United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MARY JANE JASIN, et al.,

Plaintiffs,

v.

VIVUS, INC., et al.,

Defendants.

Case No. 14-cv-03263-BLF

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

[Re: ECF 22]

This case arises out of Plaintiffs' purchase of over $2.8 million in common stock and options of Defendant VIVUS, Inc. ("Vivus"). Plaintiffs bring suit alleging violations of federal securities laws, as well as seven state law claims, based on purported false statements made by Leland Wilson, Vivus' former Chief Executive Officer; Peter Tam, Vivus' former President; and Timothy Morris, Vivus' former Chief Financial Officer (collectively the "individual Defendants"), regarding the success and approval of Vivus' obesity drug Qsymia.

Defendants move to dismiss on several grounds. With regard to Plaintiffs' federal securities claims, Defendants argue that Plaintiffs have not satisfied the heightened pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), and have failed to establish that any of the alleged misleading statements were false or were made with the requisite scienter. With regard to Plaintiffs' state law claims, Defendants argue that the claims are barred because of Plaintiffs' dismissal, with prejudice, of a state court action which included state law claims arising out of these same factual circumstances.

The Court submitted this motion for adjudication without oral argument on May 28, 2015, pursuant to Civil Local Rule 7-1(b). Having reviewed the parties' submissions and the governing law, the Court GRANTS the motion to dismiss. The Court will grant Plaintiffs leave to amend

with regard to their federal securities claims, but finds that Plaintiffs' state law claims are barred under res judicata by their dismissal with prejudice of the state court action.

I. BACKGROUND

Plaintiffs are two investors who reside in Lancaster, Pennsylvania. Beginning in 2012, they purchased over $2.8 million in Vivus stock. *See* FAC ¶ 11.Vivus is a Delaware biopharmaceutical company that develops therapeutic drugs related to, among other things, the treatment of obesity, diabetes, and male sexual health. *See* FAC ¶ 12. The individual Defendants, Wilson, Tam, and Morris, were directors at Vivus: Wilson served as CEO, Tam as President, and Morris as CFO and Senior Vice-President of Finance and Global Corporate Development. The individual Defendants are residents of California. *See* FAC ¶¶ 13-15. Plaintiffs allege that they purchased Vivus stock and options due to Defendants' failure to disclose material adverse facts relating to the company's financial well-being and future prospects.

On November 3, 2011, Vivus issued a press release noting that the Food and Drug Administration ("FDA") had accepted its New Drug Application ("NDA") for its obesity drug Qsymia (also known as Qnexa and Qsiva, *see* FAC ¶ 4). Then, on November 8, 2011, Vivus filed its Form 10-Q with the SEC for the period ending on September 30, 2011. This 10-Q announced a decreased loss from the prior year, and Vivus' stock value climbed to more than $10 per share. Vivus' shares continued to increase throughout the first half of 2012, reaching a high of $31.21 on July 18, 2012. Plaintiffs contend that this increase in value was due to anticipation of the successful launch of Qsymia in the United States and, pending regulatory approval, Europe. Vivus' stock closed 2012, however, at a value of approximately $13 per share. *See* FAC ¶¶ 17-19.

Plaintiffs allege that Defendants made misrepresentations and failed to disclose material facts, through both public statements and direct, one-on-one conversations between Defendant Morris and Plaintiff Thomas Jasin, *see* FAC ¶ 15, in four specific areas: (1) The risks to, and potential unenforceability of, Vivus' Qsymia patent; (2) That the European Union's medical regulatory agency, the European Medicines Agency ("EMA"), was unlikely to approve Qsymia for sale in Europe; (3) Vivus' misleading statements that it would have a "full" launch of Qsymia and that it was "ready to spring into action now"; and (4) Defendants' misleading statements

regarding the timing of Vivus' plan to offer additional common stock to investors.

A. Disclosures Regarding the Qsymia Patent

Qsymia is composed of a combination of two drugs: phentermine and topiramate. *See* FAC ¶ 51. Dr. Thomas Najarian provisionally filed for a patent on this two-drug composition for obesity treatment on June 14, 1999 (the "Najarian Patent"). Plaintiffs allege the existence of two other patents which they contend posed risks to the Najarian Patent: an earlier filed February 24, 1999 patent filed by Dr. Susan McElroy, the "McElroy Patent," U.S. Patent No. 6,323,236, addressing "the same or similar combination of phentermine and topiramate for the treatment of obesity," and the "Shank Patent," U.S. Patent No. 6,071,537, which was held by Johnson & Johnson until an August 25, 2014 transfer of the patent to Vivus, which patented topiramate alone for the treatment of obesity, *see* FAC ¶ 51. Plaintiffs contend that Defendants did not sufficiently disclose these risks.

In its November 2011 10-Q and February 2012 10-K forms filed with the SEC, Vivus disclosed that it had in 2001 entered into an assignment agreement with Dr. Najarian whereby "[t]he Combination Therapy [of phentermine and topiramate] and all related patent applications, or the Patents, were transferred to the Company with worldwide rights to develop and commercialize the Combination Therapy and exploit the Patents." FAC ¶ 52. Vivus went on to state in its February 2012 10-K that it "believe[d it had] strong intellectual property supporting several opportunities in obesity and related disorders." FAC ¶ 53. Vivus nonetheless also disclosed that it was "aware of issued patents for the use of topiramate alone or in combination with other specific agents (zonisamide and mirtazapine) for treatment of obesity and related indications, e.g., prevention of weight gain." FAC ¶ 54. Plaintiffs allege that when Defendant Wilson signed the 2001 Najarian assignment agreement Vivus was aware of the McElroy Patent because the assignment made future payments to Dr. Najarian contingent on "certain events relating to the McElroy Patent that would reduce or eliminate the risk of freedom-to-operate or infringement challenges to Vivus's use of the Najarian Patent." FAC ¶ 57.

