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12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 OAKLAND DIVISION

15
16 MERLE KOVTUN, Individually and on
Behalf of Others Similarly Situated,

17 Plaintiff,

18 v.

19 VIVUS, INC., LELAND F. WILSON, and
20 WESLEY W. DAY, Ph.D.,

21 Defendants.
22

Case No. 4:10-CV-04957-PJH

**REPLY MEMORANDUM IN FURTHER
SUPPORT OF DEFENDANTS' MOTION
TO DISMISS SECOND AMENDED CLASS
ACTION COMPLAINT**

Date: April 18, 2012
Time: 9:00 a.m.
Courtroom: 3 – 3rd Floor

The Honorable Phyllis J. Hamilton

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1 **I. INTRODUCTION**

2 As with his response to Defendants' initial motion to dismiss, Plaintiff opposes this
3 motion largely by ignoring its points. Like his Second Amended Complaint (the "New
4 Complaint"), the Opposition repeats general assertions about purported omissions based on after-
5 the-fact summaries and fragments from the FDA Advisory Committee's July 15, 2010 hearing.
6 He misses entirely that he needs *facts*, existing at the time of Defendants' supposed misstatements,
7 that support a strong inference that Defendants' class-period statements were false or misleading
8 when made, and that Defendants were at least deliberately reckless in not so recognizing. It is not
9 enough to repeat most every question raised by a Committee member as if it reflected an
10 established, serious side effect of Qnexa that was undisclosed but known to Defendants all along
11 – particularly when the Committee record makes clear that many issues that Plaintiff posits as
12 major safety concerns were not so viewed, and in some cases were not observed in the trials at all.

13 To plead securities fraud, Plaintiff must address, with specific factual allegations, two
14 critical points. First, he must show that there was some clinically significant side effect apparent
15 from the trial data that Defendants knew about when they spoke, but did not disclose. Despite
16 access to the entire Advisory Committee record for 18 months now, Plaintiff points to none
17 because there were none. Second, Plaintiff needs to plead specific facts that make it more
18 plausible than alternative explanations that the side effects observed in the clinical trials, viewed
19 in the context both of the known safety profiles of Qnexa's components and of the drug's efficacy
20 data, were of a nature that Defendants, at the time they were making positive statements about
21 Qnexa, in fact believed that those safety issues rendered the drug either not approvable or not
22 saleable. Despite its substantial added heft, the New Complaint offers no new substance on these
23 points. Nor does Plaintiff's Opposition offer any fresh perspective to explain his pleading
24 deficiencies. Consequently, Defendants refer to, and renew, their arguments from both their
25 opening papers and prior briefing, all of which apply equally here, as grounds for dismissal.

26 This time around, however, there is more. Were there any doubt about the inadequacy of
27 Plaintiff's claims, it was put to rest on February 22, 2012, when the Advisory Committee met
28 again to consider Qnexa, this time on a record that included a second year of trial data. After the

1 FDA stated in its briefing memorandum that the second year’s data “was consistent with the
 2 safety profile” that VIVUS reported in its original New Drug Application (“NDA”), the Advisory
 3 Committee voted 20-2 to *recommend Qnexa for approval*. The issue now awaits FDA
 4 consideration. In contrast with Plaintiff’s failure to offer facts showing their story of alleged
 5 fraud to be the “more plausible” explanation for the stock price decline, the February 2012
 6 Committee vote vindicates Defendants’ stated optimism about Qnexa and its prospects, and their
 7 commitment of tens of millions of dollars to the Qnexa clinical trials in the effort to gain approval
 8 for the drug. The 2012 action confirms the prior Committee vote to have been precisely what the
 9 record of the July 15, 2010 deliberations – read as a whole, rather than in snippets – shows: a
 10 cautious Advisory Committee, though seeing nothing alarming in the one-year data, wanted to
 11 confirm the drug’s safety over a longer period given that many patients would likely remain on
 12 the drug for an extended time.

13 What happened on July 15, 2010 was the adverse resolution of a disclosed risk inherent in
 14 an investment in drug-development company like VIVUS. In his New Complaint, Plaintiff offers
 15 many more words. But in the end, he fails to allege anything beyond a negative vote by the
 16 Advisory Committee to support his conclusory assertion that the detailed Qnexa clinical trial data
 17 somehow contradicted Defendants’ statements made during the alleged class period, much less
 18 that Defendants knew, or were deliberately reckless in not knowing, that the negative vote was, as
 19 Plaintiff terms it, “inevitable.” The New Complaint comes nowhere close to meeting the
 20 stringent requirements for pleading securities fraud. It should be dismissed, with prejudice.

21 **II. ADDITIONAL FACTUAL BACKGROUND**

22 In its Complete Response Letter (“CRL”) to VIVUS on October 28, 2010, the FDA asked
 23 VIVUS to submit the results of its year-long continuation trial of Qnexa (“SEQUEL”) and to
 24 address two specific areas of interest: teratogenicity and cardiovascular risk. ¶ 239.¹ As
 25 described in the New Complaint, VIVUS re-submitted its NDA for FDA approval in the fall of
 26 2011. *Id.* ¶ 241. On February 17, 2012, the FDA released its briefing document analyzing

27 ¹ Despite Plaintiff’s reference to it in the New Complaint, VIVUS has not included the CRL, a
 28 confidential document, in the record on this motion. If the Court considers it significant, VIVUS
 would be pleased to provide it with entry of an order permitting its submission under seal.

1 VIVUS's new submission, including the two-year data from the SEQUEL trial. *See* Reply Ex. 1.²
 2 Summarizing the safety data, the FDA stated that “[i]n general, safety data from the 52-week
 3 extension study, OB-305, was consistent with the safety profile noted in the 1-year safety cohort.”
 4 *Id.* at 3; *see also id.* at 76 (same). On February 22, 2012, another Advisory Committee (the “2012
 5 Committee”), including many of the same members as in July 2010, but as well as additional
 6 experts, met to consider Qnexa again. Reply Ex. 2. Recognizing that the strong safety data
 7 presented after one year remained consistent through a second year of use, the 2012 Committee
 8 voted overwhelmingly, 20-2, to recommend approval. Reply Exs. 3, 4.³

9 **III. ARGUMENT**

10 **A. The New Complaint Does Not Comply with the Court's October 2011 Order**

11 Plaintiff stands behind his technique of first quoting Defendants' public statements in full,
 12 and then pasting after nearly every sentence a selection from a stable of repeated “reasons” those
 13 statements are misleading or false. Plaintiff says he has met his obligation because the New
 14 Complaint purportedly describes why each statement was false and misleading “with exhaustive
 15 particularity” and contains “a mountain of detailed factual information.” *Opp.* at 6. While the
 16 New Complaint is indeed mountainous and exhausting, it satisfies neither the Court's October 13,
 17 2011 Order nor the exacting pleading standards applicable to Plaintiff's case.

