IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

JERRY TWINDE, on behalf of himself and all others similarly situated,

Plaintiff,

v.

THRESHOLD PHARMACEUTICALS, INC.; HAROLD E. "BARRY" SELICK; and JANET I. SWEARSON,

Defendants.
_____/

No. C 07-4972 CW

CLASS ACTION

ORDER GRANTING IN PART DEFENDANTS' MOTION TO DISMISS

This is a securities fraud class action case on behalf of purchasers of the publicly traded common stock of Threshold Pharmaceuticals, Inc. Defendants Threshold, Harold E. "Barry" Selick and Janet Swearson are alleged to have defrauded investors by promoting a drug despite indications that it was not likely to pass Food and Drug Administration (FDA) approval. Defendants have filed a motion to dismiss the Consolidated Second Amended Class Action Complaint (SAC). Lead Plaintiff Michael Hentosh[1] opposes

[1]In an order dated November 5, 2007, the Court granted Michael Hentosh's unopposed motion to serve as Lead Plaintiff.

the motion. The motion was heard on February 5, 2009. Having considered all of the parties' papers and oral argument on the motion, the Court grants in part Defendants' motion to dismiss. The claims that are dismissed pursuant to this order were previously dismissed with leave to amend on July 11, 2008. Because Lead Plaintiff failed to cure the deficiencies in the first amended complaint as instructed by the Court, those claims are now dismissed without leave to amend.

BACKGROUND[2]

Defendant Threshold Pharmaceuticals is a development-stage drug company that was founded in 2001. Threshold's research focuses on a process it describes as "metabolic targeting," in which drugs target abnormal glucose metabolism to starve and kill off diseased cells while leaving healthy cells with normal glucose metabolism unharmed. Defendant Selick is Threshold's Chief Executive Officer (CEO) and a member of its Board of Directors. Defendant Swearson was Threshold's Chief Financial Officer (CFO) during the class period.

Lead Plaintiff Michael Hentosh purports to represent a class of persons and entities who purchased Threshold's publicly traded common stock between February 4, 2005 and July 14, 2006, including those who purchased stock in or traceable to Threshold's February, 2005 initial public offering (IPO) or its October, 2005 follow-on offering.

Lead Plaintiff alleges that in the months leading up to its

[2] All facts are taken from Lead Plaintiff's SAC and are assumed to be true for purposes of these motions.

IPO, Threshold was in the process of developing three drugs, including TH-070, a drug intended to treat Benign Prostatic Hyperplasia (BPH). BPH is a disease common among middle-aged and older men that causes the prostate to enlarge. This enlargement can partially or completely block the urethra, leading to a variety of urinary and bladder symptoms. Lead Plaintiff characterizes BPH as "a common and relatively non-serious, though bothersome, side effect of aging that affects nearly all men by the time they reach 70 years old." SAC ¶ 34. If left untreated, severe BPH can lead to kidney and bladder damage, bladder stones and incontinence.

The estimated market for a fast, safe and effective treatment for BPH is $1.6 billion. Lead Plaintiff alleges that, at the time of the IPO, one of Threshold's other two drugs in development, glufosfamide, was farther along in the development process, but that the market for that drug, which was intended to treat pancreatic cancer, was only $400 million. Therefore, Threshold elected to emphasize its progress with TH-070, despite the drug's early stage of development, in its efforts to convince investors to purchase shares through its IPO. TH-070 was a preparation of lonidamine, a drug that has never been approved for distribution in the United States and had, at the time Threshold began developing TH-070, been approved only in Italy and for treating seriously ill cancer patients.

Lead Plaintiff further alleges that, in January, 2004, when Threshold realized it would need public investors to support its clinical trials for TH-070 and glufosfamide, it

> planned a quick study of 60 patients in Bari, Italy

> treated with lonidamine. Before the Bari Study was complete, Threshold got the results it wanted [and] cancelled the second half of the study . . . .

SAC ¶ 4. The results of the Bari Study were available to Defendants at the time of the IPO and, in the IPO documents, Threshold predicted that it would "publish results of this trial in the second quarter of 2005." Mitchell Decl., Ex. A at 49. Lead Plaintiff alleges that Threshold misused the results of the abbreviated Bari Study when it

> told investors it had statistically significant results demonstrating that TH-070 worked better than existing BPH treatments, including blockbuster drugs Flomax and Proscar. Threshold also told investors that TH-070 was well tolerated and safe, with no serious side effects.
>
> Threshold repeatedly trumpeted the purportedly positive results of the Bari Study to the market, permitting it to complete both its IPO and the Follow-on Offering and raising more than $100 million in cash. . . . Threshold used this money to fund phase 2 and 3 clinical trials of TH-070 and glufosfamide, as well as to pay generous salaries and bonuses and provide potentially lucrative stock options to its senior management, including Selick and Swearson.

SAC ¶ 4-5.

