FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

In re: RIGEL PHARMACEUTICALS, INC. SECURITIES LITIGATION,

INTER-LOCAL PENSION FUND GCC/IBT, on behalf of itself and all others similarly situated,
Plaintiff-Appellant,

v.

ANDRE DELEAGE, Executor, Estate of Jean Deleage,
Appellee,

RIGEL PHARMACEUTICALS, INC.; JAMES M. GOWER; RYAN D. MAYNARD; DONALD G. PAYAN; RAUL R. RODRIGUEZ; ELLIOTT B. GROSSBARD; BRADFORD S. GOODWIN; GARY A. LYONS; WALTER H. MOOS; HOLLINGS C. RENTON; PETER S. RINGROSE; STEPHEN A. SHERWIN; CREDIT SUISSE SECURITIES (USA) LLC; OPPENHEIMER & CO. INC.; THOMAS WEISEL PARTNERS LLC; JEFFERIES & COMPANY, INC.,
Defendants-Appellees.

No. 10-17619
D.C. No. 3:09-cv-00546-JSW
OPINION

Appeal from the United States District Court
for the Northern District of California
Jeffrey S. White, District Judge, Presiding

Argued and Submitted
February 17, 2012—San Francisco, California

Filed September 6, 2012

Before: Procter Hug, Jr., Betty B. Fletcher, and Richard A. Paez, Circuit Judges.

Opinion by Judge Hug

COUNSEL

Sanford Svetcov, Robbins Geller Rudman & Dowd LLP, San Francisco, California, for the appellant.

John C. Dwyer, Cooley LLP, Palo Alto, California, for the appellees.

OPINION

HUG, Senior Circuit Judge:

I. INTRODUCTION

Plaintiff Inter-Local Pension Fund GCC/IBT ("Plaintiff") brought a securities fraud action[1] individually and on behalf[2] of all other persons who purchased or otherwise acquired the common stock of Rigel Pharmaceuticals, Inc. ("Rigel") between December 13, 2007 and February 3, 2009, pursuant to sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5. Plaintiff also brought claims on behalf of itself and persons who purchased Rigel stock traceable to the registration statement and prospectus issued in connection with Rigel's February 2008 stock offering, pursuant to sections 11, 12, and 15 of the Securities Exchange Act of 1934, 15 U.S.C. §§ 77k, 77l, and 77o.

The complaint focuses on alleged statements by Rigel and other individuals concerning the results of a clinical drug trial and alleged statements about partnership prospects for Rigel. Named defendants include Rigel, James M. Gower, Ryan D.

[1]Two separate complaints originally were filed. On March 19, 2009, the district court ordered the two actions consolidated. Plaintiff then filed a consolidated complaint on July 24, 2009. On December 21, 2009, the district court dismissed that complaint with leave to amend. On January 27, 2010, Plaintiff filed the consolidated amended complaint that is the subject of this appeal ("the complaint"). On August 24, 2010, the district court granted the defendants' motion to dismiss the consolidated amended complaint, but gave Plaintiff leave to amend. On September 22, 2010, Plaintiff informed the district court that it was electing to stand on the consolidated amended complaint. The district court then entered a final judgment on October 8, 2010.

[2]The district court did not certify a class.

Maynard, Donald G. Payan, Raul R. Rodriguez, Elliott B. Grossbard, Jean Deleage, Bradford S. Goodwin, Gary A. Lyons, Walter H. Moos, Hollings C. Renton, Peter S. Ringrose and Stephen A. Sherwin ("Defendants").

Plaintiff timely appealed the district court's August 24, 2010 order granting defendants' motion to dismiss the complaint.[3] We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

II. BACKGROUND

A. R788 and The Clinical Trial

Rigel is a clinical-stage drug development company that discovers and develops novel, small-molecule drugs for the treatment of inflammatory and autoimmune diseases, certain cancers, and other diseases. One of those drugs is R788, which Rigel is developing to treat and stop the progression of rheumatoid arthritis.

Rigel conducted a Phase IIa clinical trial to evaluate the safety and preliminary clinical efficacy of R788 in patients who were suffering from active rheumatoid arthritis despite therapy with methotrexate. The clinical trial was a multicenter, randomized, double-blind, placebo-controlled, ascending dose study involving 189 patients in the United States and Mexico. Rigel placed patients into one of three cohorts receiving either 50, 100, or 150 mgs of R788 orally twice daily over a twelve week period. Based upon a three to one ratio, Rigel assigned patients within each cohort to receive R788 or a placebo respectively.

[3]In its opening brief, Plaintiff has not raised any issues concerning the district court's dismissal of Plaintiff's section 12(a)(2) claim and therefore has waived any issues concerning that claim. *See In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1410 n.7 (9th Cir. 1996); *Officers for Justice v. Civil Serv. Comm'n of City & Cnty of San Francisco*, 979 F.2d 721, 726 (9th Cir. 1992).

