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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

In re NUVELO, INC. SECURITIES
LITIGATION

) Master File No. 3:07-cv-04056-MJJ
)
) CLASS ACTION

This Document Relates To:
ALL ACTIONS.

) [PROPOSED] ORDER DENYING (1)
) DEFENDANTS' MOTION TO DISMISS
) CONSOLIDATED COMPLAINT FOR
) VIOLATIONS OF THE FEDERAL
) SECURITIES LAWS AND (2) DENYING IN
) PART AND GRANTING IN PART
) DEFENDANTS' REQUEST FOR JUDICIAL
) NOTICE

1 Before the Court are Defendants’ Motion to Dismiss Consolidated Complaint for Violations
2 of the Federal Securities Laws (“Motion to Dismiss) and Defendants’ Request for Judicial Notice
3 (“RJN). For the reasons stated herein, the Motion to Dismiss is DENIED in its entirety, and the
4 RJN is DENIED IN PART AND GRANTED IN PART.

5 **I. BACKGROUND**

6 This is a class action for securities fraud brought on behalf of a putative Class of investors
7 who purchased the publicly-traded securities of Nuvelo, Inc., (“Nuvelo of the “Company) between
8 January 5, 2006 and December 8, 2006 (the “Class Period). Plaintiffs allege that Nuvelo and three
9 of its four executive officers during the Class Period – Chief Executive Officer Ted Love, Chief
10 Financial Officer Gary Titus, and Vice President of Research and Development Michael Levy –
11 misled investors about the clinical trials for its lead product candidate, alfimeprase, for the treatment
12 of two medical conditions: catheter occlusion (“CO) and peripheral arterial occlusion (“PAO).

13 Plaintiffs allege that defendants misled investors in two principal respects. First, plaintiffs
14 allege that defendants knew, but failed to disclose, that for the Phase 3 CO clinical trials to succeed,
15 the results would have to reach a “p-value of 0.00125. A p-value is a measure of statistical
16 significance used by the U.S. Food and Drug Administration (“FDA) to determine whether the
17 results of a clinical drug trial are sufficient to establish that the drug is safe and effective, or whether
18 the results may instead be explained merely by chance. Plaintiffs allege that the FDA typically uses
19 a p-value of 0.05 to test statistical significance, a level that is 40 times less stringent than the p-value
20 used in the Phase 3 CO trial. Defendants do not dispute any of these facts.

21 Second, plaintiffs allege that defendants knew, but failed to disclose, that blood flow could
22 often be restored in patients suffering from PAO when the intravenous catheter used to deliver the
23 drug disrupted the blood clots originally causing the blockage in flow. Plaintiffs allege that
24 defendants’ failure to disclose this fact misled investors about the significance of the results of Phase
25 2 alfimeprase trials for PAO, which did not involve a placebo arm, and the risks to the success of the
26 Phase 3 PAO trials that were ongoing during the Class Period, which did contain a placebo arm.
27 Again, defendants do not dispute that they knew that the catheter used in the Phase 2 trial could have

1 restored blood flow in some of the patients being tested, nor do they contend that the risk this
 2 presented to the reliability of the Phase 2 results or the potential success of the Phase 3 trial was ever
 3 specifically disclosed to investors.

4 Plaintiffs allege that the failure to disclose these facts caused certain statements defendants
 5 made during the Class Period to become misleading by omission, including statements about: (1) the
 6 extent to which alfimeprase had “demonstrated its ability to dissolve clots in the Phase 2 PAO
 7 trials, and that, based on these results, Nuvelo had designed a Phase 3 clinical trial that, even with
 8 “conservative assumptions about placebo rates, had “overwhelming statistical power to succeed;¹
 9 (2) statements that, based on the convincing results of the Phase 2 trials, where alfimeprase was so
 10 successful Nuvelo had closed the trial early, defendants “expect the Phase 3 trial results to confirm
 11 the ability of alfimeprase to restore function to occluded catheters in 15 minutes or less, as
 12 demonstrated in our Phase 2 trial (¶¶54, 100); and (3) statements that the PAO and CO indications
 13 provided a “low risk path to regulatory approval and a “rapid and low risk entry strategy with a
 14 “high probability of success that would allow alfimeprase to be “rapid to market where it could be
 15 exploited for treatment of more financially-lucrative conditions, including deep vein thrombosis and
 16 ischemic stroke (¶¶6, 71, 94, 95, 101, 102, 109).

