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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

MERLE KOVTUN, Individually And On Behalf Of All Others Similarly Situated, Plaintiff, v. VIVUS, INC., LELAND F. WILSON, and WESLEY W. DAY PH.D., Defendants.	Case No. 4:10-cv-04957-PJH CLASS ACTION PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS SECOND AMENDED CLASS ACTION COMPLAINT **JURY TRIAL DEMANDED** Date: April 18, 2012 Time: 9:00 a.m. Courtroom: 3

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Lead Plaintiff John Ingram respectfully submits this memorandum of law in opposition to the motion to dismiss filed by Vivus, Inc. ("Vivus" or the "Company"), Leland F. Wilson ("Wilson"), and Wesley W. Day, Ph.D ("Day") (collectively, "Individual Defendants"; with Company, "Defendants").[1]

I. SUMMARY OF ARGUMENT

Vivus is a small biopharmaceutical company that had just over 100 employees during the Class Period (September 9, 2009 to July 15, 2010, inclusive) and one U.S. Food and Drug Administration ("FDA") approved drug on the market. ¶¶4, 243. Commencing before the Class Period, Defendants were attempting to obtain FDA approval to commercialize an obesity drug in development at Vivus, Qnexa. ¶4. FDA approval of Qnexa would have allowed the Company to generate billions in revenue given the continued rise of obesity in the United States. ¶¶41-42.

The Complaint specifically identifies each of the materially false and misleading statements and omissions made by Defendants during the Class Period regarding Qnexa, its safety profile, and the undisclosed risks to it receiving FDA approval. In sum, on the first day of the Class Period, Defendants already knew, but failed to disclose to investors, the serious adverse side effects and indications associated with Qnexa that they learned from its clinical trials, including, *inter alia*, potential teratogenicity, increased suicide ideation, cognitive issues, decreased bicarb, tachycardia, possible renal stones, increased incidence of psychiatric adverse effects, doubling of the rate of depression in the top dose group, an increased heart rate, and cardiovascular risks. Instead, during the Class Period, Defendants repeatedly told the market that they had "state-of-the-art therapy for the treatment of obesity" that was "remarkably safe." *See, e.g.*, ¶¶5, 46, 56, 125, 268, 293. Further, Defendants knew, or willfully blinded themselves to the fact, that the adverse side effects and indications revealed by the Qnexa trials would compel the FDA to require longer studies to fully understand and evaluate the safety risks of long-term use of Qnexa on its target population of obese persons who would need to take the drug for extended periods of time to maintain its intended benefit of reducing obesity, thereby

[1] All citations and internal quotation marks omitted unless otherwise noted. The paragraph references ("¶") are to the Second Amended Class Action Complaint ("Complaint"), Dkt. No. 41. Defendants' Memorandum of Points and Authorities in Support of Motion to Dismiss the Second Amended Class Action Complaint, Dkt. No. 44, will be referred to as "Def. Br."

inevitably delaying approval of the drug (if at all) for an indeterminate period of time. Nevertheless, Defendants concealed these facts and known risks from investors. *See, e.g.*, ¶¶10, 125, 219, 225, 234. Ultimately, and inevitably, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee (the "FDA Panel") was dissatisfied with the outcome and scope of Qnexa's clinical data and its safety profile, voting overwhelmingly (10 to 6) against approving the drug. ¶¶8, 207. The summary minutes of the FDA Panel meeting ("Summary Minutes") confirm the FDA Panel's consensus that the Qnexa data raised serious safety concerns warranting further investigation, with even those voting in favor of approval voicing serious reservations about the adequacy of the data and safety of the drug. ¶¶209-14.

The Complaint alleges, with great particularity, a plethora of facts that, taken collectively, demonstrate that Defendants, in their desperate quest for Qnexa's FDA approval, either knew or deliberately blinded themselves to the obvious safety risks of Qnexa exposed in its clinical trials. *See, e.g.*, ¶¶243-52. Defendants knew that phentermine – an essential component of Qnexa – was associated with the infamous Fen-Phen weight-loss drug that was shown to cause potentially fatal pulmonary hypertension and heart valve problems, eventually leading to Fen Phen's withdrawal from the market and billions of dollars in compensatory damages to its users. ¶¶44, 253-55. The Complaint cites six confidential witnesses ("CW(s)"), all former Vivus employees who either directly worked on the Qnexa clinical trials or were in sales positions (and, thus, were well positioned to know about the safety issues inherent in Qnexa), who explain that Defendants knew of the material adverse events and indications observed in the Qnexa clinical studies during the Class Period. ¶¶244, 247-48, 253, 255-58, 261. Indeed, one CW who personally worked on the Qnexa clinical trials explained that the Company provided potassium supplements to participants which manipulated and skewed the participants' potassium levels because low potassium levels are indicative of irregular heartbeat, abnormal electrocardiograms and increased blood pressure, ¶¶264-68, thereby masking Qnexa's potentially serious cardiovascular risks – risks that would be magnified in the drug's target obese patients. In addition to the CWs detailing Defendants' knowledge and hands-on involvement in the Qnexa clinical trials and FDA approval process, the inference of *scienter* is particularly strong here because Qnexa was the Company's most important drug in development and its approval and success were pivotal to

the Company's future financial success. Further, Vivus was a small company with just over a 100 employees, and Qnexa was the heart and soul of its core operations. ¶¶243-82. The Complaint also alleges that Defendants had strong, personal pecuniary motives to make the materially false and misleading statements. ¶¶275-96. These well-plead facts – individually as well as collectively – raise a strong and cogent inference of *scienter*.

Finally, the Complaint's claims under §§20(a) and (b) of the Securities Exchange Act of 1934 ("1934 Act") should also be sustained because Plaintiff has adequately pled a primary violation of §10(b) of the 1934 Act ("§10(b)"). For these reasons, and those more fully discussed below, this Court should deny Defendants' motion to dismiss in its entirety.

II. FACTUAL BACKGROUND

With the continued rise of obesity, drug manufacturers have been racing to obtain approval for their appetite suppressing weight loss drugs so that these drugs can be marketed to the masses for long-term use. ¶41. A weight loss drug that wins regulatory approval has the potential of bringing in billions of dollars a year. In recent years, however, the FDA has raised the bar for new drug approvals, particularly those where long-term use is contemplated, mandating strenuous and fairly lengthy safety results. ¶42. To date, weight loss drugs that have reached the market or gotten to the final stage of the FDA approval process have repeatedly been derailed by serious side effects and safety issues – particularly upon longer term use and, therefore, have been unable to obtain FDA approval. ¶¶44, 47.

Vivus is a small biopharmaceutical company that has one FDA-approved drug on the market, MUSE® ("MUSE"), a prescription treatment for erectile dysfunction, and its lead product in clinical development is Qnexa, which is a blend of two separate, pre-existing, drugs, phentermine and topiramate,[2] combined into a new, single experimental drug. ¶44. In December 2009, Vivus submitted a New Drug Application ("NDA") to the FDA to have Qnexa approved as an obesity drug, and on March 1, 2010, the FDA agreed to review that NDA. ¶7.

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[2] Phentermine is FDA-approved and has been used as a short-term weight loss formula, notwithstanding the drug's association with the infamous Fen-Phen weight-loss drug. ¶44. Topiramate has also been FDA-approved and has been used as an anticonvulsant to treat epilepsy, as treatment for migraines, or as an antidepressant, but has a history of negative side effects. *Id.*

Throughout the Class Period, Defendants made materially false and misleading statements to the market regarding the safety and efficacy of Qnexa, which led investors to believe that FDA approval of Qnexa was all but assured. *See, e.g.*, ¶¶54-183. Defendants, however, knew, by the first day of the Class Period, of the serious adverse side effects observed in Qnexa's phase 3 trials ("Phase 3 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. Nevertheless, Defendants continuously emphasized Qnexa's "remarkable safety," while materially understating or failing to disclose known adverse side events and indications observed in the data. *See, e.g.*, ¶¶5, 46, 56, 125, 268, 293. Thus, investors were misled into believing that Qnexa was safe and that the data from the clinical trials would support FDA approval, *see, e.g.*, ¶122, which caused the Company's stock to trade at artificially inflated prices throughout the Class Period, ¶¶5, 183, and permitted top Vivus officers/directors, including defendant Wilson, to reap over $3.6 million from insider sales. ¶183.