Rigel measured efficacy for each participant based on the American College of Rheumatology ("ACR") criteria, which denote at least a twenty percent improvement (ACR20), at least a fifty percent improvement (ACR50), or at least a seventy percent improvement (ACR70). For scientific and ethical reasons, people conducting clinical trials generally select their trial methodology, including primary efficacy endpoints and statistical methodology, before the clinical trial begins. Rigel's chosen primary efficacy endpoint for the trial was the percentage of patients who were ACR20 responders by the end of the 12-week trial. ACR50 and ACR70 were secondary endpoints.

B. Reports of the Top-Line Results of the Clinical Trial

The complaint alleges that, on December 13, 2007, Rigel issued a press release concerning its Phase 2 clinical study for R788.[4] Among other things, the press release stated:

> Rigel Pharmaceuticals, Inc. . . . today announced that its oral syk kinase inhibitor, R788 (tamatinib fosdium), has demonstrated statistically significant results in treating Rheumatoid Arthritis (RA) patients in a recently completed Phase 2 clinical trial. 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 efficacy results for the 100mg and 150mg dose groups were fairly comparable. Dramatically, the onset of the effect in these dose groups occurred as early as one week after initiation

[4]Rigel allegedly filed a registration statement with the SEC on January 24, 2008 in connection with its secondary offering. Plaintiff alleges that, as a result of incorporating documents into the registration statement, Defendants made the December 13, 2007 press release, including the allegedly false and misleading statements contained in that press release, part of the registration statement.

> of therapy. We believe that the significant ACR scores and good tolerability observed in this clinical trial, and the further benefit of oral delivery may make R788 a favorable alternative to the currently marketed biological agents.

The press release included the following chart, entitled "Efficacy Results":

Treatment Assigned po bid	Number (N)	ACR20 % (N)	ACR50 % (N)	ACR70 % (N)	DAS28-CRP 2.6 % (N)
Placebo	47	38% (18)	19% (9)	4% (2)	17% (8)
50 mg	46	32% (15)	17% (8)	2% (1)	20% (9)
100 mg	49	65% (32) (p=.008)	49% (24) (p=.002)	33% (16) (p<.001)	35% (17) (p=.005)
150 mg	47	72% (34) (p<.001)	57% (27) (p<.001)	40% (19) (p<.001)	47% (22) (p<.001)

The press release also included information concerning side effects, stating:

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

In addition, the press release also provided:

The key safety results are shown in the table below:

	Placebo po BID N=47	50mg po BID N=46	100mg po BID N=49	150mg po BID N=47
Completed Study at Reduced Dose (N)	1	0	5	13
Dropouts (N):	11	6	6	8
Withdrew Consent	6	3	2	1
Adverse Event	2	1	3	6
Other	3	2	1	1
Neutropenia (N) Requiring dose reduction	0	0	5	10
ALT>3XULN (N)	2	0	0	3
Diarrhea (N) (severity moderate or greater)	0	3	2	10
Upper GI side effects (N) (gastritis, nausea, dyspepsia) (severity moderate or greater)	2	1	2	12
Hypertension (N) (severity moderate or greater)	0	0	2	0

The complaint alleged that, on the same day that Rigel issued its press release, it also held a conference call with, among others, Gower and Dr. Grossbard. During the conference call, Dr. Grossbard referenced the handout and discussed some of the results. When discussing efficacy and the statistical significance of the results, Dr. Grossbard stated:

> The p values are uniformly less than .008, usually less than .001. . . . We have concluded that the 100 milligram and 150 milligram dose groups have impressive and statistically significant improvements over placebo, and that the onset occurs very, very early. The efficacy results for the two effective doses

> were fairly comparable, and the 100 milligrams bid dose kind of caught up by the end so that they were really equivalent. The 50 milligram dose [does] not appear to be much better than placebo, and so overall there was a good dose response.

Dr. Grossbard then went on to discuss the reported safety results. As part of that discussion, he allegedly stated:

> 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.

Dr. Grossbard explained that there "is a dose response, so the higher the dose, the more side effects." He also noted that the most common side effects were neutropenia and gastrointestinal side effects and that those side effects were most prevalent with the 150 mg dose.

During the conference call, Dr. Grossbard stated that he would be writing a paper with Dr. Michael Weinblatt, Professor of Medicine at Harvard Medical School, and that the paper would be "the next significant statement about the results of this study."

On July 8, 2008, Rodriguez allegedly presented efficacy and safety graphs at the Collins Stewart 4th Annual Growth Conference. Among other things, Rodriguez allegedly stated

that, during the clinical trial, there was "[a] bit of hypertension here and there."

C. Presentation of Detailed Results and Analysis to Doctors and Scientists

The complaint alleges that Defendants subsequently reported additional information about the clinical trial when Drs. Weinblatt and Grossbard gave a presentation to physicians at the ACR Annual Scientific Meeting on October 27, 2008 and when a scholarly article was published in the November 2008 issue of the medical journal "*Arthritis and Rheumatism*." This information was more academic and detailed.