18 Plaintiff mistakes mind-numbing repetition for factual particularity, in his New Complaint
 19 even more than in his prior effort. Breaking out each Defendant disclosure sentence by sentence
 20 and adding dozens of pages to the New Complaint means nothing when the “reasons” for falsity
 21 that comprise Plaintiff's mantra are either (1) not facts, but are instead later-expressed opinions or
 22 concerns of Committee members (*see, e.g.* ¶¶ 57(b)(i), (iii) (vi), (ix)); or (2) facts that were either
 23 disclosed by Defendants early in the class period and/or constitute additional detail consistent

24 _____
 25 ² *See* Supplemental Request for Judicial Notice in Support of Motion to Dismiss Second
 26 Amended Complaint (“Reply RJN”) and accompanying exhibits. Numbered exhibits to the Reply
 27 RJN are referred to as “Reply Ex.,” while “Ex.” refers to lettered exhibits to the Diggs
 28 Declaration filed with Defendants' opening brief, the (“Mot.”). All references to “¶” are to the
 New Complaint unless otherwise indicated.

³ The 2012 Committee included 12 members who had participated in the July 2010 Advisory
 Committee, including 7 who previously voted against approval. Six of those 7 voted for approval
 at the February 2012 Committee meeting.

1 with Defendants' disclosures (*see, e.g.* ¶¶ 57(b)(iii), (iv), (vii), (viii)).⁴ Plaintiff has not complied
 2 with the Court's October 13 Order to provide a clear and comprehensible account of which
 3 Defendant statements are false and misleading and what specific facts support that grave assertion.

4 Plaintiff primarily relies on incomplete summaries of *opinions* of Advisory Committee
 5 members and attempts to pass them off as *facts*. But even if the opinions were facts, Plaintiff fails
 6 to explain how they demonstrate that Defendants' many quoted statements were false or
 7 misleading when made. Plaintiff still leaves it to Defendants and the Court to provide the logical
 8 and factual linkage between the quoted statements and his grab-bag of "reasons" – a matching
 9 exercise that Plaintiffs' swollen New Complaint has complicated further. As the Ninth Circuit
 10 explained even before the Private Securities Litigation Reform Act, a complaint does not plead
 11 fraud with specificity where it alleges merely that "defendant said A whereas the true fact is B."
 12 Unless a plaintiff *explains why* A and B are supposed to be inconsistent with one another, he has
 13 not adequately pled fraud. *Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1553 n.11 (9th Cir. 1994).
 14 Plaintiff must allege with specificity *why* and *how* the alleged misstatements are false. *Marolda*
 15 *v. Symantec Corp.*, 672 F. Supp. 2d 992, 1000-01 (N.D. Cal. 2009). He comes nowhere close.

16 Eschewing his burden under Rule 9(b) and the PSLRA, Plaintiff says he need not plead
 17 "evidence" or "specific factual details not ascertainable in advance of discovery." Opp. at 6,
 18 quoting *Gibson v. United States*, 781 F.2d 1334, 1340 (9th Cir. 1986). That pre-PSLRA, pre-
 19 *Iqbal* and *Twombly*, *civil rights* case does not mention Rule 9(b) and has no relevance to the
 20 insufficiency of Plaintiff's pleading here. Specific facts are *exactly* what the securities fraud
 21 pleading standards require; and the public record from which those facts might be drawn, if they
 22 existed, is extensive in this case.⁵ That Plaintiff cannot provide that factual information, but

23 _____
 24 ⁴ As Defendants have discussed before, the conclusion that the facts disclosed in the complete
 25 FDA briefing were consistent with, not contradictory to, Defendants' prior statements is evident
 26 not only from a plain comparison, but also from the substantial positive reaction to public release
 of the detailed data, including a 17% increase in VIVUS's stock price on June 13, 2010. Had
 there been some "bombshell" in the data that contradicted earlier optimistic statements, the
 markets would have reacted in precisely the opposite way. *See infra* at Part III.C.1.

27 ⁵ What factual information Plaintiff claims to provide underscores, rather than refutes, the New
 28 Complaint's deficiencies. Plaintiff says the "mountain of detailed factual information" includes
 "the substance of the Summary Minutes, Vivus's decision to conduct another fetal outcome study,
 and the problems with combining phentermine and topiramate." But he fails to allege how a brief

1 instead disclaims the need to do so, speaks volumes.

2 **B. The Advisory Committee’s Lopsided February 22, 2012 Vote Recommending**
Approval Shows the Fallacy of Plaintiff’s Claims

3 As noted, the FDA Advisory Committee reconsidered Qnexa on February 22, 2012, and
 4 voted overwhelmingly to recommend approval. Through two motions to dismiss, Defendants
 5 have contended that many members of the July 15, 2010 Advisory Committee who voted against
 6 approval did so *not* because of issues with the data gathered to that point, but out of a desire to
 7 *confirm* that those data held up over time. *See, e.g.* Mot. at 9. Plaintiff responds that Defendants
 8 “knew or should have known that the [approval] effort was doomed to failure based on the
 9 outcome of the clinical studies.” Opp. at 25 n.24. That dispute has now been decisively resolved.
 10 The two-year data demonstrated a safety profile consistent with data gathered over one year (*see*
 11 Reply Ex. 1 at 3, 76) and confirmed the safety profile of Qnexa that Defendants reported on the
 12 first day of the alleged class period. Ex. B. The recent lopsided vote for approval shows that
 13 many Committee members who first voted against approval needed precisely what they said in
 14 July 2010 – to see the safety profile reflected in the Phase 3 trial data to that point sustained over
 15 a longer period. *E.g.*, Ex. G at 354 (“I think we need more data”), 361 (“we just need longer term
 16 data”). That fact sinks Plaintiff’s argument that Qnexa’s demonstrated side effects “doomed” any
 17 prospect of a favorable Committee vote, and that Defendants knew that when they made positive
 18 statements about Qnexa’s safety. Without that argument, Plaintiff’s entire fraud claim dissolves.

19 Plaintiff will no doubt say that the 2012 vote, coming after the alleged class period, is
 20 irrelevant.⁶ But Plaintiff’s theory of fraud is that Qnexa’s safety data, which Defendants knew
 21 about but purportedly did not disclose, was so bad that Defendants knew Qnexa “could not and
 22 would not be approved.” Opp. at 4; ¶¶ 54-203. Over and over Plaintiff alleges that “the Phase 3

23 summary of some opinions expressed in 372 pages of transcript at the Advisory Committee or an
 24 October 2011 announcement of a follow-up study shows the much earlier statements by to have
 25 been false when made. Nor does he plead facts – beyond his own say-so – suggesting new issues
 26 specific to combining Qnexa’s two component drugs. *See* Mot. at 15-16; *infra* at Part III.C.3.
 Despite the Court’s clear directive, Plaintiff still leaves it to Defendants and the Court to guess 1)
 27 *what* facts support Plaintiff’s allegations and (2) *how* those supposed facts might support his
 28 claims of fraud.

