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United States District Court
For the Northern District of California

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

**IN re NUVELO, INC, SECURITIES
LITIGATION**
_____ /

**Master File No
C 07-4056 VRW**

**This Document Relates to:
All Actions**
_____ /

**Class Action
ORDER**

Plaintiffs filed an amended consolidated complaint ("Prior Complaint") alleging violations of federal securities laws on November 9, 2007. Doc #31. On December 4, 2008, the court granted defendants' motion to dismiss the Prior Complaint ("Prior Order"). Doc #69. The Prior Order granted plaintiffs leave to amend. Doc #69 at 34-35. Plaintiffs did so on January 23, 2009, filing a second consolidated amended complaint ("SAC"). Doc #76. On March 24, 2009, defendants moved to dismiss the SAC. Doc #78. This order addresses that motion.

I

1
2 As an initial matter, defendants request judicial notice
3 of 42 documents contained in Jeffrey Kaban's declaration (Doc #80,
4 Exhs A-¶) relating to defendants' motion to dismiss. Doc #79.
5 Federal Rule of Evidence 201 allows courts to take judicial notice
6 of matters that are "capable of accurate and ready determination by
7 resort to sources whose accuracy cannot reasonably be questioned."
8 Fed R Evid 201(b).

9 Plaintiffs do not oppose the court taking judicial notice
10 of exhibits A-GG and LL-¶. Doc #91 at 2. Because the request for
11 judicial notice is unopposed as to those documents, and they are
12 either referenced in the SAC or demonstrate information available
13 to the market during the class period, the court takes judicial
14 notice of exhibits A-GG and LL-¶. Doc #80. Doc #91 at 2-4.

15 Plaintiffs do, however, oppose defendants' request for
16 judicial notice of exhibits HH-KK. Doc #91 at 2. Exhibits HH-KK
17 include a Pharmaceutical Statistics journal article (Exh HH), two
18 Food and Drug Administration ("FDA") publications (Exhs II, KK) and
19 an FDA PowerPoint presentation (Exh JJ). All four documents relate
20 to a factual dispute relevant to defendants' motion to dismiss:
21 FDA guidance on the statistical standard required to pass placebo-
22 controlled studies. Plaintiffs argue that "the purported 'facts'
23 that Defendants seek to prove by these documents may not be
24 judicially noticed because they are subject to dispute." Doc #91
25 at 2.

26 While the court recognizes that the facts described in
27 the four disputed documents are not the proper subject of judicial
28 notice, defendants merely seek judicial notice of the fact that

1 these documents were publicly available during the time the fraud
2 alleged in this action occurred. Doc #94 at 2. Courts hearing
3 securities fraud cases routinely take judicial notice of documents
4 with unquestioned authenticity that demonstrate the information
5 available to the market during the class period. See Construction
6 Laborers Pension Trust of Greater St Louis v Neurocrine
7 Biosciences, Inc, 2008 US Dist LEXIS 38899, *5 (S D Cal May 12,
8 2008) (taking judicial notice of FDA guidelines because they were
9 "publicly available to a reasonable investor"). These documents
10 may be considered "to establish 'whether and when certain
11 information was provided to the market' not the truth of the
12 matters asserted in the reports." In re Infonet Servs Corp
13 Securities Litigation, 310 F Supp 2d 1106, 1116 (C D Cal 2003),
14 quoting In re PetSmart, Inc Securities Litigation, 61 F Supp 2d
15 982, 987 n1 (D Ariz 1999). Accordingly, the court GRANTS
16 defendants' request for judicial notice of exhibits HH-KK in order
17 to consider the complete record of the defendants' alleged
18 fraudulent statements and omissions in light of the other
19 information available to the market.

20
21 II

22 In deciding a motion to dismiss, the court must accept
23 all well-pleaded factual allegations in the complaint as true.
24 Blake v Dierdorff, 856 F2d 1365, 1368 (9th Cir 1988). Accordingly,
25 the following allegations appear in the SAC. Doc #76.

26 Plaintiffs are a class consisting of all purchasers of
27 the publicly traded securities of defendant Nuvelo between January
28 5, 2006 and December 8, 2006, inclusive (the "Class Period"). Doc

1 #76 at 4. Defendants are a biopharmaceutical company Nuvelo and
2 several of Nuvelo's senior officers and managers: Ted Love, Gary
3 Titus and Michael Levy. Id at 20-21. The SAC alleges that Nuvelo
4 stock traded at artificially high prices during the Class Period
5 because of fraud by defendants. Id at 4, 82-83.

6 Prior to and during the Class Period, Nuvelo was engaged
7 in preclinical and clinical testing of medical drugs. Id at 4.
8 Nuvelo's "lead product" was a drug called alfimeprase that Nuvelo
9 was testing for its safety and ability to dissolve blood clots.
10 Id. Nuvelo was in the process of testing alfimeprase in order to
11 gain regulatory approval of the drug and to bring it to market.
12 Id.

13 To gain regulatory approval, the FDA requires that the
14 sponsor of a drug demonstrate that it is safe and effective in
15 three human clinical trials ("phase 1", "phase 2" and "phase 3").
16 Id at 28. The FDA does not approve a drug in general, but rather
17 approves a drug for a specific use, or "indication." Id.

