UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MERLE KOVTUN, et al.,

Plaintiffs,

v.

VIVUS, INC., et al.,

Defendants.
_____/

No. C 10-4957 PJH

ORDER GRANTING MOTION TO DISMISS

Defendants' motion for an order dismissing the second amended complaint came on for hearing before this court on April 18, 2012. Plaintiff appeared by lead plaintiff's counsel David Bower, and defendants appeared by their counsel Michael Charlson and Benjamin Diggs. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby GRANTS the motion.

BACKGROUND

This is a securities fraud case, filed as a proposed class action. Defendants are VIVUS, Inc., a pharmaceutical company ("VIVUS" or "the company"); Leland F. Wilson ("Wilson"), the CEO of VIVUS, and also a director of the company; and Wesley W. Day, Ph.D. ("Day"), the Vice President of Clinical Development of VIVUS. The members of the proposed class are "all persons who purchased or otherwise acquired VIVUS securities during the class period," which is defined as the period between September 9, 2009, and July 15, 2010.

At the time plaintiff filed the present action, VIVUS' lead product in clinical

development was Qnexa, an experimental drug for the treatment of obesity. Qnexa combines two ingredients previously approved by the U.S. Food and Drug Administration ("FDA") – phentermine (approved in 1959 for short-term treatment of obesity), and topiramate (approved for prevention of seizures in 1996 and migraine headaches in 2004). Both phentermine and topiramate have some history of negative side effects, but both also have a well-documented safety profile, developed through use on millions of patients.

Under the Federal Food Drug and Cosmetic Act ("FDCA"), Pub.L. No. 75–717, ch. 675, 52 Stat. 1040 (1938), codified as amended at 21 U.S.C. § 301 et seq., a company seeking approval to market a drug must test the drug in the laboratory, and then submit an Investigational New Drug ("IND") Application asking the FDA to approve clinical trials using human subjects. See 21 C.F.R. § 312, et seq. If the IND Application is approved, the company must complete three phases of clinical trials to determine the drug's dosing, assess its efficacy, and monitor its safety. See 21 C.F.R. § 312.21. Upon successful completion of the clinical studies, the company submits a New Drug Application ("NDA") seeking FDA approval to market the drug. 21 U.S.C. § 355(a).

Within 60 days of receipt of the NDA, the FDA makes "a threshold determination that the application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101. During the review, the FDA evaluates the NDA and then sends either an approval letter or a "complete response letter" asking for more information. 21 C.F.R. § 314.100. The FDA uses "its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105. The FDA may convene an "advisory committee" of doctors and other scientists to consider whether a drug's health benefits outweigh its known risks, and issue a recommendation to the FDA. See 21 CFR §§ 14.160, 14.171.[1]

As of the beginning of the class period – September 9, 2009 – VIVUS had

[1] Here, there was such an advisory committee – the FDA Endocrinologic and Metabolic Advisory Committee (referred to herein as the "Advisory Committee").

completed certain Phase III clinical trials of Qnexa. The trials involved more than 4500 overweight and obese adult patients, and included a six-month trial known as EQUATE, and two year-long trials known as EQUIP and CONQUER. Each of these trials was a randomized, double-blind, placebo-controlled study, and included two of three Qnexa dose levels (full-dose, mid-dose, low dose). Two of the trials were completed under a Special Protocol Assessment ("SPA") from the FDA, indicating that the design, clinical endpoints, and proposed analyses were acceptable for FDA approval.

On September 9, 2009, VIVUS released its top-line Phase III trial results, and issued a press release announcing key results of its EQUIP and CONQUER trials: that obese patients on Qnexa had achieved an average weight loss of 14.7% for study completers at the top dose; that the results exceeded FDA efficiency benchmarks for obesity treatment; and that Qnexa had demonstrated a favorable safety profile.

In December 2009, VIVUS submitted an NDA supported by these clinical trial results, seeking to have Qnexa approved as an obesity drug. On March 1, 2010, the FDA accepted the NDA and agreed to review Qnexa. Thereafter, the FDA evaluated the NDA, and convened a meeting of the Advisory Committee.

As detailed in the second amended complaint, between the release of the initial Phase III trial results on September 9, 2009 and late June 2010, VIVUS made a number of public statements through press releases, conference calls, presentations, and SEC filings regarding trial results, VIVUS' partnership opportunities, and Qnexa's prospects for FDA approval and marketability.

In each of the press releases and conference calls, VIVUS underscored the risks inherent in investing in developmental drugs such as Qnexa. As an example, the September 9, 2009 press release identified "risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals[,]" adding that "[a]s with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products[,]" and "[t]here are no guarantees that . . . any product will receive regulatory approval for any indication or

prove to be commercially successful." The press release recommended that investors read "the risk factors set forth in VIVUS Form 10-K for the year ended December 31, 2008, and periodic reports filed with the Securities and Exchange Commission."

VIVUS listed extensive risk factors in its SEC filings. For example, the VIVUS Form 10-K for the year ended December 31, 2009 included 47 pages of risk factors relating to all aspects of the company's business. In a 17-page portion of that discussion, the Form 10-K identified and analyzed "risks relating to our product development efforts," which included the risks that the FDA might find one of defendants' investigational products – including Qnexa – not safe and effective, or might find the data from clinical trials insufficient to support approval, or might require additional clinical studies. These risks and all their potential ramifications were spelled out in considerable detail in the Form 10-K.

On July 13, 2010, two days before the date set for the Advisory Committee meeting, the FDA publicly released VIVUS' "VI-0251 (Qnexa®) Advisory Committee Briefing Document," and the FDA's own analysis of the Qnexa clinical trial data (dated June 17, 2010). Following this release, the price of VIVUS' stock climbed 17%, its largest one-day increase since VIVUS had released its top-line Phase III trial results on September 9, 2009.

On July 15, 2010, the Advisory Committee convened a public hearing where it heard testimony from VIVUS representatives and an FDA staff reviewer regarding Qnexa's efficacy and safety. VIVUS presented testimony by medical experts who opined that the clinical studies had shown Qnexa to be beneficial and effective, and that any observed side effects should not preclude approval. There was no dispute regarding efficacy, but the FDA staff presenter and some Committee members raised concerns about long-term safety, which they felt could not be fully evaluated based on the data from trials conducted over only one year.

Following the testimony and discussion, the Committee voted 10 to 6 against recommending Qnexa's approval at that time, based on an "overall risk-benefit assessment." A number of the Committee members indicated that the decision whether or not to recommend approval was a difficult one, and many of the members that voted to

recommend approval emphasized that VIVUS should conduct further studies in order to obtain longer-term data regarding certain health risks.

On October 28, 2010, six weeks after the close of the class period, the FDA officially denied VIVUS' NDA for Qnexa, as recommended by the Advisory Committee on July 15, 2010. Following this announcement, there was a substantial drop in the price of VIVUS stock. However, the FDA also asked VIVUS to resubmit the NDA, with additional data. On November 2, 2010, plaintiff Merle Kovtun filed this lawsuit, alleging claims under the Securities Exchange Act of 1934. On February 12, 2011, the court granted plaintiff John Ingram's motion to be appointed lead plaintiff and for approval of his choice of counsel.