Plaintiffs point to two misleading statements made by Defendants regarding the risks facing the Qsymia patent: one public and another between Defendant Wilson and Mr. Jasin. First,

they describe a July 18, 2012 interview of Defendant Tam on Bloomberg TV in which Mr. Tam was asked "about the patent only going out to 2020 and analyst concern that eight years might not be long enough." FAC ¶ 38b. Tam responded: "Well the patent, those are the patent laws, goes out to 2020. The company, Vivus, has a strategy to extend the patent life and then there are certainly strategies in place that could potentially increase the patent termination term for the product." *Id.* Plaintiffs state that they relied on Mr. Tam's interviews, including the July 18, 2012 interview with Bloomberg TV, when deciding to purchase Vivus stock. FAC ¶ 44. Second, Plaintiffs point to a report published by an entity called Citron the day after Mr. Tam's appearance on Bloomberg TV, in which Citron stated it was "astounded by the weakness of Vivus's intellectual property protection." FAC ¶ 59. On July 19, 2012, the day after the publication of the Citron report, which included specific concerns regarding the Najarian and Shank Patents, Vivus' stock price dropped 11 percent. *See* FAC ¶ 60. Then, on July 23, 2012, Mr. Jasin spoke with Defendant Morris via telephone where he "asked if any of the concerns expressed in recent reports about Qsymia patents were true," to which Morris responded "unequivocally that the reports were bogus and assured him the patents were rock solid." FAC ¶ 61. Plaintiffs, based on these assurances, purchased over 38,000 additional Vivus shares between July 25 and August 17, 2012. *See id.*

Finally, Plaintiffs point to an August 22, 2014 complaint filed by Janssen Pharmaceuticals, Inc. ("Janssen"), in the District of Delaware, which contended that the use of Qsymia for the treatment of obesity infringed upon the Shank Patent. On August 25, 2014, Vivus announced that it had acquired a group of patents from Janssen, including the Shank Patent, and that it had assumed the rights to Janssen's license of the McElroy Patent. As part of this agreement, Janssen dismissed its suit. *See* FAC ¶¶ 64-66. Plaintiffs allege that "the lawsuit and subsequent settlement [were] the culmination of negotiations between Vivus and Janssen that started in 2007 and resumed in July of 2012." FAC ¶ 67.

Ultimately, Plaintiffs allege that Defendants "failed to adequately disclose the risks from the Shank Patent and McElroy Patent which could, at the least, expose Vivus to a legal challenge . . . and potentially prevent sales of Qsymia," despite knowing, based on the Najarian assignment agreement and its negotiations with Janssen beginning in 2007, that Qsymia's patent position was

weaker than was being publicly disclosed. FAC ¶ 71. Plaintiffs state they would not have purchased Vivus stock nor entered into any options for Vivus stock had they known the truth regarding its intellectual property position. *See* FAC ¶ 72.

B. Disclosures Regarding EMA approval of Qsymia

In December 2010, Vivus submitted an application to European regulatory authorities seeking approval of Qsymia to be sold in Europe. FAC ¶ 74; *see also* FAC ¶ 80. On its November 7, 2011 third quarter earnings conference call, Vivus reported that:

> In Europe we held a productive clarification meeting with our Rapporteur and Co-rapporteur [voting members of the Committee for Medical Products for Human Use, or CHMP, which prepares opinions regarding approval of medicines used by humans] in September. Our response to the 120-day questions from the CHMP is nearly complete. . . . We anticipate the CHMP will issue their 180-day opinion in the first quarter of 2012."

FAC ¶ 74.

During this same time period, Vivus was engaged in the regulatory approval process with the FDA. On the third quarter earnings call, Defendant Wilson stated that "in all our discussions with [the] FDA, we've never talked about a preapproval cardiovascular study." FAC ¶ 76. Plaintiffs allege that a "preapproval study would mean a costly delay for Vivus," delaying Qsymia's entrance into the market and costing "the company tens, if not hundreds, of millions of dollars. FAC ¶ 77.

In its February 2012 10-K, Vivus stated that:

> In May 2011, we received a response to our MAA from the CHMP.
>
> The 120-day questions covered a broad range of topics including, without limitation, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; heart rate and limited long-term safety data in high-risk patients; and known and suspected effects of topiramate which include CNS and teratogenic potential.
>
> The 120-day questions were consistent with the issues previously raised in the FDA review process."

FAC ¶ 81.

The 10-K went on to state that "[t]here can be no assurance that our response [to these questions] will be adequate or that our MAA will be approved by the CHMP." *See id.* Plaintiffs

relied on the 10-K in making their decision to continue purchasing and holding Vivus stock and options. *See* FAC ¶ 84.

Plaintiffs state that before February 27, 2012 (and therefore before the filing date of Vivus' February 28, 2012 10-K), Mr. Jasin contacted Defendant Morris "and asked him to elaborate on Vivus's statement that CHMP and FDA questions were consistent . . . [and] whether Vivus needed to do anything different for European approval." FAC ¶ 85. Mr. Morris responded that "the CHMP did not ask Vivus to provide any more information than what Vivus had available for the FDA." *Id.* Then, on July 23, 2012, Mr. Jasin again contacted Mr. Morris to ask about the status of its European marketing authorization request. Mr. Morris told him "there was nothing new to report, because nothing negative, positive, or unusual had happened, but that it was 'looking real good for approval.'" FAC ¶ 90. Plaintiffs state that "[n]ot knowing of any issues with Qsymia's approval in Europe, Plaintiffs further invested in Vivus." FAC ¶ 89.