17 Plaintiffs allege that the truth concealed by defendants’ alleged fraudulent statements and
 18 omissions was revealed to the market on December 11, 2006, when Nuvelo first announced that both
 19 the Phase 3 trials had failed because alfimeprase had not performed any better than a placebo in
 20 _____

21 ¹ ¶¶69, 92, 101, 116, 120, 125. *See also* ¶92 (“Alfimeprase . . . has been shown in clinical
 22 studies to provide rapid clot dissolution.); ¶116 (the “announced results from the NAPA-1 trial, a
 23 Phase 2 dose escalation study, demonstrated that alfimeprase can restore arterial blood flow within
 24 four hours of initiation of dosing); ¶120 (the Company “took a conservative case scenario and
 25 allowed for a certain percentage of patients to be deemed to respond to placebo and that, even so
 26 “the statistical power is still overwhelming for this trial) and (in talking about the Phase 3 PAO
 27 trial, Titus told investors that: “really the driver here is not the statistical power for approving
 efficacy, because we believe that can be done with a relatively small patient sample, but we need to
 generate a reasonable size patient safety database to seek approval. We believe we still have
 overwhelming statistical power to detect the difference between active therapy such as alfimeprase –
 which is indeed very active based on our Phase 2 studies to date – and placebo.) Unless otherwise
 noted, paragraph references (“¶__ or “¶¶__) are to the Consolidated Complaint for Violations of
 the Federal Securities Laws filed on November 9, 2007 (the “Complaint).

28

1 clearing catheters in the PAO trial, and that alfineprase had failed to achieve the required p-value of
2 0.00125 to achieve success in the CO trial. ¶¶10-11, 60-63, 84-88, 153-59.

3 **II. LEGAL STANDARD**

4 (a) Fed. R. Civ. P. 12(b)(6)

5 A motion to dismiss pursuant to Rule 12(b)(6) tests the legal sufficiency of a claim. *Navarro*
6 *v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Because the focus of a 12(b)(6) motion is on the legal
7 sufficiency, rather than the substantive merits of a claim, the Court ordinarily limits its review to the
8 face of the complaint. *See Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir.
9 2002). Generally, dismissal is proper only when plaintiff has failed to assert a cognizable legal
10 theory or failed to allege sufficient facts under a cognizable legal theory. *See SmileCare Dental*
11 *Group v. Delta Dental Plan of Cal., Inc.*, 88 F.3d 780, 782 (9th Cir. 1996); *Balisteri v. Pacifica*
12 *Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988); *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d
13 530, 534 (9th Cir. 1984). Further, dismissal is appropriate only if it appears beyond a doubt that
14 plaintiff can prove no set of facts in support of a claim. *See Abramson v. Brownstein*, 897 F.2d 389,
15 391 (9th Cir. 1990). In considering a 12(b)(6) motion, the Court accepts the plaintiff's material
16 allegations in the complaint as true and construes them in the light most favorable to the plaintiff.
17 *See Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000).

18 (b) Section 10(b) of the Securities Exchange Act

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

23 Relatedly, Rule 10b-5 makes it unlawful for any person to use interstate commerce:

24 (a) to employ any device, scheme, or artifice to defraud;

25 (b) to make any untrue statement of material fact or to omit to state a material
26 fact necessary in order to make the statements made, in the light of the
circumstances under which they were made, not misleading; or

27 (c) to engage in any act, practice, or course of business which operates or would
28 operate as a fraud or deceit upon any person, in connection with the purchase
or sale of any security.

1 17 C.F.R. §240.10b-5.

2 For a claim under §10(b) and Rule 10b-5 to be actionable, a plaintiff must allege: (1) a
3 misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the
4 plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184
5 F.3d 1059, 1063 (9th Cir. 1999). Concomitantly, as indicated above, pursuant to Fed. R. Civ. P. 9(b),
6 to survive dismissal, plaintiff must plead both the falsity and scienter elements with particularity.
7 *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001). As the Ninth Circuit explained:

8 Because falsity and scienter in private securities fraud cases are generally strongly
9 inferred from the same set of facts, we have incorporated the dual pleading
10 requirements of 15 U.S.C. §§78u-4(b)(1) and (b)(2) into a single inquiry. In
11 considering whether a private securities fraud complaint can survive dismissal under
12 Rule 12(b)(6), [the court] must determine whether ‘particular facts in the complaint,
13 taken as a whole, raise a strong inference that defendants intentionally or [with]
14 ‘deliberate recklessness’ made false or misleading statements to investors.’ Where
15 pleadings are not sufficiently particularized or where, taken as a whole, they do not
16 raise a ‘strong inference’ that misleading statements were knowingly or [with]
17 deliberate recklessness made to investors, a private securities fraud complaint is
18 properly dismissed under Rule 12(b)(6).

19 *Id.* (citations and internal quotation marks omitted).

