

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

In re RIGEL PHARMACEUTICALS, INC.
SECURITIES LITIGATION

No. C 09-00546 JSW

This Document Relates To:

ALL ACTIONS.

**ORDER GRANTING
DEFENDANTS' MOTION TO
DISMISS PLAINTIFF'S
CONSOLIDATED AMENDED
COMPLAINT**

Now before the Court is the motion of defendants Rigel Pharmaceuticals, Inc. ("Rigel"), James M. Grower ("Grower"), Ryan D. Maynard ("Maynard"), Donald G. Payan ("Payan"), Raul R. Rodriguez ("Rodriguez"), Elliot B. Grossbard ("Grossbard"), Jean Deleage ("Deleage"), Bradford S. Goodwin ("Goodwin"), Gary A. Lyons ("Lyons"), Walter H. Moos ("Moos"), Hollings C. Renton ("Renton"), Peter S. Ringrose ("Ringrose") and Stephen A. Sherwin ("Sherwin") (collectively, "Defendants") to dismiss the Consolidated Amended Complaint ("CAC") and their motion to strike. Having carefully reviewed the parties papers and considered their arguments and the relevant legal authority, and good cause appearing, the Court hereby grants Defendants' motion to dismiss.¹

¹ The Court GRANTS the motion of Defendants Credit Suisse Securities (USA) LLC, Thomas Weisel Partners LLC, Oppenheimer & Co. Inc., and Jefferies & Company, Inc. to join in the motion to dismiss and the motion to strike. The Court GRANTS Defendants' request to take judicial notice of Exhibits A through R, Plaintiff's request to take judicial notice, and Defendants supplemental request to take judicial notice of Exhibits T through X, but DENIES Defendants' request to take judicial notice of Exhibit S. See Fed. R. Evid. 201.

The Court further GRANTS Defendants' motion to strike the declaration of Daniel L.

1 **BACKGROUND**

2 Lead Plaintiff Inter-Local Pension Fund GCC/IBT (“Plaintiff”) brings this action
 3 individually and on behalf of all other persons who purchased or otherwise acquired the
 4 common stock of Rigel between December 13, 2007 and February 3, 2009 (the “Class
 5 Period”),² pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15
 6 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including
 7 SEC Rule 10b-5, 17 C.F.R. 240.10b-5. Plaintiff further bring claims on behalf of itself and
 8 persons who purchased Rigel stock traceable to the registration statement and prospectus issued
 9 in connection with Rigel’s February 2008 offering, pursuant to Sections 11, 12, and 15 of the
 10 Securities Exchange Act of 1934, 15 U.S.C. §§ 77k, 77l, and 77o.

11 Plaintiff alleges that Defendants made material misrepresentations when they disclosed
 12 the results of a clinical trial for R788. Rheumatoid arthritis is an autoimmune disease
 13 characterized by chronic inflammation that affects the joints and other tissues. (CAC, ¶ 3.) Rigel
 14 was developing a new drug, R788, for the treatment of rheumatoid arthritis. Rigel conducted a
 15 Phase IIa clinical trial to evaluate the safety and preliminary clinical efficacy of R788 in
 16 patients with active rheumatoid arthritis despite therapy with methotrexate. (*Id.*) The clinical
 17 trial was a multi-center, randomized, double-blind, placebo-controlled, ascending dose study
 18 involving 189 patients in the United States and Mexico. (*Id.*) The patients were placed into
 19 cohorts receiving either 50, 100, or 150 mg of R788 orally twice daily over a twelve week
 20 period. Within each cohort, patients were assigned on a three to one basis to receive R788 or a
 21 placebo. (*Id.*, ¶ 52.) Rigel measured efficacy for each participant based on the American
 22 College of Rheumatology criteria (“ACR”), which denote at least a twenty percent

23
 24
 25 _____
 26 Bloch. Although Plaintiff may include Bloch’s nonconclusory assertions within their
 27 complaint, the Court finds that an expert affidavit does not meet the definition of a “written
 28 document” under Federal Rule of Civil Procedure 10(c). *See DeMarco v. DepoTech Corp.*,
 149 F. Supp. 2d 1212, 1219-22 (S.D. Cal. 2001).

² The Court has not yet certified a class and refers to the time period involved as the
 “Class Period” for ease of reference.

1 improvement (ACR 20), at least a fifty percent improvement (ACR 50), or at least a seventy
 2 percent improvement (ACR 70). (*Id.*)

3 On December 13, 2007, Rigel issued a press release entitled: “Rigel’s R788
 4 Demonstrates Significant Improvement in Rheumatoid Arthritis in Phase IIa Clinical Study;
 5 Achieves Statistically Significant ACR20, ACR50 & ACR70 Results.” (*Id.*, ¶ 60.) The press
 6 release stated, in part:

7 Rigel Pharmaceuticals, Inc. . . . today announced that its oral syk kinase
 8 inhibitor, **R788** (tamatitinib fosdium), **has demonstrated statistically significant**
 9 **results in treating Rheumatoid Arthritis (RA) patients in a recently completed**
 10 **Phase 2 clinical trial. Groups treated with R788 at 100mg and 150mg po bid**
 11 **(orally, twice daily), showed higher ACR20, ACR50, ACR70 and DAS28**
 12 **response rates than the placebo group. The efficacy results for the 100mg and**
 13 **the 150mg dose groups were fairly comparable. Dramatically, the onset of the**
 14 **effect in these dose groups occurred as early as one week after initiation of**
 15 **therapy. We believe that the significant ACR scores and good tolerability**
 16 **observed in this clinical trial, and the further benefit of oral delivery may make**
 17 **R788 a favorable alternative to the currently marketed biological agents.**

18 * * *

19 **“This clinical study has shown that R788 treatment can achieve**
 20 **impressive ACR response rates,”** said Elliott Grossbard, M.D., senior vice
 21 president of medical development at Rigel. “In this clinical trial both the 100mg
 22 and 150mg doses improved arthritis symptoms and did so quickly. We plan to
 23 initiate the next clinical trial with R788 in RA in 2008,” he added.