During the October 27, 2008 presentation, Rigel allegedly provided dose response information, broken down based on whether the patient received R788 in Mexico or in the United States. The following chart was presented:

	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 Mexico 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%)

On the day that this data was presented, Dr. Grossbard allegedly 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.

Dr. Grossbard explained, "you get the same difference but different points of departure." The journal article contained a similar discussion, stating that there were "higher clinical responses being observed in patients enrolled from Mexico in both the placebo group and the R788 groups. Even with this difference in response rates between the 2 countries, the difference between active drug and placebo remained >20%."

The journal article contained much more extensive, detailed, and scientific information. For example, the article reported the data regarding age, gender, and race of the patient participants, the number of tender and swollen joints, the number of patients on prednisone, and the dosage of methotrexate that patients were receiving. Details also included all the adverse events experienced by patients in three percent or more of any group, regardless of severity, causation, frequency, treatment, or dosage. Thus, in addition to the more severe adverse events disclosed in the original reports, the journal article showed that, out of the 142 patients receiving the drug, six patients had experienced smaller elevations of liver enzymes, three patients had experienced mild hypertension, five patients had experienced less significant neutropenias that did not require dose adjustment, and 19 patients had experienced mild diarrhea. The article included information about the number of patients receiving the placebo who experienced these kinds of adverse events and it reported on other kinds of adverse events experienced by

study participants, such as headaches, coughs, rashes, and fatigue.

The journal article repeated some of the same earlier information regarding efficacy, including the same p-values. In addition, the journal article discussed statistical analysis used for the study.

D. Rigel's Statements Regarding a Potential Partnership

The complaint alleges that Defendants made misleading comments about Rigel's prospects for obtaining a partner for development of R788. On October 27, 2008, Gower allegedly 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." He indicated that the end of the first quarter of the following year would be "ideal," but that "it's certainly not in our control that it would be." In addition, he acknowledged that he could not know that potential partners would not "freak out" about the credit crisis occurring at the time and also recognized that partnership deals can take a long time to put in place. On November 3, 2008, Gower allegedly stated: "We expect to establish a collaboration partnership to further these ends, and that in fact is going quite well."

III. STANDARD OF REVIEW

The decisions of a district court on motions to dismiss are reviewed de novo. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). We must accept as true all well-pleaded allegations in the complaint. *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008). "If support exists in the record, the dismissal may be affirmed on any proper ground, even if the district court did not reach the issue or relied on different grounds or reasoning." *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1295 (9th Cir. 1998).

Rule 8(a) of the Federal Rules of Civil Procedure requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 12(b)(6) authorizes courts to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To avoid dismissal, the complaint must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true. *Id.* Our review of challenges to a dismissal for failure to state a claim is generally limited to the face of the complaint, materials incorporated into the complaint by reference, and matters of which we may take judicial notice. *Zucco*, 552 F.3d at 989.

In addition to the pleading requirements of Rule 8, there are more demanding pleading requirements for certain causes of action, especially securities fraud. We discuss those specific requirements in the relevant sections below.

IV. ANALYSIS

A. Section 10(b) and Rule 10b-5

The district court dismissed the section 10(b) and Rule 10b-5 claim on the grounds that the complaint failed to sufficiently allege a false or misleading statement or omission and failed to sufficiently allege scienter. We conclude that this was not error.

1. Elements and Pleading Requirements

[1] Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful for any person to:

> use or employ, in connection with the purchase or sale of any security registered on a national securi-

> ties exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b). One of those rules promulgated under the Act is Securities and Exchange Commission Rule 10b-5, which makes it unlawful to, among other things, "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b).

To sufficiently plead a primary violation of Rule 10b-5 based on misstatements, a plaintiff must adequately allege the following: 1) a material misrepresentation or omission by the defendant; 2) scienter; 3) a connection between the misrepresentation or omission and the purchase or sale of a security; 4) reliance upon the misrepresentation or omission; 5) economic loss; and 6) loss causation. *Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008). In the case before us, the district court held that Plaintiff had failed to sufficiently plead that there was a misrepresentation or omission and also had failed to sufficiently plead scienter.

[2] At the pleading stage, a complaint alleging claims under section 10(b) and Rule 10b-5 must not only meet the requirements of Rule 8, but must satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *Zucco*, 552 F.3d at 990. Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Thus, Rule 9(b) requires particularized allegations of the circumstances constituting fraud, including identifying the statements at issue and setting forth what is false or misleading

about the statement and why the statements were false or misleading at the time they were made. *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-49 (9th Cir. 1994).

The PSLRA imposes additional specific pleading requirements, including requiring plaintiffs to state with particularity both the facts constituting the alleged violation and the facts evidencing scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007).

Under the PSLRA, to properly allege falsity, a securities fraud complaint must now "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); *see also Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 n.4 (2011); *Zucco*, 552 F.3d at 990-91.

To adequately plead scienter under the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A); *see also Tellabs*, 551 U.S. at 314.

