UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DAVID APPLESTEIN, *et al.*,

Plaintiffs,

v.

MEDIVATION, INC., *et al.*,

Defendants.

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No. C-10-0998 EMC

**ORDER GRANTING DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' THIRD AMENDED COMPLAINT**

**(Docket No. 147)**

Defendants' motion to dismiss Plaintiffs' third amended complaint came on for hearing before the Court on March 16, 2012. Docket No. 147. For the reasons set forth below, the Court **GRANTS** Defendants' motion to dismiss.

## I. FACTUAL & PROCEDURAL HISTORY

Lead Plaintiff Catoosa Fund LP filed this securities class action against Defendants Medivation, Inc. and Medivation senior officers David T. Hung, C. Patrick Machado, Lynn Seely, and Gregory Bailey.

Plaintiffs' case concerns the clinical testing of Dimebon for use in treating Alzheimer's disease. Docket No. 147 ¶ 3 ("TAC"). In general, to receive approval by the Food and Drug Administration ("FDA"), a manufacturer must demonstrate the drug's safety and effectiveness. TAC ¶ 35. Approval by the FDA involves three phases of clinical trials on humans. TAC ¶ 38. Phase 1 is a preliminary test that assesses "whether small doses of the drug causes any immediate safety problems that could make continuation of the trial impossible." TAC ¶ 39. Phase 2 tests the effectiveness of the drug and is often a double-blind test where neither the investigators nor the

patients know which group of patients is receiving the active drug or the placebo. TAC ¶ 40. Approximately 33% of drugs are successful at Phase 2. TAC ¶ 41. Phase 3 primarily focuses on confirming that the drug is effective and safe, and involves thousands of patients to produce additional information about the effectiveness and safety of the drug. TAC ¶ 42. Plaintiffs allege that 90% of drugs that reach a Phase 3 trial are successful in confirming the effectiveness and safety of the drug. TAC ¶ 43.

Dimebon was originally approved in Russia as an over-the-counter oral antihistamine for the treatment of allergies. TAC ¶ 46. Testing of Dimebon for the treatment of Alzheimer's disease began in Russia in the early 1990s. TAC ¶ 47. In 2001, Dimebon passed the Phase 1 study based on a clinical study involving 14 patients in Russia. TAC ¶¶ 52, 53.

In October 2003, Defendant Medivation bought the rights to Dimebon. TAC ¶ 54. Defendants then conducted a 6-month Phase 2 Dimebon Alzheimer's study that involved 183 patients at 11 different sites in Russia. TAC ¶¶ 55, 56, 64. Plaintiffs allege that Defendants did not, contrary to their public representations, conduct a double-blind test. The test was not double-blind because the Dimebon pills used were distinguishable from the placebo by taste and appearance. TAC ¶ 65.

In support of this allegation, Plaintiffs offer the statements of three confidential witnesses who are employed by Organica, the Russian pharmaceutical company which produced the Dimebon pills for Defendants' Phase 2 study. TAC ¶ 66. CW-1 is a Senior Technology Engineer who informed CW-2 that Organica supplied uncoated Dimebon pills for Defendants' Phase 2 study. TAC ¶¶ 67, 68. As a result, the Dimebon pills were distinctly bitter. TAC ¶ 68. CW-3 is a long-time Organica employee responsible for testing new medicines, who informed CW-2 that Organica supplied both the Dimebon pills and placebos for Defendants' Phase 2 studies and that Organica failed to produce placebo tablets that matched the Dimebon pills. TAC ¶ 70. This failure allegedly resulted in Dimebon pills and placebos that were distinguishable by taste and appearance. TAC ¶ 70. Finally, CW-2 is a member of Organica's board, who after consulting with CW-1 and CW-3, verified that Organica provided uncoated Dimebon pills and unmatched placebos for Defendants' Phase 2 studies. TAC ¶ 69. Plaintiffs also offer Dr. Lon S. Schneider's statement as corroboration

of the statements by the confidential witnesses. Dr. Schneider believes that the active Dimebon and placebos were distinguishable for two reasons. TAC ¶ 73. First, Dr. Schneider cites Defendants' failure to describe in detail the pills used in the study in their clinical trial paper as suspicious. TAC ¶ 75. Second, Dr. Schneider states that his unnamed colleague attended a presentation where Defendants Hung and Seely admitted that the Phase 2 studies were not identical. TAC ¶ 76.