18 In 2003, Nuvelo began conducting clinical trials of
19 alfimeprase for two indications: dissolving blood clots in the
20 legs (PAO) and dissolving blood clots in occluded catheters for
21 patients undergoing treatment (CO). Id at 24. The FDA approves
22 particular claims of efficacy based on the results of the trials.
23 Id at 28. So Nuvelo designed its alfimeprase trials to demonstrate
24 particular claims about the drug for the treatment of both PAO and
25 CO.

26 A

27 Nuvelo called its clinical program for CO SONOMA (Speedy
28 Opening of Non-functional Occluded catheters with Mini-dose

1 Alfimeprase). Doc #76 at 36. SONOMA's primary endpoint, or the
2 claim Nuvelo was attempting to get approval for, was alfimeprase's
3 ability to clear occluded catheters fifteen minutes after
4 administration of the drug. Id at 28-29. If Nuvelo could prove
5 that alfimeprase increased blood flow rates of occluded catheters
6 in fifteen minutes, it would gain an advantage over a competing
7 drug — Genentech's Cathflo Activase, which had been proven in
8 clinical trials to increase blood flow rates of catheters in thirty
9 minutes. Id at 29.

10 Nuvelo completed the phase 2 trials for CO (SONOMA-1) in
11 2004. Id at 37. In a December 2004 press release, Nuvelo reported
12 that one dose of alfimeprase produced cumulative blood flow rates
13 of fifty percent in occluded catheters at fifteen minutes compared
14 to zero percent for Cathflo after fifteen minutes. Id at 37.

15 In May 2005, Nuvelo announced its phase 3 clinical trial
16 program for CO. Id at 38. The program consisted of two phase 3
17 trials: SONOMA-2 and SONOMA-3. Id. SONOMA-2 was a randomized,
18 double-blind, 300 patient study testing the efficacy of alfimeprase
19 in restoring blood flow to occluded catheters after fifteen
20 minutes. Id. Two-thirds of the patients received alfimeprase and
21 the remainder received a placebo, or a substance having no effect.
22 Id. SONOMA-3 was an 800 patient trial evaluating the safety of
23 alfimeprase. Id.

24 The success of SONOMA-2 rested on the statistical
25 difference in the restoration of function between the alfimeprase
26 group and the placebo group after fifteen minutes. Id. To gain
27 approval, the FDA requires a statistically significant difference.
28 Doc #76 at 29. "Statistically significant" means that a given

1 result is unlikely to have occurred by random chance or due to
2 factors outside the control of the study. Id. Statistical
3 significance is expressed as a "p-value," which represents a
4 probability that a particular hypothesis tested by a trial happened
5 by chance. Id. Statistical significance consisting of a p-value
6 of less than 0.05 has "traditionally been considered convincing
7 evidence by the FDA." Id at 29.

8 The SAC alleges that defendants misled investors by
9 failing to divulge that Nuvelo had an agreement with the FDA that
10 regulatory approval rested on SONOMA-2 achieving a much higher
11 threshold for statistical significance: a p-value of 0.00125. Id
12 at 38-39. The May 26, 2005 press release announcing the design of
13 the phase 3 CO program stated that the program was "modeled after
14 the Cathflo® Activase® program in this indication." Id at 54.
15 According to the SAC, this statement and others like it were
16 misleading because the Cathflo Activase trial used the customary p-
17 value of 0.05 as the threshold for statistical significance and
18 investors reasonably expected SONOMA-2 to use the same standard.
19 Id. Defendants' failure to disclose SONOMA-2's more stringent
20 statistical standard misled investors about the likelihood that
21 SONOMA-2 would succeed.

22
23 B

24 Nuvelo called its clinical trial program for PAO "NAPA"
25 (Novel Arterial Perfusion with Alfimeprase). Doc #76 at 31. PAO,
26 also known as "leg attack," involves restricted blood flow in the
27 legs and can be treated by balloon angioplasty, open surgery,
28 catheter based intervention and off-label use of thrombolytic

1 agents. Doc #76 at 31. NAPA's primary endpoint was the number of
2 PAO patients treated with alfimeprase who avoid open surgery after
3 30 days. Id at 28. If Nuvelo could prove that patients treated
4 with alfimeprase had a high likelihood of avoiding surgery,
5 alfimeprase could be marketed as a less-invasive and more cost-
6 effective alternative to surgery. Id at 32.

7 Nuvelo's phase 2 PAO trial (NAPA-1) was a "safety trial,"
8 attempting to demonstrate that administering alfimeprase to PAO
9 patients was safe. Id at 32. NAPA-1, however, also measured a
10 number of other endpoints, including avoidance of open surgery
11 after 30 days — the endpoint Nuvelo would later attempt to use in
12 phase 3 to gain approval for a claim of efficacy. Doc #76 at 32.
13 In the trial, patients received alfimeprase via a side hole
14 catheter inserted through the blood clot. Id. In a January 31,
15 2006 Prospectus Supplement, relating to a Nuvelo stock offering,
16 defendants touted the results of NAPA-1, stating: "Up to 69% of
17 study patients were able to avoid open vascular surgical
18 intervention in the 30 days following treatment with alfimeprase."
19 Id at 63.

20 The SAC alleges that "[a]ccording to a knowledgeable
21 vascular surgeon, it is known among vascular surgeons who use side
22 hole catheters to deliver the Genentech thrombolytic drug as a
23 treatment for PAO, such catheters often break up blood clots that
24 are not too large which restores some native blood flow." Id at
25 32. This order refers to the breaking up of blood clots solely due
26 to the insertion of the catheter through the clot, and not due to
27 any drug administered through the catheter, as the "catheter
28 effect." Because there was no placebo group, "the proportion of

1 patients in NAPA-1 who avoided open surgery due to alfimeprase
2 could not be determined accurately due to the [catheter effect]."
3 Doc #76 at 33.