24 ***Efficacy Results***

<i>Treatment Assigned</i>	<i>Number</i>	<i>ACR 20</i>	<i>ACR 50</i>	<i>ACR 70</i>	<i>DAS28-CRP 2.6,</i>
<i>po bid</i>	<i>(N)</i>	<i>% (N)</i>	<i>% (N)</i>	<i>% (N)</i>	<i>% (N)</i>
<i>Placebo</i>	<i>47</i>	<i>38% (18)</i>	<i>19%(9)</i>	<i>4% (2)</i>	<i>17% (8)</i>
<i>50 mg</i>	<i>46</i>	<i>32% (15)</i>	<i>17% (8)</i>	<i>2% (1)</i>	<i>20% (9)</i>
<i>100 mg</i>	<i>49</i>	<i>65% (32)</i> <i>(p=.008)</i>	<i>49% (24)</i> <i>(p=.002)</i>	<i>33% (16)</i> <i>(p<.001)</i>	<i>35% (17)</i> <i>(p=.005)</i>
<i>150 mg</i>	<i>47</i>	<i>72% (34)</i> <i>(p<.001)</i>	<i>57% (27)</i> <i>(p<.001)</i>	<i>40% (19)</i> <i>(p<.001)</i>	<i>47% (22)</i> <i>(p<.001)</i>

25 * * *

26 James M. Gower, chairman and chief executive officer of Rigel said,
 27 **“These very important clinical trial results are a major milestone for Rigel as**
 28 **we establish the potential of R788 in RA and its value as an alternative to**

1 *current therapies.* In addition, *given these results* and the recent results in ITP,
2 *we believe that R788 may be a useful drug in the treatment of autoimmune*
3 *diseases.”*

4 Safety Results

5 *The most common clinically meaningful adverse events noted in the*
6 *clinical trial were dose-related neutropenia, mild elevations of liver function*
7 *tests, and gastrointestinal (GI) side effects.* Dose reduction (to one half the
8 assigned dose, by taking the drug once per day) was pre-specified in the protocol,
9 contingent on neutrophil counts and/or liver function tests. Notably, a vast
10 majority of the patients (19 out of 21) who had their dose reduced, successfully
11 completed the clinical trial with minimal safety issues.

12 *The key safety results are shown in the table below:*

	<i>Placebo po BID N=47</i>	<i>50mg po BID N=46</i>	<i>100mg po BID N=49</i>	<i>150mg po BID N=47</i>
Completed Study at Reduced Dose (N)	1	0	5	13
Dropouts (N): Withdrew Consent Adverse Event Other	11623	6	6231	8161
<i>Neutropenia (N) Requiring dose reduction</i>	<i>0</i>	<i>0</i>	<i>5</i>	<i>10</i>
<i>ALT > 3XULN (N)</i>	<i>2</i>	<i>0</i>	<i>0</i>	<i>3</i>
<i>Diarrhea (N) (severity moderate or greater)</i>	<i>0</i>	<i>3</i>	<i>2</i>	<i>10</i>
<i>Upper GI side effects (N) (gastritis, nausea, dyspepsia) (severity moderate or greater)</i>	<i>2</i>	<i>1</i>	<i>2</i>	<i>12</i>
<i>Hypertension (N) (severity moderate or greater)</i>	<i>0</i>	<i>0</i>	<i>2</i>	<i>0</i>

13 (Id.) (emphasis in original.)³

14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
³ The bolded and italicized portions in this paragraph and in paragraphs 61, 62, 151,
159, 165, 176, 177 are the statements that Plaintiff alleges were false and misleading.

1 On the same day, Rigel also held a press conference. (*Id.*, ¶ 61.) During the call
2 Grower and Grossbard made the following statements regarding the results of the Phase IIa
3 clinical trial:

4 [Gower:] We were very pleased to be able to announce **highly statistically**
5 **significant results of a Phase 2 trial of 788 in patients with rheumatoid arthritis.**
6 And I would like to introduce Dr. Elliot Grossbard to take us through the study
7 results. Elliot?

8 * * *

9 [Grossbard:] The efficacy results are shown in the graph on the handout
10 that many of you may have downloaded. **As you can see, the highly significant**
11 **effect for both the ACR 20, 50, 70 and DAS28 score. The p values are uniformly**
12 **less than .008, usually less than .001.** Of note, although not included in this
13 graph, is that the onset of the effect was within one week, and you could see
14 significant differences between the patients at one week after the initiation of
15 treatment.

16 **We have concluded that the 100 milligram and 150 milligram dose**
17 **groups have impressive and statistically significant improvements over placebo,**
18 and that the onset occurs very, very early. The efficacy results for the two
19 effective doses were fairly comparable, and the 100 milligrams bid dose kind of
20 caught up by the end so that they were really equivalent. The 50 milligram dose
21 [does] not appear to be much better than placebo, and so overall there was a good
22 dose response.

23 With regard to safety, which is going to be a close focus of the future
24 program, because **I think this study fairly establishes with certainty that this drug**
25 **is effective in rheumatoid arthritis.**

26 * * *

27 **The incidence of neutropenia,** as I mentioned, was modest. **In the 100**
28 **milligram dose I think there were five patients out of the 49,** but it was a much
higher percentage of the dose 150 milligrams twice a day.

In terms of ALP elevations greater than three times the upper limit of
normal, which is the marker that FDA recently recommended in their guidelines
for development of new (technical difficulty) **there were two patients in the**
placebo group who had ALP elevations, and three in the high dose group, and
none in the two intermediate groups. The most prevalent side effect beyond
neutropenia in the high dose group was a combination of gastrointestinal side
effects, diarrhea and nausea, dyspepsia and so on.

The incidence of reported moderate hypertension was quite low, although
the way case report forms are filled out an occasional patients [sic] had a notation
for his systolic blood pressure increase, and an occasional one had diastolic blood
pressure increase. And it is hard to know exactly what that means, so I'm
reporting to you here those where the case report forms noted, hypertension of
moderate severity. **So in conclusion we think the 100 milligram dose was well**
tolerated. The 150 milligram dose somewhat less so. But with dose reductions
almost all the patients were able to finish the study.

