mismanaged the Phase III Trial in selecting KCR, an allegation unable to carry a compelling inference of scienter. Finally, Defendants'

transparency in the Registration Statement and Prospectus outweighs Plaintiff's limited allegations of scienter concerning the enrollment and timeline statements. Given Plaintiff's failure to plead facts supporting a strong inference of scienter, the complaint is subject to dismissal on that basis alone. The Court need not reach Defendants' additional arguments at this time.

Accordingly:

IT IS ORDERED that Defendants XBiotech Inc., John Simard, and Queena Han's Motion to Dismiss [#37] is GRANTED to the rights of any party with each party to bear their own costs; and

IT IS FINALLY ORDERED that Lead Plaintiff Kresimir Corak shall have TWENTY (20) DAYS from date of entry of this Order in which to file an amended complaint, or this case will be closed.

SIGNED this the 23rd day of September 2016.

SAM SPARKS
UNITED STATES DISTRICT JUDGE