2. Falsity

Plaintiff's allegations regarding falsity fall into three general categories: 1) statements related to efficacy; 2) statements related to safety; and 3) statements about Rigel's future partnership prospects.

a. Statements Related To Efficacy

Plaintiff contends that the district court's analysis of the alleged statements relating to efficacy was erroneous because Plaintiff adequately pled falsity with respect to reported study

results and adequately pled falsity with respect to country effect.

i) Statistical Methodology

The district court held that Plaintiff had failed to adequately plead a false statement regarding efficacy because disagreements over statistical methodology and study design are insufficient to allege a materially false statement. Plaintiff argues that it met the pleading requirements by alleging "false" study results, including allegations of "statistically 'false p-values' "[5] and inaccurate and improper statistical analysis. We hold that the district court did not err.

In order to allege falsity, a plaintiff must set forth facts explaining why the difference between two statements "is not merely the difference between two permissible judgments, but rather the result of a falsehood." *In re GlenFed, Inc. Securities Litigation*, 42 F.3d 1541, 1549 (9th Cir. 1994) (en banc).

It is apparent from the complaint that Plaintiff's allegations of "falsity" were based on its contention that Defendants should have used a particular statistical methodology, which it described in the complaint. Plaintiff did not allege that Defendants inaccurately reported the results of their own statistical analysis. Plaintiff also did not allege that Defendants had chosen or changed their statistical methodology after seeing the unblinded raw data from the clinical trial. Instead, Plaintiff challenged Defendants' reported statistical results by alleging that Defendants should have used Plaintiff's chosen statistical methodology, including calculating separate p-values for the United States and Mexico and combining those results using "Fisher's method," and using "Tukey's Studentized Range test." Plaintiff alleged that using its proposed statistical methodology would result in different p-values for the

[5]In clinical trials, p-values usually are used to determine the statistical significance of the results.

100 mg and 150 mg doses at ACR 20 and that these newly calculated p-values were not statistically significant.

[3] Thus, Plaintiff's allegations of "falsity" essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study, wrote the journal article, and selected the article for publication. The allegations therefore concern two different judgments about the appropriate statistical methodology to be used by Defendants. The allegations are not about false statements.

Although Plaintiff argues that it is simply challenging the truth of the reported results, not the study design, there are multiple problems with this argument. First, regardless of whether the statistical methodologies used to calculate p-values are considered part of the study design, Plaintiff is alleging that Defendants should have used different statistical methodologies, not that Defendants misrepresented the results they obtained from the methodologies they employed.

Second, to accept Plaintiff's argument that it is not challenging the study design, we would have to draw a line between *using* a particular method of statistical analysis that was part of a study's protocol and adopted prior to unblinding the data and *disclosing results* that were calculated using that statistical analysis. Drawing such a distinction would suggest that a company should announce statistical results that are obtained using a statistical methodology that is adopted after the study data is made available to the researchers and that is different from the methodology used as part of the clinical trial. Such a post-hoc adoption of a statistical method could raise concerns regarding reliability, biased scientific methods, or even fraud. *See United States v. Harkonen*, No. C 08-00164, 2010 WL 2985257, *4, 7-10 (N.D. Cal. July 27, 2010).[6]

[6]Plaintiff relies on *Harkonen* to argue that the p-values and clinical results reported here were "false." Plaintiff's reliance on *Harkonen* is misplaced. *Harkonen* was a criminal wire fraud case where the district court

Because there are many ways to statistically analyze data, it is necessary to choose the statistical methodology before seeing the data that is collected during the clinical trial; otherwise someone can manipulate the unblinded data to obtain a favorable result. *Id.* at *4. Thus, the principal features of the statistical analysis usually are included in the protocol and the statistical analysis plan is finalized before the data is unblinded.

[4] Neither the Supreme Court nor this court has addressed the question of whether statements concerning statistical results of a clinical trial may be considered false or misleading under Rule 10b-5 because the statistical methodology that produced those results was not the best or most acceptable methodology. However, the district courts that have addressed this issue support our conclusion that merely alleging that defendants should have used different statistical methodology in their drug trials is not sufficient to allege falsity. For example, in *Padnes v. Scios Nova Inc.*, No. C 95-1693, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996), the plaintiffs alleged that the defendants made false public statements relating to the results of a Phase II drug study. The defendants had made public statements that the results of a drug trial were statistically significant. *Id.* at *2. The plaintiffs did not allege that the defendants' statements summarizing their study inaccurately reported their own conclusions. *Id.* at *5. Rather, among other things, the plaintiffs alleged that the defendants

found that there was sufficient evidence to support the conviction because statements in the defendant's press release contradicted his own study methodology and statistical calculations, and because the defendant engaged in post-hoc calculations based on unblinded data to report a different result, without revealing the timing and process for these calculations. *Harkonen*, 2010 WL 2985257 at *3-12. In the case before us, however, we have a securities fraud action where Plaintiff may implicitly be suggesting that Defendants *should* have engaged in similar conduct, but there are no allegations that Defendants actually did engage in similar conduct.

should have included in their public summaries of the study different measurements of the study's outcome than those performed by the researchers. *Id.* at *5.