In the fall of 2011, VIVUS resubmitted the NDA, with a second year of trial data. On February 22, 2012, another FDA Advisory Committee convened, and voted 20-2 in favor of recommending approval, so long as VIVUS conducted a postmarketing study to clarify the cardiovascular risks. The Committee found the second year's data to be "consistent with the safety profile" that VIVUS had reported in its original NDA. Following a further risk evaluation, Qnexa was finally approved by the FDA on July 17, 2012, and is now being marketed under the name Qsymia™.

On October 13, 2011, the court granted defendants' motion to dismiss the first amended complaint. Plaintiff filed a 182-page second amended complaint ("SAC") on November 9, 2011, alleging violation of § 10(b) of the Securities Exchange Act, and Rule 10b-5 promulgated thereunder, against all defendants; and violation of § 20(a) and § 20(b) of the Securities Exchange Act, against the individual defendants. Defendants now seek an order dismissing the SAC, for failure to state a claim.

DISCUSSION

A. Legal Standards

1. Motions to dismiss for failure to state a claim

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests for the legal sufficiency of the claims alleged in the complaint. Ileto v. Glock, Inc., 349 F.3d 1191, 1199-1200 (9th Cir. 2003). Review is limited to the contents of the complaint. Allarcom

Pay Television, Ltd. v. Gen. Instrument Corp., 69 F.3d 381, 385 (9th Cir. 1995). To survive a motion under Federal Rule of Civil Procedure 12(b)(6) to dismiss for failure to state a claim, a complaint generally must satisfy the only the pleading requirements of Federal Rule of Civil Procedure 8 by providing a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

The court must "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." Outdoor Media Group, Inc. v. City of Beaumont, 506 F.3d 895, 899-900 (9th Cir. 2007). However, legally conclusory statements, not supported by actual factual allegations, need not be accepted. Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009). The allegations in the complaint "must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations and quotations omitted).

A motion to dismiss should be granted if the complaint does not proffer enough facts to state a claim for relief that is plausible on its face. See id. at 558-59. 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, 556 U.S. at 678 (citation omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.'" Id. at 679. In the event dismissal is warranted, it is generally without prejudice, unless it is clear the complaint cannot be saved by any amendment. See In re Daou Sys., Inc., 411 F.3d 1006, 1013 (9th Cir. 2005).

Although the court generally may not consider material outside the pleadings when resolving a motion to dismiss for failure to state a claim, the court may consider matters that are properly the subject of judicial notice. Lee v. City of Los Angeles, 250 F.3d 668, 688-89 (9th Cir. 2001); Mack v. South Bay Beer Distributors, Inc., 798 F.2d 1279, 1282 (9th Cir. 1986). Additionally, the court may consider exhibits attached to the complaint, see Hal Roach Studios, Inc. V. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555 n.19 (9th Cir. 1989), as well as documents referenced extensively in the complaint and documents that

form the basis of a the plaintiff's claims. See No. 84 Employer-Teamster Joint Counsel Pension Tr. Fund v. America West Holding Corp., 320 F.3d 920, 925 n.2 (9th Cir. 2003).

Finally, in actions alleging fraud, "the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). Under Rule 9(b), falsity must be pled with specificity, including an account of the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." Swartz v. KPMG LLP, 476 F.3d 756, 764 (9th Cir. 2007) (citations omitted). The allegations "must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." Bly-Magee v. California, 236 F.3d 1014, 1019 (9th Cir. 2001) (citation and quotations omitted). In addition, the plaintiff must do more than simply allege the neutral facts necessary to identify the transaction; he must also explain why the disputed statement was untrue or misleading at the time it was made. Yourish v. California Amplifier, 191 F.3d 983, 992–93 (9th Cir. 1999).

2. Pleading claims under the Securities Exchange Act

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

SEC Rule 10b-5, promulgated under the authority of § 10(b), makes it unlawful for any person to use interstate commerce

> (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.

To state a claim for securities fraud under § 10(b) and Rule 10b-5, a plaintiff must plead a material misrepresentation or omission by the defendant; scienter; a connection with the purchase or sale of a security; reliance; economic loss; and loss causation. Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, 552 U.S. 148, 157 (2008); see also Dura Pharms, Inc. v. Broudo, 544 U.S. 336, 341-42 (2005). At the pleading stage, a complaint stating claims under § 10(b) and Rule 10b-5 must satisfy both Rule 9(b) and the requirements of the Private Securities Litigation Reform Act ("PSLRA"). WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc., 655 F.3d 1039, 1047 (9th Cir. 2011).

The Private Securities Litigation Reform Act ("PSLRA") was enacted by Congress in 1995 to establish uniform and stringent pleading requirements for securities fraud actions, and to put an end to the practice of pleading "fraud by hindsight." In re Silicon Graphics, Inc. Sec. Litig., 183 F.3d 970, 958 (9th Cir. 1999). The PSLRA heightened the pleading requirements in private securities fraud litigation by requiring that the complaint plead both falsity and scienter with particularity. In re Vantive Corp. Sec. Litig., 283 F.3d 1079, 1084 (9th Cir. 2002); see also Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th Cir. 2009). If the complaint does not satisfy these pleading requirements, the court, upon motion of the defendant, must dismiss the complaint. 15 U.S.C. § 78u-4(b)(3)(A).

Under § 20(a) of the Exchange Act, joint and several liability can be imposed on persons who directly or indirectly control a violator of the securities laws. 15 U.S.C. § 78t(a). Under § 20(b) of the Exchange Act, "[i]t shall be unlawful for any person, directly or indirectly, to do any act or thing which it would be unlawful for such person to do under the provisions of this chapter or any rule or regulation thereunder through or by means of any other person." 15 U.S.C. § 78t(b).

A plaintiff alleging a claim that individual defendants are "controlling persons" of a company must plead facts showing a primary violation under the Exchange Act, and must also allege that the defendant exercised actual power or control over the primary violator. America West, 320 F.3d at 945; see also Howard v. Everex Sys., Inc., 228 F.3d 1057, 1065 (9th Cir. 2000).

B. Defendants' Motion to Dismiss

In the second amended complaint, plaintiff alleges that during the class period, defendants repeatedly heralded Qnexa's safety profile and expressed the view that FDA approval of Qnexa was likely, but failed to disclose the serious risks revealed by the study data and the inadequacy of the clinical data. Plaintiff asserts that prior to the July 15, 2010 Committee vote, VIVUS investors were not aware of Qnexa's serious and life-threatening health risks, or the inadequacy of the clinical data, and it was only when Qnexa's previously undisclosed and misrepresented safety issues were publicly disclosed as part of the Committee's "explanation" of the data that the price of VIVUS securities "plummeted."

1. Falsity

Defendants argue the SAC does not adequately allege falsity as required by the PSLRA. They contend that the statements regarding the safety results of Qnexa's trials were accurate in the context of the known safety profile of Qnexa's profile drugs, and that defendants' risk disclosures undercut plaintiff's claims. They also assert that other statements challenged by plaintiff are not actionable to the extent they are statements of general optimism, or forward-looking statements protected by the PSLRA's safe harbor.