20 In 1995, Congress enacted the Private Securities Litigation Reform Act (“PSLRA”), which
21 strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of
22 material misstatements or omissions under the PSLRA must “specify each statement alleged to have
23 been misleading, the reason or reasons why the statement is misleading, and, if an allegation
24 regarding the statement or omission is made on information and belief, the complaint shall state with
25 particularity all facts on which that belief is formed. 15 U.S.C. §78u-4(b)(1). The pleading
26 requirements of the PSLRA were recently clarified by the Supreme Court, in *Tellabs, Inc. v. Makor*
27 *Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007).

28 In determining whether a plaintiff has adequately alleged scienter, “courts must consider the
complaint in its entirety. . . . The inquiry is whether *all* of the facts alleged, taken collectively, give
rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation,
meets that standard. *Tellabs*, 127 S. Ct. at 2509, 2511 (emphasis in original). A strong inference of

1 scienter arises if, “[w]hen the allegations are accepted as true and taken collectively, a reasonable
2 person would “deem the inference of scienter at least as strong as any opposing inference[.]” *Id.*

3 In holding that “[t]he inference that the defendant acted with scienter need not be irrefutable,
4 *i.e.*, of the ‘smoking gun’ genre, or even the ‘most plausible of competing inferences,’ *id.* at 2510,
5 the Supreme Court lowered the standard for pleading scienter in this Circuit. Where previously,
6 under *Gompper v. VISX, Inc.*, 298 F.3d 893 (9th Cir. 2002), inferences supporting scienter had to be
7 more plausible than non-culpable inferences, now the inferences need be only equally plausible.
8 Hence, under *Tellabs*, “a tie goes to the Plaintiff. *Comm’n. Workers of Am. Plan for Employees’*
9 *Pensions & Death Benefits v. CSK Auto Corp.*, No. CV06-1503-PHX-DGC, 2007 U.S. Dist. LEXIS
10 72424, at *9 (D. Az. Sept. 27, 2007); *Sloman v. Presstek, Inc.*, No. 06-cv-377-JD, 2007 U.S. Dist.
11 LEXIS 69475, at *22 (D.N.H. Sept. 18, 2007).²

12 III. REQUEST FOR JUDICIAL NOTICE

13 At the motion to dismiss stage, the Court may only consider material within the four corners
14 of the complaint. *Branch v. Tunnell*, 14 F.3d 449, 453-54 (9th Cir. 1994). A court may, however,
15 consider documents properly submitted as part of the complaint or, under the incorporation rule,
16 documents upon which the complaint necessarily relies and the authenticity of which is not disputed.
17 *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001). The purpose for this exception is
18 to allow the court to assess the complaint allegations in context. The court may take judicial notice
19 of facts: (1) generally known within the community; or (2) “capable of accurate and ready
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21
22 ² At this stage of the litigation, a court may not “weigh the evidence that might be presented at
23 trial, but must simply determine “whether the complaint itself is legally sufficient. *In re*
24 *Converium Holding AG Sec. Litig.*, No. 04 Civ. 7897 (DLC), 2007 U.S. Dist. LEXIS 67660, at *8
25 (S.D.N.Y. Sept. 14, 2007); *see also In re NPS Pharm., Inc. Sec. Litig.*, No. 2:06-cv-00570, 2007 U.S.
26 Dist. LEXIS 48713, at *10 (D. Utah July 3, 2007) (“NPS makes various claims in support of its
27 argument that the plaintiff has failed to plead particularized facts establishing the defendants’
28 statements were false and misleading when made. The problem with all of NPS’s claims is that they
require the court to weigh evidence. Therefore, they are inappropriate at the motion to dismiss
stage.). As the Ninth Circuit observed with respect to motions to dismiss: “Our function is satisfied
when we identify issues sufficiently pled to raise triable questions. We need not consider the
probability of success. *In re Syncor*, 239 Fed. Appx., 318, 321 (9th Cir. 2007).

1 determination by resort to sources whose accuracy cannot reasonably be questioned. Fed. R. Evid.
2 201(b); *Lee*, 250 F.3d at 689.

3 Defendants seek judicial notice of various Securities Exchange Commission (“SEC”) filings,
4 press releases, and other documents submitted with the motion. The Court finds that, to the extent
5 these documents may properly be considered, the incorporation doctrine provides adequate ground
6 for the Court to do so. *Lee*, 250 F.3d at 688-89. The Court does not take judicial notice of the *truth*
7 of the matters set forth in these documents, but takes judicial notice only of the fact that the
8 statements were made on the dates indicated. *Id.* at 688-90; *In re NorthPoint Commc’n Group, Inc.,*
9 *Sec. Litig. & Consol. Cases*, 221 F. Supp. 2d 1090, 1095 (N.D. Cal. 2002).