The most common side effects were neutropenia and gastrointestinal side
effects and they are most prevalent in the 150 milligram bid dose.

1 I think – my personal opinion is that ***this study establishes with very little***
2 ***uncertainty that this drug at 100 milligrams a day – 100 milligrams twice a day***
3 ***or more is highly effective in the treatment of rheumatoid arthritis in terms of***
4 ***clinical signs and symptoms.*** We have not investigated the question of bone
erosions and joint damage – we will in a future study.

5 (*Id.*) (emphasis in original.)

6 Grossbard further stated in the conference call that he was going to be working closely
7 with Dr. Michael Weinblatt to write a paper and that the publication of the paper would be the
8 next significant statement about the results of the study. (Declaration of William S. Freeman,
9 Ex. E (transcript of December 13, 2007 conference call) at 6.)

10 During the conference call, Dr. Weinblatt stated:

11 So from my standpoint as an investigator of rheumatoid arthritis, ***this study***
12 ***accomplished exactly what we wanted to see. It established that in this first***
13 ***Phase 2 trial there was evidence of significant – by that statistically significant***
14 ***efficacy. The parameters that were changed are – were pretty dramatic with at***
15 ***least over a 30% delta between active drug and placebo, which is a very nice***
16 ***response rate.***

17 ***All I can tell you is that this study showed that there is a clinical effect which is***
18 ***significant at all major ACR response rates.***

19 (CAC, ¶ 62.)

20 On February 1, 2008, Rigel filed a Form 424B5 Prospectus, which, according to
21 Plaintiff also contained the following false and misleading statements:

22 We recently completed a Phase 2, multicenter, ascending dose, randomized,
23 double-blind, placebo-controlled, dose-ranging study evaluating three doses of
24 R788 over a 12-week period in RA patients. All of these patients continued to
25 receive their same previously scheduled dose of methotrexate. ***In this clinical***
26 ***trial, R788 demonstrated statistically significant efficacy results in treating***
27 ***RA patients at two dose levels.*** Efficacy assessments for each participant were
28 based on the American College of Rheumatology criteria which denote a 20%
(ACR 20) improvement, at least a 50% (ACR 50) improvement, or at least a
70% (ACR 70) improvement from the baseline assessment at the end of the
12-week treatment period. ***Groups treated with R788 at 100mg and 150mg po***
bid (orally, twice daily) showed higher ACR20, ACR50, ACR70 and DAS28
response rates than the placebo group. The most common clinically
meaningful adverse events noted in the clinical trial were dose-related
neutropenia, mild elevations of liver function tests and gastrointestinal side
effects. Dose reduction (to one-half the assigned dose by taking the drug once
per day) was pre-specified in the protocol and contingent on neutrophil counts
and/or liver function tests. Notably, a vast majority of the patients who had
their dose reduced successfully completed the clinical trial with minimal safety
issues. We expect to initiate a Phase 2b clinical trial evaluating dosing and
x-rays of bones over a 24-week period. We also expect to initiate a second

1 Phase 2b clinical trial treating a sub-population of RA patients with R788 by
2 the end of the first half of 2008.

3 (*Id.*, ¶ 151.)

4 On February 11, 2008, at the BIO CEO & Investor Conference, Defendant Gower made
5 the following statements that Plaintiff contends were false and misleading:

6 The Phase II study that we announced in December was a study on 190
7 patients, double-blind, placebo-controlled in 30 centers in the US and Mexico.
8 ***We saw rather unprecedented numbers in terms of the ACR scoring. As you
9 can see on the chart, significantly different as is noted by the stars in both the
10 100 milligram orally BID dose and 150 milligram orally BID dose across the
11 board and all of ACR20, ACR50, ACR70 and DAS scoring. Rather
12 spectacular numbers for the higher two dose groups specifically in the
13 ACR50's and '70s where we got between 50 and 60% ACR50 response and
14 over one-third ACR70's at 90 days*** which is relatively unprecedented in these
15 kind of studies if you want to look at previous studies done in these same
16 populations with the same protocol.

17 This was a very strict intense treat protocol. And done using the same
18 protocols that have been used for pretty much everything from Enbrel on
19 forward, certainly the same protocols and the same, some of the same groups
20 used in the studies done in the last few years with Rituxan and Orencia for
21 approvals IL-6 and the JAK3's in terms of study. So you can never compare
22 studies directly one-to-one that aren't done in exactly the same time but these are
23 using the same protocols and the same approach so they should be roughly
24 comparable.

25 ***The safety results were also good. We did have two dose dependent
26 toxicities that were noted. One was neutropenia***, which we've known from the
27 animal studies on forward that we carry a certain amount of neutropenia along
28 with the mechanism of this growth comes most likely from its ability to regulate
adhesion molecules and the monocytes. And there you are seeing a dose
dependent matter that increased from about slightly under 10% to just under 20%
of between the higher two dose groups.

29 We had prespecified a protocol based dose reduction, which cut the dose
30 in half for any patients that got a grade 2 neutropenia. This is a neutrophil count
31 of 1500. We didn't see any grade 3 or grade 4 neutropenias in the study, and as
32 many of you know those are the ones that are associated with infections. But
33 because this was an early study we wanted to be extra cautious and we cut the
34 dose in half. But when those patients hit a neutrophil count of 1500, all of those
35 patients however did fine on the reduced dose. Actually we got, if you look at
36 those as a group although we didn't – this is not prespecified as a statistical
37 endpoint, their ACR20 at 90 days was 82% and those that continued on the study
38 with the dose reductions. So they did quite well and maintained the efficacy and
39 the neutropenia has not recurred nor has anyone dropped off the study because of
40 neutropenia. But it is something which is not uncommon for this patient
41 population. As many of you know, RA patients are predisposed to neutropenia.
42 Methotrexate adds to it. Wheat appears added to that. That is something the
43 rheumatologists have to watch but doesn't seem at this point to be something that
44 is not manageable.