On September 11, 2012, Vivus issued a press release in which it stated that it expected the CHMP to recommend against approval of its MAA application for Qsymia, but that the official decision would not be made until October 2012. *See* FAC ¶ 91. Mr. Jasin states that he "believes he spoke to Mr. Morris about the press release" on September 21, 2012, and that Morris indicated that Vivus would work with the CHMP to address the regulators' concerns. *See* FAC ¶ 92.

Plaintiffs state that they invested in Vivus beginning in February 2012 in reliance on Vivus' statements "that CHMP questions relating to requirements for Qsymia approval in Europe were consistent with FDA questions relating to requirements for Qsymia approval in America." FAC ¶ 95. In 2013, however, Mr. Jasin had a telephone conversation with Philippe Lechat, who served as the co-rapporteur for Qsymia's CHMP evaluation. Mr. Lechat stated that "Vivus was notified and asked at the September 2, 2011, meeting with the CHMP to conduct a pre-approval cardiovascular study." FAC ¶ 96. Plaintiffs allege that, regardless of whether the individual Defendants were present at this meeting, the "position of the CHMP was related to them directly or to Vivus's representatives at the meeting." FAC ¶ 98.

Plaintiffs allege, therefore, that Vivus' statement in its February 2012 10-K that the EMA's "120-day questions were consistent with the issues previously raised in the FDA review process"

was materially misleading because the CHMP indicated in September 2011 that a preapproval cardiovascular study would need to be conducted, while Defendant Wilson stated in the third quarter earnings call that Vivus never spoke about such a preapproval cardiovascular safety study with the FDA. *See, e.g.*, FAC ¶ 102.

C. Misrepresentations Regarding Vivus' Future Offering of Common Stock

On February 27, 2012, Defendant Wilson appeared on CNBC's *Fast Money Halftime Show* following an FDA panel's recommendation that Qsymia be approved for sale in the United States. *See* FAC ¶ 27. Wilson and the interviewer had the following exchange:

> **Interviewer**: You are a small company as we know. Are you seeking a partner currently to help market this drug? *Will you have to raise capital?* What are your plans?
>
> **Wilson**: We're looking for a partner for the rest of the world outside of the United States. We believe that will be a major pharmaceutical company able to reach most of the countries around the world. However, in the United States we're going to launch this product on our own. We believe that we have the best understanding of this drug and how to best position this product for its long-term success. We've assembled a very experienced marketing team and feel very confident we can launch the product very successfully.

FAC ¶ 27 (emphasis added).

Wilson also stated that Vivus had "plenty of money to go through the approval process" and would "be opportunistic in raising money for the commercialization effort." FAC ¶ 28. When the interviewer asked: "Why not raise cash now? Why not raise capital when everyone is clamoring for your stock?," Wilson responded: "Well, again, what our position is, is that we have adequate money to take us through the approval process through April 17th, and we will raise capital at some time." FAC ¶ 29.

On February 27, 2012, Wilson sold 50,000 Vivus shares, and during the week leading up to the interview, Wilson and Morris both exercised options and sold over 429,000 shares of Vivus stock. *See* FAC ¶ 31. On that same day, Plaintiffs purchased 100,000 shares for $2,425,008. *See* FAC ¶ 30. The next day, Vivus announced a public offering of 8.5 million shares of common stock. *See* FAC ¶ 32. Following this announcement, share prices fell 11 percent. *See id.* Plaintiffs claim that Wilson's statement that Vivus "ha[d] adequate money" to take it through the approval

process was misleading given that the prospectus released on February 29 regarding the public offering stated that Vivus would use the capital raised to "fund the creation of the infrastructure [] necessary to commercialize Qnexa in the United States." FAC ¶ 34.

D. Disclosures Regarding Qsymia's Domestic Commercial Launch

Defendants Wilson and Tam, along with two other Vivus officers, participated in an analyst call on February 22, 2012, soon after the FDA's Endrocrinologic and Metabolic Drugs Advisory Committee recommended that the FDA grant marketing approval of Qsymia. Wilson stated on this call that Vivus was "ready to spring into action now" to launch Qsymia in the United States. FAC ¶ 106. Plaintiffs plead that Mr. Jasin called Defendant Morris "[p]rior to [their] February 27, 2012 stock purchase," seeking to understand how Vivus would maximize Qsymia sales in the United States. *See* FAC ¶ 109. Morris allegedly told Mr. Jasin that the company was negotiating with pharmaceutical sales companies to develop partnerships to sell Qsymia, though Vivus informed these suitors that it was "prepared and capable of launching Qsymia [itself] because of its expert knowledge of the obesity market." *Id.*

Thereafter, during Defendant Wilson's February 27, 2012 interview on the *Fast Money Halftime Show*, he stated that "[i]n the United States we're going to launch this product on our own. We believe we have the best understanding of this drug and how to best position this product for its long-term success. We've assembled a marketing team and feel confident we can launch this product." FAC ¶ 112. Plaintiffs allege, however, that this statement was misleading because "part of the purpose of [Vivus'] secondary offering was to fund the creation of the infrastructure including the hiring of a field sales force" and because Vivus had not yet entered into a sales force agreement, rendering Wilson's statement that they had "assembled a marketing team" allegedly materially misleading. *See* FAC ¶ 113.

Mr. Jasin again called Defendant Morris in July 2012 to ask Morris if the company had sufficient resources to sell Qsymia without a domestic launch partner. FAC ¶ 120. Plaintiffs allege that Morris told Mr. Jasin that "if there were concerns they would have been publicly announced – we are in good shape – we studied the issues, know what it will cost and have planned accordingly." *Id.* Morris further told Mr. Jasin that Qsymia would have "a full launch" and

"reiterated what CEO Leland Wilson said in a February 2012 conference call that Vivus is 'ready to spring into action now.'" *Id.*

Plaintiffs contend that Morris should have known his statements were false because Vivus had not yet entered into a sales force agreement, had not "laid the groundwork needed with payors for a successful launch," and had not "recruited enough mail order pharmacies to deliver the revenue being projected for the drug's launch." FAC ¶ 121.