10 Exhibits A-H and J-Q provided by defendants, as well as Exhibits 1 and 2 submitted by
11 plaintiffs in connection with their opposition to the judicial notice request, consist of press releases,
12 conference call transcripts and other sources explicitly relied upon in the Consolidated Complaint for
13 Violation of the Federal Securities Laws (“Complaint”). The Court therefore has considered these
14 materials under the incorporation doctrine. *Lee*, 250 F.3d at 688-89. The Court will take judicial
15 notice of the fact that the statements were made on the dates indicated, but will not take judicial
16 notice of the truth of any of the statements contained therein. *Shurkin v. Golden State Vintners*, 471
17 F. Supp. 2d 998, 1011 (N.D. Cal. 2006).

18 The Court declines to take judicial notice of or otherwise consider any of the other
19 documents submitted by the parties.³

20 **IV. RULE 12(b)(6) ANALYSIS**

21 It is well established that securities fraud liability may lie where a defendant knowingly or
22 recklessly makes false or misleading statements about ongoing drug studies, including failing to
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25 ³ Plaintiffs have also submitted additional exhibits, consisting of certain clinical trial data for
26 alimeprase’s PAO and CO trials that was published after the Complaint was filed. Plaintiffs
27 submitted these exhibits for the purpose of demonstrating additional facts that could be pled should
28 amendment of the Complaint be required. Given the Court’s finding that the existing Complaint
adequately pleads a claim for securities fraud, the Court finds there is no need to consider these
documents.

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1 disclose facts giving rise to increased risks relating to drug approval or commercialization. *E.g., In*
2 *re Amylin Pharm., Inc. Sec. Litig.*, No. 01cv1455 BTM (NLS), 2003 U.S. Dist. LEXIS 7667, at *23
3 (S.D. Cal. May 1, 2003) (“If a defendant states that it believes or expects that the FDA will approve
4 its drug but has information tending to seriously undermine the accuracy of its statement, the
5 statement is actionable. ”); *In re Viropharma, Inc. Sec. Litig.*, No. 02-1627, 2003 U.S. Dist. LEXIS
6 5623 (E.D. Pa. Apr. 7, 2003); *In re NeoPharm, Inc. Sec. Litig.*, No. 02C2976, 2003 Dist. LEXIS
7 1862, at *43-*44 (N.D. Ill. Feb. 7, 2003).

8 It is also well established that, in an omissions case such as this one, the capacity to mislead
9 investors cannot be measured merely by the “literal truth” of a statement because even a literally true
10 statement can be misleading through its context and manner of presentation if by “fair and
11 reasonable implication an ordinary investor” would be misled. *Miller v. Thane Int’l, Inc.*, 508 F.3d
12 910, 917 (9th Cir. 2007). Literal truth is an insufficient defense because “an issuer’s public
13 statements cannot be analyzed in complete isolation, but must be read in context. *In re Convergent*
14 *Tech. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991).

15 **A. Falsity and Scienter Are Both Adequately Pled**

16 Because falsity and scienter are commonly demonstrated by the same facts, the Court will
17 consider these issues together. *Ronconi*, 253 F.3d at 429. Reading the Complaint holistically and
18 presuming the truth of its allegations, as *Tellabs* requires, the Court has little difficulty in
19 concluding, at this stage of the litigation, that the statements complained of were materially
20 misleading to investors, and that each of the defendants acted with scienter in communicating this
21 misleading information to the market.

22 **1. PAO Trials**

23 The gravamen of plaintiffs’ claim, as outlined above, is that defendants misled investors by
24 failing to disclose the known fact that the catheter used to deliver alfineprase to PAO patients could
25 cause blood clots to be disrupted, thus relieving the symptoms for which treatment was sought. As a
26 result, plaintiffs’ contend, there was no way to reliably determine the extent to which the Phase 2
27 trials reflected action of the drug, or merely the effect of the catheter. As a result, plaintiffs’
28

1 contend, the statements described above regarding both the results of the Phase 2 trials and the
2 “overwhelming statistical power for the Phase 3 trials to succeed were materially false and
3 misleading to investors.

4 Plaintiffs’ claim in this respect is clearly supported by the statement of defendant Love
5 during a December 11, 2006 conference call held to discuss the failure of the drug trials, where he
6 admitted that the Company had “always known that clots could be disrupted simply by inserting the
7 drug delivery catheter:

8 So to be clear, its always been known that mechanical devices can work and
9 probably what mechanical devices do is increase the surface area of the clot which is
10 in contact with uncoagulated blood and that facilitates much like breaking an ice
11 cube apart would facilitate dissolution in water.

12 See Exhibit 1 to the Declaration of Dennis J. Herman in Support of Plaintiffs’ Opposition to
13 Defendants’ Motion to Dismiss Consolidated Complaint for Violation of the Federal Securities Laws
14 (“Herman Decl. ”); ¶37. Love further admitted that this risk, which had never been previously
15 disclosed to investors, was likely the primary cause of the misleading Phase 2 results:

16 Jim Birchenough: So I’m trying to understand why that might not have happened
17 in the Phase 2 experience where it seems you had higher
18 thrombolysis rates?