Plaintiffs allege that because the Dimebon pill was easily distinguishable from the placebo and thus the Phase-2 test was unblinded (TAC ¶ 77), the test results were biased; patients would know they were receiving Dimebon and would be more likely to report favorable outcomes because they expected a benefit. TAC ¶ 62. In addition, investigators would be less likely to identify and report treatment responses in the no-treatment group while being more sensitive to favorable outcomes in patients in the treatment group. TAC ¶ 62.

In September 2006, Defendant Medivation announced that the Phase 2 test was a success, and that Dimebon "met all efficacy endpoints in a 'randomized, double-blinded placebo-controlled Phase 2 study of 183 patients with mild to moderate Alzheimer's disease conducted in 11 sites in Russia." TAC ¶ 90. The reported results were so strong that some scientists believed Dimebon would win FDA approval even if the Phase 3 results were "only half as good as the original." TAC ¶ 93. According to Plaintiffs, Defendants misrepresented facts about the validity of the Phase 2 study and concealed the fact that the study was not double-blind and was hence flawed.

After the results were reported, Defendant Medivation's stock surged to a 52-week high with a price increase of 38.84%. TAC ¶ 12. Plaintiffs allege that Individual Defendants subsequently sold almost 1 million shares of Medivation common stock for proceeds of almost $22 million. TAC ¶ 182. Two years after announcing the Phase 2 study results, Medivation entered into an agreement with Pfizer, Inc., giving Medivation an up-front cash payment of $225 million. TAC ¶ 12.

Defendants entered into the Phase 3 study for Dimebon. Plaintiffs allege that unlike the Phase 2 study, the Phase 3 study was conducted largely in the United States and was actually double-blinded because the Dimebon pills were coated. TAC ¶¶ 100, 102. The double-blind Phase 3 test "failed miserably - patients treated with Dimebon had no statistically significant improvements . . . . Defendants reported that the Dimebon patients and the placebo patients were essentially

unimproved." TAC ¶ 103. After Defendants announced the disappointing Phase 3 results on March 3, 2010, Medivation's shares dropped 67% from $50.25 to $13.10, for a total loss of $923,217,234. TAC ¶¶ 14, 165.

Based on these allegations, Plaintiffs assert two class claims: (1) a claim for securities fraud pursuant to Securities Exchange Act § 10(b) and Rule 10b-5, and (2) a derivative claim under Securities Exchange Act § 20(a). In August 2011, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") on the ground that Plaintiffs failed to plead allegations giving rise to a strong inference of scienter. Docket No. 129 at 16 ("Dismissal Order"). Plaintiffs were given leave to file an amended complaint to add additional factual allegations. Dismissal Order at 16. In November 2011, Plaintiffs filed a Second Amended Complaint ("SAC"), including statements by CW-1 and CW-2 that Organica produced uncoated Dimebon pills for the Phase 2 study but **did not** produce the placebo pills. Docket No. 138 ¶¶ 68, 69 ("SAC"). Shortly after filing the SAC, Plaintiffs claim that they received information from CW-2 that CW-3 informed CW-2 that Organica had in fact supplied both the Dimebon pills and the Phase 2 placebo pills, but had failed to match the placebo pills. Docket No. 151 at 3 ("Opp."). Based on this new information, Plaintiffs moved for and was granted leave to file the TAC. Docket No. 144. Defendants now seek dismissal of Plaintiffs' complaint with prejudice. Docket No. 147 at 2 ("Motion").

## II. DISCUSSION

### A. Standard of Review

In general, in a motion to dismiss under Rule 12(b)(6) for failure to state a claim, the complaint must be construed in a light most favorable to the non-moving party and all material allegations in the complaint are to be taken true. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986). However, this favor does not apply to "legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). While a complaint does not normally need detailed factual allegations to survive a Rule 12(b)(6) motion, the plaintiff must provide grounds demonstrating his entitlement to relief. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Thus, the plaintiff must allege sufficient factual allegations "to raise a right to relief above the speculative level." *Id.*

While "a complaint need not contain detailed factual allegations . . . it must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009) (quoting *Ashcroft*, 129 S. Ct. at 1949). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft*, 129 S. Ct. at 1949. This threshold is reached when the plaintiff pleads sufficient facts to allow the Court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Id.* If dismissal is appropriate, leave to amend should be freely given unless "amendment of the complaint would be futile." *Albrecht v. Lurid*, 845 F.2d 193, 195 (9th Cir. 1988). Thus, where the Court "determines that the 'allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency,' then the dismissal without leave to amend is proper." *Id.* (quoting *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986))