The deception finally unraveled on July 15, 2010, when the FDA Panel, composed of independent medical experts whose recommendations carry great (often dispositive) weight within the FDA approval process, voted 10 to 6 against recommending Qnexa's approval based upon an "overall risk-benefit assessment" for use in obese individuals and certain overweight patients with other health problems such as diabetes or high blood pressure. ¶8. Particularly revealing were the Summary Minutes and comments of the FDA Panel members, which expressed concern over certain adverse events and indications necessitating additional long-term research into Qnexa's potential side effects, including, *inter alia*, cardiovascular disease, suicidal tendencies and birth defects. ¶¶209-30. As a result of the FDA Panel's rejection of Qnexa and its comments, the market price of Vivus securities plummeted, falling 55% in one day on unusually high trading volume of over 42.3 million shares. ¶233. On October 28, 2010, the FDA officially denied Vivus's NDA for Qnexa, as recommended by the FDA Panel. ¶239. Further, in the FDA's Complete Response Letter, the FDA asked Vivus to provide a thorough evaluation of the drug's potential for causing birth defects and heart problems. *Id.*

III. STANDARD OF REVIEW

In ruling on a motion to dismiss, all well pleaded allegations of material fact are taken as true

and construed in the light most favorable to the nonmoving party. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 336 (2007). As the Supreme Court noted in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), to survive a motion to dismiss, there simply must be "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" corroborating the claims. *Id.* at 556. Further, to plead *scienter* under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), a complaint must "state with particularity facts giving rise to a strong inference that defendants acted with the intent to deceive or with deliberate recklessness as to the possibility of misleading investors." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences." *Tellabs*, 551 U.S. at 324. A complaint survives if, ***"[w]hen the allegations are accepted as true and taken collectively,"*** a reasonable person would "deem the inference of scienter at least as strong as any opposing inference." *Id. at* 326 (emphasis added). As the Supreme Court clarified in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), a case presenting facts analogous to those here, courts are not to engage in a dual inquiry by first sorting through each component of *scienter* in isolation, but are to review "all the allegations holistically." *Id.* at 1324; *see also South Ferry LP v. Killinger*, 542 F.3d 776, 784-86 (9th Cir. 2008). If the parties' competing inferences are equally plausible, the complaint should be sustained. *Tellabs*, 551 U.S. at 331. Here, the collective inference of *scienter* weighs entirely in Plaintiff's favor.

IV. ARGUMENT

A. The Complaint Identifies Each Of Defendants' Materially False And Misleading Statements And Specifies The Reasons For Its Falsity

Defendants previously moved to dismiss Plaintiff's prior complaint on the grounds that it failed to sufficiently identify each statement alleged to be false and misleading. Defendants faulted Plaintiff for using block quotes followed by the same 11 reasons for falsity. This Court granted Defendants' motion because it could not "ascertain from the amended complaint exactly which statements plaintiff claims were misleading, or why," but gave Plaintiff leave to amend. *Kovtun v. Vivus, Inc.*, No. 4:10-cv-04957-PJH, 2011 U.S. Dist. LEXIS 118397, at *5 (N.D. Cal. Oct. 13, 2011). Plaintiff complied with the Court's directive, and the operative Complaint sets forth each misstatement separately and

describes, with exhaustive particularity, why each statement was false and misleading.[3] Consistent with Fed. R. Civ. P. 9(b), the PSLRA, and this Circuit's standards, the Complaint specifies "the time, date, place, and content of the alleged fraudulent representation, how or why the representation was false or misleading," *In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1065 (N.D. Cal. 2010), and "the identi[fies] [ ] the person[s] engaged in the fraud." *See id.*

Further, it is axiomatic that a plaintiff is not required to plead his evidence "or specific factual details not ascertainable in advance of discovery." *Gibson v. United States*, 781 F.2d 1334, 1340 (9th Cir. 1986). However, the Complaint contains a mountain of detailed factual information, including, *inter alia*, Defendants' risk disclosures and why they were false and/or misleading, the substance of the Summary Minutes, Vivus's decision to conduct another fetal outcome study, and the problems with combining phentermine and topiramate. Thus, Defendants' argument that Plaintiff fails to plead "factual information," *see* Def. Br. at 8, is simply incorrect.[4] Further, Defendants' observation that Plaintiff's allegations still fall into discernible patterns, repeating the reasons for falsity each time a particular misstatement concerns the same subject matter, Def. Br. at 8, offered with no authority or analysis of why this approach is invalid, fails to support their desire to escape their liability to their investors. Indeed, if Plaintiff's allegations follow certain patterns, it is simply because Defendants' misstatements, omissions, and fraudulent conduct did the same.

B. Defendants Misrepresented Qnexa's Safety Risks

1. Defendants Misled The Market About Qnexa's Psychological Risk

By repeatedly affirmatively reiterating the absence of any data signaling a suicide risk, while

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[3] Defendants now complain that the Complaint is too long. *See* Def. Br. at 1-2, 7-8. But length was a necessary (and inevitable) byproduct of conforming the Complaint to this Court's order.

[4] The clarity and particularity of the Complaint's allegations is further confirmed by a comparison to the pleading found deficient in the case cited by Defendants. *See* Def. Br. at 7-8. In *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231 (N.D. Cal. 1998), the complaint "lump[ed] all alleged misrepresentations together in one unwieldy 14-page segment" spanning ***eight months.***" *Id.* at 1243. Where a complaint simply lists ***all*** the false statements in an "undifferentiated clump" it is fair to lament the "the burden [] on the reader." *Id.* at 1244. That criticism rings hollow here where the Complaint separates the fraudulent statements chronologically, adding in facts to provide relevant context, and then explaining the specific reasons why each of the statements was materially false and misleading when made.

simultaneously omitting any mention of data in their possession showing depression among patients, Defendants' Class Period statements were rendered materially false and misleading, and thereby, misled investors regarding the risks to FDA approval of Qnexa and its commercial viability.[5] In fact, the FDA Panel members' comments demonstrate that the absence of a clear signal for suicide risk did not alleviate their concerns because of the presence of data signaling depression.

Defendants further compounded the market's misimpression of Qnexa's safety and prospects by misleadingly stressing, *inter alia*, that Qnexa "showed no signal for increased depression or depressed mood" (¶¶54, 75, 95, 100, 120), and that the incidence of "mood adverse events of a moderate and severe nature" was the same for Qnexa and placebo, ¶¶54, 110, 134, 161, while failing to disclose their knowledge that the overall incidence of depression among patients taking the highest dose of Qnexa was more than double that of the placebo – data that the FDA Panel viewed as a clinically significant signal for depression. *See, e.g.*, ¶¶209, 215, 219, 223, 228-29; *see* also ¶¶234-35 (analyst commentary linking the FDA Panel's decision to depression signal). The clear consensus of the FDA Panel that the high rate of depression was cause for concern and required further research undercuts Defendants' claim this was a mere disagreement among experts.[6]

Defendants argue that their statements denying any signal for suicidal behavior or ideation were true because the data showed no such signal. Def. Br. at 18. For confirmation, they point to a comment by FDA Panel member, Dr. Rogawski, stating that "we didn't pick up an increase in suicidality risk." *Id.* (citing ¶228). Defendants' selective quotations, however, obfuscate the actual, unambiguous concern voiced by Dr. Rogawski's statement "that doubling the rate of depression in the

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[5] Defendants (specifically Wilson) assured the market that "they are very confident that Qnexa will be approved," and were "extremely confident of the outcome," and they could say this with "credibility" based on the two products the Company previously had approved. ¶125.

[6] The Phase 3 Trials also showed that (a) Qnexa was associated with an increased incidence of psychiatric adverse effects and study discontinuations due to the effects; (b) a greater proportion of individuals treated with Qnexa reported an adverse event in the subclasses of sleep disorders, anxiety, and depression and four to seven times as many patients taking the highest dose of Qnexa, compared to patients taking lower doses or placebos, dropped out of the study because of adverse side effects; (c) the observed increase in depression levels was a serious concern, including the possibility that this could result in suicidal ideation; and (d) the patient population was not large enough to discern a definitive depression signal. *See, e.g.*, ¶55(c). None of this was disclosed during the Class Period.

top dose group is very concerning," ¶228, and thus, confirming his belief that adverse depression events in the clinical data ***raised the possibility of suicidal risks with long-term use***.

Defendants also argue that the focus of their public statements on the absence of "moderate" and "serious" adverse events was not rendered misleading by the concealment of additional, less-severe events. Def. Br. at 16. But, where "negative clinical study results are fully available to the market, investors can better weigh positive predictions, and securities are more accurately valued." *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005); *see also In re Merck & Co., Sec., Deriv. & "ERISA" Litig.*, MDL No. 1658, 2011 U.S. Dist. LEXIS 87578, at *55, *58-*60 (D.N.J. Aug. 8, 2011) (statements were "misleading in that they would appear to a reasonable investor to reveal complete information about the subject of Vioxx's safety and side effects yet were not truthful in light of undisclosed, negative information in Merck's possession."). It is undeniable that, had investors been aware of the true extent of the adverse indications revealed in the Qnexa clinical studies, they would have been able to determine the true risks associated with investing in Vivus with Qnexa as a future revenue source. Defendants denied investors this ability by concealing this information, and the absence of this information from the "total mix" prompted investors to unknowingly pay an inflated price for Vivus's shares during the Class Period. *See Matrixx*, 131 S. Ct. at 1321.