4 The SAC suggests that defendants were aware that a
5 significant catheter effect, and not alfimeprase, may have been
6 responsible for many of the NAPA-1 patients avoiding surgery.
7 Defendants allegedly discussed the catheter effect at company-wide
8 meetings in 2004 or 2005. Id. Moreover, the catheter effect is
9 "perceptible on an angiogram," and defendant Love, a senior officer
10 at Nuvelo, "saw angiograms from NAPA-1." Id at 32.

11 Nuvelo's phase 3 PAO trial program, NAPA-2, was designed
12 to test the efficacy of alfimeprase at causing patients to avoid
13 surgery after 30 days. Id at 33. In order to be sure that the
14 catheter effect was not responsible for patients who avoided
15 surgery, NAPA-2 included both a 300 patient alfimeprase trial and a
16 300 patient placebo trial. Id at 33-35. According to a February
17 27, 2006 Nuvelo press release, "[t]he [phase 3 NAPA] program
18 consist[ed] of two overlapping randomized, double-blind, multi-
19 national trials comparing * * * alfimeprase with placebo in total
20 of 600 patients." Id at 65.

21 Plaintiffs allege that an undisclosed element of the
22 design of NAPA-2 indicates that defendants believed there was a
23 significant risk that the catheter effect had biased NAPA-1's
24 avoidance of surgery endpoint. Doc #76 at 33-35. In the design of
25 NAPA-2, defendants took the "extraordinary measure" of splitting
26 the 300 patient placebo group into two groups — a 38 patient Peri-
27 Thrombus ("PT") group and a 262 Intra-Thrombus ("IT") group. Doc
28 #76 at 33. The IT group received the placebo via a side hole

1 catheter inserted through the blood clot, just as alfimeprase was
2 administered to the alfimeprase group. Id. But the PT group
3 received the placebo via a different kind of catheter inserted
4 near, but not through, the blood clot. Id at 33-34. Because the
5 placebo was administered to the 38 PT group patients in a way
6 different from alfimeprase-treated patients, the PT group could not
7 be used in the comparison with the alfimeprase trial. Id. "[T]he
8 only purpose of [the PT] group was to compare its results with the
9 [IT] placebo group, to measure the [catheter effect]." Id at 34
10 (emphasis in original). According to the SAC, the fact that
11 defendants included the PT group in NAPA-2, without informing the
12 public, reveals that defendants believed there was a much more
13 serious risk that NAPA-2 would fail due to the catheter effect.

C

16 According to the SAC, defendants' omissions about the
17 risks of a more stringent target p-value for SONOMA-2, and the
18 catheter effect bias in the results of NAPA-1, rendered multiple
19 statements misleading. All of these statements allegedly misled
20 investors about the likelihood that alfimeprase would succeed in
21 its phase 3 trials, gain regulatory approval and ultimately attain
22 commercial success.

23 On May 26, 2005, Nuvelo issued a press release announcing
24 its phase 3 alfimeprase program for CO. Doc #76 at 53. The press
25 release stated: "The Phase 3 program for alfimeprase in CO is
26 modeled after the Cathflo® Activase® program in this indication."
27 Doc #76 at 54. The Cathflo Activase program — unlike SONOMA-2 —
28 used the customary 0.05 p-value standard for statistical

1 significance. Id. According to the SAC, drawing comparisons to
2 the Cathflo Activase program without noting the more stringent p-
3 value requirement misled investors about the riskiness of SONOMA-2
4 in comparison to the Cathflo Activase program. Id at 54-55.

5 In a November 1, 2005 conference call with securities
6 analysts and investors, defendant Levy discussed Nuvelo's
7 assumptions about the catheter effect during the PAO phase 2 trial
8 NAPA-1. Id at 55-57. Levy stated, "our drug is being compared to
9 placebo in Phase 3 pivotal trials, and we expect to see the
10 preponderance of patients avoiding surgery with alfimeprase, and we
11 expect to see next to no patients being able to avoid surgery with
12 placebo." Id at 56. Levy also responded to a question about the
13 number of patients likely to avoid surgery in the placebo trial,
14 stating: "we're assuming a relatively low placebo rate. You know
15 if you wanted to guesstimate something in order of 10% or so, you
16 would be approximately right." Id at 56. The SAC suggests,
17 however, that defendants believed there was a significant risk that
18 the placebo rate was higher than ten percent because the catheter
19 effect would cause many patients to avoid surgery even if they were
20 only administered a placebo.

21 While Levy disclosed Nuvelo's allegedly fraudulent belief
22 that the catheter effect was low, defendants continued to omit
23 information about the 38 patient PT placebo group. Id at 56-57.
24 In addition to hiding defendants' concern about the catheter
25 effect, the omission about the 38 patient PT placebo group also
26 allegedly misled investors about the likelihood that the phase 3
27 PAO program would succeed because the 38 PT placebo group could not
28 be compared to the alfimeprase phase 3 trial given the different

1 catheter delivery mechanism. Doc #76 at 57-59. That is to say,
2 because the PT patients received a placebo via a different catheter
3 from the alfimeprase patients, any comparison between those two
4 groups was meaningless. Id. Accordingly, the undisclosed PT group
5 meant that the actual quantity of patients in the placebo group,
6 for purposes of comparison, was only 262. Id.