Where, as here, the plaintiffs assert a claim for securities fraud pursuant to § 10(b) and Rule 10b-5, the plaintiffs must allege: "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir. 2005) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)). To allege a claim pursuant to § 20(a), the plaintiffs must allege: "(1) a primary violation of federal securities law, and (2) that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys.*, 228 F.3d 1057, 1065 (9th Cir. 2000). Here, the primary violation claimed is a violation of § 10(b) and Rule 10b-5. If Plaintiffs fail to plead a claim for securities fraud under § 10(b) and Rule 10b-5, the § 20(a) claim fails as well.

To assert a § 10(b) and Rule 10b-5 claim, the plaintiffs must meet the particularity requirements of Federal Rule of Civil Procedure 9(b). *In re Daou Sys.*, 411 F.3d at 1014. Rule 9(b) states that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." The pleading requirement is further heightened by the Private Securities Litigation Reform Act ("PSLRA"), which requires that a plaintiff "plead with particularity both falsity and scienter." *Id.* To properly plead falsity, a securities fraud complaint must "specify

each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and if an allegation regarding the statement or omission is made on information and belief, state with particularity all facts on which that belief is formed." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990-91 (9th Cir. 2009) (citation omitted). Likewise, to properly plead scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* at 991 (quoting 15 U.S.C. § 78u-4(b)(2) (2006)). In determining whether there is a "strong inference," the court must find sufficient allegations of scienter such that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)). Thus, the court must consider the complaint in its entirety and "compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Id.*

B. Falsity

Plaintiffs allege that Defendants committed fraud when they stated that the Phase 2 study was: (1) double-blind, (2) used matching Dimebon pills and placebos, (3) was performed in accordance with FDA-approved procedures, and (4) demonstrated that Dimebon significantly helped Alzheimer's patients. TAC ¶ 11. In order to establish fraud, Plaintiffs must first establish that the statements were false: *i.e.*, that the study was in fact not double-blind and was therefore flawed.

1. Confidential Witness Statements

In support of their contention that Defendants conducted a Phase 2 study that was not double-blind, Plaintiffs rely on statements by three confidential witnesses claiming that Defendants used uncoated Dimebon pills that were distinguishable from the placebo by color and taste. TAC ¶¶ 65-70. The Court finds that these confidential witness statements alleged in the complaint are not sufficiently reliable, and are not consistent with the PSLRA to serve as the basis for Plaintiffs' contention that the Dimebon pills were distinguishable from the placebo.

Under the PSLRA, a complaint relying on statements from confidential witnesses must "provide[] sufficient detail about a confidential witness'[s] position within the defendant company to

provide a basis for attributing the facts reported by that witness to the witness'[s] personal knowledge." *Zucco Partners, LLC*, 552 F.3d at 995. If the complaint relies on both confidential witnesses and other factual information, the plaintiff "need not name their sources as long as the latter facts provide an adequate basis for believing that the defendants' statements were false." *Id.* (quoting *In re Daou Sys.*, 411 F.3d at 1015). Where the complaint relies only upon the confidential witness statements, the confidential witnesses must be "described 'with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.' Accordingly, the complaint must provide an adequate basis for determining the witnesses in question have personal knowledge of the events they report." *Id.* (quoting *In re Daou Sys.*, 411 F.3d at 1015). The Court must also look at "the level of detail provided by the confidential sources, the corrobative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* (quoting *In re Daou Sys.*, 411 F.3d at 1015).

In *Daou*, the Ninth Circuit found that the plaintiffs had described the confidential witnesses with sufficient specificity. There, the plaintiffs described each confidential witness's job description and responsibilities; for example, confidential witness six was described as "a former Daou executive who worked in the Finance Department. CW6 dealt with audit issues, Security and exchange ("SEC") reporting and budget matters. As such, CW6 was familiar with Daou's process of collecting project cost information. CW6 reported to defendant McGee." 411 F.3d at 1016. Likewise, confidential witness nine was described as "a former Daou Regional Vice President of Sales. As Vice President of Sales, CW9 was responsible for reporting weekly or bi-weekly sales information, such as sales status/backlog and forecast/pipeline information, to Daou's Vice presidents and corporate officers." *Id.* The Ninth Circuit found that these descriptions were sufficiently specific to meet PSLRA's requirements for confidential witnesses.