On August 7, 2012, Vivus stated in its Form 10-Q that it had entered into a rented sales force agreement on May 22, 2012, and that it had entered into a commercial manufacturing agreement to produce Qsymia on July 17, 2012. *See* FAC ¶ 123. In this 10-Q, Vivus also disclosed that it would distribute Qsymia through Cardinal Health and "a small number of home delivery pharmacies." FAC ¶ 124. Plaintiffs allege that at the time Qsymia was launched, "Vivus had not procured enough pharmacies to enable patients to get the drug," because Vivus had, by October 8, 2012, lined up only three pharmacies. FAC ¶ 130. Plaintiffs contend that the individual Defendants misled investors by consistently stating that there would be no problems with Qsymia's domestic launch, and that Vivus could handle such a launch on its own. *See* FAC ¶ 131. Within ten days of Qsymia's launch, Vivus' stock had lost 25 percent of its value. Plaintiffs purchased 180,000 shares of Vivus during this "launch period." FAC ¶ 132.

As of November 6, 2012, the stock had decreased in value to $11.82 per share, FAC ¶ 135, but by November 15, 2012, Defendant Wilson admitted that Vivus had "made mistakes" with the Qsymia launch, *see* FAC ¶ 136. Plaintiffs state that had Defendants "accurately represented the readiness of the company to launch Qsymia," Plaintiffs would not have purchased Vivus stock "and would have liquidated their holdings." FAC ¶ 138.

II. LEGAL STANDARD

A. Rule 12(b)(6)

A motion to dismiss under Rule 12(b)(6) concerns what facts a plaintiff must plead on the face of its complaint. Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Any complaint that does not meet this requirement can be dismissed pursuant to Rule

12(b)(6). A "short and plain statement" demands that a plaintiff 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), which requires that "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court must "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519, F.3d 1025, 1031 (9th Cir. 2008). The Court, however, "need not accept as true allegations contradicted by judicially noticeable facts."[1] *Kane v. Chobani, Inc.*, 973 F. Supp. 2d 1120, 1127 (N.D. Cal. 2014).

B. Rule 9(b) and the PSLRA

A plaintiff asserting a private securities fraud action must meet the heightened pleading requirements imposed by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *See, e.g., In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *see also In re VeriFone Holdings*, 704 F.3d at 701. Similarly, the PSLRA requires that "the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1)(B). The PSLRA further requires that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). "To satisfy the requisite state of mind element, a complaint must allege that the defendant[] made false or misleading statements either intentionally or with deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701 (internal quotation marks and citation omitted) (alteration in original). Such scienter allegations must give rise not only to a plausible

[1] Defendants request that the Court take judicial notice of 19 documents: 14 documents that were publicly filed with the SEC, two transcripts of telephone conference calls on which Plaintiffs rely in their FAC, two documents filed with the FDA, and a document that shows the trading price of Vivus stock from February 15, 2012 to February 28, 2012. *See* RJN, ECF 23. Plaintiffs do not oppose. *See* Opp. at 1 n.1. These documents are appropriate for judicial notice, *see, e.g., Metzler Inv. GmbH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008), and the Court GRANTS Defendants' request.

inference of scienter, but to an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). "Facts showing mere recklessness, or a motive to commit fraud and opportunity to do so, provide some reasonable inference of intent but are not sufficient to establish a strong inference of deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701 (citation omitted). As such, the Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 323-24.

III. DISCUSSION

A. The Federal Securities Claims

1. Count One: Plaintiffs' Section 10(b) and Rule 10b-5 Claim

To state a claim for securities fraud, a plaintiff must plead six things: (1) a material misrepresentation or omission on the part of 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. *See, e.g.*, *Reese v. Malone*, 747 F.3d 557, 567 (9th Cir. 2014).

A statement or omission is material when "there is 'a substantial likelihood that the disclosure of the [] fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 (2011) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). However, "[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not. [Therefore,] to be actionable under the securities laws, an omission . . . must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Under *Tellabs*, scienter allegations are evaluated first individually, and then holistically, to determine whether Defendants acted with the requisite intent. 551 U.S. at 310 (holding that the complaint should be dismissed unless the inference of scienter is "cogent and at least as compelling" as an alternative inference).

Defendants move to dismiss Count One on the grounds that Plaintiffs have not identified

facts giving rise to an inference of falsity or scienter. The Court first examines the alleged misleading facts, and then whether Plaintiffs have set forth with particularity facts giving rise to scienter, with regard to (1) the Qsymia Patent, (2) Qsymia's European approval, (3) Vivus' February 2012 stock offering, and (4) Qsymia's domestic launch. The Court ultimately agrees with Defendants that Count One must be dismissed, with leave to amend.

a. The Qsymia Patent

First, with regard to the Qsymia patent, Plaintiffs allege in the FAC that three statements were false or misleading: (1) Mr. Tam's July 18, 2012 statements that Vivus had a strategy for increasing the length of time before the Qsymia patent was set to expire, *see* FAC ¶ 38; (2) that Defendants in their SEC filings "failed to adequately disclose the risks from the Shank Patent and McElroy Patent," *see* FAC ¶ 71, *see also* Opp. at 7 (citing Mr. Morris' April 4, 2012 statement, made on a conference call, that "We don't believe there's (sic) any issues. . . . [W]e're not concerned at all about J&J [the then-holder of the Shank Patent]."); and (3) Mr. Morris' statements via phone call with Mr. Jasin that Vivus' patents were "rock solid" and that the Citron report was "bogus," *see* FAC ¶ 61. Defendants contend that the Plaintiffs have not pled scienter and that the alleged omitted information was publicly disclosed. *See* Mot. at 8-10; *see also* Reply at 4.