19 Dr. Ted W. Love: . . . I actually think it did probably happen in Phase 2.

20 Herman Decl., Ex. 1; ¶62.

21 In seeking dismissal of the Complaint, defendants do not directly challenge this admission,
22 but instead dispute the reports of certain confidential witnesses described in the Complaint. These
23 witnesses generally describe that Love and Levy each had significant responsibilities for the design
24 and/or conduct of the PAO trials and, in one instance, recount that the risk was specifically raised
25 internally during a pre-Class Period meeting at Nuvelo as a possible explanation for the seemingly
26 positive Phase 2 results. ¶40. While these allegations, standing alone, might not be enough to
27 demonstrate scienter, the Court finds that, in combination with Love’s admissions set forth above,
28 they meet the PSLRA pleading requirements. *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1232, 1234 (9th Cir. 2004) (corporate executives admissions as to what they knew and what information they had access to collectively sufficient to raise strong inference of

1 scienter); *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.*,
 2 320 F.3d 920, 943 n.21 (9th Cir. 2003) (rejecting as “patently incredible, that high-ranking officers
 3 were unaware of major business events likely to have a significant impact on company’s financial
 4 condition).

5 The Court is not persuaded by defendants’ contention that the reports of these witnesses
 6 should be discounted merely because some of them left Nuvelo prior to the Class Period. Rather, the
 7 Court is persuaded, under the circumstances of this case, that the information provided by these
 8 witnesses is sufficient to demonstrate, for purposes of pleading, that the undisclosed facts and
 9 heightened risks to the on-going clinical trials were known to defendants prior to the time that they
 10 made the statements alleged to be misleading. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72
 11 (2d Cir. 2001) (pre-class period data relevant to show knowledge at start of class period); *In re*
 12 *Merck & Co. Sec. Litig.*, 432 F.3d 261, 272 (3rd Cir. 2005). This is a more than sufficient basis on
 13 which to credit the information they provide. *Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th
 14 Cir. 2005); *see also In re Cabletron Sys., Inc.*, 311 F.3d 11, 29-30 (1st Cir. 2002).

15 Nor is the Court persuaded by defendants’ contention that, to successfully plead a claim
 16 under the circumstances of this case, plaintiffs must establish both defendants’ knowledge of the
 17 undisclosed risks and that they knew the trials would fail because of those risks. Defs.’ Mem. at 2,
 18 12, 18.⁴ Plaintiffs need not plead that defendants knew that the trials would fail. Rather, plaintiffs
 19 need only plead facts supporting the inference that defendants knew of the undisclosed facts and
 20 concealed risks, because it was the material omission of this information that misled investors about
 21 the current prospects for success of the alfimeprase trials:

22 Whether the Defendants had to predict the FDA’s decision is irrelevant. They are
 23 liable under 10b-5 if they made statements that a reasonable investor would consider
 24 in deciding whether to buy stock. All investing is based on investor’s perceptions
 about the future. . . . Accuracy in these types of factual statements lies at the heart of
 what the securities laws are trying to protect.

25
 26 ⁴ “Defs.’ Mem. refers to Defendants’ Notice of Motion and Motion to Dismiss Consolidated
 27 Complaint for Violations of the Federal Securities Laws; Memorandum of Points and Authorities,
 filed on December 21, 2007.

1 *Viropharma*, 2003 U.S. Dist. LEXIS 5623, at *17-*18; *see also* *Warshaw v. Xoma Corp.*, 74 F.3d
2 955 (9th Cir. 1996) (predictions of FDA approval made while discounting risks to ongoing clinical
3 trials are actionable statements); *In Re Xcel Energy, Inc., Sec., Deriv. & "ERISA" Litig.*, 286 F.
4 Supp. 2d 1047, 1058 (D. Minn. 2003) (court rejected defendants' claim that they were not obligated
5 to disclose risky provisions in the company's credit facilities because they did not have a "crystal
6 ball to foresee that the provisions would come into play; defendants' assertions did "not address
7 defendants' duty to give complete information on a subject once raised).

8 2. CO Trials

9 The foregoing discussion is equally applicable to plaintiffs' claims that defendants misled
10 investors about the conduct of the CO trials. Plaintiffs need only plead that defendants were
11 deliberately reckless to the existence of the material risks to that trial – *i.e.*, the 0.00125 p-value –
12 and knew that the facts giving rise to that risk had not been disclosed to investors. Again, the Court
13 has little difficulty in concluding, given the existence of an express agreement with the FDA
14 requiring this p-value to be met, together with defendants' roles in and responsibility for the drug
15 development efforts and the importance of alimeprase to the Company's overall financial success,
16 that each of the defendants knew about this p-value at the time they made optimistic statements to
17 the market regarding the reliability of the Phase 2 data and the likelihood of success of the Phase 3
18 trials. *Nursing Home Pension Fund, Local 144*, 380 F.3d at 1234; *Am. West*, 320 F.3d at 943.