⁶ Of course, Plaintiff has no trouble relying on post-class period developments where he thinks
 they *help* his case. *See, e.g.* ¶¶ 238-41 (detailing post-class period analyst reports, the FDA’s
 October 2010 denial of VIVUS’s NDA, and VIVUS’s 2011 resubmission of that NDA).

1 Trials showed significant, potentially serious and life-threatening adverse effects of the type that
 2 scuttled approval for other obesity drugs” and that “fact” made every Defendant statement false.
 3 Defendants have noted that what Plaintiff characterizes as problems that the clinical data
 4 “showed” were in fact cited by Committee members as *potential* issues. *See, e.g.*, Mot. at 13 n.6;
 5 Ex. G at 151, 304, 320, 350, 367; *see also id.* at 53 (only death in the Phase 3 trials was a patient
 6 in one study’s placebo arm). The 2012 Committee vote confirms Defendants’ position and
 7 resolves those “potential” issues in favor of approval in nearly every member’s mind. The 2012
 8 Committee vote is relevant because it points up the problem with Plaintiff’s reliance on out-of-
 9 context, incomplete citation to Committee members’ opinions and expressions of concern, rather
 10 than facts. The facts – that is, the Qnexa safety profile demonstrated by Phase 3 data – have not
 11 changed; but with confirmation of those data over a longer time, the Committee’s conclusions
 12 have, and the vote outcome is very different. Plaintiff’s house of cards has collapsed.⁷

13 **C. Plaintiff Fails to Allege Facts Showing That Defendants’ Statements About**
 14 **Safety Data from the Qnexa Trials Were Materially False or Misleading**

15 1. The market reaction supports Defendants’ statements.

16 Plaintiff cannot dispute that both the VIVUS and FDA briefing documents analyzing the
 17 Qnexa trial data were publicly released on July 13, 2010. His claim that previously undisclosed
 18 negative data contradicted Defendants’ prior positive statements is undermined by the fact that
 19 when the detailed Qnexa data and analysis were disclosed, two days before the Committee
 20 meeting, VIVUS’s stock price jumped dramatically. The market, awaiting these materials,
 21 understood that the data confirmed what the Company had previously said; and investors voted
 22 their dollars accordingly. As we have explained before, this fact is a death knell to Plaintiff’s
 23 claims; not surprisingly, his attempt to square it with his own imagined story of fraud conflicts
 24 with both his own allegations and the judicially noticeable record.

25 ⁷ Plaintiff may argue that Defendants knew Qnexa’s demonstrated safety data meant Qnexa
 26 would not be recommended for approval after *one year*, but might be after two years, and therein
 27 lies the fraud. Beyond that Plaintiff alleges no facts to support that parsing interpretation, the
 28 conclusion conflicts with the fact the Phase 3 trial design and endpoints were cleared with the
 FDA under a Special Protocol Assessment (“SPA”) and the fact that the FDA’s Guidance for
 Industry states “a reasonable estimation of the safety of a weight-management product upon
 which to base approval generally can be made ... [after] 1 year of treatment.” Ex. D. at 246.

1 Plaintiff again hypothesizes that “investors needed the expert guidance and comments
 2 from the FDA Panel to fully digest and comprehend the true meaning of the voluminous safety
 3 data.” Opp. at 18. This directly contravenes Plaintiff’s efficient-market allegations, (¶¶ 34-35) –
 4 allegations necessary to support Plaintiff’s invocation of a “fraud-on-the-market” theory of
 5 reliance. *See In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1074 (N.D. Cal. 2010).
 6 Plaintiff cannot have it both ways, at once alleging that “the market for Vivus securities *rapidly*
 7 *absorbed all publicly material information* regarding Vivus and that information was reflected in
 8 the price of Vivus securities” (¶ 35), but then claiming that “the market took two days to process
 9 the significance of these analyses and the underlying data” (Opp. at 18). Plaintiff notes that the
 10 briefing documents with exhibits ran 555 pages. Opp. at 18. But all of the key safety
 11 “revelations” upon which his fraud theory appears to rely – the “double rate of depression,” the
 12 “four times as many cognitive adverse effects,” the “increased heart rate” and so forth – are
 13 summarized within the *first seven pages* of the FDA Memo. *See* Ex. J at 3-7. In any event, the
 14 fallacy of Plaintiff’s version of market-efficiency theory is underscored by the fact that VIVUS’s
 15 stock *was* responsive: on July 13 when the data came out, the stock posted its largest one-day
 16 gain since September 2009.⁸ The July 13 FDA release and price reaction contradict Plaintiff’s
 17 assertion that “[t]he deception finally unraveled on July 15, 2010” (Opp. at 4); the only thing that
 18 happened on July 15 was the Advisory Committee vote.⁹ There can be no real dispute under
 19 Plaintiff’s own efficient-market allegations: the market evaluated the information released on
 20 July 13 and made its own positive determination. That fact negates Plaintiff’s assertion that

21 _____
 22 ⁸ Plaintiff’s reliance on the *No. 84 Employer-Teamster* and *Gilead* cases is misplaced. Opp. at 18.
 23 In those cases, the share-price decline was delayed either by revelation of previously undisclosed
 24 information or by a continuing misrepresentation. *See In re Gilead Sciences Sec. Litig.*, 536 F.3d
 25 1049, 1054 (9th Cir. 2008) (impact of off-label marketing and FDA Warning Letter about it
 26 revealed only later, when Gilead released its quarterly financial results showing disappointing
 sales of the subject drug); *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am.*
West Holding Corp., 320 F.3d 920, 935 (9th Cir. 2003) (price response delayed because America
 West continued to reassure analysts that compliance with the subject settlement agreement would
 have no noticeable economic effect on the company). Nothing analogous is alleged here.

27 ⁹ Plaintiff claims that by not arguing loss causation as a specific ground for dismissal on this
 28 motion, Defendants “conceded that the report of the vote of the FDA Panel...did, indeed, reveal
 the truth of Defendants’ prior misrepresentations and omissions to the market,” causing loss to
 Class Members. Opp. 18 at n.15. Of course, Defendants concede nothing of the sort.

1 VIVUS's earlier optimistic statements about Qnexa's prospects were false or misleading.¹⁰

2 2. The Committee's discussion shows a close vote, not fraud.