In contrast to the cases Defendants cite, Defendants' misstatements were not simply incomplete. *See, e.g., Philco Invs., Ltd. v. Martin*, No. 10-02785, 2011 U.S. Dist. LEXIS 12951, at *8 (N.D. Cal. Feb. 9, 2011). Rather, the ***combined*** effect of Defendants' optimistic statements reiterating Qnexa's "remarkable safety" and the absence of more serious events in ***conjunction*** with their failure to quantify the much higher rate of adverse depression events overall affirmatively misled investors into believing depression concerns presented no risk to FDA approval. *See Robbins v. Moore Med. Corp.*, 788 F. Supp. 179, 186 (S.D.N.Y. 1992) (defendant misled investors because "revelation of unquantified difficulties at [the company] omitted reference to particular ongoing problems and was coupled with optimistic statements downplaying the extent of the company's troubles"). *See also Matrixx*, 131 S. Ct. at 1309 (investors misled when it was stated that reports indicating that Zicam caused anosmia were "completely unfounded and misleading" when there was contrary evidence).

2. Defendants Misled Investors About Qnexa's Cognitive Risk

The Complaint identifies Defendants' materially false and misleading statements regarding Qnexa's effect on cognitive function. *See, e.g.*, ¶54 (no "clinically significant change in overall cognitive function"); ¶60 ("no clinically relevant effects seen" on cognitive function); ¶61 (same). Defendants dismiss the Complaint's allegations that "patients taking Qnexa had a 4 times higher risk of cognitive impairment," arguing that the FDA Panel expressed no surprise or concern at this fact. Def. Br. at 19.[7] According to the Summary Minutes, however, the overall "committee agreed that the cognitive effects of PHEN/TPM were subtle ***but of concern***." ¶210 (emphasis added); *see also* ¶219 (flagging "brain-related" cognitive issues as being of particular concern to Dr. Proschan); ¶220 (listing "cognitive issues" among the "serious potential issues" that led Dr. Burman to vote no).[8]

Defendants also attempt to contrast their purportedly subjective judgment of "clinical significance" with an objective standard of "statistical significance." *See* Def. Br. at 17. However, the Supreme Court dispositively put that type of shell game to rest, holding that "statistical significance" is ***not*** a prerequisite to a duty to disclosure. *See Matrixx*, 131 S. Ct. at 1321 ("This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link"). Here, a "contextual inquiry" reveals concerns voiced by the FDA Panel that the data showing adverse cognitive effects was serious and a factor in their decision to vote against recommending Qnexa's approval.[9]

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[7] Further, because the Phase 3 Trials were unbalanced and heavily favored women, it was almost impossible to know the cognitive effects in a broader population. *See, e.g.*, 55(f).

[8] Defendants also cite one analyst's commentary that cognitive events were not a surprise. Def. Br. at 19. However, the analyst also concluded that "cognitive adverse events were considered to be important, and warranted further investigation." *See* ¶235. Moreover, that analyst's commentary is belied by Drs. Proschan and Burman's above-cited comments expressly acknowledging that concern about cognitive events was a factor in their votes. ¶¶219-20.

[9] Defendants attempt to distinguish *Matrixx* preemptively by falsely claiming that Plaintiff advocates burying investors under an avalanche of information. Def. Br. at 17. As Defendants themselves admit, however, the omitted information in this case only includes "around 20" items. *Id.* at 9. Defendants' claim disingenuously seeks to conflate their disclosure duty with the length of the Complaint, which is the result of pleading requirements and in no way reflects the amount of information Plaintiff alleges should have been disclosed. Further, it is not unusual for securities law complaints alleging fraud in connection with clinical studies and FDA approval of a drug to be lengthy as the subject matters tend to be complex. *See, e.g., Merck & Co., Inc. v. Reynolds*, 130 S. Ct. 1784 (2010) (affirming reversal of dismissal of a 178-page securities fraud complaint); *In re Merck & Co., Inc., Sec., Deriv. & "ERISA"*

3. Defendants Misled The Market About Qnexa's Cardiovascular Risk

The Complaint also alleges that Defendants misled investors by repeatedly playing up Qnexa's cardiovascular safety, while omitting material information about adverse cardiovascular events and indications in its clinical trials. *See, e.g.*, ¶54 ("[s]tatistically significant improvements in cardiovascular, metabolic and inflammatory risk factors among patients treated with Qnexa"); ¶119 (defendant Wilson reporting that the Phase 3 Trials' results were "very outstanding" and noted "highly statistically significant improvements in all cardiovascular and all metabolic endpoints if they are on the high doses of Qnexa"); ¶147 ("In terms of the cardiovascular risk factors, again, we've seen very, very strong signals for improvements and this is really where the double-digit weight loss really comes into effect."). Defendants attempt to spin the Complaint's compilation of FDA Panel's cardiovascular risk concerns as evidencing simply the desire for more research. Def. Br. at 20. Again, however, Defendants' attempt to spin the seriousness of those concerns is negated by the Summary Minutes, which reflect the agreement by members on both sides of the vote that "that the observed increased heart rate was a significant concern." ¶212. Nor could this consensus have been a surprise to Defendants. One of Qnexa's components, phentramine, is associated with the infamous Fen-Phen weight-loss drug that was shown to cause potentially fatal pulmonary hypertension and heart valve problems, leading to the drug's withdrawal from the market and $13 billion dollars in liabilities. ¶44. Given phentramine's history, together with the undisclosed increased heart-rate signal in the Qnexa clinical data, it was virtually guaranteed that Qnexa would face "strong scrutiny" of any cardiovascular issues during the FDA review process – a fact Defendants, while in possession of non-public adverse information regarding cardiovascular events and indications from Qnexa test subjects, either knew, or recklessly ignored. *Id.*[10] It can be stated without fear of gainsay that investors would want to know if there was any adverse cardiovascular indications from the use of Qnexa to assess whether any drug

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Litig., MDL No. 1658, Dkt. No. 4.

[10] Defendants suggest that because the cardiovascular signal was consistent with known side effects of phentermine, this negates an inference of falsity. Def. Br. at 21. However, Defendants' statements were still misleading because they failed to disclose that they were in possession of information indicating that the combination of phentermine and topiramate increased the risks and magnitude of the side effects of the individual drugs and/or created new side effects. ¶46.

using phentramine as a component could be safe and marketable. *See In re Nuvelo, Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1230 (N.D. Cal. 2009) ("[T]he SAC need not allege that defendants knew SONOMA-2 would fail; the SAC need merely allege that defendants misled investors by omitting to disclose a material risk that SONOMA-2 would fail.").

Likewise, Defendants' attempt to segregate and atomize the related allegations concerning their introduction of potassium supplements to manipulate and mask cardiovascular results among Qnexa trial participants must fail. Not only does this gambit fly in the face of the mandate of *Tellabs* that the Complaint be read holistically, but their arguments defy logic. For example, Defendants argue in one section of their brief that it was not misleading for defendant Day to state "that there is no cardiovascular signal to speak of because, given the measured drop in blood pressure, a one beat per minute increase has no statistical or clinical significance and was of no concern," Def. Br. at 20, and then dismiss Plaintiff's particularized allegations about the manipulation of potassium levels in test subjects in another section of their brief. *See id.* at 28. Defendants' efforts at dissembling notwithstanding, the Complaint makes clear that potassium plays a role in the regulation of heart rate and blood pressure. ¶263. Low potassium is associated with irregular heartbeat and abnormal electrocardiogram, and studies have linked low levels of dietary potassium with high blood pressure. *Id.* There is also evidence that potassium supplementation can decrease blood pressure. *Id.* The Complaint alleges that potassium supplements were provided to manipulate cardiovascular results to mask potentially adverse indications from the use of Qnexa during clinical studies. This is directly relevant to the question of falsity because Defendants themselves minimized the significance of ***increased*** heart rate as a clinical signal by highlighting the non-mitigating measured ***decrease*** in blood pressure. ¶75. Moreover, potassium supplementation during clinical studies of a drug with a known adverse cardiovascular substance in its chemistry does not occur by accident and, thus, the most plausible inference (if not the only inference) is that Defendants introduced the potassium supplements intentionally to mask the adverse cardiovascular indications for Qnexa to salvage its prospects for approval and conceal the falsity of their statements regarding its cardiovascular safety. Therefore, far from being a "red herring" as Defendants label it, their failure to mention their practice of using

potassium supplements supports inferences of falsity and *scienter* as to Defendants' misstatements concerning Qnexa's cardiovascular safety. ¶¶262-68.