1 ***The other thing that we saw that seems dose-related was lower GI***
 2 ***disturbance***, also something fairly common in this disease. Methotrexate alone
 3 as you would notice in the placebo group, those were all methotrexate plus a
 4 dummy 788, has a number of patients that have lower GI symptoms. We had a
 5 modest number in the intermediate dose group, slightly higher number in the
 6 upper dose group. As with the neutropenia no patients found this uncomfortable
 7 enough to want to drop off the study. None were hospitalized. None had to be
 8 rehydrated. But certainly it is a tolerance issue. ***Everything else that showed up***
 9 ***is no different between the placebo group and the control group on the safety***
 10 ***elements of the study. So, so far, so good.***

11 (*Id.*, ¶ 159.)

12 On July 8, 2008, at the Collins Stewart 4th Annual Growth Conference, Defendant
 13 Rodriguez made the following statements that Plaintiff contends were false and misleading:

14 Speaking of that, we last year started – reported a Phase II RA clinical
 15 trial. This is the data we reported in December of last year. This is a
 16 three-month study looking at R788 in patients with active RA all on a
 17 methotrexate background. It's a three-month study looking at those signs and
 18 symptoms.

19 ***What we saw, and you see in this graph, is that we had some dramatic***
 20 ***improvement in the signs and symptoms looking at ACR20, ACR50, and***
 21 ***ACR70 at the 100 milligram and the 150 milligram dose groups.*** This is all
 22 b.i.d. The 50 looked pretty much like placebo. ***The others looked quite***
 23 ***dramatic[].***

24 In fact compared to other TNF agents or other products that are in the
 25 market now or in development now, this is in the higher range of those efficacy
 26 measures. So very dramatic improvement. We also saw a couple of things that
 27 we saw the benefit occur within the first two weeks of therapy. That is, even
 28 within the first week, we are able to see a dramatic improvement in signs and
 29 symptoms into the trial. That was sustained throughout the three months of the
 30 trial. So very nice results. Per the protocol, if we ran into any trouble with say
 31 neutropenia or elevated liver enzymes, the protocol required us to cut the dose
 32 in half. That is what occurred in a few cases.

33 ***You see some of the safety background on these various doses in this***
 34 ***chart. We had some cases of neutropenia, five in the 100 milligram and 10 in***
 35 ***the 150 milligram dose groups that required the dose to be reduced.*** A few
 36 liver enzymes elevated in 150 milligram. I should note that all the patients that
 37 had their dosage reduced, about 18 of them, completed the trial and their
 38 ACR20 scores, 82% of them met their ACR20 scores. So they had a very nice
 39 benefit even though their dose was reduced.

40 So effectively, if you had a benefit it occurred early in the trial and then
 41 if you needed your dose reduced it didn't seem to undermine the benefit that
 42 you did receive. So we were very satisfied with this. ***We had some GI side***
 43 ***effects and they were somewhat random and transient, more in the 150 than***
 44 ***the 100. A bit of hypertension here and there, but, basically, a fairly good***
 45 ***safety profile.***

46 ***The 100 milligram dose group had a very nice and profound efficacy***
 47 ***result and a pretty good safety profile.*** So that is going to be the lead dose that

1 we go forward. However, the drug does have a very good PKA; we have about
2 a 17-hour half-life. So we are going to try to push that a little bit and see if once
3 a day works.

3 (*Id.*, ¶ 165.)

4 According to Plaintiff, the statements made on December 13, 2007, February 1, 2008,
5 February 11, 2008, and July 8, 2008 were false because: (1) Defendants failed to report ACR
6 response data by country; (2) the Phase IIa RA clinical trial results were not significantly
7 significant; (3) Defendants improperly pooled the data, used an improper statistical analysis,
8 and failed to correct the multiple comparisons problem, all of which inflated the efficacy results
9 of R788; (4) Defendants failed to disclose that (i) there was a dose-dependent increase in
10 average systolic blood pressure of 3-5mm Hg in 100mg patients and 8-9mm Hg in the 150 mg
11 patients which signaled the potential for increased cardiovascular risk and presented additional
12 hurdles to regulatory approval and commercial partnership, (ii) five patients (not two, as
13 reported on December 13, 2007) experienced hypertension, with blood pressure increases as
14 high as 20-30mm Hg, (iii) hypertension was one of the two most common clinically meaningful
15 drug related adverse events, (iv) nine patients (not three, as reported on December 13, 2007)
16 experienced increased liver enzymes compared to patients taking the placebo, (v) 20 patients
17 (not 15, as reported on December 13, 2007) experienced neutropenia, (vi) 34 patients (not 15, as
18 reported on December 13, 2007) experienced diarrhea, and (vii) 35 patients (not 15, as reported
19 on December 13, 2007) experienced upper gastrointestinal side effects. (*Id.*, ¶¶ 69, 74, 75, 78,
20 80, 91, 153-156, 160-164, 166-169.)

21 On October 27, 2008, Rigel disclosed the following ACR response data by country for
22 the first time:

	Placebo	50MG	100MG	150MG
# of U.S. patients	25	46	21	5
ACR20	6 (24%)	15 (33%)	11 (52%)	2 (40%)
ACR50	1 (4%)	8 (17%)	6 (29%)	2 (40%)
ACR70	0 (0%)	1 (2%)	3 (14%)	2 (40%)

	Placebo	50MG	100MG	150MG
# of Mexican patients	22	0	28	42
ACR20	12 (55%)	0 (0%)	21 (75%)	32 (76%)
ACR50	8 (36%)	0 (0%)	18 (64%)	25 (60%)
ACR70	2 (9%)	0 (0%)	13 (46%)	17 (40%)

(*Id.*, ¶ 70.)

On October 27, 2008, Grossbard acknowledged that he knew about the differing response rates on December 13, 2007. He stated:

The issue of Mexico/US interaction before the study – I think we actually mentioned this at our original discussion on the Web after the study was over. I was concerned that there might be such an interaction.