3 Plaintiff says that Defendants made statements "which led investors to believe that FDA
4 approval of Qnexa was all but assured" while in possession of data that, when it became public,
5 meant "Qnexa could not and would not be approved by the FDA based on existing safety data".
6 Opp. at 4. That all-or-nothing theory discounts not only the market's ability to interpret the data
7 as noted above, but also the expertise and judgment of the Committee members who voted to
8 recommend approval in July 2010. Plaintiff's claim that the Committee's negative vote was
9 "inevitabl[e]" (*id.* at 2) cannot be squared with, for example, Dr. Hendricks's feeling that VIVUS
10 "did an outstanding job producing the data, and that the data does show ... that the drug is
11 reasonably safe and that we should approve it." Ex. G at 364. How could Defendants' statements
12 to the same end be fraudulent? Neither the New Complaint nor the Opposition explains this basic
13 inconsistency: if the clinical data plainly contradicted Defendants' statements about Qnexa's
14 approval prospects, how could six Committee experts have recommended approval (and much of
15 the investing public concluded approval was likely)? Cf. ¶ 238 (citing news article calling
16 Committee result a "surprise vote"). The answer, of course, is that those voting for approval did
17 not miss some land mine in the data; they merely judged the data and the balancing of risks
18 differently from those who wanted a longer look. This rebuts a claim of fraud.

19 The *AstraZeneca* case involved similar claims – that AstraZeneca misrepresented the
20 safety and potential approvability of its trial drug, Exanta. *In re AstraZeneca Sec. Litig.*, 559 F.
21 Supp. 2d 453, 456 (S.D.N.Y. 2008). There, plaintiffs alleged that when the FDA briefing was

22 _____
23 ¹⁰ Plaintiff's attempt to parse the language of two July 13, 2010 articles reporting on the release
24 of the FDA analysis is as unavailing as his attempt to avoid the consequences of his efficient-
25 market allegations. See Opp. at 18. First, his assertion that the market reacted only to the "tone"
26 of the FDA Memo and not to any safety information is belied by the article Plaintiff quotes. That
27 article states, among other things, that "[t]he FDA review focuses mainly on the drug's safety,
28 notably the potential for birth defects, psychiatric and cognitive side effects, ... metabolic acidosis,
and cardiovascular risks." Ex. F at 1 (also noting other side effects and stating the "panel may be
reluctant to recommend approval with the safety risks"). To suggest that investors received only
data on efficacy and not safety is just wrong. See also Exs. AA, BB. Second, Plaintiff's efforts
to explain away these *particular* articles miss the point. The *data and the FDA's analysis of it*
were public and, together with these and other media and analyst reports on all sides, were
reflected in the market price for VIVUS stock, which rose 17%.

1 released days before the advisory committee meeting, AstraZeneca stock dropped 6%, and at least
 2 one analyst stated that the FDA briefing revealed new safety issues not previously disclosed. *Id.*
 3 at 462-63. Shortly thereafter, plaintiffs claimed, an advisory committee voted 11-1 against
 4 recommending approval, and AstraZeneca was lambasted in the media for concealing the extent
 5 of Exanta’s safety issues. *Id.* at 463. Even so, after reviewing the FDA and company briefings to
 6 the advisory committee, the court found no knowingly false or misleading statements. “It is
 7 impossible to read the FDA document and the AstraZeneca document without concluding that
 8 both present the honest analysis and conclusions of their authors.” *Id.* at 471. The vote against
 9 approval, even at 11-1, “does not mean that [the sponsor] was not conscientious in advocating the
 10 drug [] before the FDA, nor does it mean that the information issued publicly over the course of
 11 more than a year was dishonest or recklessly disseminated.” *Id.*

12 The logic of *AstraZeneca* applies even more forcefully here, where: (1) VIVUS’s stock
 13 price rose sharply upon release of the FDA briefing materials; (2) Plaintiff alleges no
 14 contemporaneous public or media reaction suggesting the briefing materials disclosed previously
 15 unknown risks; (3) the Committee voted 10-6, with the Committee chair stating that “the
 16 committee seems to be closer than perhaps appears....” (Ex. G. at 351); and more recently, (4) an
 17 expanded Advisory Committee reconvened and voted overwhelmingly to recommend approval
 18 once an additional year’s data substantially confirmed the safety data initially presented. Nothing
 19 in the New Complaint transforms this debate between honestly held positions into a tale of fraud
 20 and deception. Mot. at 12-13; *see also Padnes v. Scios Nova, Inc.*, 1996 WL 539711, at *5 (N.D.
 21 Cal. Sept. 18, 1996); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001).

22 3. Plaintiff ignores the context of Defendants’ statements and
 23 mischaracterizes the *Matrixx* decision.

24 Despite the close July 2010 vote by a divided panel, Plaintiff asserts that certain
 25 Committee members’ desire to see longer-term safety data reflected a “consensus as to the
 26 inadequacy of Qnexa’s safety data” from its year-long Phase 3 trials. Opp. at 14. Like his
 27 contention that the safety data made a negative Committee vote “inevitable,” the record belies this
 28 assertion as well. Yes, some Committee members, like Dr. Proschan, said that “I think if we had

1 had longer follow-up, I probably would have voted [for approval]. But I just don't feel
2 comfortable with one year follow-up." Mot. at 11; Ex. G at 351. But lack of data about longer-
3 term safety does not equate to a *demonstrated* lack of long-term safety – as the additional year of
4 data that VIVUS submitted with its renewed NDA shows. Plaintiff cites no findings to
5 undermine the truth of Defendants' statements about the results observed in the one-year trials, a
6 period selected based on the FDA's Guidance for Industry and approved in SPAs. *See* Mot. at 12.
7 Nor were calls by some Committee members for longer-term data based on a stated view that
8 *observed* safety issues precluded approval. Instead, they expressed concern about *potential* safety
9 issues (known to be issues with Qnexa's components) and a desire to ensure that those issues did
10 not present themselves as serious after prolonged use of the drug. *Id.* at 10 n.3. As discussed, the
11 2012 Committee vote reflects that that desire was satisfied by the two-year data.