Additionally, Defendants accuse Plaintiff of conflating claims of Qnexa's ***effectiveness*** with data on its ***safety***, Def. Br. at 19-20, but FDA approval is a combination of ***both*** variables. Defendants stressed Qnexa's safety, telling the market that "this drug is remarkably safe," and that based on Vivus's previous experience from submitting two drugs to the FDA for approval, they were "very confident that Qnexa will be approved." ¶125. Further, by continually emphasizing Qnexa's cardiovascular benefits, while failing to disclose negative data about its cardiovascular risk, Defendants consciously misled investors by painting a falsely optimistic picture of Qnexa's chances for approval and commercial viability. *See, e.g.*, *Immune Response*, 375 F. Supp. 2d at 1019.

4. Defendants Failed To Disclose The Risk Of Teratogenicity and Adverse Metabolic Acidosis Events

The Complaint alleges that Defendants failed to disclose adverse events of metabolic acidosis and the risk that concerns about teratogenicity would result in Qnexa receiving a Pregnancy Category X label from the FDA. *See, e.g.*, ¶¶57(b), 62(b),116(k). Defendants claim they "disclosed the very risks Plaintiff alleges were kept secret." Def. Br. at 21-22. But the disclosures Defendants point to mischaracterized the seriousness of the risks to pregnant women using Qnexa as Defendants publicly proposed a label with a "pregnancy category C" warning, which denotes "potential benefits may warrant use of the drug in pregnant women despite potential risks." ¶221. By contrast, the FDA analysis memorandum ("FDA Memo") recommended "pregnancy category X," the strongest warning label possible, indicating that the risk of using Qnexa during pregnancy "clearly outweighs any possible benefit," and that Vivus's labeling include risk evaluation and mitigation strategies for patients in case of accidental pregnancy by Qnexa users. *Id.*[11]

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[11] In fact, topiramate was reclassified as a Pregnancy Category D (from Pregnancy Category C) on March 4, 2011 due to "new data that show that there is an increased risk for the development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with topiramate . . . during pregnancy." ¶221. *See also* ¶259 (Defendants admitting in SEC filings that at least one study, published in July 22, 2008, showed that topiramate has been associated with teratogenic risk). Any argument that Defendants had a reasonable basis in fact to believe Qnexa, with topiramate as an ingredient, would receive a less restrictive label than topiramate verges on the absurd. *See Virginia Bankshares v.*

Defendants will no doubt claim there is little difference between categories C and X, but the FDA specifically cited the potential for confusion created by Vivus's proposed category C labeling as a serious concern because of the "large potential" for women to become pregnant while taking the drug, thereby triggering risk of birth defects. *Id.* The Company has, moreover, conceded the materiality of the pregnancy risk to Qnexa's viability by agreeing to conduct an analysis to assess fetal outcomes in offspring of women exposed to topiramate before it resubmits its NDA for Qnexa. ¶¶241, 260; *see Matrixx*, 131 S. Ct. at 1323 (viewed "as a whole, the complaint alleges facts suggesting a significant risk to the commercial viability of Matrixx's leading product.").

5. Defendants' Statements Were Not Mere Puffery

During conference calls, Defendants repeatedly emphasized Qnexa's safety profile and their "extreme" confidence the drug would be approved. *See, e.g.*, ¶¶56, 68, 85 (Defendants, particularly Wilson, repeatedly discussed Qnexa's "remarkable safety" and "excellent risk/benefit profile," stating that "adverse events that we saw were few and there was no pattern of any one particular item," "there is nothing of concern," that the observed "adverse events are not related to [the] drug," that "drug-related SAE's were not different between Qnexa and placebo as well and clearly at a very low level," and that "[n]o serious adverse events occurred in this study."). Defendants dismiss these statements as mere puffery, noting the predictions of FDA approval and new partnership opportunities were typically prefaced with the qualifier "we believe." Def. Br. at 22-23. But many of these same statements referred to the objective clinical data or were accompanied by other statements referring to that data. Accordingly, Defendants had an obligation to disclose and quantify adverse events in that data that rendered the statements about Qnexa's safety and FDA approval misleading. *See In re Quintel Entm't Inc. Sec. Litig.*, 72 F. Supp. 2d 283, 293 (S.D.N.Y. 1999) ("Quintel publicly hyped its unique and exciting partnership with AT&T . . . therefore there was a duty to disclose when Quintel received information that rendered that hype misleading."); *Goldman v. Belden*, 754 F.2d 1059, 1063 (2d Cir.

Sandberg, 501 U.S. 1083, 1090-94 (1991) (investors are entitled to rely on the opinions of management as to matters relating to their company but management must have reasonable, verifiable basis for any such opinions expressed or be held liable); *see also Merck*, 2011 U.S. Dist. LEXIS 87578, at *75.

1985) (defendant misled investors by making positive predictions about the marketing prospects of a system while omitting the "grave uncertainties and problems concerning future sales of" the system).

Further, even assuming, *arguendo*, that Defendants qualified their statements, the facts existing during the Class Period strongly suggest Defendants lacked any reasonable basis for those beliefs, making their misstatements actionable nevertheless. *See Virginia Bankshares*, 501 U.S. at 1093-94 (finding that a statement as to beliefs or opinions "may be actionable if the opinion is known by the speaker at the time it is expressed to be untrue or to have no reasonable basis in fact."); *Merck*, 2011 U.S. Dist. LEXIS 87578, at *75 (finding opinions lacked any reasonable basis in fact); *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01-1455, 2003 U.S. Dist. LEXIS 7667, at *25-*26 (S.D. Cal. May 1, 2003) ("Defendants were privy to information . . . which seriously undermines any belief Defendants may have had regarding the sufficiency of the trials. . . . [E]ven if the statements . . . can be characterized as statements of opinion, [they] are actionable.").

C. The FDA Panel's Overall Consensus As To The Inadequacy Of Qnexa's Safety Data Supports An Inference Of Material Falsity

A significant majority (10 of 16) of the FDA Panel members voted against recommending Qnexa's approval. Defendants nevertheless accuse Plaintiff of taking "snippets" of the FDA Panel's comments out of context to exaggerate members' safety concerns. Def. Br. at 11. They insist the "record as a whole" negates any inference of fraud because even those who voted against Qnexa were "conflicted."[12] *Id.* at 11, 13. Defendants' accusation is belied by the Summary Minutes, which expressly reflect the ***general*** consensus that the Qnexa data raised potentially serious safety concerns:

- The committee ***agreed*** that the observed increase in depression levels was a serious concern, including the possibility that this could result in suicidal ideation.
- There was a ***general consensus*** that the population studied is not an adequate

[12] Defendants make much of the fact that many of those who voted against recommending FDA approval admitted they could have voted the other way. Def. Br. at 11-12. But precisely the same can be said of many of those who voted to ***recommend*** approval. *See* Declaration of Benjamin T. Diggs ("Diggs Decl."), Dkt. No. 45, Ex. G, at 348 (Dr. Henderson: "I did vacillate between yes and no because of the lack of long-term safety data and also the real world applications that we all discuss we're worried about."); *id.* at 349 (Dr. Goldfine: "I've been on many committees, and I've never found a vote actually harder [because of the safety concerns, particularly the pregnancy issues]."); *id.* at 362 (Dr. Kaul: "My yes vote comes with a lot of conditions [related to safety issues like cardiac risk]. And I will not hold it against the sponsor if they interpret my yes vote as a no vote.").

> representation of the "real world". . . . In particular, there was a concern that the prevalence of adverse mental health effects may be significantly larger in at-risk groups such as patients with epilepsy and other medical illnesses.
> - ***Overall***, the committee ***agreed*** that the cognitive effects of PHEN/TPM were subtle but of concern.
> - The committee discussed the implications of cognitive impairment for job-performance and safety and ***agreed*** that the risks are more significant when compounded with the likelihood that some patients may abuse PHEN/TPM (the higher the dose, the more effects observed).
> - The committee ***agreed*** that metabolic acidosis is a potentially serious side-effect of PHEN/TPM and one which warrants considerable attention. ***Overall***, the committee ***agreed*** that the long-term clinical effects of PHEN/TPM-induced metabolic acidosis are unclear and should be further studied. . . .
> - The committee ***agreed*** that the observed increased heart rate was a significant concern, as this poses a risk of atrial fibrillation and other cardiac abnormalities.