The court held that the fact that the plaintiffs disagreed with the researchers about the import of the data did not make the defendants' summaries of the study false or misleading. *Id.* In addition, the court concluded that the securities laws do not require that companies report information only from optimal studies, even assuming that scientists could agree on what is optimal, and that companies reporting information from imperfect studies are not required to disclose alternative methods for interpreting the data. *Id.* The court therefore held that the plaintiffs did not plead facts sufficient to explain why the defendants' summaries of the study were false or misleading. *Id.*; *see also In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) (where plaintiffs' statistician identified what he believed were problems with a defendant's statistical analysis of a clinical trial, plaintiff merely alleged a disagreement about how to conduct and analyze the study, not a false or misleading statement); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim.").

[5] We find this reasoning persuasive. Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results.

ii) Statements Relating to Country Interaction and Corresponding Dose Response

Plaintiff argues that the complaint adequately alleges falsity by alleging that Defendants' initial presentation of results

based on combined data[7] from the United States and Mexico misled investors because the combination of data from the two countries concealed the existence of a country interaction and consequently falsely indicated that there was a strong ascending dose response (i.e. higher doses of R788 corresponded to greater improvement in patients) between the 100 mg dose level and the 150 mg dose level.

We reject this argument. In fact, according to Plaintiff, the press release regarding the results of the study stated that the "efficacy results for the 100mg and 150mg dose groups were fairly comparable." Similarly, during the conference call conducted that same day, Dr. Grossbard allegedly also stated that the efficacy results for those two doses were "fairly comparable." The clear import of these alleged statements was that there was *not* an ascending dose response between the 100 mg and 150 mg dose levels. Therefore, Plaintiff did not adequately plead falsity with respect to country interactions or dose response.

[6] Accordingly, we affirm the district court's ruling that Plaintiff did not sufficiently plead falsity with respect to the allegations relating to efficacy.

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[7]To the extent Plaintiff is challenging the statistical methodology used by Defendants, that issue is addressed above.

In addition, to the extent Plaintiff suggests that parties conducting clinical trials necessarily are required to release all the detailed data or break that data down by categories that may plausibly be of interest to some investors, Plaintiff is incorrect. Section 10(b) and Rule 10b-5 do not categorically prohibit statements that are incomplete or that report cumulative figures instead of detailed breakdowns of the underlying data or subcategories of data. *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006, 1006 n.8 (9th Cir. 2002); *see also In re Adolor Corp. Securities Litigation*, 616 F. Supp. 2d at 569 (holding that company was not required to provide data or analysis on subgroups of patients in clinical trial even if sub-group information was material and the company had made public statements about top-line results).

b. Statements Related to Safety

Plaintiff contends that the district court erred when it ruled that Plaintiff failed to adequately plead falsity with respect to Defendants' initial statements about certain safety-related results from the clinical trial.[8] Plaintiff argues that Defendants should have disclosed more information concerning side effects on the day of the initial press release because the omission of some information related to side effects made the initial statements misleading. For example, Plaintiff argues that Defendants should have reported more information related to blood pressure or liver enzyme levels.

[7] The December 13, 2007 press release clearly identified its table of results for certain side effects as "*key* safety results," not "all safety results" or even just "safety results."

[8]Although the district court held that Plaintiff had not adequately pled false or misleading statements, much of Plaintiff's argument on appeal concerns the significance of allegedly omitted information to possible investors rather than whether the alleged omission of information made the alleged statements misleading. The materiality of information is different from the issue of whether a statement is false or misleading.

Plaintiff contends that, after the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309 (2011), once a company chooses to disclose any safety information, it must disclose all material information regarding safety. This contention misconstrues the Supreme Court's opinion in *Matrixx*. *Matrixx* established that section 10(b)(5) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information; section 10(b) and Rule 10b-5 prohibit only misleading and untrue statements, not statements that are incomplete. *Matrixx*, 131 S. Ct. at 1321-22. The *Matrixx* Court made it clear that not all adverse events would be material and, more importantly, that not all material adverse events would have to be disclosed. *See id.* "Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id.* at 1322. Thus, as long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant.

Defendants never claimed that these were all of the safety results or that these results included every occurrence of every possible side effect.

[8] Moreover, for each category of side effect the press release did address, the press release made clear what the criteria were for including patients in the category. For example, for hypertension, the press release stated that it was including hypertension of moderate severity or greater. The press release did not state that it was including all incidents in which a patient experienced an increase in blood pressure during the course of the trial. With regard to liver function, the press release did not state that it was including all patients in which there was any increase in liver enzymes regardless of the degree or impact of the increase. Rather, the press release stated that it was noting cases in which a liver enzyme (ALT) was three times the upper limit of normal (3XULN). It also stated that, for neutropenia, patients were included based on whether dose reduction was necessary. For diarrhea and upper GI side effects, the press release stated that it was including incidents of moderate severity[9] or greater.