19 Nor is the Court persuaded that investors knew that a standard for statistical significance
20 lower than the traditional p-value of 0.05 imposed by the FDA was being used in the CO trials. As
21 plaintiffs correctly point out, Nuvelo reported to investors that there would be two pivotal trials for
22 the Phase 3 trial of alimeprase. ¶100. Since defendants' entire argument is premised on their
23 contention that investors understood that only a single pivotal trial was being performed, their
24 argument fails of its own accord. Moreover, the Court notes that, even if only one trial were being
25 performed, nothing in the FDA guidance documents relied upon by defendants require a p-value of
26 0.00125 to be used, much less put investors on notice that such a stringent requirement for
27 demonstrating statistical significance had been imposed. Defendants' repeated reliance on the

1 comparisons with a prior drug trial performed by Genentech – where a p-value of 0.05 was used –
2 together with the suspicious connection between the required p-value and the “target market profile
3 for the drug – which was also undisclosed to investors during the Class Period – make it crystal clear
4 to this Court that dismissal at this juncture is not warranted.

5 3. **Statements About the “Low Risk” Nature of the CO and PAO** 6 **Trials**

7 Plaintiffs allege that, throughout the Class Period, defendants repeatedly told investors that
8 Nuvelo was starting its clinical testing of alfimeprase with the PAO and CO indications because that
9 provided a “low risk path to regulatory approval and a “rapid and low risk entry strategy with a
10 “high probability of success. ¶¶6, 71, 94, 95, 101, 102, 109. The Court finds that, for the reasons
11 set forth above, these defendants knew or were deliberately reckless to the fact that these statements
12 were materially false and misleading to investors because they failed to disclose known, substantial
13 risks to the ongoing trials – *i.e.*, that the seemingly positive Phase 2 PAO results could have been
14 caused by the catheter dislodging the blood clot rather than alfimeprase dissolving it, and that, for
15 the CO trial to succeed, an extraordinarily difficult p-value of 0.00125 had to be met. *Miller*, 508
16 F.3d at 917; *Convergent*, 948 F.2d at 512.

17 The Court further finds that, at this stage, it cannot be said that defendants’ risk warnings
18 were sufficient to prevent investors from being misled, because neither of the specific risks described
19 above were disclosed by those warnings. When considered together with defendants’ public
20 statements touting the Phase 2 results for both indications and strongly suggesting that the Phase 3
21 trials would succeed and the drug would be marketable, it is possible to conclude, as plaintiffs allege,
22 that the generic and incomplete risk warnings contained in Nuvelo’s public SEC filings were
23 materially misleading to investors. *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1122 (C.D.
24 Cal. 2005); *Amylin*, 2003 U.S. Dist. LEXIS 7667, at *21 (“[t]he warnings were not tailored to
25 Defendants’ statement regarding the sufficiency of the trial results); *In re Seebeyond Tech.*
26 *Corp. Sec. Litig.*, 266 F. Supp. 2d 1150, 1169 (C.D. Cal. 2003) (cautionary language is not
27 meaningful where “it does not sufficiently identify those facts that the plaintiff alleges made the
28 press release false or misleading); *In re InfoSonics Corp. Sec. Litig.*, No. 06cv1231 BTM(WMc),

1 2007 U.S. Dist. LEXIS, at *30-*31 (S.D. Cal. Aug. 7, 2007) (language did not contain “meaningful
2 cautionary statements because it did not reveal that “[d]efendants already knew that Infosonics had
3 lost its biggest U.S. customer. . .). Accordingly, defendants have failed to meet their burden to
4 establish that there was enough cautionary language so that ‘reasonable minds could not disagree
5 that the challenged statements were not misleading. *Livid Holdings Ltd. v. Salomon Smith Barney,*
6 *Inc.*, 403 F.3d 1050, 1056 (9th Cir. 2005); *Asher v. Baxter Int’l Inc.*, 377 F.3d 727, 734 (7th Cir.
7 2004) (“[t]here is . . . no reason that a court can accept at the pleading stage, before plaintiffs have
8 access to discovery – that the items mentioned in [defendant’s] cautionary language were those that
9 at the time were the (or any of the) ‘important’ sources of variance’).