7 The SAC alleges other fraudulent statements in 2006 — on
8 January 6, January 31, February 27, March 15, April 10, April 24,
9 May 5, July 7 and August 3 — but they all essentially repeat the
10 same fraudulent statements alleged in 2005. Id at 59-73. Each of
11 these statements allegedly misrepresented the risks associated with
12 the phase 3 alfimeprase trials due to the accompanying omissions
13 concerning the FDA-agreed p-value for SONOMA-2 and the likely
14 catheter effect biasing the results of NAPA-1.

15
16 D

17 According to the SAC, just prior to the start of trading
18 on December 11, 2006, Nuvelo revealed that alfimeprase failed to
19 meet its primary endpoints in the phase 3 clinical trials for both
20 PAO and CO. Doc #76 at 50. Alfimeprase failed to meet the primary
21 endpoint for the CO treatment, which was to restore blood flow in
22 catheters after 15 minutes demonstrated to a p-value of 0.00125.
23 Id at 51. Alfimeprase also failed to prevent surgery for 30 days
24 in PAO patients, which was the primary endpoint for the PAO
25 indication. Id at 50-51. A December 11 press release announced
26 that enrollment in future trials — NAPA-3 and SONOMA-3 — had been
27 suspended. Doc #76 at 51.

28 //

1 According to the SAC, during a December 11, 2006
2 conference call, defendants disclosed that alfimeprase failed NAPA-
3 2 and SONOMA-2 due to factors that had been previously undisclosed
4 or downplayed as risks. Doc #76 at 40-41. Defendants explained
5 that for PAO, although alfimeprase dissolved some clots, it did not
6 perform significantly better than the placebo group because, as it
7 turns out, the catheter effect dissolved "a substantial number of
8 clots" in both groups. Id at 40. Defendants Love and Levy
9 "admitted that since none of the Company's prior clinical testing
10 had included the use of a placebo, any past instances of
11 alfimeprase 'dissolving blood clots' was more likely than not
12 simply attributable to the [catheter effect]." Id. For CO,
13 defendant Love revealed that Nuvelo "'had an agreement with the FDA
14 that the p-value would be far lower than 0.05.'" Id at 41. Love
15 also stated, "'While the data from the SONOMA-2 trial show a
16 statistically significant difference in the rate at which
17 alfimeprase and placebo dissolve clots in venous catheters at 15
18 minutes, this result did not meet the high threshold established by
19 the FDA for regulatory approval based on only one control trial.'"
20 Id at 41.

21
22 E

23 The SAC alleges that defendants' fraudulent statements
24 and omissions described above caused plaintiffs' losses by
25 inflating the price of Nuvelo stock during the Class Period. Doc
26 #76 at 82-90. While the SAC does not allege that the price
27 increased following each — or any — of the alleged fraudulent
28 statements, the SAC points to two dramatic changes in price of the

1 stock and attributes them to the alleged fraud. Doc #76 at 83.

2 The first dramatic change in the stock price occurred on
3 January 5, 2006 — not coincidentally, the start of the class
4 period. Id at 45. On January 5, Nuvelo announced it had entered
5 into a "financial alliance" with the pharmaceutical giant Bayer.
6 Id. "The Bayer deal provided a \$50 million upfront payment to
7 Nuvelo and included up to \$385 million in additional fees and
8 payments." Id. Nuvelo's stock price increased from a previous
9 close of \$9.01 to close at \$12.67 on January 5 — an increase of
10 41%. Id.

11 While defendants' alleged fraudulent statements and
12 omissions had been alive in the market for months by the time the
13 Bayer deal was announced, plaintiffs allege that those statements
14 and omissions were still substantially responsible for the dramatic
15 rise in Nuvelo's stock price. Id at 86. According to the SAC,
16 "[t]he synergistic effect of Defendants' false and misleading
17 statements combined with Defendants' new-found actual ability to
18 fund the testing caused Nuvelo's stock price to skyrocket." Id.
19 This synergy allegedly occurred in two ways. First, "the market
20 recognized" Bayer's involvement with Nuvelo and alfimeprase as an
21 "endorsement" of the prior false and misleading statements. Doc
22 #76 at 86. Second, before the Bayer deal, Nuvelo may not have been
23 able to afford the phase 3 alfimeprase trials; Bayer gave Nuvelo
24 the necessary financial backing to move forward. Id. Accordingly,
25 the SAC alleges that the significant increase in the price of
26 Nuvelo stock that occurred on January 5 was caused in part by
27 defendants' fraudulent statements and omissions about alfimeprase.
28 Doc #76 at 86.

1 particularity requirements of FRCP 9(b). In re Stac Electronics
2 Securities Litigation, 89 F3d 1399, 1404 (9th Cir 1996). FRCP 9(b)
3 requires a plaintiff alleging fraud to "set forth what is false or
4 misleading about [the] statement, and why it is false." In re
5 GlenFed Securities Litigation, 42 F3d 1541, 1548 (9th Cir 1994)
6 (superseded by the Private Securities Litigation Reform Act
7 ("PSLRA") on other grounds).