However, in *Zucco*, the Ninth Circuit found that a specific description of the confidential witnesses was alone insufficient. There, the Ninth Circuit found that while the complaint "describe[d] the confidential witnesses' job titles and employment information with ample detail to satisfy *Daou*'s requirement that a complaint make apparent a confidential witnesses' position within

the defendant corporation . . . the SAC fails to allege with particularity facts supporting its assumptions that the confidential witnesses were in a position to be personally knowledgeable of the information alleged." *Zucco Partners, LLC*, 552 F.3d at 996. For example, the court noted that "[s]ome of the confidential witnesses were simply not positioned to know the information alleged, many report only unreliable hearsay, and others allege conclusory assertions of scienter." *Id.* Despite the sufficiently detailed descriptions of the confidential witnesses' job positions and responsibilities, the Ninth Circuit found that other factors made the statements too unreliable to rely upon. *Id.*

Here, Plaintiffs have failed to sufficiently describe the confidential witnesses' job positions and responsibilities under *Daou*. CW-1 is described as a "Senior Technology Engineer at Organica." TAC ¶ 67. CW-2 is described as "a shareholder of Organica and a member of Organica's Board." TAC ¶ 69. Finally, CW-3 is described as "a long-time Organica employee responsible for testing and introducing new medicines and occupied that position when Dimebon was tested." TAC ¶ 70. Plaintiffs do not describe the job responsibilities of CW-1 and CW-3, and does not give the job title of CW-2 and CW-3. Plaintiffs fail to describe the confidential witnesses with sufficient specificity to satisfy *Daou*.

Even if Plaintiffs had provided more complete descriptions of the confidential witnesses, the statements are still unreliable. First, Plaintiffs fail to adequately allege that the confidential witnesses were in a position to have the knowledge they profess. Plaintiffs do not state that any of the confidential witnesses were connected to Organica's work for Medivation; for example, the TAC does not explain what a Senior Technology Engineer does and why someone in that position would have knowledge about the Dimebon pills produced for the Phase 2 study. The TAC does not explain CW-2's involvement with Dimebon, only generally stating that he is a board member and would therefore have access to Organica's employees to "verify" the information passed onto him by CW-1 and CW-3. At oral argument, Plaintiffs' counsel asserted CW-2 conducted an investigation into Organica only after being contacted by Plaintiffs' counsel. But this fact is not alleged in the TAC. Moreover, the TAC also fails to explain how CW-2 "verified" the information he received, and why his verification was reliable. This is problematic given that CW-2 had previously "verified" CW-1's

assertion that Organica did not produce the placebo at all, *see* SAC ¶¶ 68, 69, only to have that verification contradicted by CW-3 as discussed below. Finally, the TAC does not explain why CW-3 was involved with the production of Dimebon when CW-3 was responsible for the testing and introduction of *new* medicines. TAC ¶ 70. Dimebon has been approved for use in Russia since 1983, and is no longer a new medicine. TAC ¶ 46. While Plaintiffs argue that Dimebon was a new drug for Defendant Medivation, CW-3 is not a Medivation employee but an Organica employee, and Plaintiffs' own complaint states that Organica "has been producing Dimebon for *many years.*" TAC ¶ 66 (emphasis added). Thus, CW-3 would have no reason to be involved in the production of Dimebon, given that CW-3 worked on new medicines and Organica had already produced Dimebon for many years.

Second, the confidential witness statements in the TAC are unreliable because they contradict statements made by the same group of witnesses in the SAC. In the SAC, CW-1 not only stated that the Dimebon pills provided for the Phase 2 study were uncoated, but that "Organica did not receive an order to produce and or provide placebo pills for the Phase 2 clinical trials." SAC ¶ 68. CW-2 thereby "verified" that Organica did not receive an order for the placebo pills. SAC ¶ 69. However, in the TAC, Plaintiffs omit CW-1's statement that Organica did not receive an order for the placebo pills, and modifies CW-2's statement so that it now states that CW-2 "also verified after consultations with CW-3 that Organica *did*, in fact, produce the placebos for Phase 2 testing." TAC ¶¶ 68, 69 (emphasis added). In short, CW-2 claimed that he verified CW-1's information that Organica *did not* produce the placebo, but now claims that he verified CW-3's information that Organica *did* provide the placebos. The TAC fails to explain this inconsistency in the confidential witnesses' statements and how CW-2 could have verified two flatly inconsistent statements.