¶¶209-14 (emphasis added). The foregoing sample of the Summary Minutes confirms the agreement between those on both sides of the FDA Panel vote that Qnexa's data contained a "number of signals of adverse effects that really could not be ignored," requiring further research into the possible "suicidality risk, the potential for cardiovascular risk based on the mechanism of action of these drugs and the heart rate signal, and of course the teratogenicity." ¶227 (quoting Dr. Heckbert's comments); ¶¶218-30 (quoting similar concerns by other FDA Panel members).[13]

Defendants' argument that their statements that Qnexa presented "no issues of concern at this point" and "no surprises" were all accurate within the context of the known safety profiles of Qnexa's components, phentermine and topiramate, Def. Br. at 14-15, not only asks this Court to become the ultimate trier of fact on a Fed. R. Civ. P. 12(b)(6) motion, but is without any scientific basis. As the Complaint explains, it is an undeniable scientific fact that a chemical compound that standing alone is safe can become unsafe in combination with other chemical compounds or in combination "can increase the risks and magnitude of the side effects found in the individual constituent compounds or create new side effects not seen in the individual compounds." ¶46. Defendants failed to disclose clinical data suggesting the particular combination of phentermine and topiramate increased the known risks and magnitude of the side effects beyond those associated with each component individually

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[13] Defendants insist Plaintiff alleges mere disagreement between experts over the interpretation of data. *See* Def. Br. at 12. However, the existence of scientific disagreement does not preclude a finding of material falsity. *See Merck*, 2011 U.S. Dist. LEXIS 87578, at *75 (misstatements were actionable despite "ongoing scientific debate" over naproxen hypothesis).

and/or was creating new, potentially serious side effects. *See, e.g.*, ¶¶106(g), 126(e)(iv) & (g).[14]

Moreover, even assuming, *arguendo*, the accuracy of Defendants' claims, falsity is not measured by literal truth. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Defendants' public discussions of side effects heavily concentrated on benign matters, such as "dry mouth, tingling, constipation, altered taste" and were accompanied by affirmative false reassurances that there was "no signal of any increase in depression," and "no cardiovascular signal to speak of." ¶¶51-52, 61, 64, 67. By manipulatively cherry-picking the focus of their discussions of side effects and adverse indications, Defendants misled investors into believing that the data revealed during Qnexa's clinical trials represented no real hurdles to FDA approval, *Robbins*, 788 F. Supp. at 186, when in reality, the data, if accurately and prominently revealed, would have materially altered investors' assessments of the risks to Qnexa of FDA approval and commercial success. *See Warshaw v. Xoma Corp.*, 74 F.3d 955 (9th Cal. 1996) (finding defendant "made misleading, optimistic public statements that the E5 FDA-approval process was progressing positively" despite knowing "based on its clinical studies, that E5 might not work and would never be approved by the FDA."); *Nuvelo*, 668 F. Supp. 2d at 1230 (finding that defendants "misled investors by omitting to disclose a material risk that SONOMA-2 would fail."); *In re Connetics Corp. Sec. Litig.*, No. 07-02940, 2008 U.S. Dist. LEXIS 62515, at *23 (N.D. Cal. Aug. 14, 2008).

Immune Response, 375 F. Supp. 2d 983, is particularly instructive. There, plaintiffs claimed that defendants committed fraud when they "continuously misrepresented REMUNE's efficacy in treating HIV or its likelihood of receiving FDA approval, and suggested that no significant issues posed a threat." *Id*. at 1019. The court found the plaintiffs had successfully alleged falsity:

> Plaintiffs do not allege that Defendants' public statements were knowingly false in the sense that they reported fictional clinical findings supporting REMUNE's efficacy. Rather, Plaintiffs allege that ***Defendants committed fraud by publicly reporting results that they knew or should have known were either so incomplete or so statistically flawed as to lack clinical significance. In other words, Plaintiffs' criticism is not that what was said was inaccurate, but that it was incomplete, thus portraying the results***

[14] Defendants dismiss these allegations as "made-up" and lacking any evidentiary basis. Def. Br. at 15-16. Again, however, Plaintiff is not required to plead evidence, *Gibson*, 781 F.2d at 1340, but is fully prepared to support his claims with evidence at an appropriate stage of the litigation.

> ***of the clinical trial in an unduly optimistic light.*** Whether Defendants' statements were accurate is not an issue at this stage.

Id. (emphasis added). Here, as in *Immune Response*, Plaintiff establishes "falsity by alleging facts demonstrating that the statements failed to reflect the [drug's] true condition at the time the statements were made." *Id.* at 1020. Here, Defendants knowingly painted a falsely optimistic picture of Qnexa's safety data and, consequently, its prospects for FDA approval and commercial viability through a combination of optimistic reassurances and omissions of serious adverse effects that were observed (*i.e*., depression, tachycardia, cognitive impairment) that made FDA approval improbable without long-term data clearly demonstrating these concerns were unfounded. These "allegations of specific problems undermining a defendant's optimistic claims suffice to explain how the claims are false." *Id.*

Plaintiff's claims do ***not*** turn on whether Defendants could have predicted the safety of Qnexa or the likelihood of its FDA approval. *See Immune Response,* 375 F. Supp. 2d at 1020 ("Whether Defendants had to predict the efficacy of REMUNE is irrelevant."). Rather, "Defendants are liable . . . if they made misstatements that a reasonable investor would consider in deciding whether to buy [Vivus's] stock." *Id.* "[A] fact is material if there is a substantial likelihood that a reasonable investor would consider it important in his or her decision making." *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am West Holding Corp.*, 320 F.3d 920, 934 (9th Cir. 2003). In this case, nearly every FDA Panel member on both sides of the vote voiced substantial safety concerns about Qnexa. It must, therefore, follow that a reasonable investor would also have considered adverse side effects and indications in the Qnexa clinical data that Defendants concealed from the public "an important factor in his or her decision making." *Id.* at 934. *See also Matrixx*, 131 S. Ct. at 1321 ("[I]n some cases . . . reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.").

D. The Market's Reaction To The Disclosure Of The Data And FDA's Rejection Corroborates The Complaint's Allegations Of Material Falsity

Plaintiff alleges that Vivus's share price plummeted when, on July 15, 2010, the FDA Panel voted against recommending approval for Qnexa based on inadequacy of Qnexa's safety data and its potentially serious health risks. ¶¶13, 233, 302. Defendants counter that the clinical trial data informing the FDA Panel's decision was actually released on Tuesday, July 13, 2010, two days before

the FDA Panel's vote and consequent drop in Vivus's share price. Def. Br. at 10. Defendants argue that since the market's reaction to this data was initially positive, as indicated by the rise in the Company's share price and the positive analyst commentary, this somehow negates falsity.[15] As an initial matter, the very analyst commentary relied on by Defendants suggests the market was actually reacting to the perceived positive "tone" of the accompanying FDA Memo, rather than the actual safety data. *See* Diggs Decl., Ex. F ("The tone of the FDA seems fairly benign . . . they're not hammering away at the company."); Ex. I ("anxious investors breathed a sign of relief over the [FDA's] relatively benign review of Qnexa, which didn't yield any 'Uh Oh!' revelations"). Share-price movement in response to the "tone" of a disclosure is irrelevant to the question of fraud. *See In re Omnicom Group, Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010).

A more reasonable inference is that investors needed the expert guidance and comments from the FDA Panel to fully digest and comprehend the true meaning of the voluminous safety data and dispel Defendants' campaign of deception driven by their prior materially false and misleading statements about Qnexa's safety and prospects. ¶12; *see No. 84 Employer-Teamster*, 320 F.3d at 935 (materiality of information supported by delayed stock drop upon disclosure of full economic impact); *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1054 (9th Cir. 2008) (subsequent events made the significance of the prior disclosure apparent to the public). Indeed, by Defendants' own admission, the clinical trial data was accompanied by some ***555 pages*** of analysis by the FDA and Vivus. *See* Def. Br. at 10. It should be no surprise, therefore, that the market took two days to process the significance of these analyses and the underlying data accurately.[16]

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[15] Importantly, Defendants do not argue these facts somehow negate the element of loss causation. Accordingly, Defendants conceded that the report of the vote of the FDA Panel and its accompanying statements explaining the basis for the rejection of Qnexa did, indeed, reveal the truth of Defendants' prior misrepresentations and omissions regarding the drug to the market and that the revelation of that truth caused the decline in the share price of Vivus's securities and the losses to Class members. *See, e.g.*, *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 297 n.18 (D.N.J. 2007) (for loss causation "in addition to formal disclosure by a defendant, the market may learn of possible fraud [from] a number of sources: e.g., from whistleblowers, analysts questioning financial results . . . newspapers and journals, etc."). *See also In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1114-15 (9th Cir. 1989).