8 Additionally, a complaint must satisfy the more stringent
9 requirements imposed on securities fraud pleadings by the PSLRA.
10 The PSLRA requires that a complaint: (1) "specify each statement
11 alleged to have been misleading [and] the reason or reasons why the
12 statement is misleading" (15 USC § 78u-4(b)(1)); (2) for any such
13 allegations based on information and belief, "state with
14 particularity all facts on which that belief is formed" (15 USC §
15 78u-4(b)(1)) and (3) "with respect to each act or omission * * *
16 state with particularity facts giving rise to a strong inference
17 that the defendant acted with the required state of mind" (15 USC §
18 78u-4(b)(2)). To meet the required state of mind element —
19 scienter — the complaint must allege "that the defendants made the
20 false or misleading statements either intentionally or with
21 deliberate recklessness." In re Daou Systems Inc, 411 F3d 1006,
22 1015 (9th Cir 2005), citing In re Silicon Graphics Securities
23 Litigation, 183 F3d 970, 974 (9th Cir 1999).

24 As noted above, the Prior Order dismissed the Prior
25 Complaint on December 4, 2008. Doc #69. The court based dismissal
26 on three grounds: (1) Nuvelo failed adequately to plead loss
27 causation because there were no allegations to support the fact
28 that the changes in the price of Nuvelo stock resulted from

1 defendants' fraudulent statements or omissions (Id at 6-17); (2)
2 the alleged fraudulent statements and omissions were not misleading
3 (Doc #69 at 17-32); (3) some of the alleged fraudulent statements
4 and omissions were protected by the PLSRA safe harbor for forward
5 looking statements (Id at 32-34). Defendants argue that none of
6 these maladies has been cured in the SAC and also that the SAC
7 fails to allege scienter. This order addresses these four issues
8 in turn.

9
10 A

11 The loss causation element of a securities fraud action
12 requires "a causal connection between the material
13 misrepresentation and the loss." Dura Pharmaceuticals v Broudo,
14 544 US 336, 342 (2005). "[A]s long as the complaint alleges facts
15 that, if taken as true, plausibly establish loss causation, a Rule
16 12(b)(6) dismissal is inappropriate. This is not 'a probability
17 requirement * * * it simply calls for enough fact to raise a
18 reasonable expectation that discovery will reveal evidence of' loss
19 causation." In re Gilead Scis Sec Litig, 536 F3d 1049, 1057 (9th
20 Cir 2008), quoting Bell Atlantic Corp v Twombly, 550 US 544, 556
21 (2007).

22 In the Prior Order, the court dismissed the Prior
23 Complaint, in part, because plaintiffs failed to link the alleged
24 fraudulent statements and omissions to changes in the price of
25 Nuvelo stock. While plaintiffs devoted many pages of the Prior
26 Complaint to a discussion of events prior to the start of the Class
27 Period, the only alleged material fraudulent statements and
28 omissions occurred during the Class Period. Doc #69 at 10. The

1 court analyzed Nuvelo's stock price before and after each of the
2 alleged fraudulent statements and omissions and found that the
3 stock price did not appear to respond in a material way to any of
4 the alleged misstatements or omissions. Id at 11. Additionally,
5 the alleged fraudulent statements consisted mostly of information
6 that was already known to the market before the Class Period began.
7 Id at 13. The court found that "[b]ecause the complaint does not
8 allege the relationship between the defendants' alleged
9 misstatements about phase 2 studies and the plaintiffs' loss" it
10 failed to plead loss causation. Doc #69 at 14.

11 Defendants argue that the loss causation deficiencies
12 pointed out in the Prior Order persist in the SAC. Defendants cite
13 language from the Prior Order stating "[t]he period of the alleged
14 price distortion and the class period in an open market securities
15 fraud action must coincide," Doc #78, quoting Doc #69 at 10, in
16 arguing that the court should dismiss the SAC. It appears,
17 however, that the court's prior statement was incomplete. While
18 loss causation is easier to allege if the stock price reacts
19 immediately to the alleged fraudulent statements or omissions in a
20 fraud on the market claim, there appear to be cases in which the
21 reaction of the stock price may not coincide, and thus the Class
22 Period may not coincide with the false or misleading statement.
23 For example, in In re Gilead Scis Sec Litig, 536 F3d 1049 (9th Cir
24 2008), the Ninth Circuit found that loss causation remained
25 plausible despite a "limited temporal gap" between a disclosure
26 correcting an alleged fraudulent statement and the ensuing decrease
27 in stock value. 536 F3d at 1058. In re Gilead found that the
28 corrective disclosure might plausibly have only affected the stock

1 price after subsequent events (negative economic data) made the
2 corrective disclosure's significance more apparent to the public.
3 536 F3d at 1058. This lag effect, according to the Ninth Circuit,
4 did not per se render loss causation implausible. Id.

5 The SAC contains sufficient new allegations that, if
6 taken as true, demonstrate loss causation. Plaintiffs now allege
7 that the fraud on the market began on May 26, 2005 — several
8 months prior to the start of the Class Period — and that the stock
9 price did not respond until January 5, 2006, the date of the Bayer
10 deal. Doc #76 at 53. The SAC alleges that the stock price
11 increased on January 5 due to "[t]he synergistic effect of
12 Defendants' false and misleading statements combined with
13 Defendants' new-found actual ability to fund the testing caused
14 Nuvelo's stock price to skyrocket." Id. This new allegation of a
15 synergy between the Bayer deal and the previous fraudulent
16 statements and omissions arguably renders the SAC's loss causation
17 allegations plausible — at least for pleading purposes. Id. If,
18 prior to the Bayer deal, Nuvelo did not have the financial ability
19 to fund phase 3 trials for alfimeprase, then investors might have
20 ignored Nuvelo's statements concerning the phase 2 trials. The
21 financial support provided by the Bayer deal on January 5 may have
22 therefore added new significance to defendants prior fraudulent
23 statements and omissions.