12 Plaintiff's efforts to equate this case with others actually involving material omissions of
13 negative trial data again underscore what is missing from the New Complaint. In several cases
14 Plaintiff cites, courts found fraud adequately pled where defendants continued to assure the public
15 of strong trial results when underlying data allegedly known to them revealed no observable
16 difference between outcomes on the drug and placebo arms, and no basis for believing the drugs
17 were at all effective. *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1020 (S.D. Cal.
18 2005), *In re Nuvelo Inc. Sec. Litig.*, 668 F. Supp. 2d 1217, 1222 (N.D. Cal. 2009), and *Warshaw*
19 *v. Xoma Comp.*, 74 F.3d 955, 960 (9th Cir. 1996). That could not be more different from the
20 situation here, where efficacy is unchallenged. Instead, Plaintiff's focus is on supposed
21 nondisclosure of additional (but less severe) adverse events beyond the top-line data VIVUS
22 released at the start of the class period. *See Heywood v. Cell Therapeutics, Inc.*, 2006 WL
23 5701625, at *6 (W.D. Wash. May 4, 2006) (dismissing case and distinguishing *Immune Response*
24 and *In re Amylin Therapeutics, Inc. Sec. Litig.*, 2003 WL 21500525 (S.D. Cal. May 1, 2003), as
25 instances where "defendants either grossly misrepresented some specific material fact, or failed to
26 disclose some concrete indication that they could not expect FDA approval"). Plaintiff does not,
27 and cannot, point to any similarly negative data withheld from the market. *In re Merck & Co.,*
28 *Inc. Sec., Deriv. & ERISA Litig.*, 2011 WL 3444199 (D.N.J. Aug. 8, 2011), on which Plaintiff

1 relies, is another case in point. In sustaining the complaint there, the court identified specific
 2 internal e-mails acknowledging the problems defendants publicly claimed did not exist and
 3 discussing how to avoid disclosing them, as well as documents showing that defendants
 4 disbelieved the hypotheses they proposed publicly. *Id.* at *11-12, 14. Here, by contrast, Plaintiff
 5 points at most to some additional mild side-effect events, later-voiced Committee member
 6 concerns, and vague and undated confidential witness assertions. The difference is dramatic.

7 As forecast in Defendants' opening papers, Plaintiff relies on *Matrixx Initiatives, Inc. v.*
 8 *Siracusano*, 131 S. Ct. 1309 (2011), asserting that some adverse events must be disclosed even if
 9 not statistically significant. *See* Mot. at 17; Opp. at 17.¹¹ Plaintiff offered this same overreading
 10 of *Matrixx* in opposition to Defendants' prior motion. Prior Opp. at 8-11. And as we responded
 11 the last time, nothing in *Matrixx* suggests that VIVUS's top-line safety disclosures were
 12 inadequate. Prior Reply at 6-9. In *Matrixx*, the issuer elected not to disclose reports of adverse
 13 side effects of its over-the-counter cold remedy *not* because it believed they were meaningless
 14 "but because it understood their likely effect on the market." 131 S. Ct. at 1324–25. Nothing
 15 alleged in the New Complaint suggests that was the case here, and the "effect on the market"
 16 when complete data were disclosed confirms it was not. *Accord Philco Invs. v. Martin*, 2011 WL
 17 500694, at * 7-8 (N.D. Cal. Feb. 9, 2011) (release of top-line trial results for Alzheimer's drug not
 18 rendered misleading because it did not include all information later released or because plaintiffs
 19 disagreed with defendants about data's importance); *see also Philco Invs. v. Martin*, 2011 WL
 20 4595247, at *7 n.11 (distinguishing *Matrixx* and dismissing amended complaint with prejudice).

21 The fact is that *Matrixx* reinforces a point that VIVUS has urged and that Plaintiff
 22 continues to ignore – *context matters*. The context that Plaintiff disregards is the extensive, well-
 23 documented history of Qnexa's two component drugs, phentermine and topiramate – drugs that
 24 have been approved for decades and that have been prescribed to literally millions of patients at

25 _____
 26 ¹¹ Plaintiff makes the bizarre argument that Defendants somehow equate the "avalanche of
 27 information" *Matrixx* says need *not* be disclosed with the *length* of Plaintiff's New Complaint.
 28 Opp. at 9 n.9. That nonsensical contention aside, *Matrixx* does undercut Plaintiff's claim that
 Defendants misled the market by disclosing serious and moderate adverse events regarding, for
 example, psychological and cognitive data without simultaneously presenting *all* of the safety
 data, including the large number of mild adverse events observed. *See* 131 S.Ct. at 1318.

1 much higher doses than in Qnexa. Mot. at 14-15. That context was known and understood by the
 2 FDA, by the Advisory Committee *and by the markets*. *Id.* And VIVUS *specifically disclosed*
 3 risks relating to the known side effects of these components, *e.g.*, Ex. P at 36-39, including many
 4 of the very risks that Plaintiff says VIVUS hid, *cf.* ¶ 57(a)(i) (potential for cognitive and
 5 psychological side effects); 57(b)(i) (longer-term studies potentially required).

6 When VIVUS disclosed that the Qnexa trials showed “nothing unexpected,” it was
 7 understood that the baseline expectations were established by the component drugs – a point
 8 repeatedly emphasized in the statements Plaintiff challenges. *See, e.g.*, ¶¶ 70, 150. In his
 9 Opposition, Plaintiff adheres to his unsupported assertions that the combination of the drugs
 10 “increased the known risks and magnitude of the side effects beyond those associated with each
 11 component individually and/or was creating new, potentially serious side effects.” Opp. at 15-16,
 12 10 n.10. But as noted in our opening papers, this assertion is made without reference to any data,
 13 Committee member comment, media analysis or other factual underpinning. Mot. at 15. Plaintiff
 14 has just invented these assertions for his New Complaint; he offers no facts to support his
 15 insinuation that Defendants’ statements about the consistency of the Qnexa safety profile with
 16 that of its components was in any sense false or misleading. His only response now is that he is
 17 “not required to plead evidence.” Opp. at 16 n.14. Once again, Plaintiff ignores his substantial
 18 pleading burden, and he confuses evidence with the specific fact-based allegations that absolutely
 19 *are* required under applicable pleading rules.

20 4. Defendants’ statements about trial results related to specific potential side
 21 effects were truthful.

22 Defendants will not repeat the detailed arguments regarding Plaintiff’s various safety-
 23 related assertions from their opening brief and prior briefing as Plaintiff’s basic assertions about
 24 these matters are unchanged. Mot. at 14-21. *See also* Prior Mot. at 14-21; Prior Reply at 9-14.
 25 However, a few comments in response to the Opposition are in order to demonstrate the lengths
 26 to which Plaintiff goes to concoct a fraud.

27 **Psychiatric Results.** Plaintiff says Defendants’ statements about psychiatric events in the
 28 Phase 3 trials were misleading because they “repeatedly affirmatively reiterate[ed] the absence of

1 any data signaling a suicide risk,” and “omitt[ed] any mention of data in their possession showing
 2 depression among patients.” Opp. at 6; *see also id.* at 1. But even Plaintiff recognizes that the
 3 FDA Committee members noted “the absence of a clear signal for suicide risk.” Opp. at 7
 4 (quoting Dr. Rogawski – who voted for approval – that “we didn’t pick up an increase in
 5 suicidality risk”). Given the data, which Plaintiff does not challenge, it was entirely accurate for
 6 Defendants to note the absence of a signal for suicide. *Accord* Reply Ex. 1 at 3 (“no reported
 7 adverse events regarding suicidality in the 2-year safety cohort”). While he repeats the word
 8 “suicide” over and over in both his New Complaint and Opposition, Plaintiff pleads no facts to
 9 contradict the no-signal conclusion.