[16] Defendants point to two analysts who correctly perceived the raw data raised safety concerns. Def. Br. at 11. But just because some investors understood the truth sooner than others does not negate an inference of falsity. Indeed, other analysts did not apparently comprehend the significance of the safety

Defendants infer that Vivus's share price increase was in response to the positive "review of Qnexa's safety data" in the FDA Memo. But this inference is contradicted by Defendants' own cited article, which states: "The FDA chose ***not*** to state its own opinion of Qnexa's overall ***safety*** in Tuesday's [July 13, 2010] review documents." *See* Diggs Decl., Ex. I (emphasis added). Thus, the market took no news as good news. Tellingly, the only actual data mentioned by the article relates solely to Qnexa's ***efficacy***, which Vivus repeatedly stressed throughout the Class Period in an effort to distract investors from what Defendants knew was the real concern – that the Qnexa data was so fraught with serious adverse safety issues which would lead to denial of FDA approval.[17]

E. The Complaint's Allegations - Corroborated By CWs, Core Business Inference, And Motive - Collectively Raise A Strong Inference Of *Scienter*

Defendants cannot demonstrate under the facts alleged in the Complaint – the only permissible source for review at this juncture – that an inference of non-fraudulent intent is more plausible than the competing inference of fraud.[18] *Tellabs*, 551 U.S. at 314 (the court can only consider "competing

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data or its likely consequences. As reported by Jefferies & Company, Inc. on July 16, 2010, "the FDA did not intervene much during the panel deliberations, and thus, we were struck when they did intervene with comments revealing a high level of concern on the teratogenicity risk and the lack of sufficient data to understand the suicidality risk with Qnexa." ¶302 & n.26. Ironically, the analysts whose comments Defendants point to clearly undercut Defendants' overall position that the data did not suggest serious Qnexa safety risks.

[17] Defendants also quote a comment from TheStreet.com that "all safety issues raised by FDA Memo had been anticipated by investors as major areas of discussion at the [FDA Panel] meeting." Def. Br. at 9. But Plaintiff's contention is ***not*** that the market was completely ignorant that Qnexa might pose possible safety risks. Rather, Plaintiff contends investors were misled by Defendants' statements into believing those risks were minor or non-existent and were not serious enough to stand in the way of Qnexa's approval and commercial success when, in fact, Defendants were aware that those risks were very serious and potentially disastrous for the drug and, consequently, for the Company. *See In re Credit Suisse-AOL Sec. Litig.*, 465 F. Supp. 2d 34, 50 n.17 (D. Mass. 2006) (that defendants continued to publish optimistic assessments of the company's financial position was "akin to a statement that the reader need not worry much about the generic risk disclosures that appeared from time to time").

[18] For example, Defendants question why they "poured millions of dollars into clinical trials for an approval process they purportedly knew was doomed." Def. Br. at 25. But it is entirely reasonable to infer that a small company like Vivus would double down on its investment in Qnexa, which promised ***five times*** the revenues of the Company's only other FDA-approved drug on the market. Further, that Defendants might hope against hope (reasonably or unreasonably) that they could solve the safety problems with the drug or persuade the FDA to overlook those serious safety risks does not provide a defense to their failure to disclose those serious safety risks to the public under the federal securities laws. *See Makor Issues & Rights, Ltd. v. Tellabs*, 513 F. 3d 702, 710 (7th Cir. 2008). Moreover, Vivus management are not, as with some companies, majority shareholders of their company. Thus, the funds they expended in the reckless and otherwise morally questionable effort to commercialize a drug with potentially very serious adverse side effects allowed them to use other people's money that, without a

inferences rationally drawn from the facts alleged."). Defendants contend that a reasonable inference from the facts alleged is that Vivus was "legitimately excited" about Qnexa's efficacy, safety, and prospects for FDA approval and commercial success. Def. Br. at 25. Whether or not Defendants were "excited" or not about Qnexa, as demonstrated throughout the Complaint, that excitement led them to intentionally or recklessly make unfounded, over-optimistic, materially false and misleading statements about Qnexa's safety and its prospects.

Further, in weighing this inference against the competing inference of fraud, Defendants simply ignore some *scienter* allegations and scrutinize others in isolation, rather than collectively, as required by law. *Tellabs*, 551 U.S. at 323; *Matrixx*, 131 S. Ct. at 1324. This approach must fail. Defendants also accuse Plaintiff of alleging mere fraud in hindsight and insist the Complaint must allege facts that "Defendants actually concluded that Qnexa was unlikely to be approved or marketable." Def. Br. at 26. Understandably that is the theory Defendants wish the Complaint espouses, but it does not and Plaintiff's theory of his case is all that matters at this juncture. The question here – based on what the Complaint actually alleges – is ***not*** whether Defendants "actually concluded" Qnexa would fail to obtain FDA approval or fail to be commercially viable, but whether the adverse safety data that Defendants knew but failed to reveal would have altered a reasonable investor's assessment of the risk to Qnexa of FDA approval and, consequently, its commercial value. *See Nuvelo*, 668 F. Supp. 2d at 1230. A review of the Complaint's *scienter* allegations confirms that while Defendants knew the adverse facts related to the safety of Qnexa and recognized the significance of that data and its likely impact on FDA approval for Qnexa, they chose not to share this knowledge with investors.

1. CWs Confirm Defendants' Knowledge

Adverse clinical events and indications were observed within a context of close scrutiny of, and hyper-sensitivity to, Qnexa's potential safety issues. Six confidential former employees report that Defendants knew or should have known about the adverse clinical events and indications revealed in

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product in development (no matter how unlikely its commercial prospects), would have left Vivus with few, if any, future financial upside as a Company and little to offer to the public as an inducement to invest in Vivus, which would have very negatively impacted the Individual Defendants' personal Vivus holdings which, most likely, represented the lion's share of their personal wealth.

the Qnexa trials and, thus, Defendants knowingly or with deliberate recklessness made statements that were materially false and misleading. ¶¶244, 247-48, 254, 255-58. A complaint relying on confidential witnesses must describe personal sources of information "with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009). The descriptions of the CWs here more than meet this standard. *See, e.g.*, ¶244 ("CW1, who was the Senior Clinical Project Manager at Vivus from September 2008 until January 2010 directly involved in the Qnexa research and clinical studies, was hired by and directly reported to defendant Day."); *see also* 248 (CW2 and CW3); ¶247 (CW4 and CW6); ¶256 (CW5). Nothing more is required.

The CWs, all former Vivus employees, who either directly worked on the Qnexa clinical trials or were in sales, explained that there was a constant discussion between scientists, management and other Vivus employees about the various health issues arising out of the use of Qnexa in those trials.[19] Cardiovascular concerns were at the forefront of these discussions because a significant component of Qnexa was also a component in the controversial weight-loss drug Fen-Phen. CW4, who was a regional sales representative for Vivus in California from approximately early 2004 until October 2010, was aware of and stated that the risk of previously identified side effects with the Fen-Phen component of Qnexa was the biggest concern of people at Vivus. ¶253. Corroborating CW4, CW2, who was a scientist at the Lakewood, New Jersey location from 2006 until 2008, stated that during her/his employment, she/he and others at the Company discussed some of the likely problems associated with Qnexa considering that part of Qnexa's components was a drug that had been part of Fen Phen, which caused valve damage in the heart, and whether Qnexa could be approved. ¶255.

CW6, a former Vivus regional sales representative covering the Mid-West region, corroborated that there was debate by Company scientists over whether Qnexa could overcome or avoid the

[19] Defendants are certainly correct that "constant discussion" of safety issues among researchers at drug companies is desirable. Def. Br. at 27. But a failure by the Company and its management to disclose those safety issues to investors while simultaneously consistently and continuously emphasizing to investors a drug's safety and prospects crosses the line to fraud.

cardiovascular problems that Fen-Phen had caused. *Id.* CW6 stated that Company representatives told the sales staff that if there was a problem with cardiovascular issues, they would get it approved with a "black label," which is the "strongest warning for an FDA approved product" that can have a serious implications for the manufacturer of the drug and "a profound effect on the sales of the drug." ¶256 & n.17. CW5, who had been the New England Regional Sales Manager from April 2008 until November 2010, corroborated this plan and stated that defendant Wilson, as well as other management, thought Vivus could overcome the problem through labeling. CW5 reiterated that there were internal discussions about having Qnexa approved with a black box label. ¶256. *See Daou*, 411 F.3d at 1012 ("Such discrepancy between what Daou executives reported and the allegedly true state of affairs of Daou's employ is adequately misleading to state a claim").

Additionally, CW1 discussed the manipulation of phase 1 trials by potassium augmentation to mask any potential adverse cardiovascular effects, which was not disclosed to investors. ¶¶262-68.[20] CW1 specified that defendant Day and Dr. Yee (defendant Day's wife) received electronic reports that included data concerning potassium and heart rate, and had access to a spreadsheet tracking the potassium level for all patients, which was maintained by CW1 at Dr. Yee's direction. ¶¶266-67. Also, CW1 stated that she/he spoke to Dr. Yee and defendant Day about his/her concerns with the potassium data. *Id.*; *see also In re Toyota Motor Corp. Sec. Litig.*, No. 10-922, 2011 U.S. Dist. LEXIS 75732, at *10 (C.D. Cal. July 7, 2011) (*scienter* pled where defendant admitted "that Toyota had been covering up the true nature and severity of the unintended acceleration defects").