The Court agrees with Defendants. First, Mr. Tam's July 18 statement, a forward-looking statement about the "plans and objectives of management for future operations" of Vivus, is actionable only if Plaintiffs show that the statement was "made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B)(i); *see also Police Retirement Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1058-59 (9th Cir. 2014). Plaintiffs have not pled any such facts in the FAC.

Second, Plaintiffs fail to plead sufficient facts suggesting that either of Mr. Morris' statements about the Qsymia patent were made with the requisite scienter. Both of Morris' statements involve Vivus' belief as to the strength of the Qsymia patent. Vivus disclosed in its February 2012 10-K a number of risks regarding the Qsymia patent, including that a patent had issued for the use of topiramate for weight loss therapy. *See* February 2012 10-K, RJN Exh. B at 85-87. Though the February 2012 10-K does not identify the Shank Patent by name, the Shank

Patent is a patent for weight loss therapy using topiramate alone, and falls within this disclosure. Further, Defendants disclosed Vivus' assignment agreement with Dr. Najarian, which included provisions related to the McElroy Patent, and provided a copy of the agreement with its March 2010 10-K. *See* RJN Exh. A at 25 Exh. 10.79.

Third, though Citron stated that it was "astounded by the weakness of Vivus's intellectual property protection," *see* FAC ¶ 58, Defendants are correct that the information on which the Citron report relied had already been publicly disclosed by Defendants. *See, e.g.*, February 2012 10-K, RJN Exh. B. Plaintiffs have not pled any facts to show that Citron revealed in its report *any* new information that had not previously been disclosed. Plaintiffs have failed to show that Mr. Morris' statements that the Citron report was "bogus" and that Vivus' patents were "rock solid" were materially misleading given Vivus' prior disclosures, or that the statements were made with the requisite scienter in an attempt to mislead investors, including Plaintiffs. *See* FAC ¶ 61. Finally, Plaintiffs have also failed to plead loss causation with regard to Citron report. The Citron report was released on July 19, 2012, thereafter, "between July 25, 2012 and August 17, 2012," Plaintiffs purchased 38,000 shares of Vivus stock. *See* FAC ¶ 61. Plaintiffs have not pled facts that establish a causal connection between the Citron report and any economic loss. *See Dura Pharmaceuticals v. Broudo*, 544 U.S. 336, 344 (2005) (holding that a party is liable to a purchaser "for the loss the purchaser sustains when the facts [that were misrepresented] become generally known and as a result share value depreciate[s]") (citing the Restatement (Second) of Torts, § 548A, cmt. B at 107). Nor have Plaintiffs alleged that after they made their stock purchases that any corrective disclosures were made.

b. European Approval

Second, with regard to the EMA approval, Plaintiffs allege Mr. Wilson's response in the November 2011 earnings call that Vivus had "never discussed" a pre-approval cardiovascular study with the FDA, coupled with Vivus' 10-K which stated that the issues discussed with the EMA were "consistent with" the issues raised by the FDA, is false or materially misleading because one of Vivus co-rapporteur's told Vivus in September 2011 that "it was the co-rapporteur's position that Vivus had to perform a successful cardiovascular study before approval

would be granted" for Qsymia to be sold in Europe. *See* FAC ¶ 97. Plaintiffs therefore infer that since Vivus discussed a cardiovascular study with the EMA but not the FDA, despite later informing investors that the issues raised by the EMA were "consistent with" those raised by the FDA, Mr. Wilson's November 2011 statement is a material misrepresentation. Plaintiffs further challenge a public statement by Mr. Tam regarding Qysmia's side effects where he listed dry mouth and constipation as side effects but not cardiovascular risk, and a July 23, 2012 statement by Mr. Morris that there was "nothing new to report" about the EMA process, as false or misleading. *See* FAC ¶ 90. Defendants move to dismiss on the grounds that these statements were not false or misleading and that Plaintiffs have not pled scienter with specificity.

The Court agrees with Defendants. As to the purported statement made by Vivus' co-rapporteur, Defendants are correct that Vivus was not required to report every communication it had received from a regulator to its investors. *See, e.g.*, *In re Genzyme Corp.*, 2012 WL 1076124, at *10 (D. Mass. Mar. 30, 2012) ("It simply cannot be said that every critical comment by a regulatory agency – even about matters as important as good manufacturing practices – has to be seen as material for securities law reporting purposes, especially in an industry like Genzyme's, where there is constant and close supervision by the FDA."). Plaintiff's FAC pleads that the co-rapporteur expressed only *his* position that Vivus would need to perform a successful cardiovascular study prior to EMA approval, not the CHMP or EMA's position. *See* FAC ¶ 97. Further, Vivus' February 2012 10-K disclosed that EMA approval was not guaranteed, and specifically disclosed that "the CHMP . . . may request additional studies *including cardiovascular outcome studies* . . . prior to granting approval of Qnexa in the EU." *See* February 2012 10-K at 48. Plaintiffs have failed to allege sufficient facts to support their claim that Defendants in February 2012 failed to fully disclose that a cardiovascular study would need to be performed prior to the EMA approving Qsymia for sale in Europe. *See id.* at 10, 17, 42-43.

Nonetheless, Plaintiffs' cardiovascular study allegations are the strongest in the FAC. Though Vivus' 10-K disclosed the risk that a cardiovascular study may be needed by the EMA, *see id.*, Defendants' later statements may be misleading to the extent they suggest that this prior risk was no longer a concern for the company. Plaintiffs have not pointed to specific statements

where a Defendant said that the risk of a cardiovascular study had been resolved or otherwise mooted, but may amend the FAC to plead additional facts to support an inference that Defendants' statements regarding the need for a cardiovascular study were materially misleading.