24 Additionally, defendants argue that the SAC fails to link
25 sufficiently the drop in the stock price on December 11, 2006 to
26 the alleged fraud. Doc #78 at 30-31. The Ninth Circuit has held
27 that "[a]s long as the misrepresentation is one substantial cause
28 of the investment's decline in value, other contributing forces

1 will not bar recovery under the loss causation requirement but will
2 play a role in determining recoverable damages." In re Daou
3 Systems Inc, 411 F3d 1006, 1025 (9th Cir 2005). Defendants argue
4 that December 11, 2006 was not only the date that defendants
5 corrected previous alleged fraudulent statements and omissions, but
6 it was also the date the market learned that alfimeprase failed
7 phase 3 trials. Doc #78 at 30. According to defendants, the SAC
8 fails to allege that the correction of the fraud, rather than the
9 failure of the trials, substantially caused plaintiffs' losses by
10 causing the stock price to plummet. Doc #78 at 30-31.

11 The SAC alleges that "[h]ad defendants corrected their
12 false statements and made meaningful disclosure of the risks prior
13 to or during the Class Period, Nuvelo's securities would not have
14 traded as high as they did during the Class Period, or would have
15 declined sooner than they did following the end of the Class
16 Period." Doc #76 at 83. The SAC alleges that defendants concealed
17 their knowledge — not that the phase 3 trials would certainly fail
18 — but that they included significant undisclosed risks. The
19 disclosures on December 11 that the trials failed, therefore,
20 revealed to the market not only the concealed risks of the trials
21 but also that those risks had led to the failure of the trials.
22 The drop in the stock price can be attributed in part to both
23 disclosures. And, as defendants argue, it is not clear on the face
24 of the SAC the exact amount to apportion to each of these
25 disclosures.

26 But, at this stage, plaintiff's allegations are
27 sufficient. The SAC alleges that "a substantial part of the
28 inflation" of the stock price eliminated on December 11 was the

1 result of the corrected fraud. Doc #76 at 87. This together with
2 the allegations about the synergistic Bayer deal plausibly suggest
3 that a substantial portion of plaintiffs' losses on Nuvelo stock
4 were the result of the alleged fraudulent statements and omissions.

5
6 B

7 The Prior Complaint contained similar allegations to
8 those of the SAC about the defendants' fraudulent statements and
9 omissions. See Doc #31. Both complaints alleged that defendants
10 omitted or downplayed risks that NAPA-2 was likely to fail because
11 the catheter effect inflated previous results in NAPA-1 about
12 restored blood flow in patients. Compare Doc #76 at 44, with Doc
13 #31 at 27. Both complaints also alleged that defendants omitted or
14 downplayed risks that SONOMA-2 was likely to fail due to the
15 agreement between Nuvelo and the FDA that to gain approval
16 alfimeprase would have to achieve a more stringent p-value than the
17 traditional measure. Compare Doc #76 at 42, with Doc #31 at 22.
18 Finally, both complaints allege that defendants omitted to disclose
19 a secret target p-value that they required SONOMA-2 to achieve in
20 order to ensure that alfimeprase would be commercially viable.
21 Compare Doc #76 at 18, with Doc #31 at 24-25. The SAC alleges
22 facts to bolster the allegations about the undisclosed risks of the
23 catheter effect and the more stringent p-value, but the allegations
24 about the undisclosed target product profile remain inadequate to
25 constitute a plausible securities fraud allegation.

26 1

27 The Prior Order found that the Prior Complaint failed to
28 allege that omissions about the catheter effect on the results of

1 the PAO trials were misleading. Doc #69 at 22-24. The Prior Order
2 found that defendants' disclosure that they assumed ten percent of
3 patients who received a placebo would avoid surgery was not
4 misleading because the market was aware of uncertainty related to
5 assumptions and there were no allegations that defendants knew the
6 catheter effect would cause any more than ten percent of placebo
7 patients to avoid surgery. Id.

8 The SAC contains two new allegations relevant to the
9 alleged fraudulent statements and omissions about the catheter
10 effect. The SAC alleges that defendant Love had access to
11 information during the phase 2 PAO trial, NAPA-1, indicating
12 whether patient blood clots were broken up by a catheter effect.
13 Doc #76 at 32. Specifically, the SAC alleges that Love "told
14 analysts he saw angiograms from NAPA-1" and that "[t]he appearance
15 on an angiogram of a clot broken up by a catheter is different than
16 that of a clot dissolved by a [] drug." Id. Additionally, the SAC
17 alleges that defendants took an "extraordinary measure" and
18 designed NAPA-2 to contain a secret group of thirty-eight patients
19 who were administered alfimeprase via a PT catheter that was solely
20 included in the phase 3 program to test the catheter effect. Id at
21 33-34.

22 Defendants argue that these new allegations are
23 insufficient because the SAC still does not allege that defendants
24 omitted to disclose a known risk that the catheter effect was
25 likely to cause the PAO phase 3 trial to fail. Doc #78 at 18-19.
26 Defendants argue that "[t]here is no basis to conclude that
27 Defendants included the [PT] group because they were concerned that
28 the catheter, as opposed to alfimeprase, was disrupting the clot in

1 a material number of patients." Doc #78 at 19. Defendants then
2 list a number of other reasons defendants may have included the PT
3 group. Id.