[9] Plaintiff does not allege that Defendants omitted information that fell into these categories. Rather, Plaintiff alleges that Defendants should have initially reported other information concerning side effects instead of waiting to report that information in the journal article. However, the subsequent release of more extensive information, such as a few cases of mild hypertension or some cases of neutropenias that did not require dose reductions, was not inconsistent[10] with the results

[9]Plaintiff's contention that investors might not understand that a term such as "moderate" did not include side effects of lesser severity has no merit. Any investor reading the press release would understand that Rigel had set thresholds for reporting its "key safety findings" and that the press release did not include all side effects experienced by participants in the drug trial.

[10]Thus, the facts in the instant case are very different from those in *Matrixx*. In *Matrixx*, the defendant allegedly had evidence of a biological

that originally were reported. Moreover, even if some investors might have wanted more extensive information related to blood pressure, liver enzymes, or other matters, that would not be sufficient to make the alleged original statements false or misleading. Accordingly, we hold that Plaintiff did not adequately allege that the initial statements related to possible side effects were false or misleading.

c. Statements Related to Partnership Prospects

Plaintiff contends that the district court erred when it held that Plaintiff had not sufficiently alleged that Defendants' statements regarding partnership prospects were false or misleading. The complaint alleges that, on October 27, 2008, Gower falsely stated: "[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. I doubt it will be this year." The complaint also alleges that, on November 3, 2008, Gower falsely stated: "We remain committed to doing everything possible to develop and commercialize R788 in RA. We expect to establish a collaboration partnership to further these ends, and that in fact is going quite well."

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link between its drug's key ingredient and anosmia and had not conducted any studies of its own to disprove that link. 131 S. Ct. at 1319-23. However, the defendant allegedly did more than withhold this information from the public; it allegedly contradicted its own information, publicly stating that reports indicating that its drug caused anosmia were "completely unfounded and misleading" and that "the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established." *Id.* at 1323 (internal quotation marks omitted). Accordingly, the Court concluded that, assuming the alleged facts to be true, the undisclosed causation information was not only material, but constituted facts "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." *Id.* (internal quotation marks omitted). The Court therefore held that the plaintiff adequately pleaded a misrepresentation or omission. *Id.* Here, in contrast, although the allegedly omitted information was more detailed and extensive than the alleged original statements, the omitted information did not contradict, or render misleading, the original reports of the top-line results.

[10] The complaint further alleges that, because potential partners had access to the clinical trial data, and because Defendants "knew" the results were not really statistically significant, Rigel was not on track for a partnership and defendants knew it.[11] Plaintiff does not allege any specific facts that would show that Defendants did not really expect to enter into a partnership, that Rigel was not really moving towards a partnership,[12] or that Defendants believed that the clinical trial results were not statistically significant. Rather than adequately pleading that the statements regarding partnership plans and expectations were *false*, the complaint effectively pleads only that Defendants should have had different expec-

[11]In concluding that the allegations were inadequate, the district court reasoned, in part, that Plaintiff had not alleged any facts showing that Defendants "believed" or "knew" that their statements regarding partnership prospects and the clinical trial results were false. Plaintiff argues that the district court thus improperly conflated falsity and scienter. However, because the allegations relating to partnership prospects concerned the Defendants' statements about their *expectations*, Defendants' mental states were at issue when analyzing falsity. Moreover, Plaintiff's complaint claims that Defendants' statements regarding partnership prospects were false because Defendants "knew" at the time that the results of the clinical trial had derailed Rigel's partnership prospects. When the alleged false statements are about a defendant's own beliefs and expectations, the analysis of falsity and scienter often will involve examination of the same facts. *See, e.g.*, *Ronconi v. Larkin*, 253 F.3d 423, 429-30 (9th Cir. 2001).

[12]The district court did not take judicial notice of the fact that Rigel did subsequently enter into a partnership agreement with AstraZeneca. We do not take judicial notice of the partnership agreement either. In any event, our analysis would be the same regardless of whether Rigel entered into a partnership agreement. The mere fact that stated expectations fail to come to pass does not make a statement concerning expectations or plans false. *See Ronconi*, 253 F.3d at 429-30.

In their brief, Defendants argue that it would be appropriate for us to take judicial notice of a number of other documents in order to address misrepresentations made by Plaintiff with respect to other issues such as clinical trial results and analyst reports. Although we understand Defendants' frustrations, we decline to take judicial notice of any documents. The record is sufficient for us to address any issues that are relevant to our analysis.

tations and beliefs concerning partnership prospects. Because the complaint does not allege that Defendants falsely represented their actual partnership plans and expectations, the allegations are insufficient to plead falsity. *See Ronconi v.* Larkin, 253 F.3d 423, 429-30 (9th Cir. 2001) (holding that complaint did not sufficiently plead falsity where it alleged that defendant made false statements about earnings and sales expectations and that defendant stated that plan to cut jobs and costs was "on track," but complaint did not allege facts showing that defendant knew at the time that the predictions were inaccurate).