Under the PSLRA – whether alleging that a defendant "made an untrue statement of a material fact" or alleging that a defendant "omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading" – the complaint must "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, . . . [must] state with particularity all facts on which that belief is formed." Gompper v. VISX, Inc., 298 F.3d 893, 895 (9th Cir. 2002) (quoting 15 U.S.C. § 78u-4(b)(1)).

A statement or omission is misleading in the securities fraud context "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 985 (9th Cir. 2008) (quoting Brody v. Transitional Hosp. Corp., 280 F.3d 997, 1006 (9th Cir. 2002)).

However, "vague claims about what statements were false or misleading [and] how they were false" are subject to dismissal. Falkowski v. Imation Corp., 309 F.3d 1123, 1133 (9th Cir. 2002); see also Metzler Inv. GMBH v. Corinthian Colls., Inc., 540 F.3d 1049, 1070 (9th Cir. 2008).

Plaintiff alleges that defendants' statements about Qnexa's prospects were false and misleading when made because defendants omitted to reveal relevant information about the product's health risks, and misrepresentated the likelihood that Qnexa would be approved by the FDA. Plaintiff asserts that defendants made false and misleading statements in four press releases, three investor conference calls, one press interview, four filings with the U.S. Securities and Exchange Commission, and fifteen healthcare investment conferences, as previously alleged in the FAC. Each of the statements alleged to be false or misleading – generally relating either to the results of the clinical trials, or to Qnexa's prospects for FDA approval – is followed by a list of between two and twelve reasons (drawn from a list of approximately 20 reasons) that each statement is alleged to be false.

For example, plaintiff quotes various VIVUS statements regarding efficacy and safety in the clinical trials – such as that the studies "have produced . . . not only remarkable efficacy, but remarkable safety as well; that "we have found literally no issues of concern at this point; that "there were no differences in either total serious adverse effects or drug-related serious adverse events between Qnexa and placebo;" that Qnexa had a good "safety/risk profile;" and that there was "nothing of concern from the side effect standpoint" – and alleges that such statements were false or misleading.

Each of these statements is followed by a list of "reasons" that the statement was false or misleading. Among other things, plaintiff asserts that the Phase III trials showed "significant, potentially serious and life-threatening adverse effects of the type that scuttled approval for other obesity drugs, including potential teratogenicity, increased suicidal ideation, cognitive issues, decreased bicarb, tachycardia, and possible renal stones;" that Qnexa was associated with an "increased incidence" of psychiatric adverse side effects;

that there was a doubling of the rate of depression in the top dose group; that patients taking Qnexa reported an increased heart rate; that there was "a potential for cardiovascular risks;" that patients taking Qnexa had a "4 times higher rate of cognitive impairment;" that "a greater proportion of individuals treated with Qnexa" reported an adverse side effect in the areas of "sleep disorders, anxiety, and depression;" that during the Phase I trial, "a depletion of potassium in patients was noticed;" and that "patients in the Phase I trial were provided with an increase in potassium to mask the potential cardiovascular effect."[2]

However, nowhere does plaintiff point to a statement made by defendants regarding a specific Phase III trial result and explain exactly what in the trial data (or elsewhere) shows that the statement about the trial results was false at the time it was made. That is, plaintiff has failed to allege facts showing "why the difference between the earlier and later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." Philco Investments, Ltd. v. Martin, 2011 WL 500694 at *8 (N.D. Cal. Feb. 9, 2011).

Nor does plaintiff claim that defendants ever represented that no participant in the Qnexa trials experienced adverse effects, or that defendants attempted to gloss over the well-known and well-documented possible side effects of either of Qnexa's two component drugs (including the history of adverse effects experienced by some individuals who used "Fen-Phen"[3]). A plaintiff cannot rely on conclusory allegations, but must instead allege specific facts that show how these alleged health risks necessarily precluded FDA

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[2] Notwithstanding the amendment, the SAC still leaves it to the court and to defendants to try to match up a list of "reasons" with a series of snippets alleged to have been false statements. A complaint does not plead fraud with specificity when it alleges only that the defendant said one thing whereas the true fact is the opposite. Unless a plaintiff can plead facts showing that an alleged fraudulent statement is inconsistent with contemporaneous statement or condition, he has not pled fraud. See In re Glenfed, Inc. Sec. Litig., 42 F.3d 1541, 1553 n.11 (9th Cir. 1994).

[3] Fen-Phen was a product that combined fenfluramine – which had been approved in 1973 for short-term treatment of obesity – and phentermine. Fen-Phen was used for weight loss in the 1990s, but the FDA requested that manufacturers withdraw it from the market in 1997 because of indications that it caused pulmonary hypertension and valvular heart disease.

approval. See Ronconi v. Larkin, 253 F.3d 423, 434 (9th Cir. 2001).

Here, defendants' SEC filings discussed the Fen-Phen history in some detail, and also prominently disclosed that each of Qnexa's two constituents has its own side effect profile (including the adverse effects and side effects identified by plaintiff) included in its current product label and prescribing information, which defendants anticipated would be included on the label for Qnexa, assuming it was approved by the FDA. Thus, as defendants stated in some of the allegedly misleading statements, the trial results presented "no issues of concern at this point" and "no surprises."

Plaintiff acknowledges that the side-effect profiles of phentermine and topiramate were well-known long before the commencement of the class period, but alleges in the SAC that "certain drugs should not be combined and the combination of these drugs can increase the risks and magnitude or the side effects found in the individual constituent compounds or create new side effects not seen in the individual compounds." For this point, plaintiff cites to a 1999 article in the Journal of the American Medical Association, which appears to have no particular relevance to the question of Qnexa's safety. Moreover, while plaintiff alleges that during the class period, defendants "were in possession of information" indicating that Qnexa "suffered from [this] effect[,]" the SAC points to nothing in the trial data confirming that phentermine and topiramate, when combined, did in fact increase the risks of the two, taken separately.

In short, because the side-effect profiles of phentermine and topiramate were well-known and understood by the FDA, by the Advisory Committee, and by the markets, the defendants' statements regarding the Qnexa trials must be viewed in that context. Thus, when defendants reported that the Qnexa trials showed "nothing unexpected," it was clear that the baseline expectations were set by the component drugs, and that understanding is repeatedly emphasized in the very statements that plaintiff challenges.

Plaintiff alleges that defendants failed to adequately disclose multiple "serious" and even "life-threatening" risks posed by Qnexa, which assertedly included psychiatric-related adverse effects (suicidal ideation and depression), cognitive-related adverse effects

(confusion, difficulty with concentration/attention/memory, speech problems), cardiovascular adverse effects, teratogenicity (risk of birth defects in children born to women who might be taking Qnexa), metabolic acidosis, and cardiovascular adverse effects.

In response, defendants argue that their statements about trial results that related to specific potential side effects were truthful. They claim that plaintiff has taken isolated comments regarding the above-listed side effects or adverse events, and has removed them from the context, and has also failed to identify anything in the clinical data that contradicted the statements made by defendants.