Lead Plaintiff alleges that, through these communications, Defendants misrepresented the likelihood that TH-070 would be approved by the FDA and failed to disclose negative information already in their possession. More specifically, Lead Plaintiff alleges that Defendants negligently published materially false and misleading information in the prospectuses and registration statements related to the February, 2005 IPO and the October, 2005 follow-on offering when they emphasized the positive results of the Bari Study with respect to the safety of TH-070 and downplayed or failed to "accurately or completely disclose the specific risks

associated with" the drug. SAC ¶ 65.

For example, Lead Plaintiff alleges that, in the February 4, 2005 prospectus relating to the IPO, Defendants misleadingly stated that the "primary objective" of the Bari Study was "to determine the safety and tolerability of TH-070 in patients with BPH." SAC ¶ 64. However, Lead Plaintiff alleges that "the Bari Study was not designed to demonstrate the safety and efficacy of TH-070. To the contrary, the safety of TH-070 was assumed based on its prior use in treating cancer patients in Europe, while trends in prior animal and human studies indicating that the drug might cause abnormal liver functions were overloaded [sic] or disregarded." Id. at ¶ 66(g).

On May 19, 2005, after the IPO, but before the follow-on offering, Threshold announced the publication of the results of the Bari Study. In a press release issued that day, Threshold summarized the results of the study and advised,

> Detailed results of the study will be published by MedReviews in the quarterly journal of Reviews in Urology available at the American Urology Association (AUA) annual meeting in San Antonio, Texas May 22-28, 2005. The information will also be available May 18th online at the MedReviews website http://www.medreviews.com.

Mitchell Decl., Ex. D.

Lead Plaintiff alleges that, in 2005 and into 2006, after the IPO and follow-on offering, Defendants "repeatedly trumpeted the positive results of the Bari Study," including in press releases dated March 20, 2006 and April 5, 2006 "announcing the completion of enrollment and other milestones in ongoing phase 2 and 3 trials of TH-070" as well as in a March 1, 2006 conference call and

related press release discussing Threshold's financial results for the fourth quarter of 2005. SAC ¶ 85. Lead Plaintiff alleges that these press releases announced only the completion of enrollment in Threshold's clinical trials and other milestones, but did not "disclose the concealed risks regarding the safety and efficacy of the drug." Id.

Similarly, Lead Plaintiff alleges that Threshold's May 10, 2006 press release announcing its financial results for the first quarter of 2006 included statements that "were materially false and misleading to investors because the release failed to warn investors that liver problems had already arisen in the ongoing clinical trials of TH-070." SAC ¶ 10. Lead Plaintiff asserts that Defendants had a duty to disclose that six individuals in their clinical trials had demonstrated problems related to liver toxicity. Further, Lead Plaintiff alleges that, on May 10, 2006, Defendants must have known about these individuals because they reported these serious adverse events (SAEs) to the FDA on May 11, 2006. Lead Plaintiff alleges that by April, 2006, three of the six SAEs were being discussed within the Company. Moreover, Lead Plaintiff alleges that Threshold knew that it had not achieved its clinical milestones with respect to TH-070 as of May 10, and that Defendants knew that such milestones would not be reached.

On May 11, 2006, Threshold issued a press release announcing that its TH-070 trials had been placed on "partial clinical hold" by the FDA due to the abnormal liver test results reported by six patients in the trials. Lead Plaintiff alleges that this "sudden and unexpected news caused Threshold's stock to collapse, falling

$10.56 or 75.4% in a single day." SAC ¶ 112. Nonetheless, Lead Plaintiff alleges that "the Company sought to stem further losses by falsely reassuring the market that TH-070 was safe and effective, and that the Company already had plans to reinitiate clinical trials under a modified dosing regimen." Id. Moreover, Defendant Selick and Alan Colowick, Threshold's Chief Medical Officer (CMO), downplayed known trends of liver problems among dogs and people dosed with lonidamine. However, Lead Plaintiff asserts that these reassurances were false or misleading because "the liver toxicity problems with the drug were much more significant than revealed on that call" and "the drug did not work any better than a placebo in treating BPH." SAC ¶ 116.

Lead Plaintiff alleges that, as soon as the clinical trials were placed on hold, Threshold instructed every clinical site to stop administering TH-070 to patients in the study. Threshold gathered and analyzed the data collected by May 11, 2006 and, on July 17, 2006, the last day of the class period, announced that it planned to discontinue its development of TH-070 for BPH. The press release states that the decision was based on "the safety and efficacy results" of its trials. SAC ¶ 123. Threshold's stock fell $1.63, a 51.3% drop in value.

The Court dismissed the first amended complaint in its entirety. Lead Plaintiff was given leave to amend his claims to allege facts curing the deficiencies discussed by the Court. As discussed below, the SAC cures some but not all of those deficiencies.

LEGAL STANDARD

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). On a motion under Rule 12(b)(6) for failure to state a claim, dismissal is appropriate only when the complaint does not give the defendant fair notice of a legally cognizable claim and the grounds on which it rests. See Bell Atl. Corp. v. Twombly, 550 U.S. 554, 127 S. Ct. 1955, 1964 (2007).