As to Mr. Tam's statement regarding Qsymia's side effects, Defendants are correct that cardiovascular issues were thoroughly disclosed in Vivus' February 2012 10-K as a possible side effect. *See, e.g.*, *id.* at 7. There are no factual allegations to support a conclusion that Mr. Tam intended to mislead when he listed only some, but not all, of the possible side effects of Qsymia during his television interview, given that Vivus otherwise fully disclosed those risks in its public filings. In fact, the FAC shows that Mr. Tam responded to a question regarding anticipated label warnings on side effects. *See* FAC ¶ 40 ("What will the label list as, in terms of precautions and side effects?"). There are no allegations that Mr. Tam knew of other label warnings that he excluded from his response to this question.

Finally, as to Morris' statement that there was "nothing new to report" and that the drug was "looking real good for approval" by the EMA, *see* FAC ¶ 90, Plaintiffs have not sufficiently alleged falsity because Vivus had already reported in its February 2012 10-K, over four months earlier, that the EMA might require a cardiovascular study prior to approving Qsymia for European sales, and the statement "looking real good for approval" is the type of "mildly optimistic, subjective assessment" that courts have found does not rise to the level of a securities violation. *See, e.g.*, *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010); *see also Intuitive Surgical* at 1060.

c. The Additional Stock Offering in 2012

Third, with regard to Vivus' 2012 stock offering, Plaintiffs challenge Mr. Wilson's statement that Vivus had sufficient funds to take it through the FDA approval process and that Vivus would raise capital "at some time," because Vivus, the day after these statements were made, announced a public stock offering. *See* FAC ¶ 29. Defendants contend that Plaintiffs have not pled falsity or scienter with regard to these statements.

The Court agrees with Defendants. During his interview on the *Fast Money Halftime Show*, Wilson stated that Vivus had sufficient money to take it through the FDA approval process.

In that same interview he predicted that the FDA would approve the drug in April 2012. Plaintiffs contend that this statement was false because the next day Defendants sought to raise several million dollars through a public stock offering. This, however, does not follow: Mr. Wilson stated in that interview that Vivus would *soon* seek to raise capital for its commercialization efforts, which would take place following FDA approval. *See* FAC ¶¶ 28-29. Plaintiffs' allegations do not support the conclusion that Defendants materially misled the public in stating that they would soon seek to raise capital when they, the day after making this statement, sought to raise capital. Plaintiffs' argument that Mr. Wilson was obligated to inform the public that Vivus would make a public offering the next day is unsupported in the case law. *Cf. Brody*, 280 F.3d at 1006 (holding that a statement is misleading only if it "[creates] an impression of a state of affairs that differs in a material way from the one that actually exists").

Plaintiffs' statements regarding the stock offering also do not give rise to a plausible inference of scienter. Plaintiffs' allegations are not as compelling as any opposing inference of non-fraudulent intent, as is required under *Tellabs*. 551 U.S. at 314. Though Defendant Wilson's statement that Vivus would raise capital "at some time" occurred a day before Vivus announced its stock offering, which may give *some* inference of scienter, Plaintiffs have not sufficiently alleged facts that show Wilson knew Vivus had insufficient capital to get through the FDA approval period, or was attempting in saying "soon" instead of "tomorrow" to mislead investors. Further, the announced offering was based on the need to raise funds for commercialization, not FDA approval, *see* FAC ¶ 28, and Plaintiffs have not pled facts to show that this stated need was false or misleading.

d. The Failure of Vivus' Commercial Launch

Finally, with regard to the Vivus' commercial launch, Plaintiffs allege two false or misleading statements: (1) Mr. Wilson's February 22, 2012 statement that Vivus was "ready to spring into action" to launch Qsymia, and (2) Mr. Morris' statement to Mr. Jasin, via telephone, in July 2012 that Qsymia would see a full launch. *See* FAC ¶ 120.[2] Plaintiffs contend that these

[2] Defendants argue in their motion that Plaintiffs' allegations involve only a September 2012 email statement from Morris to Mr. Jasin, in which Morris said Qsymia would see a full launch.

statements were false because Vivus had not yet entered into a sales force agreement, had not laid the groundwork for payors necessary for a successful launch, and had not yet recruited a sufficient number of mail-order pharmacies to domestically launch Qsymia. *See* FAC ¶¶ 121-24.

Defendants contend that the first statement is a "broad assurance of corporate optimism" that is not actionable under the securities laws. Reply at 9; *see also Intuitive Surgical* at 1060. The Court agrees that the statement "ready to spring into action" is corporate puffery, similar to the statement "[we are] in a pretty good position" that the court in *Intuitive Surgical* found unactionable. *See id.* Though "general statements of optimism, when taken in context, may form a basis for a securities fraud claim," *Warshaw v. Xoma Corp.*, 74 F.3d 955, 959 (9th Cir. 1996), Plaintiffs have not shown that Defendants were aware that Vivus was failing in its ability to launch Qsymia *at the time they made such statements*. *See Fecht v. Price Co.*, 70 F.3d 1078, 1084 (9th Cir. 1995) (statements that an expansion of operations was "successful" and had increased the company's earnings potential were actionable only because the individual making the statements was aware that the expansion had in fact failed).

As to the second statement, though Defendants publicly disclosed in their February 2012 10-K that they could face issues garnering sufficient insurance payor coverage, Plaintiffs do identify at least one way in which Morris' statement that the launch would be "full" could be misleading – Defendants had obtained the commitment of only three pharmacies to distribute Qsymia when it had publicly stated that the company would focus on signing up six pharmacies prior to the launch. FAC ¶ 118. However, Plaintiffs fail to show how this statement was materially misleading, given that Morris' statement regarding the number of pharmacies Vivus would attempt to have at launch, made in May 2012, was forward-looking and in the context of public disclosures that had set forth the risks facing Vivus in seeking to sign up mail-order pharmacies. Mr. Morris' statement would not have given a reasonable investor the impression of a state of affairs markedly different from the on that existed. Further, Plaintiffs fail to plead sufficient facts to show scienter. Plaintiffs plead only a single statement made by phone that the launch would be

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The FAC, however, also includes an allegation that Morris told Mr. Jasin there would be a full launch in July 2012. *Compare* FAC ¶ 120 *with* FAC ¶ 125.