And so, I requested before the study was unblinded that we do a country interaction and it turned out there was one. And the issue of the interaction was that *the placebo rate was much higher in Mexico than in the US. And the response rate was much higher in Mexico than in the US.*

(*Id.*, ¶ 71) (emphasis in original.)

Plaintiff also alleges that Defendants made false and misleading statements regarding Rigel's partnership prospects. On October 27, 2008, Grower stated that Rigel was "[s]till on track for what we've been saying all along, which is putting the partnership in place as early as the early part of next year." (*Id.*, ¶ 176.) On November 3, 2008, Grower further stated: "We expect to establish a collaboration partnership to further these ends, and that in fact is going quite well." (*Id.*, ¶ 177.) According to Plaintiff, these statements were false and misleading because Defendants knew that the Phase IIa RA clinical trial results had derailed Rigel's partnership prospects. Rigel was not on track for partnership because it had not demonstrated statistically significant results in this clinical trial. (*Id.*, ¶ 178.)

ANALYSIS

A. Applicable Pleading Standards.

1. Motion to Dismiss for Failure to State a Claim.

A motion to dismiss is proper under Federal Rule of Civil Procedure 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. The complaint is construed in

1 the light most favorable to the non-moving party and all material allegations in the complaint
2 are taken to be true. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986). Rule 8(a) requires
3 only “a short and plain statement of the claim showing that the pleader is entitled to relief.”
4 Accordingly, motions to dismiss for failure to state a claim pursuant to Rule 12(b)(6) are
5 typically disfavored; complaints are construed liberally to set forth some basis for relief, as long
6 as they provide basic notice to the defendants of the charges against them. *In re McKesson*
7 *HBOC, Inc. Sec. Litig.*, 126 F. Supp. 1248, 1257 (N.D. Cal. 2000). Where a plaintiff alleges
8 fraud, however, Rule 9(b) requires the plaintiff to state with particularity the circumstances
9 constituting fraud. *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-49 (9th Cir. 1994).

10 Even under the liberal pleading standard of Rule 8(a), “a plaintiff’s obligation to provide
11 the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a
12 formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corporation*
13 *v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).
14 Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must
15 instead allege “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570.
16 “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to
17 draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft*
18 *v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 556). “The plausibility
19 standard is not akin to a probability requirement, but it asks for more than a sheer possibility
20 that a defendant has acted unlawfully. ... When a complaint pleads facts that are merely
21 consistent with a defendant’s liability, it stops short of the line between possibility and
22 plausibility of entitlement to relief.” *Id.* (quoting *Twombly*, 550 U.S. at 556-57) (internal
23 quotation marks omitted). The Court may consider the facts alleged in the complaint,
24 documents attached to the complaint, documents relied upon but not attached to the complaint
25 when the authenticity of those documents is not questioned, and other matters for which the
26 Court can take judicial notice. *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th
27 Cir. 2009).

28 In the securities context, the pleading requirements are even more stringent.

1 **2. Private Securities Litigation Reform Act.**

2 To plead a claim under section 10(b) and Rule 10b-5 based on misstatements, a plaintiff
3 must allege (1) a misrepresentation or omission, (2) of material fact, (3) made with scienter, (4)
4 on which the plaintiff justifiably relied, (5) that proximately caused the alleged loss.

5 *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1177 (9th Cir. 2009); *Zucco Partners*
6 *LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). To plead a claim based on market
7 manipulation, a plaintiff must allege, *inter alia*, that the defendant engaged in manipulative acts,
8 that plaintiff suffered damage, which was caused by his or her reliance on an assumption that
9 the market was free of manipulation, and that the defendant acted with scienter. *See, e.g., ATSI*
10 *Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 102 (2d Cir. 2007).

11 “At the pleading stage, a complaint stating claims under section 10(b) and Rule 10b-5
12 must satisfy the dual pleading requirements of ... Rule 9(b) and the PSLRA.” *Zucco Partners*,
13 552 F.3d at 990. Thus, the PSLRA requires that “a complaint ‘plead with particularity both
14 falsity and scienter.’” *Id.* (quoting *Gompper v. VISX*, 298 F.3d 893, 895 (9th Cir. 2002), in turn
15 quoting *Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001)). Where a plaintiff asserts a
16 Section 20(a) claim based on an underlying violation of section 10(b), the pleading
17 requirements for both violations are the same. *See In re Ramp Networks, Inc. Sec. Lit.*, 201 F.
18 Supp. 2d 1051, 1063 (N.D. Cal. 2002).

19 Under the PSLRA, actions based on allegations of material misstatements or omissions
20 must “specify each statement alleged to have been misleading, the reason or reasons why the
21 statement is misleading, and, if an allegation regarding the statement or omission is made on
22 information and belief, the complaint shall state with particularity all facts on which that belief
23 is formed.” 15 U.S.C. §78u-4(b)(1). In order to adequately plead scienter, the PSLRA requires
24 that the plaintiff “state with particularity facts giving rise to a strong inference that the
25 defendant acted with the required state of mind.” *Id.* at 991 (quoting 15 U.S.C. § 78u-4(b)(2)).

26 “To adequately demonstrate that the ‘defendant acted with the required state of mind,’ a
27 complaint must ‘allege that the defendants made false or misleading statements either
28 intentionally or with deliberate recklessness.’” *Zucco Partners*, 552 F.3d at 991 (quoting *In re*

1 *Daou Sys., Inc.*, 411 F.3d 1006, 1014-15 (9th Cir. 2005)). The Ninth Circuit recently clarified
2 that a court should “conduct a dual inquiry,” when it evaluates the scienter element. *Id.* at 991-
3 92. First, a court should determine “whether any of the plaintiff’s allegations, standing alone
4 are sufficient to create a strong inference of scienter.” *Id.* at 992. Second, “if no individual
5 allegations are sufficient,” a court should “conduct a ‘holistic’ review of the same allegations to
6 determine whether the individual allegations combine to create a strong inference of intentional
7 conduct or deliberate recklessness.” *Id.*; accord *Siracusano*, 2009 WL 3448282 at *12.