Further, CW5 stated that suicidality and heart problems were two major internal concerns prior to the FDA Panel meeting because everyone, including senior management, knew the drug had the potential for these problems. ¶257. CW1, a former Vivus Senior Clinical Project Manager, also stated that there were discussions regarding possible adverse effects with Qnexa when it was mixed with antidepressants, which occurred near the end of 2008 and included defendants Day and Wilson, as well

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[20] Former Vivus employees have also confirmed defendant Day's integral role in the Qnexa clinical trials. CW1, who was directly involved in the Qnexa research and clinical studies, was hired by and directly reported to defendant Day. Defendant Day also helped design and monitor Phase 1. ¶244.

as Peter Tam. Importantly, the FDA Panel noted that the lack of data on Qnexa's interaction with prevalent medications used in the obese population (including psycho-active medications) was a concern. ¶261. CW1 further indicated that concern existed regarding the need to gather more long term data on the safety of patients who became pregnant while participating in the trials. ¶258.

The inference Defendants ask the Court to draw from these facts is that everyone at this small Company was aware of the problems with Qnexa's safety data ***except*** senior management. Against this backdrop, however, "it would be absurd to suggest that management was without knowledge" of the safety data withheld from investors. *South Ferry*, 542 F.3d at 784; *Makor Issues*,513 F.3d at 709-10; *Toyota*, 2011 U.S. Dist. LEXIS 75732, at *11 ("The defects at issue were simply too significant for it to be plausible that top Toyota management was not aware of the possible ramifications of the problem by the time the statements at issue were made").

2. Qnexa's Importance To Vivus's Core Operations Supports A Strong Inference Of *Scienter*

Defendants have chosen to ignore that the commercialization of Qnexa was, in a very real sense, Vivus's core operation and that, as such, the Complaint alleges a strong inference of *scienter*. ¶¶243-82. Under Ninth Circuit precedent, allegations "that rely on the core-operations inference are among the allegations that may be considered in the complete PSLRA analysis," but are generally insufficient by themselves to establish the requisite strong inference. *South Ferry*, 542 F.3d at 784. But the core-operations inference can satisfy the PSLRA by itself either: (1) where there are "allegations regarding a management's role in the company" that are "particular and suggest that the defendant had actual access to the disputed information," or (2) 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." *Id*. at 786; *Zucco Partners*, 552 F.3d at 1000. In this case, ***both*** exceptions apply. As described in the Complaint, Vivus is a small company with just over 100 employees during the Class Period, and even fewer since the FDA's rejection of Qnexa. ¶243. At the time that Qnexa was in clinical trials, Vivus had only one FDA-approved drug on the market (MUSE), approved in 1997, with

a projected market of about $1 billion annually. *Id.* The Company conceded in its public filings that "the potential worldwide pharmaceutical market for obesity could approach $5 billion annually." *Id.*;[21] *see also Makor Issues*, 513 F.3d at 709 ("That no member of the company's senior management who was involved in authorizing or making public statements about the demand for the 5500 and 6500 knew that they were false is very hard to credit"); *In re Toyota*, 2011 U.S. Dist. LEXIS 75732, at *14.

Similarly, given the size and make-up of Vivus, as well as the importance of Qnexa's success to its bottom line, the only reasonable inference is that Defendants knew of every aspect of the chain of events in the development of Qnexa. *See Batwin v. Occam Networks, Inc.*, No. 07-2750, 2008 U.S. Dist. LEXIS 52365, at *34-*35 (C.D. Cal. July 1, 2008) (finding *scienter* due to company's relatively small size and defendants' considerable involvement with the company's generation and reporting of revenues); *see also In re Commtouch Software Ltd.*, No. 01-00719, 2002 U.S. Dist. LEXIS 13742, at *27-*28 (N.D. Cal. July 24, 2002).[22] Of particular relevance, Defendants publicly admitted to their hands-on oversight of Qnexa specifically and the Company generally during investor calls. ¶¶244, 246. Defendant Day spoke on conference calls and at conferences putting himself out there as the person most knowledgeable regarding Qnexa. Vivus's website also lists defendant Day as the responsible party for the Phase 3 Trials. ¶244. Further, the Company's proxy statement stressed "Wilson's scientific background and extensive drug development and marketing experience afford the Board of Directors unique insight and guidance into strategic issues and opportunities that face the Company." ¶246.[23] Such specific admissions of Defendants' knowledge and close involvement strongly suggest

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[21] As noted in the Company's March 10, 2010 Form 10-K: "We are largely dependent on the success of our two investigational product candidates: Qnexa, for treatment of obesity, and avanafil, for treatment of erectile dysfunction, and cannot be certain that either product candidate will receive timely regulatory approval, if at all, or be successfully commercialized." ¶271.

[22] And if Defendants did not inform themselves of every aspect of the chain of events during the Class Period, then their Class Period statements reiterating the safety of Qnexa were made without a basis, and that fraudulent conduct alone supports Plaintiff's claims and warrants denial of Defendants' motion. *Virginia Bankshares*, 501 U.S. at 1093-94.

[23] The Individual Defendants each had a detailed knowledge of the FDA approval process and its requirements through their professional backgrounds and experience, such that they knew, based on the lack of long-term data and the true nature of the adverse effects and indications from the Qnexa clinical trials, the risks involved in commercializing the drug that were concealed from the public. *See* ¶¶250-52. *See also FSP Stallion 1 v. Luce*, No. 2:08-01155, 2009 U.S. Dist. LEXIS 41592, at *15-*16 (D.

they had "actual access to disputed information." *South Ferry*, 542 F.3d at 785; *Zucco Partners*, 552 F.3d at 1000; *Daou*, 411 F.3d at 1022 ("[S]pecific admissions from top executives that they are involved in every detail of the company and that they monitored portions of the company's database are factors in favor of inferring scienter in light of improper accounting reports.").

3. Defendants' Motives Contribute To A Strong Inference Of *Scienter*

A personal pecuniary motive is not required to plead *scienter*. *See Daou*, 411 F.3d at 1023. However, "personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325; *In re New Century*, 588 F. Supp. 2d 1206, 1232 (C.D. Cal. 2008) ("[a] motive to defraud based on compensation incentives such as bonuses . . . may strengthen an inference of scienter."). Here, Defendants' misrepresentations and omissions resulted in them being awarded bonus incentives at 100%. ¶286.[24] In 2008, defendant Wilson was paid $1,716,077 in compensation (consisting of $549,192 in salary, $971,121 in option awards, $185,625 in non-equity incentive plan compensation, and $10,139 in all other compensation). In 2009, defendant Wilson was paid $2,080,097 in compensation (consisting of $612,721 in salary, $1,190,574 in option awards, $266,063 in non-equity incentive plan compensation, and $10,739 in all other compensation). In 2010, defendant Wilson's base salary was increased to $680,813. In 2008, defendant Day was paid $708,957 in compensation (consisting of $279,493 in salary, $257,289 in option awards, $62,975 in non-equity incentive plan compensation, and $9,200 in all other compensation). In 2009, Day was paid $659,082 in compensation (consisting of $304,754 in salary, $256,364 in option awards, $88,164 in non-equity incentive plan compensation, and $9,800 in all other compensation). In 2010, defendant Day's base salary was increased to $306,224. ¶¶290-91. Further, defendant Day's wife, Dr. Yee, who performed various consulting services for Vivus and was involved in the Qnexa trials, clearly had an interest in the

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Nev. May 1, 2009).

[24] This fact too may well answer Defendants' question as to why they would spend millions of Vivus's dollars on testing and going through the motions of seeking approval of the drug when they knew or should have known that the effort was doomed to failure based on the outcome of the clinical studies, *see* Def. Br. at 25, since actual approval of the drug or revenue from its commercialization was not a requisite for the Individual Defendants to receive certain compensation, but rather simply moving the drug through various milestones in the approval process, such as filing the NDA. ¶285.

appearance of a positive outcome since her husband's salary and bonuses were based on the Company achieving certain objectives. ¶182.

Additionally, "[s]uspicious stock sales by corporate insiders are circumstantial evidence of intent to defraud." *In Re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 1001 (9th Cir. 1999). Insider trading is "suspicious when [it is] dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Bare Escentuals*, 745 F. Supp. 2d at 1078. Among the factors this Court considers are "the amount and percentage of shares sold, the timing of the sales, and whether the sales were consistent with prior trading history." *Id.* Here, the Complaint provides substantial context for the insider-trading allegations. Top Vivus officers and/or directors sold shares of their Company stock during the Class Period at inflated prices for proceeds of over $3.6 million. The lion's share of those stock sales were made by the two high-level Vivus officers, CEO Wilson and VP of Operations Guy Marsh. ¶292. Specifically, on September 9, 2009, the day defendant Wilson hosted a conference call discussing Qnexa's "remarkable efficacy" and "remarkable safety," and assuring the market of his extreme confident that Qnexa would be approved, he sold 200,000 shares of Vivus stock – the majority of his Vivus holdings – for proceeds of $2,245,000. Likewise, Marsh sold 109,296 shares of his Vivus stock on September 9, 2009 and September 10, 2009 for proceeds of $1,269,532.[25] ¶293. Defendant Wilson further sold an additional 50,000 shares on May 18, 2010 (for proceeds of $650,000) shortly after yet another conference call held on May 3, 2010, and the same day Vivus presented at the Rodman & Renshaw Global Investment Conference. Defendant Wilson's May 18, 2010 sale in fact fell on the very day marking Vivus's share price Class Period high. ¶294.