10 His assertion that Defendants omitted “any mention” of depression data is flatly untrue.
 11 VIVUS disclosed data for moderate and severe depression-related adverse events, as well as for
 12 depression-related study discontinuations, on Day 1 of the class period. Ex. L at slides 29-30.
 13 Plaintiff does not suggest the reports were inaccurate; but he says that VIVUS should also have
 14 disclosed data about *mild* depression events because the differential incidence of events between
 15 top-dose and placebo patients was wider with mild events (the majority of events) included.¹²

16 Plaintiff does not plead facts suggesting that disclosure of mild events mattered. He
 17 asserts, however, that it is “undeniable” that “had investors been aware of the true extent of the
 18 adverse indications,” they would have paid less for VIVUS shares, citing cases saying that
 19 securities are accurately valued where negative study results are available to the market. *See* Opp.
 20 at 8. But the judicially noticeable facts show precisely the opposite. In reality, when the so-
 21 called “true extent” of the psychiatric adverse events was made public in the briefing documents
 22 released before the Advisory Committee meeting, VIVUS’s stock price *rose*, and analysts noted
 23 the “low” level of psychiatric side effects (Ex. F at ¶ 3). *See supra* Part III.C.1. Moreover,
 24 contrary to Plaintiff’s claim that Defendants falsely implied depression concerns “presented no
 25 risk to FDA approval,” (Opp. at 8), VIVUS in fact made specific risk disclosures that the
 26 psychiatric side effects observed in Qnexa’s components, as well as the shadow cast by adverse

27 _____
 28 ¹² The FDA’s briefing document defines a mild event as one which “[d]oes not interfere with the
 subject’s usual function.” Ex. J at 80.

1 effects of other weight-loss drugs, could negatively affect Qnexa's approval chances. *E.g.*, Ex. P
 2 at 36-39. Finally, despite Plaintiff's table-banging about the purportedly pervasive incidence of
 3 adverse psychiatric side effects, it is notable that Plaintiff does not allege psychiatric issues as a
 4 reason listed by FDA for disapproval in its October 2010 CRL (and they were not). ¶ 239.

5 **Cognitive Results.** Plaintiff also does not and cannot allege that cognitive issues were
 6 cited in the CRL as a reason for initial disapproval of Qnexa (again, they were not). ¶ 239. Even
 7 the analyst quoted in the New Complaint stated that most of the Committee was unconcerned
 8 with cognitive issues. Mot. at 19; ¶ 235. Yet because the 2010 vote was ultimately negative,
 9 Plaintiff cries fraud here as well. The claim is that Defendants said early in the class period,
 10 based on expert analysis, that there was "no clinically significant change in overall cognitive
 11 function." Opp. at 9. They said it again in their detailed briefing to the FDA. Ex. D at 121. But
 12 the FDA Memo reflects no disagreement. Ex. J at 5. Market analysts, the FDA reviewer, and
 13 Committee members all noted that the observed cognitive effects were known side effects of
 14 topiramate. *E.g.*, ¶ 235, Ex. G at 138, 299. Those effects were covered in VIVUS's risk
 15 disclosures. *E.g.*, Exs. O at 62, P at 37. Yet Plaintiff says the public was tricked.

16 Once more, Plaintiff fails to identify anything in the trial data that contradicted public
 17 statements, but only points to additional, mild adverse events (that did not change VIVUS's
 18 conclusions when presenting the data to the FDA) and calls on *Matrixx* for salvation. But again,
 19 nothing in *Matrixx* implies that *every* adverse effect must be disclosed; indeed, it holds the
 20 opposite. 131 S. Ct. at 1321; *see also* Mot. at 17-18.

21 **Cardiovascular Results.** Plaintiff's claims about cardiovascular safety results turn on
 22 two issues that received almost no mention in the Committee's discussion: the withdrawal of the
 23 drug combination fen-phen from the market, and potassium. Opp. at 10-11. The FDA Memo
 24 disposed of the fen-phen issue by simply repeating its conclusion, reached after research
 25 following the fen-phen situation of 12 years before, that the phentermine component of that
 26 product was *not* the cause of fen-phen's cardiovascular side-effects. Ex. J at 15, 63. Nothing in
 27 the Advisory Committee record suggests that fen-phen was the reason for the negative vote in
 28 July 2010; but even if it were, VIVUS's risk disclosures throughout the class period disclosed the

1 threat that fen-phen posed to possible approval of Qnexa.¹³ Investors were not misled.

2 Nor were the Qnexa trial data showing a slight increase in heart rate among trial subjects a
3 surprise, as Plaintiff asserts. Opp. at 11. In fact, the one beat-per-minute average increase in
4 heart rate was disclosed in briefings the third day of the class period. ¶ 75. (Although he quotes
5 Dr. Day's September 11, 2009 statement, Plaintiff appears to be talking about precisely this
6 increase where he refers to "the undisclosed increased heart-rate signal." *Id.* at 10.) To contradict
7 Dr. Day's conclusion that the increase was not of clinical concern, Plaintiff makes assertions
8 about potassium that are neither supported nor linked to the Phase 3 trial data. Yes, the
9 Committee briefing documents included data on decreased potassium levels (a known side effect
10 of topiramate (¶ 262)); but the Committee never so much as mentioned potassium. Mot. at 21.¹⁴

11 Plaintiff also says that certain Committee members' concerns about cardiovascular safety
12 did more than "evidenc[e] simply the desire for more research." Opp. at 10. Yet after another
13 year of data that, according to the FDA, showed the same slight increase in average heart rate, the
14 Committee voted almost unanimously to recommend approval. Reply Ex. 1 at 3. *Cf.*
15 *Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008
16 WL 2053733 at *7 (S.D. Cal. May 13, 2008) (though FDA requested further data analysis, the
17 data provided met FDA approval guidelines, which "tends to negate the inference defendants
18

19 ¹³ See, e.g., Ex. P at 36, from risk subsection *headlined* "Association with fen-phen could lead to
20 increased scrutiny of our investigational product candidate, Qnexa": "Moreover, the adverse
21 clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased
22 FDA regulatory scrutiny of the safety or the risk/benefit profile of Qnexa and may raise potential
23 adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market
24 acceptance if Qnexa is approved for commercial sale." See also Ex. O at 61; Ex. Q at 63-64.
25 Plaintiff ignores these disclosures when he asserts, without factual support, that "Defendants ...
26 either knew, or recklessly ignored" this potential scrutiny. Opp. at 10.