The court finds that the SAC fails to allege facts showing that defendants' statements regarding the safety data from the Qnexa trials were materially false or misleading. With regard to psychiatric results, defendants disclosed data for moderate and severe depression-related adverse events, as well as for depression-related study discontinuations, and they also made specific disclosures in the 2009 Form 10-K to the effect that the psychiatric side effects observed in Qnexa's components might negatively impact Qnexa's approval chances. Moreover, the incidence of psychiatric events was not a reason cited by the FDA in 2010 for its non-approval of Qnexa. Indeed, FDA Committee members noted the "absence of a clear signal for suicide risk."

Similarly, the FDA did not cite cognitive results as a reason for the initial disapproval of Qnexa. In addition, market analysts, the FDA reviewer, and Committee members all noted that the observed cognitive effects were well-known side effects of topiramate. Plaintiff has alleged no facts showing that any of defendants' public statements about cognitive effects were false or misleading, particularly given the context of the body of information that had long been publicly available regarding the side effects of Qnexa's components.

Plaintiff's assertions regarding cardiovascular safety results turn on two issues that received almost no mention in the Committee's discussion – the withdrawal of the drug combination Fen-Phen from the market in 1997, and the depletion of potassium. The FDA

Memo disposed of the Fen-Phen issue by simply repeating its prior conclusion, reached after extensive research, that the phentermine component of that product was not the cause of Fen-Phen's cardiovascular side-effects. Nothing in the Advisory Committee record suggests that the Fen-Phen issue influenced the Committee's vote in July 2010. Moreover, VIVUS's risk disclosures throughout the class period disclosed the threat that Fen-Phen and its history posed to possible approval of Qnexa.

Nor is the court persuaded by plaintiff's claim that the Committee's suggestion of the need for further study of the cardiovascular side effects somehow shows that defendants' statements regarding cardiovascular safety were false and misleading. Plaintiff alleges no facts showing that Qnexa showed any adverse effects beyond those identified on the label for phentermine, which has been prescribed for more than 50 years. In addition, VIVUS had announced, in its Advisory Committee Briefing Document publicly issued two days prior to the July 15, 2010 Committee meeting, that it planned a comprehensive outcomes study of cardiovascular effects, with a five-year average treatment duration.

Plaintiff's assertions regarding potassium depletion – which is a well-known side effect of topiramate – are neither supported nor linked to the Phase III trial data. Moreover, while the Committee briefing documents included data on decreased potassium levels, the members of the Committee did not cite concerns regarding potassium as a reason for voting against recommending approval.

As for teratogenicity and metabolic acidosis results, the SAC alleges no statement (let alone a false and misleading one) about teratogenicity, save defendants' repeated risk disclosures explaining that pregnant women were ineligible for the Phase III trials and that Qnexa would have a label warning against use by women who are or are considering becoming pregnant. Nor does the SAC mention any statement regarding metabolic acidosis, or regarding "C labels" or "X labels," and alleges no facts showing that defendants said one thing publicly but believed something else about risk of fetal harm.

Moreover, it seems clear, from the allegations in the SAC and the judicially noticeable documents, that the FDA publicly released briefing documents, with extensive

trial data and the FDA's analysis of potential safety issues, two days before the Advisory Committee held the meeting at which it voted not to recommend approval. In response to the release of this FDA data, the price of the stock went up, not down. There are no facts pled showing that any new data came to light on July 15, 2010 – the day of the Committee vote – or that defendants concealed some material facts from the public prior to the vote. The only new thing that occurred on July 15, 2010 was that a majority of the Committee members voted not to approve Qnexa, based on data that had already been publicly released.

Moreover, it is important to note that while the vote against recommending approval was 10-6, some of the Committee members did make positive comments, to the effect that the data showed that Qnexa was reasonably safe and should be approved, and of those who voted against recommending approval, some indicated it was simply because they did not feel comfortable with only one year's worth of data, and believed the trials had not lasted a sufficiently long time.

Finally, to the extent that plaintiff argues that the fact that the FDA eventually approved Qnexa is irrelevant because such approval fell outside of the class period, the court finds it of significance because it vitiates plaintiff's theory set forth in the opposition to the present motion that defendants "knew, by the first day of the Class Period, of the serious adverse side effects observed in" the Phase III trials, and that "those side effects presented a real, immediate and known risk that Qnexa could not and would not be approved by the FDA based on the existing safety data." See Pltf's Opp. at 4 (emphasis added).

Defendants make two additional arguments in support of their motion to dismiss – that a number of the statements challenged by plaintiff are not actionable because they are statements of general optimism, or because they are forward-looking statements that are protected by numerous risk disclosures.

First, defendants assert that statements of general optimism are not actionable as fraud in securities actions. "'Vague, generalized, and unspecific assertions' of corporate

optimism or statements of 'mere puffing' cannot state actionable material misstatements of fact under federal securities laws." In re Cornerstone Propane Partners, L.P. Sec. Litig., 355 F.Supp.2d 1069, 1086 (N.D. Cal. 2005) (quoting Glen Holly Entm't v. Tektronix, Inc., 352 F.3d 367, 379 (9th Cir. 2003)); see also In re Syntex Corp. Sec. Litig., 855 F. Supp. 1086, 1096 (N.D. Cal. 1994) (internal citation omitted).

"When valuing corporations, . . . investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers." In re Cutera Sec. Litig., 610 F.3d 1103, 1111 (9th Cir. 2010). Statements such as "so far we're getting really great feedback," "we are very pleased with our progress to date," we're projecting "excellent results" have been held to be "mere puffery." See Wozniak v. Align Tech., Inc., 2012 WL 368366, at *4-5 (N.D. Cal. Feb. 3, 2012); In re Cornerstone, 355 F.Supp.2d at 1087; see also In re Copper Mountain Sec. Litig., 311 F.Supp.2d 857, 868-69 (N.D. Cal. 2004) ("run-of-the-mill" statements such as "business remained strong" are not actionable under § 10(b)). Thus, defendants assert, statements that Qnexa has an "excellent" or "compelling" risk/benefit profile, or that FDA approval or commercial success is likely, are not actionable as false or misleading statements because they are no more than statements of general corporate optimism.

To the extent that plaintiff challenges statements in which defendants merely expressed confidence in VIVUS' eventual success with Qnexa, such as statements referring to Qnexa's "excellent" or "compelling" risk/benefit profile, or statements to the effect that the trials had shown "remarkable" safety and efficacy, the court finds, under the above authority, that such statements are simply vague assertions of corporate optimism and therefore are not actionable under the federal securities laws.

Second, defendants contend that their comments about Qnexa's prospects were forward-looking statements that are protected under the PSLRA safe harbor or the "bespeaks caution" doctrine. The PSLRA provides a safe harbor for forward-looking statements that identified as such and are accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially

from those in the forward looking statement." 15 U.S.C. § 78u–5(c)(1)(A)(i).[4]

A forward-looking statement is "any statement regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions 'underlying or related to' any of these issues." America West, 320 F.3d at 936 (citing 15 U.S.C. § 78u–5(i)). "[I]f a forward-looking statement is identified as such and accompanied by meaningful cautionary statements, then the state of mind of the individual making the statement is irrelevant, and the statement is not actionable regardless of the plaintiff's showing of scienter." In re Cutera, 610 F.3d at 1112.