This history of events significantly decreases the reliability of the confidential witness statements. As to CW-1, CW-1 provided incorrect information, suggesting that CW-1's knowledge is unreliable. While Plaintiffs rely on *Rudolph v. UTStarcom* for the proposition that "[a] mistake by a confidential witness, however, does not taint all information provided," *Rudolph* makes no such statement. *See* Opp. at 14 (citing No. C 07-04578 SI, 2008 WL 4002855 (N.D. Cal. Aug. 21, 2008)). *Rudolph* concerned only a "possible inconsistency" in the allegations of the confidential

witness, whereas CW-1's statements here are directly contradicted by CW-3's statement that Organica did in fact produce the placebo. *See* 2008 WL 4002855, at *6. Likewise, CW-2's reliability is significantly decreased given CW-2's contradictory "verifications."

Third, the Court finds that the confidential witness statements are further rendered unreliable because Plaintiffs' counsel and investigators never actually spoke to CW-1 or CW-3. At the hearing on this matter, Plaintiffs admitted that their investigators only spoke to CW-2, and listened in on a phone call between CW-2 and CW-1. Plaintiffs correctly note that the Ninth Circuit has found that "the fact that a confidential witness reports hearsay does not automatically disqualify his statement from consideration in the scienter calculus." Opp. at 14 (quoting *Zucco Partners, LLC*, 552 F.3d at 998 n.4). However, while a hearsay statement is not automatically precluded, it "may indicate that a confidential witnesses' report is not sufficiently reliable, plausible, or coherent to warrant further consideration . . . ." *Zucco Partners, LLC*, 552 F.3d at 998 n.4. Applying this principle, the *Zucco* court found that the fact that "[a] majority of the confidential witnesses base their knowledge on vague hearsay . . . is not enough to satisfy *Daou*'s reliability standard." *Id.* at 997. In the instant case, the fact that Plaintiffs rely on hearsay statements passed onto CW-2 further underscores the unreliability of the confidential witness statements in this case. There is very little detail about the information that CW-2 received or how he "verified" the information that he received. Combined with the lack of information about the positions and responsibilities of each of the confidential witnesses, the questionable basis for the information of each of the witnesses, and the contradictory statements, the hearsay nature of the statements reported render Plaintiffs' confidential witnesses unreliable for purposes of demonstrating falsity under PSLRA.

2. Corroboration by Other Particularized Facts

The Court further finds that the other information relied upon by Plaintiffs to corroborate the confidential witness statements are likewise unreliable, and were already rejected by the Court in dismissing the CAC. Plaintiffs again rely upon Dr. Schneider's theory that the Phase 2 study was not double-blinded as the corroborating information. The Court previously rejected Dr. Schneider's speculation as insufficient. Dismissal Order at 7-10. In the TAC, Dr. Schneider's assertion that the Phase 2 study was not double-blind is still based not on his personal knowledge, but instead on: (1)

Defendants' failure to provide a detailed description of the pills used in the Phase 2 study in *The Lancet* article publishing the results of the Phase 2 study, and (2) the statement of an unnamed attendee of the SG Cowen & Co. Annual Health Care Conference, in which Defendants Hung and Seely allegedly admitted that the pills were not identical. TAC ¶¶ 75, 76.

In the Court's prior order, the Court found that *The Lancet* article "did include a statement that the Dimebon pills and placebo were identical – *i.e.*, they were 'matched.'"[1] Dismissal Order at 9. The Court also found that the statement of the unnamed colleague was of "highly questionable" reliance, observing that:

> if Dr. Hung and Dr. Seely did in fact make an admission at the conference that the Dimebon pills and placebo were not identical, then one would expect that information to have been publicized – at the very least, in a report by the analyst who posed the question. As Defendants put it, "[i]t simply is not plausible that no one besides Plaintiff would have recognized the impact of such an 'admission.'" That the colleague is not identified or described as a reliable source further compounds the problem.

Dismissal Order at 8 (citations omitted). Accordingly, the Court finds that Dr. Schneider's statements are based on unreliable information or an insufficient factual basis, and is therefore insufficient to corroborate the unreliable statements made by the confidential witnesses.