[11] Accordingly, we hold that Plaintiff has failed to meet the pleading requirements for falsity under Rule 8, Rule 9(b), and the PSLRA.

3. Scienter

[12] Plaintiff contends that the district court erred when it concluded that Plaintiff had not sufficiently pled scienter. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (internal quotation marks omitted).

[13] To adequately plead scienter under the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). To qualify as a "strong inference," the Supreme Court has held, "an inference of scienter must be more than merely plausible or reasonable." *Tellabs,* 551 U.S. at 314. When determining whether there are sufficient allegations of scienter, courts "must consider the complaint in its entirety . . . [and inquire] 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." *Id.* at 322-23. Moreover, courts must take into account plausible opposing inferences. *Id.* at 323. A complaint will survive a motion to dismiss "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

Plaintiff argues that it met the requirements for pleading scienter by alleging that Defendants knew of the detailed study results when they made the allegedly fraudulent statements and by alleging that Defendants had financial motives for making fraudulent statements. These arguments are unconvincing, and we hold that the district court did not err when it determined that Plaintiff had not sufficiently pled scienter.

a. Knowledge of the Study Data

Plaintiff argues that Defendants knew that their statements regarding statistical significance and efficacy were false because they had access to the clinical trial results and therefore knew there was a substantial country interaction and knew what the blood pressure data was. Even assuming, *arguendo*, that Plaintiff adequately pled that all of the defendants had knowledge of the detailed clinical results at the time the allegedly false statements were made, such an allegation does not support a strong inference of scienter.

[14] Although Plaintiff notes that it alleged that Dr. Grossbard knew there was a country effect, Plaintiff points us to no allegations that Dr. Grossbard or any of the other defendants believed that they made false or misleading statements relating to a country effect or that Defendants believed that they were misrepresenting the statistical significance of their results. Moreover, to the extent Plaintiff has provided us with any indication about Dr. Grossbard's views regarding country effects, the inference is that, after looking at the results, Dr. Grossbard was not concerned about comparative patient

responses in the United States and Mexico for at least two reasons: 1) he believed the differences between the active and placebo patients were similar for both countries, but simply had different starting and ending points; and 2) he was aware of other rheumatoid arthritis drugs that had been approved by the FDA and similarly had included a significant number of Latin American patients in their clinical trials and had shown higher response rates in Latin American patients than in American and European patients during their drug trials.

[15] Plaintiff next contends that it adequately pled scienter by alleging that the earlier reports by Defendants failed to disclose some blood pressure information. Plaintiff acknowledges that Rodriguez stated that there was a "bit of hypertension here and there," but asserts that he concealed the fact that five patients experienced hypertension, not two as was initially reported. The complaint does not specifically allege that Rodriguez himself stated that there was any particular number of patients who suffered from hypertension. However, the complaint does allege that he presented a chart relating to safety. Even assuming that Plaintiff adequately alleged that this was the same chart from the December 13, 2007 press release, which reported two incidents of moderate or higher hypertension, such an allegation would be insufficient to support a finding of scienter. The complaint does not allege that there were patients excluded from that chart who experienced moderate or severe hypertension. More importantly for purposes of scienter, the complaint does not allege that Defendants *believed* that there were more patients than those listed on the chart who experienced moderate or severe hypertension. Instead, Plaintiff essentially is arguing only that Rodriguez knew he was not reporting information concerning all cases of hypertension, regardless of severity, or all incidents of increased blood pressure. This is not sufficient to allege that he or the other defendants believed that they were making false or misleading statements related to blood pressure.

In addition, as the district court noted, if Defendants were intent on misleading investors about the safety of R788, it does not make sense that the safety information they would choose to disclose in their initial, allegedly fraudulent, reports, would be the most severe adverse events.

b. Motive For Fraud

Plaintiff contends that its allegations regarding motive bolster its scienter pleadings. In support of this argument Plaintiff argues that it alleged a motive to commit fraud when it alleged that, at the time the allegedly fraudulent statements were made, Defendants were seeking a partner and were planning to raise capital in a stock offering. In addition, Plaintiff points to its allegations that individual defendants knew that they would receive higher salaries, bonuses, and stock options and that the value of their stock options would increase substantially if Rigel reported positive results from the clinical trial.

[16] However, allegations of routine corporate objectives such as the desire to obtain good financing and expand are not, without more, sufficient to allege scienter; to hold otherwise would support a finding of scienter for any company that seeks to enhance its business prospects. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002). In addition, it is common for executive compensation, including stock options and bonuses, to be based partly on the executive's success in achieving key corporate goals. Thus, especially given the holistic approach to assessing scienter adopted in *Tellabs* and the requirement that we take into account plausible opposing inferences, we will not conclude that there is fraudulent intent merely because a defendant's compensation was based in part on such successes. *See Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1166 (9th Cir. 2009) (holding that allegations of motive and opportunity were not enough to create a strong inference of scienter).