Defendants note that every VIVUS press release contained specific warnings about the uncertainties of forward-looking statements, and additionally referred investors to VIVUS' SEC filings, which in turn were chock-full of risk factors, including page after page devoted to the very risks that plaintiff claims were hidden – potential difficulties with FDA approval, the side-effect profiles of Qnexa's two component drugs, the possible resulting labeling restrictions for Qnexa, the possibility that the FDA might require additional, expensive trials, concerns regarding Qnexa's association with Fen-Phen, and many more hazards.

Similarly, a representative of VIVUS began each of the conference calls with a notice that during the course of the conference call or health care presentation, VIVUS might make projections or other forward-looking statements regarding future events, including future clinical trials or regulatory actions relating to Qnexa, and that such projections should be considered predictions and that the actual result might differ, based on the risks disclosed.

Nevertheless, plaintiff asserts that there is no "safe harbor" for any of the allegedly

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[4] The "bespeaks caution" doctrine, which was formulated by courts prior to the enactment of the PSLRA, operates in a similar fashion. This doctrine "provides a mechanism by which a court can rule as a matter of law . . . that defendants' forward-looking representations contained enough cautionary language or risk disclosure to protect the defendant against claims of securities fraud." Provenz v. Miller, 102 F.3d 1478, 1493 (9th Cir.1996) (citation omitted).

false and misleading statements because the statements were not identified as "forward looking" when made, and also to the extent that any of the statements were in fact forward-looking, there were insufficient cautionary statements identifying things that could go wrong, or the disclosures were not sufficiently specific or "meaningful," and because in many instances, the disclosures themselves were misleading because they failed to disclose material facts needed to make the statements truthful.

For example, plaintiff asserts that the disclosures that the FDA might not approve Qnexa and that VIVUS might have problems that could cause it to cancel clinical trials, were "generic" and could be applied to any company, and were also misleading because there was no mention of the potential health problems revealed by the Phase III trials. Plaintiff also contends that this risk disclosure was "nullified" by defendants' statements during the class period that they were "very confident" that Qnexa would be approved by the FDA and were "extremely confident" about the outcome. Plaintiff also cites unfavorable comments made by members of the Advisory Committee during the July 15, 2010 Committee meeting.

Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the company's plan for its product, and as such fall under the PSLRA's safe harbor rule. Each VIVUS press release or other public statement cited by plaintiff included warnings about the uncertainties of forward-looking statements, and also referred investors to VIVUS' SEC filings. Those filings, in turn, were replete with discussion of risk factors, including potential difficulties with obtaining FDA clearances and approval; the known side-effects of Qnexa's two components, and the possibility of FDA-required labeling restrictions; the risk that the FDA might require additional, expensive trials; and concerns regarding Qnexa's association with Fen-Phen.

It cannot be over-emphasized that plaintiff does not claim that defendants presented false information to the FDA or affirmatively misrepresented the data resulting from the clinical trials, or even that there was a way that defendants could have known whether the FDA would or would not approve Qnexa. Although plaintiff argues in opposition to the

present motion that the claims asserted in this case do not turn on whether defendants could have predicted the safety of Qnexa or the likelihood of FDA approval, but rather on whether defendants made misstatements that a reasonable investor would have relied on in making a decision to invest, it is undeniable that one major theme that underlies plaintiff entire theory of the case is that defendants misled investors by saying they expected Qnexa to be approved by the FDA (or by failing to disclose that they did not anticipate approval). See, e.g., SAC ¶¶ 12, 57, 201, 250, 255; see also Pltf's Opp., at 2, 19 n.17, 24 n.23, 28-29.

In order to be actionable under the securities laws, "an omission must be misleading." Brody, 280 F.3d at 1006. "[I]n other words it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." Id. That is, the failure to disclose must render an existing statement of fact false or misleading. For defendants in this case to fail to qualify the statement that they anticipated FDA approval by adding details of the results of the clinical trial was not to create an impression of a state of affairs that differed from one that actually existed, since the FDA review process had not even commenced at the time that defendants optimistically asserted that they anticipated FDA approval in the future. "[T]he fact that a prediction proves to be wrong in hindsight does not render the statement untrue when made." In re Syntex Corp. Sec. Litig., 95 F.3d 922, 929 (9th Cir. 1996).

In the absence of any facts indicating that defendants made statements about the trial results that were false at the time they were made, the statement that defendants expected that the FDA would approve Qnexa can at most be considered a reflection of a bad guess about an event that had not yet occurred. To say that investors were defrauded by defendants' statements about what a third party (the FDA) was going to do in the future is simply not plausible. Even if what plaintiff is trying to allege is that in stating that they anticipated FDA approval, defendants were attempting to persuade investors into putting money into a company without real prospects, such a scenario is unsupported by any facts in the FAC, and is also highly implausible under the facts presented.

2. Materiality

Plaintiff asserts that defendants made statements that reasonable investors relied on, and which were proven to be false when the "truth" was revealed. However, the "truth" that plaintiff refers to is the announcement by the Committee on July 15, 2010 that it had voted not to recommend approval, primarily because a majority of the Committee members were uncomfortable with recommending approval based on a one-year trial. But that is not a "truth" that contradicts prior statements made by defendants.

It is undisputed that the market rose two days prior to the July 15, 2010 announcement, when the FDA publicly released both VIVUS' briefing document and its own analysis of Qnexa's clinical trial data. The reaction of the market to the release of this information was that the price of VIVUS' stock climbed 17% on July 13, 2010, its largest one-day increase since VIVUS had released its top-line Phase III trial results on September 9, 2009. This suggests that it was not defendants' "failure to disclose" that caused the market to rise during the class period, and also suggests the claim that defendants deliberately concealed material information with the intent to defraud the public is implausible.

Plaintiff contends that the market's reaction to the disclosure of the data and the FDA's rejection of the application corroborates the SAC's allegation of material falsity. Plaintiff believes that if the information about the potential health risks of Qnexa had not been material to the decision to purchase VIVUS' stock, the market would not have reacted as it did the day after the FDA Committee announced its decision on July 15, 2010. Plaintiff claims that the fact that the price of VIVUS' stock dropped on July 16, 2010, from $12.11 to $5.41, shows that investors needed the "expert guidance and comments" from the FDA Committee in order to be able to "fully digest and comprehend the true meaning of the voluminous safety data."

According to plaintiff, it was only when the FDA Committee voted and released its comments that the investing public was able to actually perceive defendants' "campaign of deception." Plaintiff asserts that because the FDA briefing document was 555 pages long,

it required some time for investors to review it. However, the key safety data, including the supposed "revelations" upon which plaintiff's fraud claims depend, were summarized in the first seven pages of the FDA memo. Thus, plaintiff's assertion directly contradicts the "efficient market" allegations in the SAC, which plaintiff concedes are necessary to support invocation of the "fraud on the market" theory of reliance. See SAC ¶ 34.