4 While it is true that there may be explanations for the
5 PT group other than defendants' knowledge of a significant and
6 undisclosed catheter effect, at this stage, plaintiffs' allegations
7 need only be plausible. The allegation about defendant Love's
8 access to information about the catheter effect during NAPA-1,
9 together with the alleged "extraordinary measure" of including a
10 secret PT group in the placebo group of NAPA-2, carries the SAC's
11 allegations beyond the threshold of plausibility.

12 2

13 Regarding the undisclosed stringent p-value for SONOMA-2,
14 the Prior Order found that the alleged fraudulent statements and
15 omissions in the Prior Complaint were not misleading. The court
16 found that the Prior Complaint failed to account for the difference
17 between a phase 3 program that seeks FDA approval based on one
18 placebo-controlled study and a program that seeks approval based on
19 two placebo-controlled studies. Id at 26. Defendants' failure to
20 disclose that they had a target p-value for SONOMA-2 of 0.00125 was
21 not misleading, according to the Prior Order, because a reasonable
22 investor would have been aware of FDA guidance on the subject,
23 which requires a more stringent p-value when a drug company seeks
24 approval based on a single trial. Doc #69 at 26.

25 The SAC does not ignore the relationship between the
26 number of placebo-controlled trials and the p-value, as did the
27 Prior Complaint. Instead, the SAC alleges that defendants misled
28 investors by failing to disclose that Nuvelo sought regulatory

1 approval based on one trial at a stringent p-value rather than two
2 trials at a more lenient p-value. The SAC alleges that defendants
3 statements that SONOMA-2 was modeled after the Genentech Activase
4 trial and that the phase 3 program for CO consisted of two pivotal
5 trials were materially false and misleading because defendants
6 failed to disclose that the p-value for SONOMA-2 was below the
7 "traditional" standard used in the Genentech Activase trial of
8 0.05. Doc #76 at 53, 54, 66, 68.

9 Defendants respond that the market was aware that the p-
10 value for SONOMA-2 was below 0.05. Doc #78 at 22-23. Defendants
11 disclosed that their phase 3 program for CO consisted of one
12 placebo-controlled trial (SONOMA-2) and one open-label single arm
13 study (SONOMA-3). Doc #76 at 53-54. According to defendants, the
14 market must have realized that because "Nuvelo was not conducting a
15 second placebo-controlled study," that SONOMA-2 would have to
16 follow FDA Guidance to substantiate a single study and achieve "'a
17 very low p-value.'" Doc #78 at 23, quoting Doc #80-41, Exh II at
18 19.

19 Defendants' argument about market knowledge relies on
20 publications by the FDA demonstrating that a single trial "very low
21 p-value" phase 3 program would be appropriate for the CO indication
22 of alfimeprase. FDA guidance, however, is not clear on the
23 subject. The FDA publication Guidance for Industry: Providing
24 Clinical Evidence of Effectiveness for Human Drug and Biological
25 Products (1998) ("FDA Guidance"), Doc #80-41, Exh II, states that
26 FDA approval based on a single study is limited. The FDA Guidance
27 states that the FDA has relied on a single study "generally only in
28 cases in which a single multicenter study of excellent design

1 provided highly reliable and statistically strong evidence of an
2 important clinical benefit, such as an effect on survival, and a
3 confirmatory study would have been difficult to conduct on ethical
4 grounds." Id at 7. The FDA Guidance also states that "reliance on
5 only a single study will generally be limited to situations in
6 which a trial has demonstrated a clinically meaningful effect on
7 mortality, irreversible morbidity, or prevention of a disease with
8 potentially serious outcome and confirmation of the result in a
9 second trial would be practically or ethically impossible. Id at
10 17. Because SONOMA-2 tested the ability of alfimeprase to restore
11 blood flow in occluded catheters — rather than to treat a serious
12 illness or life-threatening condition — it is plausible that
13 investors did not believe that FDA would approve alfimeprase based
14 on a single, "very low p-value," trial.

15 Defendants also argue that plaintiffs fail to allege with
16 particularity that "Defendants knew that the trial would not meet
17 the p-value and would cause phase [3] trials for CO and PAO to
18 fail." Doc #78 at 24. As defendants point out, "the fact that a
19 prediction proves to be wrong in hindsight does not render the
20 statement untrue when made.'" Doc #78 at 24, quoting In re Syntex
21 Corp Securities Litigation, 95 F3d 922, 929 (9th Cir 1996).

22 But the SAC need not allege that defendants knew SONOMA-2
23 would fail; the SAC need merely allege that defendants misled
24 investors by omitting to disclose a material risk that SONOMA-2
25 would fail. If concealing the target p-value during the Class
26 Period had the effect of substantially inflating the price of
27 Nuvelo stock, then knowledge of the undisclosed risk is the subject
28 of the material fraudulent statement or omission — not knowledge

1 that the trial would surely fail. It is unclear whether plaintiffs
2 will be able to meet a higher evidentiary standard to show that the
3 undisclosed p-value had an effect on the stock price, but taking
4 plaintiffs' allegations as true, the alleged fraudulent statements
5 and omissions about the agreement with the FDA on a 0.00125 p-value
6 survive defendants' motion to dismiss.