27 ¹⁴ In our opening brief, we pointed to numerous inconsistencies in Plaintiff's story of supposedly
28 illicit potassium supplementation in a Phase 1 trial (but not in the Phase 3 trials). Mot. at 21, 28.
Plaintiff's Opposition makes no attempt to respond to or clarify the issue, simply repeating the
New Complaint's allegations. Opp. at 11. Even accepting Plaintiff's uncorroborated CW
allegations as to the Phase 1 trial as true (they are not), Plaintiff offers nothing to connect the
allegations to: (1) the Phase 3 results generally; (2) reduction in blood pressure generally (beyond
noting "*some evidence, although not universally accepted, that potassium supplementation might*
cause a slight drop in blood pressure" (¶ 263) (emphasis added)); (3) reduction in blood pressure
among Phase 3 trial patients specifically; or (4) any other measured results relevant to
cardiovascular data. Plaintiff fails to explain how this story even makes sense, let alone supports
his fraud allegations.

1 knew the FDA would not approve the Application”).

2 **Teratogenicity and Metabolic Acidosis Results.** Nowhere in the New Complaint’s
 3 exhaustive litany of supposedly false statements does Plaintiff allege any statement about
 4 teratogenicity, save Defendants’ repeated *risk disclosures* explaining that pregnant women were
 5 ineligible for the Phase 3 trials and that Qnexa would have a label “warning against use by
 6 women who are or are considering becoming pregnant.” ¶ 198; *see also* Exs. O at 62, P at 38, Q
 7 at 65, C at 10. No statements about C labels or X labels are pled, nor are facts alleged to show
 8 Defendants said one thing publicly but believed something else about risk of fetal harm. Indeed,
 9 the only Defendant reference to Category C in the record – never mentioned by Plaintiff – is the
 10 description of Qnexa’s *component* drugs in VIVUS’s briefing document, released publicly on
 11 July 13, 2010.¹⁵ Plaintiff simply alleges no false or misleading statement about teratogenicity.¹⁶

12 5. Defendants’ risk disclosures belie Plaintiff’s claims of deception.

13 VIVUS’s extensive risk disclosures included detailed cautions that specifically addressed
 14 the very issues about which Plaintiff now complains. Mot. at 23-24. The complained-of press
 15 releases disclosed myriad risks associated with Qnexa’s development, approval and marketability,
 16 and referred the reader to SEC filings that brim over with risk factors. *Id.* VIVUS’s statements
 17 about the future of Qnexa and of the Company were protected under the safe harbor and bespeaks
 18 caution doctrines, Plaintiff’s stock objections notwithstanding. *See In re Bare Escentuals, Inc.*
 19 *Sec. Litig.*, 745 F. Supp. 2d 1052, 1080 (N.D. Cal. 2010). Those statements were identified as
 20 forward-looking and were accompanied by meaningful cautionary language; and Plaintiff alleges
 21 no facts to support an inference that they were made with actual knowledge of falsity (let alone a
 22 strong inference as cogent and compelling as other, non-culpable explanations). *See* 15 U.S.C. §
 23

24 ¹⁵ Plaintiff notes topiramate was changed to Category D in 2011 and implies VIVUS advocated a
 25 label for Qnexa less restrictive than that of its components. Opp. at 12 n.11. Putting aside
 26 Plaintiff’s failure to point to *any* VIVUS statement about pregnancy categories or any fact to
 support their suggestion, there can be no doubt that both components were Category C at the time
 of VIVUS’s NDA. *E.g.*, Ex. D. at 17.

27 ¹⁶ After two complaints totaling some 250 pages and two briefs of 60 pages more, Plaintiff has yet
 28 to reference any Defendant statement on metabolic acidosis or to mention the topic in his briefs in
 any way (beyond section headings). Mot. at 21; Prior Reply at 14. Enough said.

1 78u-5(c).¹⁷ See also Mot. at 25-30; *infra* Part III.D.

2 The pages of risk disclosures included in every one of VIVUS's quarterly filings, *e.g.*, Exs.
3 P at 31-78; Q at 59-97, directly contradict Plaintiff's allegations that material information was
4 withheld from investors. See ¶¶ 184-203. The risks that resolved negatively on July 15, 2010
5 were disclosed in detail. See, *e.g.*, Exs. O at 59-63, P at 31-39, 43, Q at 59-66.

6 6. Statements of general optimism and opinion are not actionable

7 Finally, as with the previous motion to dismiss, Plaintiff makes no effort to distinguish the
8 cases holding that general statements of opinion and optimism do not support a securities fraud
9 claim. Mot at 22-23 (citing cases). At most, he makes the general point that optimistic
10 statements may be actionable if defendants fail to disclose material risks that undercut them or
11 that opinions may be actionable if they are knowingly untrue or made without reasonable basis.
12 Opp. at 14 (citing *Virginia Bankshares v. Sandberg*, 501 U.S. 1083 1093-94 (1991); *Amylin*, 2003
13 WL 21500525, at *5). As we have explained, Plaintiff does not allege specific facts to support
14 either situation. See, *e.g.*, *Yourish v. California Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999)
15 ("clearly insufficient" for plaintiffs to say that a "later, sobering revelation" makes "an earlier,
16 cheerier statement a falsehood."); Mot. at 23. Neither Plaintiff's cases nor any fact alleged in the
17 New Complaint explain how statements that, for example, Qnexa has an "excellent" or
18 "compelling" risk/benefit profile (*e.g.*, ¶¶ 55(a), 69(b)), or that trials have shown "remarkable"
19 safety and efficacy (*e.g.*, ¶ 57(d)) could be actionable. *Glen Holly Entm't Inc. v. Tektronix, Inc.*,
20 352 F.3d 367, 379 (9th Cir. 2003); *Philco*, 2011 WL 500694, at *6.

21 **D. Plaintiff Fails to Allege A Strong Inference of Scienter**

22 Plaintiff says a conclusion that VIVUS's statements about Qnexa were accurate and
23 reasonable is possible only by ignoring the collective approach to scienter required by *Matrixx*

24 _____
25 ¹⁷ Plaintiff says that some statements involved present facts. Opp. at 29. But "even a statement
26 of present fact may become a forward-looking statement if a plaintiff's sole allegation of falsity is
27 based on the existence of some future risk of failure." *In re Discovery Labs. Sec. Litig.*, 2006 WL
28 3227767, at *15 (E.D. Pa. Nov. 1, 2006). Furthermore, alleged omission of an historical fact does
not change the analysis because "when the factors underlying a projection ... include both
assumptions and statements of known fact, and a plaintiff alleges a material fact is missing, the
entire list of factors is treated as a forward-looking statement." *In re Avon Prods., Inc. Sec. Litig.*,
2009 WL 848017, at *17 (S.D.N.Y. Feb. 23, 2009).