"full" instead of "soft," FAC ¶ 120, which does not itself show that Morris intended to mislead Mr. Jasin. Instead, a non-fraudulent intent is more compelling – Morris' statement indicates that Vivus was fully launching Qsymia with the team it had in place at the time. Plaintiffs' challenge to the statements, therefore, is a challenge to Vivus' own optimistic prediction of its likelihood of success at the time of launch, which is not securities fraud.

e. Defendants' Personal Stock Sales

Plaintiffs make one other argument that the Court addresses here: Plaintiffs contend that Defendants individual stock sales, around the time the individual Defendants were making public statements about Vivus' financial health and readiness to launch Qsymia, are probative of scienter. *See, e.g.*, FAC ¶¶ 46-49. Defendants argue that all of the stock sales referenced in the FAC were made pursuant to a Rule 10b5-1 trading plan. *See* Mot. at 20; *see also* RJN Exhs. J-L. Defendants argue that since Defendants had no contemporary control over the sales at issue, they are not probative of scienter. Plaintiffs ultimately respond that Defendants nonetheless had control over their public statements at the time the trades were being made, and could have been more truthful to investors and the public. *See* Opp. at 17-19.

The Court agrees with Defendants – though the trades Plaintiffs describe were financially advantageous to Defendants, the mere existence of trades made pursuant a Rule10b5-1 trading plan is insufficient alone to give rise to an inference of scienter, and in fact can rebut such an inference. *Cf. Metzler*, 540 F.3d at 1067 ("Stock trades are only suspicious when 'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed information. . . . Sales according to pre-determined plans may '*rebut [] an inference of scienter*.'") (emphasis added).

f. Plaintiffs' "Holder" Claims and Loss Causation

Plaintiffs allege that Defendants' misstatements are actionable to the extent they "caused Plaintiff to remain in the stock and suffer more losses" – a "holder" claim cognizable under California law. *See* Opp. at 7 n.4. As the Court addresses in greater detail below, Plaintiffs' state law claims in this action are barred by res judicata. Holder claims, such as those Plaintiffs attempt to plead here, are not actionable under Section 10(b) or the PSLRA because those statutes are

directed at fraud "in connection with the purchase or sale" of a security. *See Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 733 (1975); *see also Merrill Lynch v. Dabit*, 547 U.S. 71, 80 (2006). To the extent Plaintiffs seek to assert claims based on holding stock, rather than buying or selling the stock, those claims are dismissed with prejudice.

Additionally, Plaintiffs' FAC includes a number of alleged false or misleading statements that were made by a Defendant to Mr. Jasin individually. A plaintiff pleads loss causation when he alleges facts that show a causal connection between the material misrepresentation and the loss. *See Dura Pharmaceuticals* at 342. Plaintiffs cannot plead such loss causation from these private statements between a Defendant and Mr. Jasin. *See In re Daou Sys., Inc.*, 411 F.3d 1006, 1026 (9th Cir. 2005) (upholding a district court determination that improper revenue recognition was linked to economic loss in part because "the TAC does not allege that there were *any negative public statements*, announcements or disclosures at the time the stock price dropped") (emphasis added).

g. Holistic Analysis

Finally, the Court must "consider the complaint in its entirety" to determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs* at 322-23.

Viewed holistically, Plaintiffs' FAC fails to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," because "a reasonable person would [not] deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. As the Court has noted above, Plaintiffs have pled that Defendants engaged in stock sales around the time they made allegedly false and misleading statements, and that investors may have inferred from Defendants' public statements that there was no risk that Qsymia would need to undergo a cardiovascular study prior to receiving EMA approval, despite Defendants being on notice that the EMA may require such a study. These allegations, taken together, do not give rise to a cogent inference of scienter. Instead, the more compelling inference taken from the FAC is that Vivus and its directors were optimistic about Qsymia's launch, both in the United States and Europe, which ultimately flopped

through mismanagement rather than fraud. Plaintiffs' allegations regarding the company's lack of patent protection and commercial launch further buttress this inference. *See In re VeriFone Holdings*, 704 F.3d at 701 ("Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference.").

Because the Court must "compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive if the malicious inference is at least as compelling as any opposing innocent inference," the FAC must be dismissed, with leave to amend. *See Zucco Partners*, 552 F.3d at 991; *see also City of Dearborn Heights Act 345 Police & Fire Retirement Sys. v. Align Tech., Inc.*, 2014 WL 4180845, at *14-15 (N.D. Cal. Aug. 22, 2014).

2. Count 2: Plaintiffs' Section 20(a) Claim

Section 20(a) provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as the controller person." 15 U.S.C. § 784(a). A plaintiff bringing suit under Section 20(a) must show two things: (1) a primary violation of the federal securities laws, and (2) that the "defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000). In this context, "control" means "the possession, direct or indirect, of the power to direct or cause the direction of management and policies of a person, whether through ownership of voting securities, by contract, or otherwise." 17 C.F.R. § 230.405.