The Court agrees with defendants that plaintiff has not pled sufficient facts to show that defendants' disclosures were materially misleading statements under the federal securities laws. Plaintiff concedes that defendants made numerous statements throughout the class period regarding the results of the clinical trials of Qnexa, including possible side effects. Plaintiff's objection is to the specificity and comprehensiveness of defendants' disclosures. However, it is well established that "§ 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." Matrixx Initiatives, Inc. v. Siracusano, 131 S.Ct. 1309, 1321 (2011). In general, companies have no duty to disclose facts, and must do so only "when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" Id. (quoting 17 C.F.R. § 240.10b–5(b)).

In sum, plaintiff's allegations fail to show that defendants' public statements were false or misleading when made. Nor has plaintiff alleged facts showing "a substantial likelihood that the disclosure of an allegedly omitted fact "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of the information made available." TSC Indus. Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976).

3. Scienter

Defendants argue that the SAC fails to meet the heightened standard for pleading the required state of mind for a claim under § 10(b) and Rule 10b-5. Under the PSLRA, whether alleging that a defendant "made an untrue statement of material fact" or alleging that a defendant "omitted to state a material fact," the complaint must, with respect to each alleged act or omission, "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). To allege

that the defendant acted with the required state of mind, the complaint must plead facts creating a strong inference that the defendants made false or misleading statements either intentionally or with deliberate recklessness. Zucco Partners, 552 F.3d at 991; see also In re Daou Sys., Inc., 411 F.3d at 1014-15.

In determining whether the facts as pled give rise to a strong inference of scienter, the court must take into account plausible opposing inferences. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 310 (2007). As the Supreme Court stated in Tellabs, a plaintiff sufficiently alleges scienter "only if a reasonable person would 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. The inquiry "is inherently comparative." Id. "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." Zucco Partners, 552 F.3d at 991 (citing Tellabs, 551 U.S. at 324).

In addition, when evaluating the scienter element, the court should "conduct a dual inquiry." Id. at 991-92. First, the court must determine "whether any of the plaintiff's allegations, standing alone are sufficient to create a strong inference of scienter." Id. at 992. Second, "if no individual allegations are sufficient," the court should "conduct a 'holistic' review of the same allegations to determine whether the individual allegations combine to create a strong inference of intentional conduct or deliberate recklessness." Id. If the allegations are insufficient to state a claim, a court should grant leave to amend, "unless it is clear that the complaint could not be saved by any amendment." Id. at 989 (quoting Livid Holdings, Ltd. v. Solomon Smith Barney, Inc., 416 F.3d 940, 946 (9th Cir. 2005).

In the SAC, plaintiff alleges that defendants' scienter is shown by the fact that – as established by the information attributed to the Confidential Witnesses ("CWs") – the individual defendants were involved in and knowledgeable about the "core operations" of the company, and also by the fact that defendants had a financial motive to engage in

fraud.

Defendants argue that the facts alleged are insufficient to create a strong inference of scienter. They contend that the allegations based on information attributed to the CWs add nothing; that defendant Wilson's stock sales, made pursuant to a 10b5-1 plan, cannot support an inference of scienter, much less a strong inference; and plaintiff's other "motive and opportunity" allegations fall short because such financial motives can be ascribed to corporate executives generally.

It is true, as plaintiff argues, that allegations of statements made by confidential witnesses may under some circumstances shed some light on scienter, and it is also true that the Ninth Circuit has recognized that allegations relying on the "core operations" inference and allegations regarding "motive" to defraud may be considered in the overall PSLRA analysis. In this case, however, the court finds that plaintiff has not alleged facts sufficient to give rise to a "strong inference" of scienter.

A complaint relying on statements from confidential witnesses must pass two hurdles to satisfy the PSLRA pleading requirements – the confidential witnesses whose statements are introduced to establish scienter must be described with sufficient particularity to establish their reliability and personal knowledge, and the statements that are reported by the confidential witnesses must themselves be indicative of scienter. Zucco Partners, 552 F.3d at 995; In re Daou Sys., 411 F.3d at 1015-16.

Here, the SAC incorporates statements from six confidential witnesses. CW1 was the "Senior Clinical Project Manager at VIVUS" from September 2008 until January 2010, was hired by and directly reported to Day, and was "involved in Qnexa research and clinical trials[;]" CW1, who reported to Day's wife, Dr. Yee, during the Phase I trial, "confirmed that . . . Day helped design and monitored" the Phase I clinical trial for Qnexa. CW1 stated that one "concern" was with Qnexa's clinical studies "regarding the cardiac signal," because of the depletion of potassium in patients (one of the known side effects of topiramate); and that "another issue of concern" was "the need to gather more long-term data on the safety of patients who become pregnant while involved in the trials." He also stated that the

"problem" with the depletion of potassium was "masked" because patients in the Phase I trials were provided with additional potassium.

CW2 was "a scientist at the Lakewood New Jersey location" from 2006 until 2008, and stated that "senior management should have been receiving monthly reports on how the Qnexa trials were progressing." CW2 stated that he/she and "others at the company" discussed the risk that the previously identified side effects of Fen-Phen (which included phentermine) might also apply to Qnexa.

CW3 was "employed as a regional sales representative" from 2000 to 2008, and stated that there were only 12 individuals employed in the sales force at that time. CW3 stated that all sales personnel received "verbal reports on the progress of the clinical trials of Qnexa," which were usually given by Wilson and Vice-President of U.S. Operations and General Manager Guy P. Marsh. CW3 also stated that the company did not have enough money to fund its costs of operation.

CW4 was "a regional sales representative in California" from "approximately" 2004 until October 2010, and stated that eight or nine people – including Wilson and Day – "control everything that goes on" at VIVUS. CW4 also stated that the biggest concern of "people at VIVUS" was the risk that the previously identified side effects of Fen-Phen might also apply to Qnexa. CW4 also stated that VIVUS did not have sufficient resources to take a product from development to production.

CW5 was "the New England Regional Sales Manager" from April 2008 until "around" November 2010, and stated that Wilson and Day "went over the Qnexa data as it was internally reported." CW5 also stated that after the clinical trials were complete, the data "was passed up to senior management." He stated that Wilson, "as well as other management, thought" that if Qnexa encountered any problems with approval, such problems could be overcome because "it could be labeled differently." CW5 also stated that there were discussions about "having Qnexa approved with a black box label." He/she added that "everyone, including senior management, knew" that Qnexa "had the potential for" suicidality and heart problems.

CW6 was "a former VIVUS regional sales representative covering the Mid-West region who worked at VIVUS for six years, including the class period, and left the company "sometime in 2009." CW6 "confirmed that each product in the pipeline, including Qnexa, was discussed at sales meetings." CW6 also stated that there was "debate" by "company scientists" regarding the cardiac problems associated with Fen-Phen. CW6 believed that if VIVUS was unable to obtain approval for Qnexa, the company would go out of business.