10 4. Motive Allegations

11 The Court further finds that plaintiffs’ allegations of significant stock sales by defendants
12 Nuvelo and Titus, the substantial bonuses obtained by the individual defendants, and the pattern of
13 announcing positive trial results for alfineprase as the urgent need for additional financing arose
14 serve to bolster the already strong showing of scienter. ¶¶4, 28-31, 145-47. While these allegations,
15 standing alone, might be insufficient, when considered collectively and interpreting the Complaint as
16 a whole, they do lend additional support for finding a strong inference of scienter has been pled here.
17 *See In re Portal Software, Inc. Sec. Litig.*, No. C-03-5138 VRW, 2005 U.S. Dist. LEXIS 20214, at
18 *36 (N.D. Cal. Aug. 10, 2005) (contention that “defendants were motivated to inflate artificially
19 Portal’s stock price in the short term in order to conduct a successful secondary public offering and
20 obtain much-needed operating capital’ does allege facts of a palpable motive for fraud). The Court
21 further finds that the fact that some defendants did not sell stock is insufficient to defeat the
22 inference of scienter, or to diminish the inferences flowing from the other facts alleged by plaintiffs.
23 *Tellabs*, 127 S. Ct. at 2511 (“the absence of a motive allegation is not fatal.); *Am. West*, 320 F.3d at
24 944 (“Scienter can be established even if the officers who made the misleading statements did not
25 sell stock during the class period. In other words, the lack of stock sales by a defendant is not
26 dispositive of scienter.); *Daou*, 411 F.3d at 1022 (the PSLRA “neither prohibits nor endorses the
27 pleading of insider trading as evidence of scienter . . .).

1 **B. Group Publication**

2 The “group publication doctrine misnamed as such by defendants permits the Court to infer,
3 at the pleading stage, that statements alleged to be false were made by corporate officers who had
4 day-to-day responsibility for the business operations which are the subject of the statement. *Wool v.*
5 *Tandem Computers, Inc.*, 818 F.2d 1433, 1440 (9th Cir. 1987); *In re GlenFed, Inc. Sec. Litig.*, 60
6 F.3d 591, 593 (9th Cir. 1995). Because the Ninth Circuit has not overturned *Wool* or *GlenFed* in this
7 respect, the group publication doctrine continues to survive in this Circuit following the enactment of
8 the PSLRA. *In re PETsMART, Inc. Sec. Litig.*, 61 F. Supp. 2d 982, 997 (D. Ariz. 1999) (“the
9 doctrine survives the PSLRA ”); *Pegasus Holdings v. Veterinary Ctrs. of Am., Inc.* 38 F. Supp. 2d
10 1158, 1165 (C.D. Cal. 1998); *In re Stratosphere Corp. Sec. Litig.*, 1 F. Supp. 2d 1096, 1108 (D. Nev.
11 1998) (“[d]efendants offer no case authority for their *proposition that group pleading has been sub*
12 *silentio* abolished by the PSLRA ”) (emphasis in original).

13 The Court finds that plaintiffs’ allegations regarding the responsibilities of Love, Levy and
14 Titus, Nuvelo’s small size, and the actual participation of each of these defendants in communicating
15 information about alfimeprase to investors during the Class Period are sufficient to support the
16 allegation that each of these defendants is responsible for “making those statements within the
17 meaning of the federal securities laws.

18 **C. Safe Harbor**

19 Defendants assert that certain statements are subject to dismissal under the PSRLA’s “safe
20 harbor protections for forward-looking statements. The Court finds that defendants have failed to
21 carry their burden of identifying the specific statements challenged on this ground, or explaining
22 why the statements are forward-looking. The Court further finds, based on a review of the
23 paragraphs cited by defendants in support of their conclusory argument, that the statements
24 contained therein are primarily representations about current or historical facts, rather than future
25 events.⁵ Accordingly, the Court does not find any ground to dismiss the Complaint based upon

26 _____
27 ⁵ ¶92 (Alfimeprase “ has been shown in clinical studies to provide rapid clot dissolution. ”);
28 ¶93 (The alfimeprase testing data “suggest[ed] a dramatic feat of action. ”); ¶100 (“We . . . expect the

1 defendants' safe harbor arguments. *Amylin*, 2003 U.S. Dist. LEXIS 7667, at *16 ("observed facts
2 about [drug] trial results and data are not forward-looking statements); *see also Am. West*, 320 F.3d
3 at 937 (holding that if statements of past facts and their present effects upon the company were found
4 to be forward-looking, "any corporation could shield itself from future exposure for past misconduct
5 by making present-tense statements regarding the misconduct and its effects on the corporation,
6 thereby eviscerating the Exchange Act); *In re Secure Computing Corp. Sec. Litig.*, 120 F. Supp. 2d
7 810, 818 (N.D. Cal. 2000) (statement that company was on track to meet expectations not forward-
8 looking).