1 and *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). Opp. at 20. He says that
 2 “Defendants cannot demonstrate ... that an inference of non-fraudulent intent is more plausible
 3 than the competing inference of fraud.” *Id.* at 19-20. But it is *Plaintiff* who has the burden to
 4 plead scienter sufficiently and that an inference of fraud is the more plausible one to draw from
 5 the facts alleged. It is he who has failed to carry that burden. Notwithstanding, Defendants *have*
 6 in fact shown non-fraudulent intent to be far more plausible. *Tellabs*, 551 U.S. at 323. By any
 7 fair reading of the record, the alleged misstatements, viewed in light of *all* facts alleged and in the
 8 public domain, tell a story of honest optimism, not of deceit.

9 Among those facts that make Defendants’ the more compelling interpretation are that:

- 10 • Based on the data obtained in earlier-phase trials of Qnexa, VIVUS spent tens of
 11 millions of dollars on pivotal Phase 3 clinical trials, involving thousands of patients as
 part of an effort to demonstrate the safety and efficacy of Qnexa;
- 12 • Qnexa’s year-long Phase 3 clinical trial results showed dramatic weight loss and
 13 improvements in weight-related co-morbidities to a degree far beyond the thresholds
 established to show the drug’s efficacy;
- 14 • Qnexa is composed of two drugs that have long been approved by the FDA and have
 been used, at much higher dosing levels, for decades by millions of patients;
- 15 • while dose-related side effects were observed in the Phase 3 trials, no issues were
 16 observed that were (a) outside the labels for Qnexa’s component drugs; or (b) more
 severe than expected from the components;
- 17 • while phentermine had been associated with the problematic “phen-fen” combination,
 18 evidence had shown the issues to be with the “fen” side of that combination; and
- 19 • there exists a strong market demand for a safe, efficacious drug to treat obesity.

20 Against this backdrop, a “collective” view of Plaintiff’s vague allegations does not approach a
 21 cogent and compelling inference of scienter, and certainly not one that is more plausible than that
 22 Defendants genuinely believed in the promise of this drug. The “omissions” Plaintiff has alleged
 23 – additional data on mild depression or cognitive effects; additional, consistent analysis of the
 24 disclosed slight increase in heart rate; potential longer-term side effects related to Qnexa’s
 25 component drugs – do nothing to change the big picture, to undercut Defendants’ justifiable
 26 optimism, or to explain why Defendants would have engaged in the reprehensible conduct
 27 Plaintiffs posit. *See* Mot. at 26; *AstraZeneca*, 559 F. Supp. 2d at 470 (presence of side effects that
 28 may affect a drug candidate’s risk-benefit analysis does *not* show fraud where management

1 released positive reports that were believed true or showed no reckless disregard for the truth).

2 Plaintiff's scienter allegations are based on (a) unsubstantiated assertions attributed to
3 unidentified Confidential Witnesses ("CWs"), and (b) conclusory allegations about Defendants'
4 motives extrapolated from routine corporate objectives and non-discretionary stock trades. The
5 allegations are unchanged from Plaintiff's prior pleading, (*compare* ¶¶ 242-96 with AC ¶¶ 148 -
6 89); and his arguments in opposition to our motion are substantively identical to the prior round
7 of briefing as well. *Compare* Opp. at 19-29 with Prior Opp. at 19-28. So are our responses. His
8 CW's were in no position to know anything meaningful, and nothing of any moment is attributed
9 to them anyway. Prior Reply at 17-19; *see also Applestein v. Medivation, Inc.*, 2012 WL 986276
10 (N.D. Cal. Mar. 22, 2012) (dismissing with prejudice claims based on unreliable and
11 uncorroborated CW statements). The only potentially relevant stock sales he alleges were Mr.
12 Wilson's, all of which were non-discretionary and executed under a Rule 10b-5-1 plan that was in
13 place six months before the class period began. Prior Reply at 19-20. As we have detailed now
14 multiple times, none of Plaintiff's scienter points – separately or collectively – supports any
15 inference of scienter. Mot. at 25-30; Prior Mot. at 25-30; Prior Reply at 16-20.

16 Even if Plaintiff's wafer-thin CW and motive allegations could somehow be seen to
17 support a scienter inference, it remains Plaintiff's burden to show that the inference is both cogent
18 and compelling, and as plausible as the non-culpable inference that Defendants' optimism was
19 honest. On the record as it stood *before* February 22, 2012, it was certainly plausible that
20 Defendants genuinely believed that Qnexa's safety profile supported FDA approval, particularly
21 when combined with the drug's undisputed efficacy in combatting one of America's most serious
22 public health problems. Indeed, with a split Advisory Committee vote that included a substantial
23 minority of recognized, independent experts supporting approval, it is difficult to characterize
24 Defendants' belief in Qnexa's prospects as *implausible*. Certainly nothing Plaintiff has alleged
25 undermines that notion, especially to the point that their assertion of fraud is more compelling.

26 Were there any doubt as to this outcome, the doubt cannot survive the February 2012
27 Committee meeting, where a near-unanimous panel voted to recommend approval of Qnexa. The
28 vote came after the FDA independently determined that data from a year-long extension of the

1 pivotal Phase 3 trials confirmed the safety profile for Qnexa that VIVUS had put forward a year
 2 earlier. (It also reconfirmed the drug's efficacy over the longer-term.) It took some additional
 3 time, but the news from the second year of trial data was that there was no news. The safety data
 4 was remarkable in its consistency and its confirmation of the data that had led Defendants to
 5 express their optimism in the first place. This time around, with confirmatory data to allay
 6 hypothetical concerns expressed by some in July 2010, the vote followed, with many of the same
 7 experts who had previously opted for caution and more data voting now to recommend approval.
 8 *See supra* Part II. Given the safety data that supported the new NDA and Committee vote and its
 9 consistency with the original data, the more plausible explanation of events is the non-culpable
 10 inference of Defendants' genuine belief in Qnexa's prospects. Plaintiff has offered nothing that
 11 comes close to a more cogent and compelling explanation, and this shortcoming also mandates
 12 dismissal of the New Complaint.

13 **IV. CONCLUSION**

14 For the foregoing reasons and those discussed in Defendants' opening papers, the New
 15 Complaint should be dismissed. Because Plaintiff has already been afforded the opportunity to
 16 cure his deficient pleading and has failed to do, the dismissal should be with prejudice.

17
 18 Dated: March 30, 2012

HOGAN LOVELLS US LLP

19
 20
 21 By: /s/ Michael L. Charlson
 Michael L. Charlson

22 Attorneys for Defendants
 23 VIVUS, INC., LELAND F. WILSON, and
 24 WESLEY W. DAY, Ph.D.