Finally, even if the confidential witnesses or Dr. Schneider supported Plaintiffs' allegation that the Dimebon pills were distinguishable from the placebo pills, Plaintiffs allege no facts demonstrating that the differences in the pills caused the study to become unblinded. Plaintiffs do not identify a single patient who learned that he or she was receiving Dimebon or the placebo, and do not identify any investigator who likewise became aware which of his patients received which treatment. While Plaintiffs allege that the investigators would have become unblinded because patients taking Dimebon would have complained about a bitter taste or numbing sensation, Plaintiffs

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[1] Plaintiffs also contends that Dr. Schneider's observation about the failure to provide a detailed description of the pills used in the Phase 2 study is emphasized by the fact that a paper discussing the results of a Phase 2 Huntington's disease trial with Dimebon did provide details about the encapsulation of the Dimebon pills. TAC ¶ 75. The Court already found that the encapsulation in the Huntington's disease trial was understandable given that encapsulation was necessary to mask for dose, whereas no such masking was necessary in the Alzheimer's disease trial where only a single dose was used. Dismissal Order at 9-10.

provide no evidence that there were widespread (or in fact any) reports of bitterness. No such effects were reported by *The Lancet* article, even though the article discloses all adverse events occurring in either patient population with an incidence of 3% or more and a rate at least twice that in the other group. Taken together with the other problems identified in the TAC, the Court finds that Plaintiffs have failed to adequately plead falsity in this case.

C. Scienter

In addition to Plaintiffs' failure to plead falsity, the Court finds that Plaintiffs have failed to plead sufficient allegations "giving rise to a strong inference that the defendant acted with the required state of mind." *Zucco Partners, LLC*, 552 F.3d at 991. Here, Plaintiffs contend that the TAC pleads scienter because: (1) the confidential witnesses stated that the Dimebon pills and placebos were not matched in taste or appearance, (2) Defendants Hung and Seely admitted that the pills used in the Phase 2 study were not identical, (3) Defendants omitted a description of the phase 2 study pills in *The Lancet* article, (4) Dimebon was Medivation's largest asset and drug test, and (5) Defendants received financial benefits as a result of the false statements. Opp. at 17.

1. Confidential Witness Statements

As discussed above, the Court finds that the confidential witness statements do not demonstrate scienter because they are unreliable. First, the TAC does not adequately describe the position and responsibilities of each witness. Second, Plaintiffs do not explain the basis for each confidential witness's knowledge. Third, the confidential witness statements are contradictory. Finally, the statements are nearly all hearsay, and Plaintiffs fail to provide any details explaining the circumstances of the statements so as to increase their reliability. Accordingly, the confidential witnesses do not support a finding of falsity and hence scienter.

2. Defendants Hung's and Seely's Admission that the Pills were not Identical

Again, the Court finds that there is insufficient basis for accepting Plaintiffs' allegations that Defendants Hung and Seely admitted at the SG Cowen & Co. Annual Health Care Conference that the Dimebon pills and placebos were not matched. The statement comes from an unnamed source, and it is unrealistic that no one would have noted the importance of such an admission except for

Plaintiffs. Dismissal Order at 8. Accordingly, this alleged statement does not support a finding of scienter.

3. Defendants Hung's and Seely's Authorship of *The Lancet* Article

The Court also finds that *The Lancet* article's failure to provide a detailed description of the pills used in the Phase 2 study does not itself demonstrate scienter. The article states that the pills were matched, and the fact that the article does not provide the same amount of detail as that in an article describing the pills used in the Huntington's disease trial is not particularly significant given the different circumstances of each study. Dismissal Order at 8-9. Accordingly, *The Lancet* article's failure to provide more detail about the pills used does not support a finding of scienter.

4. Importance of the Phase 2 Study to Medivation

The Court finds that the importance of the Phase 2 study to Medivation alone is insufficient to support a finding of scienter. Plaintiffs argue that because Dimebon was one of Medivation's two drugs in development, the study was so important to Defendants that there was no way Defendants could not have known that the Dimebon pill did not match the placebo. Opp. at 20-21. Plaintiffs' argument is speculative, and Plaintiffs do not otherwise plead any specific facts indicating that Defendants were informed by Organica about the distinction in the pills (if in fact they were any) or had any other reason to believe that the pills did not match.

5. Stock Sales

a. $36 Million Offering and $225 Million from Pfizer

Plaintiffs argue that Defendants had reason to increase their stock value to maximize offerings and to attract a partner so that Medivation would not need to raise cash before completing Dimebon's Phase 3 study. Opp. at 21-22. In short, Plaintiffs claim that the results from the unblinded tests would help support Defendants' $36 million offering and receive $225 million cash up-front from Pfizer. Opp. at 21.