9 **D. Puffery**

10 The Court rejects defendants' puffery argument on similar grounds. Defendants fail to meet
11 their burden of identifying the statements they contend are susceptible to dismissal on this ground, or
12 adequately explaining why this is so. A review of the paragraphs cited by defendants in support of
13 their conclusory argument again fails to support their contention that the statements contain only
14 "generalized, vague and unspecific assertions. *Glen Holly Entm't, Inc. v. Tektronix Inc.*, 352 F.3d
15 367, 379 (9th Cir. 2003); *In re Dura Pharm., Inc. Sec. Litig.*, 452 F. Supp. 2d 1005, 1033 (S.D. Cal.
16 2006) ("Statements that fall within the [puffery] rule tend to use terms that are not measurable and
17

18 Phase 3 trial results to confirm the ability of alfimeprase to restore function to occluded catheters in
19 15 minutes or less, as demonstrated in our Phase 2 trial.); ¶101 ("We have always known that
20 alfimeprase holds the potential to treat a wide range of clot disorders and that acute PAO and
21 catheter occlusion represented the most rapid and low risk market entry strategy for us.); ¶108
22 ("The Phase 2 results indicate that alfimeprase has the potential to offer significant advances in the
23 rapid resolution of a blood clot. . . . Analysis of the Phase 2 results showed that alfimeprase has the
24 potential to partially or completely break up blood clots within four hours.); ¶116 (The Phase 2
25 results "demonstrated that alfimeprase can restore arterial blood flow within four hours of initiation
26 of dosing.); ¶120 ("[W]e took a very conservative case when we prepared the [Phase 3 NAPA]
27 trial.) ("[T]he statistical power is still overwhelming for this [Phase 3 NAPA] trial.); *Id.* ("[T]he
28 driver here is not the statistical power for approving efficacy.); *Id.* ("[A]lfimeprase . . . is indeed
very active based on our Phase 2 studies to date.); *Id.* (Nuvelo's "collaboration with Bayer
HealthCare to develop and commercialize alfimeprase continues to go very well, and [that Nuvelo
was] tracking to [its] goals and milestones laid out for the program.); ¶124 ("[W]e were very
gratified . . . to find that alfimeprase worked very well on big clots and on small clots, and . . . we've
had some examples of very large clots, clots up to 60 centimeters in length, that we've dissolved
rapidly.); ¶125 (Alfimeprase "worked on what we thought were new clots and old clots.); *Id.*
("[W]e were gratified that in 40% of those patients as well we could see improvements on the
angiogram and restoration of blood flow.). *Id.*

1 not tethered to facts that a reasonable person would deem important to a securities investment
2 decision.’). Accordingly, the Court rejects defendants’ Motion to Dismiss on this ground as well.

3 **E. Loss Causation**

4 Defendants do not contend that the Complaint fails to plead loss causation with respect to
5 statements alleged to be misleading by reason of the omission of material facts regarding the ability
6 of the catheter to disrupt clots in PAO patients or the stringent p-value imposed on the Phase 3 CO
7 trial. Accordingly, the Court does not find any support for dismissing the Complaint on this ground.

8 To the extent defendants seek dismissal on loss causation grounds with respect to defendants’
9 statements regarding the market potential of alfimeprase, the Court finds that defendants’ omissions
10 regarding the target market for CO are inextricably linked to the omissions regarding the required p-
11 value for that study, such that loss causation is sufficiently pled for those claims as well. *Dura*
12 *Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005).

13 **F. Control Person Liability**

14 Given the Court’s finding that plaintiffs have adequately pled a §10(b) violation, the Court
15 rejects defendants’ argument to dismiss plaintiffs’ claims under §20(a) for lack of a predicate
16 violation. The Court further finds that plaintiffs’ allegations of control are also sufficient to permit
17 this claim to proceed. ¶¶17-20, 178; *Am. West*, 320 F.3d at 945; *Wool*, 818 F.2d at 1441 (“where . . .
18 the corporate officers are a narrowly defined group charged with the day-to-day operations of a
19 public corporation, it is reasonable to presume that these officers had the power to control or
20 influence the particular transactions giving rise to the securities violation).

21 **V. CONCLUSION**

22 For the reasons set forth above, the Motion to Dismiss is DENIED and the Request for
23 Judicial Notice is GRANTED IN PART AND DENIED IN PART.

24 SO ORDERED.

25 DATED: _____

THE HONORABLE MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

27 Submitted by:

28 [PROPOSED] ORDER DENYING (1) DEFS.’ MOTION TO DISMISS CONSOL. COMPL.
FOR VIOLATIONS OF THE FEDERAL SEC. LAWS AND (2) DENYING IN PART AND
GRANTING IN PART DEFS.’ REQUEST FOR JUDICIAL NOTICE - 3:07-cv-04056-MJJ

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DATED: February 4, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2008, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on February 4, 2008.

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