Thus, three of the CWs were "sales representatives," one was a "sales manager," one was a "scientist" at the manufacturing facility, and one was a "project manager." However, four of the six CWs – CW3, CW4, CW5, and CW6 – are not alleged to have had any experience with the development of Qnexa or the clinical trials. Rather, their connection to the company is that they were involved in sales. Since Qnexa had not at that time been approved for sale by the FDA, those CWs were necessarily involved in sales of some other drug marketed by VIVUS. Another witness – CW2 – is alleged to have been a "scientist" in the New Jersey manufacturing facility, but to have left that employment before the Qnexa Phase III trials had concluded. Only CW 1 is alleged to have had any involvement in research or clinical trials for Qnexa.

More importantly, however, the allegations regarding the CWs provide no details of any fact that contradicted defendants' public statements about Qnexa, and do not explain when such information was allegedly known or who knew it. Nor are there any allegations showing that the CWs would have known anything about those critical points. It is thus difficult to evaluate whether the CWs were in a position to have any information regarding defendants' knowledge of the supposed concealed health risks of Qnexa.

Most of the statements attributed to the CWs go either to the "core operations" theory; or to the alleged "concern" within the company regarding Qnexa's supposed health risks – particularly with regard to the possibility that participants in the Qnexa clinical trials might experience the same negative side effects as the individuals who had taken Phen-Fen in the 1990s; or to the fact that the company was allegedly short of money. However, apart from CW1, there is no allegation of interaction between the CWs and defendants, or

any detail explaining how these CWs would have been in a position to know what plaintiff claims they knew about defendants' motives or knowledge.

For example, plaintiff claims that CW3 (a regional sales manager) said that all the sales personnel received "verbal reports" on the clinical trials of Qnexa, and that Wilson and Day "went over the Qnexa data" as it was "internally reported." However, plaintiff does not say what contact a regional sales manager would have had with the company's CEO or VP of Clinical Development, and how he would have known about Wilson and Day reviewing the Qnexa data.

Other CWs are alleged to have participated in internal "debates" about various aspects of the safety of Qnexa or the progress of the clinical trials, but there is nothing ominous or even surprising about employees of a pharmaceutical company that is developing a new drug engaging in discussions about safety issues. Moreover, nowhere does plaintiff allege, for example, that a CW reported to upper management about a particular result of a clinical trial – e.g., that Qnexa caused a specific physical effect during the trial – and that upper management proposed (or agreed) to conceal this result from the public, or in fact did conceal it.

The SAC does not allege any specific information via the CWs that contradict any specific statement attributed to the defendants, and instead cites the CWs only to show there were "concerns" or "discussions" about potential safety issues within the company. Moreover almost none of the CWs links Wilson or Day to this "constant discussion" of health issues.

With regard to the "core operations" theory, plaintiff alleges that Wilson and Day were aware of "the truth" about Qnexa by reason of their professional backgrounds and their roles at VIVUS. Plaintiff notes that VIVUS was a fairly small company, and that Day served as Vice President of Clinical Development during the class period, and was identified as the person most responsible for the Qnexa studies, and that Wilson served as CEO and a director during the class period, and signed and certified SEC filings.

Plaintiff contends that by virtue of their involvement in the day-to-day operations of

the company, Day and Wilson knew that the Phase III trials had showed potentially serious and life-threatening adverse effects of the type that had "scuttled approval" for other obesity drugs, and thus knew that the statements regarding Qnexa's safety profile were false and misleading; and that they also had detailed knowledge of the FDA approval process, and therefore knew that Qnexa would not be approved by the FDA.

Plaintiff alleges that certain problems with Qnexa were discussed internally, but were not disclosed to investors. These problems involved the previously identified side-effects of Qnexa's two components – phentermine and topiramate – and the question whether Qnexa might have the same adverse effects as "Fen-Phen;" or the same adverse effects as topiramate, which (as VIVUS stated in its SEC filings during the class period) has been associated with teratogenic risks and cognitive side effects. Plaintiff also alleges that Day and Wilson were aware that topiramate can lower blood potassium, resulting in cardiac irregularities, and that this knowledge is demonstrated by the fact that they "manipulated" Qnexa Phase I clinical trials by potassium augmentation.

The "core operations" theory is used to impute to a company's key officers knowledge of "facts critical to a business's 'core operations' or an important transaction." This inference can satisfy the PSLRA either where there are allegations about management's role in a company, or where the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter. See South Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 783-86 (9th Cir. 2008); Berson, 527 F.3d at 987-89.

Under Tellabs, "core operations" allegations are considered as part of a holistic review of all of the allegations in the complaint. South Ferry, 542 F.3d at 784. However, the "core operations" inference standing alone will generally not support a strong inference of scienter absent "additional detailed allegations about the defendants' actual exposure to information." Id. at 784-85, see also id., at 785 n.3.

Here, plaintiff's position is that Wilson and Day must have known about the alleged fraud simply by virtue of their involvement in VIVUS' day-to-day business. If, in fact,

plaintiff had alleged facts showing specific misrepresentations or material omissions on the part of defendants, then this argument might be more persuasive. In the absence of adequate allegations of falsity, however, it appears to be of minimal significance, and certainly is not sufficient to create a strong inference of scienter. "Where defendants make cheerful predictions that do not come to pass, plaintiffs may not argue, based only on defendants' prominent positions in the company, that they ought to have known better. Instead, the PSLRA requires 'particular allegations which strongly imply [d]efendant[s'] contemporaneous knowledge that the statement was false when made.'" Berson, 527 F.3d at 989 (quoting In re Read-Rite Corp., 335 F.3d 843, 847 (9th Cir. 2003)).

With regard to the alleged motive to defraud, the SAC asserts that defendants had financial incentives to mislead investors. VIVUS' Form 10-K for FY 2009 indicated that the company would require additional funding to continue with the research on Qnexa, and plaintiff alleges that the company needed to raise funds through the sale of shares of stock, and also wanted to find other companies with which to jointly develop and build the market for Qnexa. Plaintiff asserts that this desire to raise capital and to initiate partnering discussions provided the impetus for defendants to deceive the public regarding Qnexa's safety and prospects.

Plaintiff alleges that the individual defendants were also motivated by various financial incentives. Plaintiff points to VIVUS' April 30, 2012 Proxy Statement, which states that compensation and bonuses for the CEO were tied to the raising of financing, and to the status and results of the clinical trial programs for Qnexa. In addition, the company's Equity Incentive Plan provided for the granting or vesting of various stock awards subject to attainment of certain performance goals.

Plaintiff asserts further that Wilson's sale of the majority of his VIVUS holdings on the first day of the class period (the same day that VIVUS issued the first press release regarding Qnexa's effectiveness and its safety profile), and further sale on May 18, 2010 (the same day another conference call was held in which the company reiterated its positive projections for VIVUS' success) strongly suggest the existence of a pre-conceived

plan by Wilson to artificially inflate the price of VIVUS' shares.

The court finds that these allegations are not sufficient to create a strong inference of scienter. First, the fact that a corporation is seeking to acquire capital through the sales of shares of stock is not in itself indicative of a motive to defraud. See, e.g., Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1038 (9th Cir. 2002).