In dismissing the CAC, the Court previously rejected Plaintiffs' argument that Defendants' motive for unblinding the Phase 2 study was to get funding for Medivation, thus demonstrating scienter. In general, courts have found that a generic desire to raise capital is insufficient to

demonstrate scienter. In its prior order, the Court cited *Lipton v. Pathogenesis*, where the Ninth Circuit found that:

> If scienter could be pleaded merely by alleging that officers and directors possess motive and opportunity to enhance a company's business prospects, virtually every company in the United States that experiences a downturn in stock prices could be forced to defend securities fraud actions. [A company's] alleged desires to obtain favorable financing and to expand abroad are in themselves ordinary and appropriate corporate objectives. Such routine business objectives, without more, cannot normally be motivations for fraud. To hold otherwise would be to support a finding of fraudulent intent for all companies that plan to lower costs and expand sales.

284 F.3d 1027, 1038 (9th Cir. 2002) (citation omitted). Thus, the mere allegation that Defendants had a motive of getting funding is insufficient to support a strong inference of scienter.

Plaintiffs rely on *In re Portal Software, Inc.*, where the court found that the "plaintiffs had alleged a 'palpable' motive to commit fraud where the need to raise capital necessary to keep Portal a 'going concern' was stronger than the generic 'desire to raise capital' which can be attributed to every company." Opp. at 21 (quoting No. C-03-5138 VRW, 2005 WL 1910923, at *12 (N.D Cal. Aug. 10, 2005)). Plaintiffs overstate the court's finding; while the court did find that the plaintiffs' contention that the defendants were motivated to artificially inflate the stock price in the short term to conduct a successful secondary public offering and obtain much-needed capital went beyond a generic desire to raise capital, the court also found that this allegation had to be "combined with allegations of other 'red flags' to be probative." 2005 WL 1910923, at *12. Because the plaintiffs had failed to allege accounting fraud with sufficient particularity, there were no "red flags" that could be combined with the motive of obtaining immediate capital. *Id.* The court concluded that there were insufficient facts to establish a strong inference of scienter.

As in *In re Portal Software, Inc.*, Plaintiffs here do not allege any other "red flags" with sufficient particularity. Furthermore, Plaintiffs fail to even allege that Medivation had an immediate need for money at the time the Phase 2 study was developed and the results disclosed. Plaintiffs claim that Medivation required money in June 2008, but the Phase 2 study results were disclosed in **September 2006**, and Defendants would necessarily have had knowledge of the defect before September 2006. Hence, there was an approximate two year gap between the alleged fraud and the

need for funding. TAC ¶ 12. Plaintiffs have failed to demonstrate that Defendants had a need for immediate capital at the time Plaintiffs claim Defendants made the false statement that the Phase 2 study was unblinded. The fact that Medivation may have required capital nearly *two years* after the results were released is itself insufficient to create a strong inference of scienter. Given this discrepancy in timing between the alleged fraud and the need for additional finding, the inference of scienter is far weaker than in *In re Portal Software*.

b. Insider Trading

Finally, the Court finds that the Individual Defendants' stock sales, of $22 million, are insufficient to create a strong inference of scienter because Defendants also lost $82 million in stock value when the Phase 3 results were released. While suspicious insider trading can be indicative of scienter, "[i]nsider trading is suspicious only when it is dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Ronconi v. Larkin*, 253 F.3d 423, 435 (9th Cir. 2001) (citation omitted). The three relevant factors in determining whether insider trading is suspicious are: "(1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history." *Id.* (citation omitted).

The Court previously found that the timing of the sales and Individual Defendants' prior trading history was consistent with scienter. Dismissal Order at 11. However, the Court found that scienter was not demonstrated because the amount and percentage of shares sold by insiders weighed heavily against a finding of scienter. Dismissal Order at 12. Although the Court acknowledged that Defendants sold almost 1 million shares of stock while in possession of the allegedly adverse inside information (*i.e.*, that the Phase 2 study was not double-blinded, thus biasing the results), resulting in proceeds of approximately $22 million to Defendants, the Court also found it significant that three of the four Individual Defendants held *more* stock in Medivation at the end of the class period than they did at the beginning because they accumulated vested options.[2]

[2] The Court again acknowledges that Defendant Bailey held less stock at the end of the class period, selling approximately 38% of his holdings. As before, this fact alone is alone insufficient to support a strong inference of scienter because:

Dismissal Order at 12. As a result, Individual Defendants lost $82 million (nearly four times the proceeds made after Phase 2 study) when the Phase 3 study results were released. Dismissal Order at 12. Under *Ronconi v. Larkin*, this fact strongly rebuts an inference of scienter on Individual Defendants.