8 “[I]n determining whether the pleaded facts give rise to a strong inference of scienter,
9 the court must take into account plausible opposing inferences.” *Siracusano*, 585 F.3d 1167,
10 1180 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007)). As the
11 Supreme Court stated in *Tellabs*, a plaintiff sufficiently alleges scienter “only if a reasonable
12 person would deem the inference of scienter cogent and at least as compelling as any opposing
13 inference one could draw from the facts alleged.” *Tellabs*, 551 U.S. at 324. The inquiry “is
14 inherently comparative.” *Id.* “A court must compare the malicious and innocent inferences
15 cognizable from the facts pled in the complaint, and only allow the complaint to survive a
16 motion to dismiss if the malicious inference is at least as compelling as any opposing innocent
17 inference.” *Zucco Partners*, 552 F.3d 991 (citing *Tellabs*, 551 U.S. at 324). If the allegations
18 are insufficient to state a claim, a court should grant leave to amend, “unless it is clear that the
19 complaint could not be saved by any amendment.” *Id.* at 989 (quoting *Livid Holdings, Ltd. v.*
20 *Solomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir. 2005)).

21 **B. Plaintiff’s Amended Consolidated Complaint.**

22 **1. Plaintiff Fails to Allege False or Misleading Statements.**

23 The PSLRA requires that plaintiffs allege with the requisite particularity each statement
24 alleged to be false or misleading, the reason or reasons why the statement was false or
25 misleading, and if those allegations are made on information and belief, all facts on which that
26 belief is formed. See 15 U.S.C. § 78u-4(b)(1)(B); see also *Employers Teamsters Local Nos.*
27 *175 and 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1134 (9th Cir. 2004). To be
28 actionable under Section 10(b) and Rule 10b-5, an alleged omission must render some

1 affirmative public statement misleading. In order for an omission to be misleading, “it must
2 affirmatively create an impression of a state of affairs that differs in a material way from the one
3 that actually exists.” *See Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir.
4 2002) (citing *McCormick v. The Fund American Cos.*, 26 F.3d 869, 880 (9th Cir. 1994)).

5 Plaintiff sets forth the statements which it contends are materially false and misleading
6 in paragraphs 60, 61, 62, 151, 159, 165, 176, 177 of the CAC. Plaintiff alleges that Defendants
7 made false and misleading statements regarding the efficacy and safety results from the clinical
8 trial. With respect to the statements regarding efficacy, Plaintiff argues that Defendants falsely
9 stated that the trial revealed statistically significant results because they did not apply the
10 correct method of statistical analysis. According to Plaintiff, Defendants improperly pooled
11 data, applied an improper statistical test, and failed to account for multiple comparisons.
12 Plaintiff alleges that, properly calculated, the p-values are much larger than those reported by
13 Defendants and at the primary efficacy endpoint, they do not meet the United States Food and
14 Drug Administration’s (“FDA”) threshold for statistical significance or support Defendants’
15 claims of efficacy. Plaintiff further contends that Defendants’ statements regarding the efficacy
16 of R788 were misleading because Defendants did not reveal that there was a country
17 interaction.

18 However, disagreements over study design and statistical analysis are insufficient to
19 allege a materially false statement. *See In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568
20 n.15 (E.D. Pa. 2009) (“The fact that [plaintiff’s] statistician reached a different conclusion than
21 [defendant] does not establish that [defendant’s] interpretation of the results were false or
22 misleading;” holding that the differing conclusions merely established that there may be a
23 disagreement about how to conduct and analyze the study); *DeMarco v. DepoTech Corp.*, 149
24 F. Supp. 2d 1212 (S.D. Cal. 2001) (“Although Plaintiffs may have established a legitimate
25 difference in opinion as to the proper statistical analysis, they have hardly stated a securities
26 fraud claim.”); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995)
27 (differences of opinion among medical researchers as to the proper interpretation of test results
28 does not by itself demonstrate fraud); *Padnes v. Scios Nova Inc.*, 1996 WL 53911, * 5 (N.D.

1 Cal. Sept. 18, 1996) (“Medical researchers may well differ with respect to what constitutes
2 acceptable testing procedures, as well as how best to interpret data garnered. ...). At most,
3 Plaintiff’s allegations demonstrate that there were alternative means for interpreting the clinical
4 trial, not that Defendants made materially false statements about the efficacy of R788.

5 According to Plaintiff, Defendants’ statements regarding good tolerability and safety
6 results were false because Defendants omitted information related to blood pressure, such as
7 there was a steep dose-dependant increase in average blood pressure, the magnitude of blood
8 pressure increases, and additional cases of hypertension. Defendants reported two incidences of
9 hypertension when, in fact, five had occurred. Defendants also failed to disclose other reported
10 side effects. Defendants reported three incidences of elevated liver enzymes when, in fact, nine
11 had occurred. Defendants reported fifteen incidences of neutropenia when, in fact, twenty had
12 occurred. Defendants reported fifteen incidences of gastrointestinal side effects when, in fact,
13 thirty-five had occurred. Finally, Plaintiff alleges that Defendants reported fifteen incidences of
14 diarrhea when, in fact, thirty-four had occurred.

15 However, Defendants stated that they were reporting on the incidents of neutropenia
16 which required a dose reduction, of a dose-dependent increase in alanine aminotransferase
17 (“ALT”) three times the upper limit of normal (“3XULN”), of diarrhea with severity of
18 moderate or greater, of upper gastrointestinal side effects, such as gastritis, nausea, dyspepsia,
19 with severity of moderate or greater, and hypertension with severity of moderate or greater.
20 Defendants stated that they were providing the “key safety results,” and did not imply that they
21 were disclosing, at that time, *all* adverse incidents. The fact that Defendants later disclosed
22 more detailed results, including incidences of lesser severity, does not render their earlier
23 statements false or misleading. *See, e.g. Padnes*, 1996 WL 539711 at *5 (“Defendants, like any
24 other company wishing to publicly discuss the results of a scientific study, had to make a
25 judgment as to which specific bits of information about the study and its conclusions to
26 disclose.”).