Second, "it is common for executive compensation, including stock options and bonuses, to be based partly on the executive's success in achieving key corporate goals." In re Rigel Pharms., Inc. Sec. Litig., __ F.3d __, 2012 WL 3858112 at *12 (9th Cir. Sept. 6, 2012). As in the Rigel Pharmaceuticals case, in view of the requirement in Tellab that the court assess scienter holistically, and that it take into account plausible opposing inferences, the court "cannot conclude that there is fraudulent intent merely because a defendant's compensation was based in part on such successes." Rigel Pharms., 2012 WL 3858112 at *12 (citing Rubke v. Capitol Bancorp Ltd., 551 F.3d 1156, 1166 (9th Cir. 2009)).

As for stock sales, only "unusual" or "suspicious" stock sales by corporate insiders may constitute circumstantial evidence of scienter. In re Silicon Graphics, 183 F.3d at 986, 1001; Lipton, 284 F.3d at 1036-37. To evaluate whether stock sales are suspicious, the court should consider the amount and percentage of shares sold; the timing of the sales; and whether the sales are consistent with prior trading history. Metzler, 540 F.3d at 1067; Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1232 (9th Cir. 2004).

Here, the allegations concerning the individual defendants' stock sales during the class period do not support a strong inference of scienter. First, Day is not alleged to have sold any VIVUS stock during this period. Wilson is alleged to have sold 200,000 shares of VIVUS stock on September 9, 2009 – the first day of the class period – and to have sold an additional 50,000 shares on May 3, 2010.

However, documents publicly filed with the SEC show that prior to the commencement of the class period, Wilson sold 50,000 shares on June 12, 2009, at

approximately $6.00 a share, and 50,000 shares on July 22, 2009, at $7.00 a share. Then, on September 9, 2009, he sold 150,000 shares at approximately $11.00 a share, and 50,000 shares at $12.00 a share. Finally, on May 18, 2010, he sold another 50,000 shares, at $13.000 a share.

In the FAC, plaintiff noted that prior to the class period, Wilson had made sales of stock pursuant to a Rule 10b5-1 trading plan that had been adopted prior to the start of the class period, but also asserted that the number of shares Wilson sold on the first day of the class period constituted a greater number of shares than he had sold during the prior year. Nevertheless, plaintiff does not mention the Rule 10b5-1 trading plan in the SAC, which is, of course, the operative complaint.

Stock sales can imply knowledge of falsity only when they are "dramatically out of line with prior trading practices at times calculated to maximize" personal benefit. In re Silicon Graphics, 183 F.3d at 986. To the extent that Wilson's sales were made pursuant to a Rule 10b5-1 trading plan calling for an automatic sale when the shares hit a certain price, they were non-discretionary. See Metzler, 540 F.3d at 1067 n.11; In re MannKind Secs. Actions, 835 F.Supp. 2d 797, 814 (C.D. Cal. 2011).

In any event, however, given Wilson's overall trading history as reflected in the SEC documents, the class period sales were not "dramatically out of line" with Wilson's prior trading practices. He sold a total of 350,000 shares between June 12, 2009 and May 18, 2010 – 100,000 of which were sold prior to the class period, and 250,00 of which were sold on two occasions during the class period.

"While it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, . . . allegations must be considered collectively; the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint." Tellabs, 551 U.S. at 325. Indeed, Ninth Circuit case law makes clear that such "motive and opportunity" evidence alone is insufficient to establish scienter at the pleadings stage. Lipton, 284 F.3d at 1035, 1038; see also Howard, 228 F.3d at 1065.

Finally, the SAC alleges that individual defendants were motivated to make false and misleading statements in order to ensure that VIVUS achieved stated corporate goals, as they stood to gain stock and other incentive awards based on the attainment of performance goals.

However, while plaintiff alleges that both Wilson and Day received substantial option awards in 2009, there are no allegations in the SAC that either defendant exercised any of those options during the class period, or that Day sold any stock at all during the class period. And while plaintiff does allege that Wilson sold stock during the class period, those sales were not "suspicious" or out of line with past trading practices.

The inference of scienter must be "strong," which means that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any oposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. That is, "[e]ven if a set of allegations may create an inference of scienter greater than the sum of its parts, it must still be at least as compelling as an alternative innocent explanation." Zucco, 552 F.3d at 1006. Here, even taking all the allegations of scienter collectively, the court finds that plaintiff has not adequately alleged that a "malicious inference is at least as compelling as any opposing innocent inference." Id. at 991.

3. Section 20 claims

Plaintiff alleges a claim under both § 20(a) and § 20(b) of the Act. Defendants argue that there can be no § 20 claim in the absence of a primary violation under § 10(b) or Rule 10b-5. See Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 (9th Cir. 2002). Because no securities fraud claim has been stated, the § 20 claims are also subject to dismissal.

CONCLUSION

In accordance with the foregoing, the court finds that the motion to dismiss the second amended complaint must be GRANTED. The alleged misstatements, viewed in light of all the facts pled and the facts that were in the public domain, do not suggest an attempt to deceive the public.

VIVUS spent tens of millions of dollars on the Qnexa Phase III clinical trials, based on data obtained in earlier-phase trials, as part of an effort to demonstrate the safety and efficacy of Qnexa. With regard to efficacy (which is not disputed), the year-long Phase III clinical trials showed dramatic weight loss and improvements in weight-related co-morbidities to a degree far beyond the established thresholds. As for safety, the two drugs that comprise Qnexa have long been approved by the FDA and have been used at higher dosing levels by millions of patients. While the facts as pled indicate that some dose-related side effects were observed in the Phase III trials, plaintiff alleges no facts indicating that any issues were observed that were outside the labels for Qnexa's component drugs, or were more severe than expected from the components.

Against this backdrop, a "collective" view of plaintiff's allegations does not approach a cogent and compelling inference of scienter, and certainly not one that is more plausible than that defendants genuinely believed in the promise of Qnexa. The "omissions" that plaintiff has alleged do nothing to undercut defendants' optimism, or to explain why defendants would have engaged in the reprehensible conduct that plaintiff believes occurred.

Further, plaintiff's scienter allegations are based on assertions attributed to the CWs, but plaintiff fails to plead facts sufficient to show that those witnesses were in a position to know anything about defendants' motives and intent; and also on conclusory allegations about defendants' motives extrapolated from routine corporate objectives (to obtain capitalization through a public offering) and non-discretionary stock trades (Wilson's sales of stock pursuant to Rule 10b5-1 plan that was in effect six months before the beginning of the class period).

Moreover, even if the CW allegations and the other motive allegations could be viewed as sufficient to support an allegation of scienter, it remains plaintiff's burden to show a strong inference of scienter, which inference is both cogent and compelling, and as plausible as any non-culpable inference that defendants' optimism was honest. The court finds that plaintiff has not met that burden.

Because the court finds that further amendment would be futile, given that plaintiff has already been given leave to amend, and based on the above discussion, the dismissal is with prejudice.

IT IS SO ORDERED.

Dated: September 27, 2012

PHYLLIS J. HAMILTON
United States District Judge