Here, Plaintiffs' Section 20(a) claims fail because they have failed to state a claim for a primary violation of the Securities Act, as outlined in detail above. *See also Bao v. SolarCity Corp.*, 2015 WL 1906105, at *5 (N.D. Cal. Apr. 27, 2015). Because Plaintiffs have been granted leave to amend with regard to their Securities Act claims, they shall also be granted leave to amend with regard to their Section 20(a) claims. *See id.*

B. The State Law Claims

Prior to filing this action, Plaintiffs filed a state court action challenging the statements and

alleged misrepresentations that also give rise to this suit. After the initial complaint in this federal action was filed, but before Plaintiffs filed the now-operative FAC, Plaintiffs and Defendants entered into agreement (the "dismissal agreement") whereby the parties agreed that "litigating two actions rather than one is not in the best interest of either the parties or the court systems involved." Dismissal Agreement, Rivas Decl., ECF 24-1 Exh. A. In this dismissal agreement, Plaintiffs agreed to dismiss the state case with prejudice and not to "assert any claim against defendants" under certain state statutes, including Section 17200 of the Business and Professions Code. *See id.* at 1. In turn, Defendants agreed not to assert a statute of limitations defense and waive service of process in the federal action. On September 15, 2014, after the parties signed the dismissal agreement, Plaintiffs dismissed the state court action with prejudice. *See* RJN Exh. X, ECF 23-24. Defendants argue that this dismissal with prejudice precludes Plaintiffs from asserting *any* state law claims in the FAC.

California law employs a three-part test when determining whether an action is barred by res judicata: "(1) the present action is on the same cause of action as the prior proceeding; (2) the prior proceeding resulted in a final judgment on the merits; and (3) the parties in the present action or parties in privity with them were parties to the prior proceeding." *Fed. Home Loan Bank of San Francisco v. Countrywide Fin. Corp.*, 214 Cal. App. 4th 1520, 1527 (2013) (citing *Bullock v. Philip Morris USA, Inc.*, 198 Cal. App. 4th 543, 557 (2011)). For res judicata purposes, a voluntary dismissal with prejudice is sufficient to satisfy the "final judgment on the merits" prong. *See Boeken v. Philip Morris USA, Inc.*, 48 Cal. 4th 788, 793 (2010).

Plaintiffs do not challenge that these three circumstances apply to this action, but instead argue in opposition that "California law recognizes that a party may waive its claim preclusion defense through an agreement between the parties," and insist that the dismissal agreement constitutes such a waiver. Opp. at 21. Plaintiffs argue that the dismissal agreement constitutes an express agreement to limit the effects of claim preclusion *only* to the specific statutory claims set forth in the agreement. *See id.* at 22. Having reviewed the governing law, the Court finds that Plaintiffs are incorrect, for several reasons.

Though parties may contract around a claim preclusion defense through agreement, "[i]n

order to invoke this exception to the normal res judicata effect of a judgment . . . an otherwise included issue [must] be withdrawn by an *express reservation*." *Perez v. Gordon & Wong Law Grp., P.C.*, 2012 WL 1029425, at *5 (N.D. Cal. Mar. 26, 2012) (citing *Ellena v. State of California*, 69 Cal. App. 3d 245, 261 (1977)) (emphasis added).[3] In *Perez*, the district court was tasked with interpreting a release and settlement agreement entered into by the parties which the defendant argued precluded claims against it. *Perez* at *5. That settlement agreement contained an explicit exclusionary term: "[N]othing contained herein shall be deemed to be a release of the Gordon & Wong Law Group [or certain individual defendants]." *Id.* The court found that this term expressly reserved claims against the named defendant, and rejected defendant's res judicata argument.

The dismissal agreement between the parties in this action contains no such express reservation. To the contrary, it sets forth only certain statutes under which Plaintiffs would not assert claims in the federal action. *See* Dismissal Agreement at 1 ¶ 2 ("Plaintiffs will not assert any claim against defendants under Sections 25400-25401 and 25500-25501 of the California Corporations Code or Section 17200 of the Business and Professions Code in any amended complaint in the Federal Action or in any other complaint filed in federal court."). A mere statement of claims Plaintiffs would not assert in the future is not an express reservation, and nowhere in the dismissal agreement do the parties agree that Plaintiffs would be entitled to reassert state law claims in their federal action.

The preclusive effect of this dismissal agreement is made even clearer by the context in which it was signed. At the time of the agreement, Plaintiffs' federal suit – this action – included *only* the two federal securities claims, and did not include any state law causes of action. *See* Compl., ECF 1. Had Plaintiffs wished to preserve their ability to add state law claims through amendment, they could have done so expressly in the dismissal agreement. But they did not. Further, Plaintiffs produce for the Court email correspondence between the attorneys in which counsel for Defendants states: "We understand that plaintiffs will move forward on the basis of

[3] Such an express reservation may be shown through extrinsic evidence, such as the dismissal agreement attached to Plaintiff's opposition. *See, e.g.*, *Ellena* at 261.

those same facts [at issue in the state court litigation] with claims *under the federal securities laws*, and we will not attempt to use the dismissal of the state action in any way to prevent plaintiffs from doing that." Rivas Decl. Exh. B at 1 (emphasis added). "The primary goal of contract interpretation is to give effect to the mutual intent of the parties." *See, e.g., Villacres v. ABM Indus., Inc.*, 189 Cal. App. 4th 562, 598 (2010). Plaintiffs are unable to point to any language in the dismissal agreement that expresses the mutual intent of the parties to expressly reserve to Plaintiffs the right to bring state law claims in this federal action. *See Perez* at *5. As such, Plaintiffs' third, fourth, fifth, sixth, seventh, eighth, and ninth causes of action must be dismissed, with prejudice, because they are barred by res judicata.

IV. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that Plaintiffs' first and second causes of action are dismissed, with leave to amend. Plaintiffs must file a second amended complaint **no later than August 14, 2015**. Plaintiffs' causes of action arising under state law, counts three through nine, are dismissed, WITH PREJUDICE, because they are barred by res judicata.

IT IS SO ORDERED.

Dated: June 18, 2015

BETH LABSON FREEMAN
United States District Judge

United States District Court
Northern District of California