Defendants argue that, because Wilson's sales were made pursuant to 10b5-1 trading plans, this negates an inference of *scienter*. Def. Br. at 29. However, the use of a trading plan is an affirmative defense that is inappropriate to consider on a motion to dismiss. *Stocke v. Shuffle Master, Inc.*, 615 F.

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[25] Defendants argue Marsh's sales are irrelevant because he is a non-defendant. But the Ninth Circuit has considered sales by other "executives as well as [even] defendants' family members" as part of the mix "sufficient to create a strong inference" of *scienter*. *Daou*, 411 F.3d at 1022, 1024.

Supp. 2d 1180, 1193 (D. Nev. 2009). Nevertheless, the number of shares sold in Class Period sales dwarfed the number of shares sold in any prior sales. Notably, the 200,000 shares that defendant Wilson sold on September 9, 2009 constitutes a greater number of shares than the combined total that defendant Wilson had sold during the entire preceding year and is four times bigger than each of his pre-Class Period sales. ¶295. The circumstances surrounding the sales strongly suggest the existence of a pre-conceived plan by both defendant Wilson and Marsh to profit from the sale of Vivus's shares whose price they would artificially inflate by means of calculated misrepresentations concerning Qnexa's clinical trials. Both defendant Wilson's and Marsh's sales were made pursuant to a trading plan adopted by each on March 12, 2009, only a few months before the Class Period commenced. No sales made by any Vivus insiders other than defendant Wilson or Marsh were made pursuant to a trading plan adopted so close to the start of the Class Period. ¶296.

Further, particularized corporate motives can demonstrate *scienter*. *See, e.g., In re Am. Bank Note Holographics Sec. Litig.*, 93 F. Supp. 2d 424, 444-45 (S.D.N.Y. 2000). As of December 31, 2009, the Company had incurred a cumulative deficit of $234.1 million, expected to incur additional operating losses, and needed additional funding to continue operations. ¶275. Thus, Defendants were motivated to make the false and misleading statements to actually raise $108.7 million in gross proceeds from a public offering. *See* ¶¶276-77. *See In re Williams Sec. Litig.*, 339 F. Supp. 2d 1206, 1234 (N.D. Okla. 2003) ("the Complaint alleges that Defendants had a strong motive to misrepresent WCG's financial statements because WCG's continued viability was dependent upon certain measures of WCG's financial performance"); *In re MicroStrategy Inc. Sec. Litig.*, 115 F. Supp. 2d 620, 648-49 (E.D. Va. 2000) (particularized allegations that company was "further motivated [by a desire] . . . to portray the Company favorably with actual and potential creditors from whom MicroStrategy needed to borrow funds" was sufficient to plead motive). Indeed, a company's sale of its own shares in a public offering have been held to be the equivalent of insider trading, *see Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1203-04 (1st Cir. 1996), and such trading gives rise to a motive analogous to the motive raised by an individual officer's insider trading for the purposes of pleading a strong inference of *scienter*. Further, the Complaint alleges that Defendants were further motivated because they were

looking for potential companies to partner up with to develop and build the market for Qnexa. ¶¶279-80. This also supports a cogent inference of *scienter*. *See In re Vivendi Universal, S.A. Sec. Litig.*, No. 02-5571, 2004 U.S. Dist. LEXIS 7015, at *28-*29 (S.D.N.Y. April 22, 2004) (finding *scienter* where defendants were motivated to engage in fraud to expand their enterprise); *see also Gross v. Medaphis Corp.*, 977 F. Supp. 1463, 1472 (N.D. Ga. 1997) (finding *scienter* where defendants knowingly made false statements in order to inflate its share price to acquire other companies).

4. The Proximity Of The Statements And The Truth Supports *Scienter*

Several weeks prior to the FDA Panel vote, Vivus issued false and misleading statements about Qnexa at a Wells Fargo Securities Healthcare Conference. *See, e.g.*, ¶¶180-81. The short time period between the misstatements and the disclosures evidences *scienter*. *See Fecht v. Price Co.*, 70 F.3d 1078, 1083-84 (9th Cir. 1995). *See also Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 9 (1st Cir. 2006); *Shaw*, 82 F.3d at 1224-25. Thus, when the overwhelming indicia of *scienter* is considered in totality, as it must be, it is clear that Plaintiff has adequately pled Defendants' *scienter*.[26]

F. Defendants' Statements Are Not Protected By The Safe Harbor Provision

The PSLRA safe harbor protects only those forward-looking statements that are: (1) identified as forward-looking and accompanied by meaningful cautionary language; (2) immaterial; or (3) not made with actual knowledge of falsity. 15 U.S.C. §78u-5(c). "[T]he Ninth Circuit has held that the . . . PSLRA's safe harbor provision should be applied narrowly, and courts should dismiss claims based on the bespeaks caution doctrine only where documents containing defendants' challenged statements include enough cautionary language that reasonable minds could not disagree that the challenged statements were not misleading." *Immune Response*, 375 F. Supp. 2d at 1036.

Defendants' attempts to claim safe harbor protection for their statements regarding FDA approval and new partnership opportunities utterly fail to meet this standard. Def. Br. at 24-25. Indeed,

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[26] The Complaint adequately alleges a violation of §20(a). Defendants do not challenge that defendants Day and Wilson were control persons. Defendants only argue that the Complaint fails to plead a primary violation. Def. Br. at 30. As the preceding argument establishes, however, Plaintiff has successfully alleged primary violations, making control-person liability appropriate. Further, because primary violations have been established, Plaintiff's §20(b) claims should be sustained as well.

the Complaint alleges that Defendants' cautionary statements were not specific or meaningful and, in many instances, were materially false and misleading because they misrepresented and failed to adequately disclose material adverse facts known to, or recklessly disregarded by, Defendants at the time the risk disclosures were made. ¶¶184-203. Defendants reject these allegations for the same reasons they reject all of the Complaint's allegations, but their arguments fail for the reasons above.

Additionally, Defendants' statements regarding Qnexa's FDA approval and commercial prospects typically referred to, or were accompanied by references to, misleading, mischaracterized or misrepresented clinical data intended to bolster the statements regarding Qnexa's FDA approval and commercial prospects, which rendered those statements false and misleading. Such mixed statements, therefore, were not forward looking because they involved present or historical facts. *See Immune Response*, 375 F. Supp. 2d at 1034 ("To the extent that Agouron highlights Study 806 results that were already available at the time, such statements are not forward-looking"); *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03-3111, 2005 U.S. Dist. LEXIS 1350, at *39 (S.D.N.Y. Feb. 1, 2005) (no safe harbor because the statements "involve representations of present or historical facts concerning . . . the effectiveness, safety, and tolerability of AXOKINE.").

Further, the availability of this clinical data also supports a strong inference Defendants knew their statements were misleading when they made them. "[E]ven when a forward-looking statement is accompanied by the requisite cautionary language, the speaker may still be liable if the statement is made with actual knowledge, and, where a strong inference of actual knowledge has been raised, the safe harbor provision would not apply." *In re Dura Pharm., Inc. Sec. Litig.*, 548 F. Supp. 2d 1126, 1143 (S.D. Cal. 2008). Accordingly, these statements do not qualify for safe harbor protection. Finally, Defendants' purported warnings were insufficiently specific to warrant safe-harbor protection. "[A] meaningful cautionary statement must identif[y] important factors that could cause actual results to differ materially from those in the forward-looking statement." *Immune Response*, 375 F. Supp. 2d at 1035. Defendants' press releases refer generally to the risk of failure of clinical studies and denial by FDA, but do not identify what specific factors might cause those risks to materialize. Instead, investors are referred "to the SEC filings for additional warnings," which "is similarly general in nature." *Id.*; *see*

also Dura Pharm., 548 F. Supp. 2d at 1144 ("The press releases refer vaguely to the contingency of FDA approval, but do not disclose the specific clinical trials. Instead, the press releases leave plaintiff investors in the position of having to obtain the SEC filings and compare them with the press releases.").

V. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss Plaintiff's claims should be denied. In the alternative, Plaintiff requests that any dismissal be without prejudice and that Plaintiff be given leave to amend under Fed. R. Civ. P. 15(a). *See Eminence Capital L.L.C. V. Aspeon, Inc.* 316 F.3d 1048, 1052-53 (9th Cir. 2003); *Bare Escentuals*, 745 F. Supp. 2d at 1083 (Fed. R. Civ. P. 15(a) "dictates that leave to amend be freely given when justice so requires.").

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