27 Plaintiff argues that Defendants’ use of the words severity of moderate or greater were
28 terms of art, and thus it was misleading to not disclose side effects that Defendants deemed to

1 be mild. In support of this argument, Plaintiff relies on *Berson v. Applied Signal Technology,*
2 *Inc.*, 527 F.3d 982 (9th Cir. 2008). In *Berson*, the issue was whether the term “backlog”
3 included stopped work or just work still in progress or work yet to be started on ongoing
4 contracts. *Id.* at 986. Defendants argued that an exchange in which one defendant was asked
5 whether “the \$143 million [of backlog] include-is that net of any potential debooking?” and the
6 defendant answered “[t]hat includes the \$12 million that has not been debooked” put investors
7 on notice that the backlog included stopped work because three months earlier the company had
8 disclosed that \$12 million was the amount of work halted by the first stop order. *Id.* at 986-87.
9 The Ninth Circuit held that it was far from clear that a reasonable investor could have decoded
10 that meaning at the time. In the absence of evidence that investors would have understood the
11 words “debook” and “potential debooking” as terms of art that refer to stop-work orders, the
12 court held it could not determine, as a matter of law, that the defendants disclosed that backlog
13 included stopped work. *Id.* at 987. In contrast here, Defendants are not arguing that investors
14 should have known that some undisclosed, technical term, was included in the words moderate
15 severity or greater. Instead, by labeling the disclosed side effects as those of moderate severity,
16 it would have been clear to reasonable investors, as well as the general public, that there may
17 have also been side effects of lesser severity that had not yet been disclosed. Moderate severity
18 or greater are not technical terms of art.

19 Notably, Plaintiff has not pointed to a single document showing or a confidential
20 witness attesting that Defendants actually believed that the side effects they characterized as
21 more mild and disclosed in October 2008 were actually not mild and should have been
22 disclosed with the initial key results. Therefore, the Court finds that Plaintiff has not alleged
23 facts that show Defendants’ statements regarding the safety results were false or misleading.

24 Plaintiff also argues that the following statements made on October 27, 2008 and
25 November 3, 2008, respectively, regarding partnership prospects were false and misleading: (1)
26 “[S]till on track for what we’ve been saying all along, which is putting the partnership in place
27 as early as the early part of next year;” (CAC, ¶ 176) and (2) “We expect to establish a
28 collaboration to further these ends, and that in fact is going quite well.” (CAC, ¶ 177.)

1 According to Plaintiff, these statements were false and misleading because Defendants knew
2 that the Phase IIa RA clinical trial results had derailed Rigel's partnership prospects because the
3 trial did not demonstrate statistically significant results. (*Id.*, ¶ 178.) However, as discussed
4 above, the Court found that Defendants' statements regarding efficacy were not false and
5 misleading and that they did not withhold material information regarding efficacy that would
6 have rendered false Defendants' initial statements regarding the clinical trial. In the absence of
7 any evidence that Defendants believed their statements regarding the clinical trial were false or
8 misleading, Plaintiff does not allege any facts to support a belief that Defendants knew, at the
9 time that the statements regarding partnership prospects were made, that such statements were
10 not true. Again, Plaintiff does not point to any internal document or statement from confidential
11 witness to support an inference that Defendants knew, when they made such statements, that
12 their partnership prospects were not on track or that they would not consummate a partnership
13 in 2009.

14 Accordingly, the Court finds that Plaintiff has not sufficiently alleged any false or
15 misleading statement or omission.

16 **1. Plaintiff Has Not Alleged Facts Sufficient to Show a Strong Inference of**
17 **Scienter.**

18 Plaintiff argues that it has alleged scienter based on the following allegations: (1)
19 Defendants had "actual knowledge of the results of the clinical trial that directly contradicted
20 their positive statements;" and (2) Defendants' motives to stave off insolvency and receive
21 additional financial compensation.

22 As discussed above, Plaintiff fails to allege facts sufficient to demonstrate that
23 Defendants had actual knowledge of results that "directly contradicted" their positive
24 statements. Defendants had reported the moderate to severe cases of hypertension. The fact
25 that there were other, more mild blood pressure reactions, does not directly contradict or render
26 false Defendants' statements regarding blood pressure issued on December 13, 2007.
27 Moreover, the fact that there was another statistical method by which the clinical trial results
28 could be analyzed does not render the statistics stated by Defendants to be false. Notably,

1 Plaintiff does not submit or allege a single document, internal report, or other information to
2 show that any Defendant actually believed the difference in response rates among patients in
3 different countries, the less severe side effects, or the mild dose-dependent effect on blood-
4 pressure should have been disclosed in December 2007 and that without such information, the
5 initial results revealed in December 2007 were false and misleading.

6 Plaintiff also alleges that Defendants' motive for giving false and misleading statements
7 was to stave off insolvency and receive additional financial compensation. Plaintiff asserts that
8 while its motive allegations are not necessary, they provide additional support for scienter.
9 According to Plaintiff, Rigel needed to raise capital and would have become insolvent by the
10 third quarter of 2008. Rigel sold more than five million shares at \$27 per share from the
11 February 2008 offering and raised \$127.5 million. Plaintiff argues that Rigel's February 2008
12 offering is analogous to insider trading because, due to the proceeds from the offering, Rigel
13 avoided insolvency and the Individual Defendants continued to be highly compensated.
14 Plaintiff further argues that the Individual Defendants profited from withholding the allegedly
15 negative information about the clinical trial by receiving substantial salary increases, bonuses
16 and stock options at the end of 2007, due to the false and misleading statements. However, by
17 holding onto their shares and options through the end of the class period, and after the
18 disclosure in October 2008 of the additional information regarding the clinical trial, the
19 Individual Defendants actually lost a substantial sum of money. The five Defendants lost \$18.7
20 million by retaining their shares beyond October 2008, when they allegedly knew "the truth
21 would come out." (Freeman Decl., ¶¶ 18-20, Exs. Q and R.) According to Plaintiff's
22 allegations, these five Individual Defendants only received less than \$2.3 million in increased
23 compensation and bonuses in 2008, which is significantly less than what they lost by retaining
24 their shares. (CAC, ¶¶ 143, 144.)