In addition, the individual defendants' conduct concerning their stock is inconsistent with Plaintiff's theory that financial motive establishes scienter here. The complaint alleges that individual defendants knew that the value of their stock options would increase if Rigel reported positive results from the clinical trial. However, because none of the defendants sold stock during the period between the allegedly fraudulent statements and the subsequent public disclosure of the detailed data, which is the period during which they would have benefitted from any allegedly fraudulent statements, the value of the stock and stock options does not support an inference of scienter. *See Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 (9th Cir. 2008) (holding that, where a defendant sold no stock at all, this suggested that there was no insider information from which to benefit and there was not a strong inference of scienter); *Ronconi v. Larkin*, 253 F.3d 423, 436 (9th Cir. 2001) (holding that, where knowledgeable insiders did not sell stock at a time that would have taken advantage of allegedly fraudulent statements, there was not a strong inference of scienter). In fact, it supports the opposite inference.[13]

Moreover, if the individual defendants were acting based on their belief that they had a financial motive to conceal the "true" results of the clinical trial, they would not have voluntarily publicly disclosed all the data and the statistical methodology. They also would not have decided that the people to receive that detailed information should be the people most likely to identify any problems with the study — the doctors and scientists who were at the scientific meeting and who were publishing and reading the journal article.

[13]Similarly, the argument that Defendants made the allegedly fraudulent statements in order to obtain a partner makes no sense given that Defendants disclosed the detailed information before entering into a partnership agreement.

c. Holistic Review

[17] Overall, the inference of scienter here is weak, and certainly not as strong as the inference that Defendants had a non-fraudulent intent. Thus, the district court did not err when it determined that Plaintiff did not sufficiently plead scienter.

B. Section 11 Claim

Plaintiff contends that the district court erred when it dismissed the section 11 claim.[14] The district court concluded that Plaintiff's section 11 claim was grounded in fraud and therefore was subject to the pleading requirements contained in Rule 9(b), which it then held were not met. Alternatively, the court held that Plaintiff had failed to allege a material omission or misrepresentation.

The particularity requirements of Rule 9(b) apply to claims brought under section 11 when such claims are grounded in fraud. *Stac Elecs.*, 89 F.3d at 1404-05. Plaintiff argues that its section 11 claim is not grounded in fraud, pointing out that it disclaimed in its complaint any allegation of fraud in connection with the section 11 cause of action, and contending that it did not incorporate any of the section 10(b) conduct allegations in its section 11 claim.

We have held that a plaintiff's nominal efforts to disclaim allegations of fraud with respect to its section 11 claims are unconvincing where the gravamen of the complaint is fraud and no effort is made to show any other basis for the claims. *Stac Elecs.*, 89 F.3d at 1405 n.2. "To ascertain whether a complaint 'sounds in fraud,' we must normally determine, after a

[14]Section 11 of the Securities Act creates a private remedy for purchasers of a security if the registration statement "contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a); *Stac Elecs.*, 89 F.3d at 1403.

close examination of the language and structure of the complaint, whether the complaint 'allege[s] a unified course of fraudulent conduct' and 'rel[ies] entirely on that course of conduct as the basis of a claim.' " *Rubke v. Capitol Bancorp Ltd*, 551 F.3d 1156, 1161 (9th Cir. 2009) (*quoting Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003)) (alterations in original). A plaintiff "may choose not to allege a unified course of fraudulent conduct in support of a claim, but rather to allege some fraudulent and some non-fraudulent conduct." *Vess*, 317 F.3d at 1104.

[18] Here, although the section 11 claim does not adopt all of the allegations contained in the rest of the complaint, it does not allege different misrepresentations. Instead, it merely relies on the same alleged misrepresentations from the December 13, 2007 press release that are central to Plaintiff's section 10(b) fraud claim. Accordingly, Plaintiff's section 11 claim is grounded in fraud and Plaintiff must meet Rule 9(b)'s pleading requirements. This does not mean, as Plaintiff contends, that it may not plead alternative theories of liability; it merely means that, with both the section 10(b) and the section 11 claims, Plaintiff must meet the pleading requirements of Rule 9(b). For the same reasons discussed above regarding the section 10(b) claim, we hold that, for the section 11 claim, Plaintiff has failed to meet Rule 9(b)'s pleading requirements with respect to pleading a false or misleading statement.[15]

C. Section 15 and Section 20(a) Claims

[19] Section 20(a) and section 15 both require underlying primary violations of the securities laws. 15 U.S.C. §§ 77o, 78t(a). Because Plaintiff here has failed to adequately plead a violation of the federal securities laws, it follows that Plaintiff also has failed to adequately plead violations of section 20(a) and section 15.

[15]In addition, the allegations do not even meet Rule 8(a)'s requirements because they do not allege a material omission or misrepresentation.

V. Conclusion

For the foregoing reasons, the district court's order granting the motion to dismiss is **AFFIRMED.**