7 3

8 The SAC also alleges that defendants omitted to disclose
9 a "secret product profile" that defendants believed was necessary
10 for alfimeprase to meet in order to be a "commercial success." Doc
11 #76 at 18. The SAC alleged that this secret product profile was
12 more stringent than the standard for FDA approval and consequently,
13 and unbeknownst to investors, rendered commercialization of
14 alfimeprase even less likely.

15 Prior Complaint alleged a similar omission to disclose a
16 secret product profile and the court found it to be not misleading.
17 The Prior Order stated that "the risk that a product may receive
18 federal approval but not the marketplace's acceptance should be
19 obvious. Plaintiffs do not explain how defendants 'affirmatively
20 create[d] an impression of a state of affairs that differ[ed] in a
21 material way from the one that actually exist[ed]." Doc #69 at 30,
22 quoting Brody v Transitional Hospitals Corp, 280 F3d 997, 1006 (9th
23 Cir 2002). The SAC does not cure this defect. Accordingly, the
24 SAC's allegations about the omission to disclose the secret product
25 profile are DISMISSED for failure to state a claim.

26
27 C

28 Defendants also argue that the SAC, like the Prior

1 Complaint, alleges fraud for "forward-looking statements," which
2 are not actionable when accompanied by cautionary language under
3 the PLSRA safe harbor provision. Doc #78 at 29-30. The PLSRA
4 defines forward-looking statements as including "a projection of
5 revenues," "plans and objectives of management" and "assumptions
6 underlying or relating to" the above. 15 USC § 78u-5(i)(1)(A)-(D).
7 A defendant "shall not be liable" with respect to any forward-
8 looking statement that is "identified as a forward-looking
9 statement, and is accompanied by meaningful cautionary statements
10 identifying important factors that could cause actual results to
11 differ materially from those in the forward-looking statement." 15
12 USC § 78-u-5(c)(1). The Prior Order found that the Prior
13 Complaint's alleged fraudulent statements about alfimeprase's "path
14 to regulatory approval" and potential for "transformative"
15 commercial success were shielded by the PLSRA safe harbor
16 provision. Doc #69 at 32.

17 The SAC does not allege that defendants' optimistic
18 statements about alfimeprase's path to regulatory approval or
19 commercial success are the fraudulent statements giving rise to
20 liability. Rather, the SAC focuses on known present risks about
21 the interpretation of the phase 2 results and the design of phase
22 3. These statements were not allegedly misleading because they
23 failed to predict the future, but because they concealed or
24 downplayed known present risks related to regulatory approval.
25 Accordingly, the PLSRA does not shield defendants from liability
26 for the alleged fraudulent statements in the SAC.

27 //

28 //

D

1
2 Defendants also argue that the SAC's allegations fail to
3 create a strong inference of scienter. Doc #78 at 28. Defendants
4 state that the "far more compelling and cogent inference to be
5 drawn from the allegations in the SAC and the materials subject to
6 judicial notice is that Defendants were not engaged in fraud." Id
7 at 28 (emphasis in original). Defendants rely on the facts that
8 "[d]rug development is an inherently risky venture" and that
9 "Plaintiffs do not claim that Defendants knew the trials would not
10 succeed." Id. Defendants also emphasize that there are no
11 allegations that defendants sold their stock at the alleged
12 inflated prices during the Class Period and that Bayer invested in
13 Nuvelo after, one would think, extensive due diligence. Id at 28-
14 29. According to the stock records, only one of the individual
15 defendants sold any stock during the Class Period and one of the
16 individual defendants purchased stock during the Class Period. Doc
17 #80, Exh CC-FF.

18 As the Ninth Circuit has held, in securities cases
19 falsity and scienter "are generally strongly inferred from the same
20 set of facts and the two requirements may be combined into a
21 unitary inquiry under the PLSRA." In re Vantive Corp Securities
22 Litigation, 283 F3d 1079, 1091 (9th Cir 2002) (internal citations
23 omitted). The discussion of the allegedly misleading nature of the
24 fraudulent statements and omissions described above demonstrates
25 that, when the allegations in the complaint are taken as true, the
26 SAC satisfies the scienter element. As described above, the SAC
27 does not allege that defendants knew the alfimeprase phase 3 trials
28 would fail; the SAC alleges that defendants concealed known risks

1 of failure that, if disclosed, would have reduced the price of
2 Nuvelo's stock to account for the greater risk of failure. As
3 another district court has held, "[t]here is nothing wrong with
4 taking a calculated risk. However, if, as Plaintiffs allege,
5 Defendants misled Plaintiffs about such risk by making assurances
6 * * * , Defendants may be held liable." In re Amylin
7 Pharmaceuticals Securities Litigation, 2003 WL 21500525, at *5 (S D
8 Cal).

9
10 IV

11 Based on the foregoing, the SAC satisfies the heightened
12 pleading standards of the PSLRA in all but one respect. The
13 alleged fraudulent omission about the secret product profile are
14 not misleading under the same reasoning articulated in the Prior
15 Order. The other alleged fraudulent statements and omissions,
16 however, when taken as true, survive defendants motion to dismiss.
17 Accordingly, defendants' motion to dismiss (Doc #78) is GRANTED IN
18 PART and DENIED IN PART.

19 The parties shall meet and confer about a discovery and
20 pretrial preparation schedule and contact the courtroom deputy to
21 arrange a case management conference to be scheduled within sixty
22 days of the entry of this order.

23
24 IT IS SO ORDERED.

25 

26
27 VAUGHN R WALKER
28 United States District Chief Judge