Plaintiffs respond by theorizing about other reasons why Individual Defendants did not sell more of their stock, thus mitigating the fact that Defendants held more stock than they sold shortly after the alleged fraud. For example, Plaintiffs argue that by granting themselves options during the Class Period, Defendants were able to replace about 70% of their shares and thus replace the Class Period shares that they sold, concealing their fraud by making it appear that Defendants' holdings were constant. Opp. at 23. If one were to ignore the options granted, the percentage of stock sold would increase substantially. Opp. at 24. However, this argument would require the Court to ignore the vested options, which contradicts Ninth Circuit authority requiring that vested options be considered in determining whether there are suspicious insider trades. *See In re Silicon Graphics*, 183 F.3d at 986-87; *see also* Dismissal Order at 12 n.9 ("Per Ninth Circuit authority, the vested options should be considered."). Plaintiffs also argue that if Individual Defendants had sold all of their stock, it would have suggested that something was wrong and Pfizer would not have entered into a collaboration agreement with Medivation. Opp. at 23-24. However, this argument is largely speculative and unsupported by any specific facts. Plaintiffs fail to demonstrate that Defendants could not have sold a greater portion of their shares without jeopardizing the Pfizer agreement.

Taken as a whole, Individual Defendants' stock sales do not give rise to a strong inference that Defendants acted with scienter. While Plaintiffs rely heavily on the fact that Individual Defendants sold $22 million worth of stock, Plaintiffs conceded at the hearing that Individual

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> the Ninth Circuit concluded that an insider's sale of 43.6% of his holdings did not give rise to a strong inference of scienter, either on his part or on the part of the other insiders, because his sales comprised only 5% of *total* insider sales. based on Defendants' chart, Mr. Bailey's sales accounted for only 6-7% of total insider sales (*i.e.*, 259,000/3,956,043), and therefore *Silicon graphics* dictates that there is no strong inference of scienter.

Dismissal Order at 13 (citing *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 987 (9th Cir. 1999)).

Defendants could have sold even more of the stock than they did. Instead of selling more stock after the Phase 2 study, Individual Defendants as a whole substantially increased their stock holdings during the Class Period, with three of the four Individual Defendants holding far more stock at the end of the Class Period than the beginning. As a result, Defendants lost $82 million when the Phase 3 results were released. The loss suffered by Defendants gives rise to a strong inference that Defendants did not act with scienter.

Medivation's actions after the Phase 3 results were released further contradict an inference of scienter. If, as Plaintiffs allege, Defendants' sole goal was to benefit from the stock increase as a result of the Phase 2 study, Defendants would have no reason to conduct three additional studies after the Phase 3 results were released in March 2010. Instead, Defendants have continued to pour resources into Dimebon research for Alzheimer's disease and Huntington's disease (and thus further jeopardizing the value of their stock holdings), not announcing until in January 2012 – nearly two years after the March 2010 results were announced – that they would cease testing on Dimebon. The fact that Defendants would continue to run clinical tests on Dimebon contradicts Plaintiffs' allegation that Defendants knew that Dimebon would have no beneficial effect on patients, and suggests that Defendants had reason to believe that Dimebon could be a successful treatment. Accordingly, the Court finds that Plaintiffs have failed to plead facts giving rise to a strong inference of scienter.

## III. CONCLUSION

For the reasons stated above, the Court **GRANTS** Defendants' motion to dismiss. It does so with prejudice. The Court finds that this is already Plaintiffs' fourth attempt to plead sufficient facts. The TAC also relies on the same flawed theories of the previously dismissed CAC, with the only material addition being the highly unreliable confidential witness statements. A major aspect

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of that unreliability is the contradictions between their statements, contradictions that cannot be undone by a further amendment to the complaint. Moreover, Plaintiff have been given ample opportunity to plead their case. Thus, the Court concludes further amendment would be futile, and dismissal with prejudice is warranted. Judgment shall be entered, and the Clerk of the Court is directed to close the file in this case.

This order disposes of Docket No. 147.

IT IS SO ORDERED.

Dated: March 22, 2012

EDWARD M. CHEN
United States District Judge