25 Moreover, as Defendants point out in their reply, Plaintiff's theory does not make
26 logical sense. Defendants revealed some, and according to Defendants the most severe, of the
27 adverse effects in December 2007. Then, in October of 2008, before Rigel secured a partner,
28 Rigel voluntarily revealed the remaining adverse effects. This voluntary disclosure was made

1 before any of the Individual Defendants sold a single share of Rigel stock.⁴ If Defendants had
 2 actually been acting with scienter, then it would have made more sense to continue to withhold
 3 the information disclosed in October 2008 until after Rigel has established their goal of
 4 collaborating with a third-party to develop and market R788.⁵

5 Thus, Defendants' acts actually undermine an inference of scienter. Therefore, upon a
 6 thorough and holistic review of Plaintiff's allegations and the facts upon which the Court may
 7 take judicial notice, the Court finds that a reasonable person would not "deem the inference of
 8 scienter cogent and at least as compelling as any opposing inference one could draw from the
 9 facts alleged." *Tellabs*, 551 U.S. at 324.⁶

10 3. Plaintiff's Section 11 and 12(a)(2) Claim.

11 Section 11 of the Securities Act of 1933 imposes liability for false statements or
 12 omissions of material fact made in registration statements. 15 U.S.C. § 77k. To state a claim
 13 under Section 11, a plaintiff must allege: "(1) that the registration statement contained an
 14 omission or misrepresentation, and (2) that the omission or misrepresentation was material, that
 15 is, it would have misled a reasonable investor about the nature of his or her investment."
 16 *Kaplan v. Rose*, 49 F.3d 1363, 1371 (9th Cir.1994). Similarly, Section 12(a)(2) imposes
 17 liability for false statements or omissions of material fact made in a prospectus, among other
 18 documents. 15 U.S.C. § 77l.

19 Plaintiff's Section 11 and 12 claims are not governed by the heightened pleading
 20 standards under the PSLRA. *Falkowski v. Imation Corp.*, 309 F.3d 1123, 1133 (9th Cir. 2002);

22 ⁴ Plaintiff's argument that Defendants were hampered in their ability to sell stock
 23 during a "large chunk of the Class Period" is grossly exaggerated. Plaintiff alleges a class
 24 period of 419 days. (CAC, ¶ 1.) As part of the February 2008 offering, Defendants were
 prevented from selling stock for only 45 days. (Supplemental Declaration of William S.
 Freeman, Ex. U.)

25 ⁵ Strangely, Plaintiff argues that the "lack of insider sales during this critical time
 26 with Rigel was looking for a partner to back R788" made sense because stock sales would
 27 have been questioned by potential partners. (Opp. at 24.) But if that were true, then it would
 have made more sense for Rigel to wait to disclose the more detailed results until after a
 partnership deal had been completed.

28 ⁶ Because the Court concludes that Plaintiff has not alleged facts sufficient to state a
 claim under Section 10b-5, Plaintiff's Section 15 and 20(a) claims also must be dismissed.

1 *Miller v. Thane Intern., Inc.*, 519 F.3d 879, 886 (9th Cir. 2008). Nevertheless, these claims may
2 still be subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b)
3 if they are “grounded in fraud.” See *In re Stac Elec. Sec. Lit.*, 89 F.3d 1399, 1404-1405 (9th
4 Cir. 1996). A claim is “grounded in fraud” if the plaintiff alleges a unified course of fraudulent
5 conduct and relies entirely on that course of conduct as the basis of his or her claim. *Vess v.*
6 *Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1104 (9th Cir. 2003); see also *In re Daou Systems, Inc.*
7 *Sec. Litig.*, 411 F.3d 1006 (9th Cir. 2005) (holding that, even in the Section 11 context, a
8 plaintiff may be subject to Rule 9(b)’s particularity mandate where the complaint ‘sounds in
9 fraud’).

10 The Court finds that Plaintiff’s Section 11 and 12 claims are “grounded in fraud” and
11 thus subject to the pleading requirements of Federal Rule of Civil Procedure 9(b). Although
12 Plaintiff alleges that it does not assert that Defendants named in their Section 11 and 12 claims
13 are liable for fraudulent or intentional conduct, (CAC, ¶¶ 223, 231), the Ninth Circuit has held
14 that a nominal disclaimer of fraud is unconvincing where the gravamen of the complaint is
15 plainly fraud and no effort is made to show any other basis for the claims. *In re Stac Elec. Sec.*
16 *Lit.*, 89 F.3d at 1405 n.2. Here, the Court finds that Plaintiff’s disclaimer is merely nominal.
17 The same factual predicate of Plaintiff’s other claims underlie the Section 11 and 12 claims, and
18 such claims remain grounded in fraud. However, even if the disclaimer were sufficient, as
19 discussed above, Plaintiff fails to allege a material omission or misrepresentation. Thus,
20 Plaintiff’s Section 11 and 12 claims fail for this additional reason.

21 CONCLUSION

22 For the foregoing reasons, the Court grants Defendants’ motion to dismiss. There have
23 only been two iterations of the consolidated complaint in this matter, and the Court cannot
24 conclude that, at this point, it would be futile to grant Plaintiff leave to amend. Accordingly,
25 Plaintiff shall be granted leave to amend the CAC to address the deficiencies identified in this
26 Order. Plaintiff shall file any amended complaint within thirty days of the date of this Order. If
27 an amended complaint is filed, Defendants shall either file an answer or move to dismiss within
28

1 twenty days of service of the amended complaint. If Plaintiff does not file an amended
2 complaint within thirty days, the Court will dismiss this action without prejudice.

3 **IT IS SO ORDERED.**

4
5 Dated: August 24, 2010



6 JEFFREY S. WHITE
7 UNITED STATES DISTRICT JUDGE
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28