In considering whether the complaint is sufficient to state a claim, the court will take all material allegations as true and construe them in the light most favorable to the plaintiff. NL Indus., Inc. v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). Although the court is generally confined to consideration of the allegations in the pleadings, when the complaint is accompanied by attached documents, such documents are deemed part of the complaint and may be considered in evaluating the merits of a Rule 12(b)(6) motion. Durning v. First Boston Corp., 815 F.2d 1265, 1267 (9th Cir. 1987).

When granting a motion to dismiss, the court is generally required to grant the plaintiff leave to amend, even if no request to amend the pleading was made, unless amendment would be futile. Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc., 911 F.2d 242, 246-47 (9th Cir. 1990). The court "may deny leave to amend due to 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment.'"

Leadsinger, Inc. v. BMG Music Publ'g., 512 F.3d 522, 532 (9th Cir. 2008) (quoting Foman v. Davis, 371 U.S. 178, 182 (1962)).

REQUESTS FOR JUDICIAL NOTICE

Defendants request that the Court take judicial notice of Exhibits A-N of Christopher Mitchell's Declaration in Support of Defendant's Motion to Dismiss. Federal Rule of Evidence 201 allows a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Even where judicial notice is not appropriate, courts may also properly consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleadings." Branch v. Tunnell, 14 F.3d 449, 454 (9th Cir. 1994).

Having reviewed the exhibits, the Court grants Defendants' request as to Exhibits A, B and N because SEC filings may be judicially noticed. See Dreiling v. American Exp. Co., 458 F.3d 942, 946 (9th Cir. 2006). Because Lead Plaintiff disputes the accuracy of the contents of Exhibits D-H, press releases issued by Threshold, the Court takes judicial notice of the fact that these statements were made to the public on the dates specified, but not of the truth of the matters asserted therein. The Court also grants Defendants' request as to Exhibits C and I-M, scientific articles to which the complaint refers, but not for the truth of their contents.

DISCUSSION

I. Sections 11 and 12(2) of the Securities Act

Lead Plaintiff makes claims under §§ 11 and 12(2) of the Securities Act for statements Defendants made in documents related to the IPO and the follow-on offering.

> Under § 11 of the Securities Act, anyone who buys a security pursuant to a false and misleading registration statement may sue for damages. Section 11 states that any signer of the registration statement, any partner or director of the issuer, any professional involved in preparing or certifying the statement, and any underwriter of a registration statement may be liable "[i]n case any part of the registration statement, when such part became effective, 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."

Kaplan v. Rose, 49 F.3d 1363, 1371 (9th Cir. 1994) (quoting 15 U.S.C. § 77k (1988)). "The plaintiff in a § 11 claim must demonstrate (1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material, that is, it would have misled a reasonable investor about the nature of his or her investment." Id. "No scienter is required for liability under § 11; defendants will be liable for innocent or negligent material misstatements or omissions." Id.

"Under § 12(2) of the Securities Act buyers have an express cause of action for rescission against sellers who make material misstatements or omissions 'by means of a prospectus.'" Gustafson v. Alloyd Co., Inc., 513 U.S. 561, 564 (1995) (quoting 15 U.S.C. § 77l(a)(2). More specifically, "§ 12(2) establishes liability for those persons who sell a security 'by means of a prospectus or oral

communication, which includes an untrue statement of material fact or omits to state a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading." In re Verifone Sec. Litig., 11 F.3d 865, 868 (9th Cir. 1993). Section 12(2) has been called "a strict liability provision, in that the purchaser need not prove scienter, fraud, or negligence on the part of the seller." George F. Gabel, Jr., Annotation, Defense of Ignorance of Untruth or Omission in Civil Actions Under § 12(2) of Securities Act of 1933, 109 A.L.R. Fed. 444 (1992); see also Casella v. Webb, 883 F.2d 805, 809 (9th Cir. 1989). "However, once the purchaser establishes a prima facie case under § 12(2), the seller of the security is provided with a statutory defense to liability if he establishes that he did not know, and in the exercise of reasonable care could not have known, of the misstatements or omissions." 109 A.L.R. 444; see also Casella, 883 F.2d at 809.

A. Pleading Standard

The Court previously ruled that Lead Plaintiff's claims sound in fraud and are therefore subject to Federal Rule of Civil Procedure 9(b)'s heightened pleading standards. See Falkowski v. Imation Corp., 309 F.3d 1123, 1133 (9th Cir. 2002); In re Stac Elec. Sec. Litig., 89 F.3d 1399, 1404-05 (9th Cir. 1996). Rule 9(b) provides, "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). The allegations must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that

they can defend against the charge and not just deny that they have done anything wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985). Statements of the time, place and nature of the alleged fraudulent activities are sufficient, Wool v. Tandem Computers, Inc., 818 F.2d 1433, 1439 (9th Cir. 1987), provided the plaintiff sets forth "what is false or misleading about a statement, and why it is false." In re GlenFed, Inc., Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc). Scienter may be averred generally, simply by saying that it existed. See id. at 1547; see Fed. R. Civ. P. 9(b) ("Malice, intent, knowledge, and other condition of mind of a person may be averred generally"). As to matters peculiarly within the opposing party's knowledge, pleadings based on information and belief may satisfy Rule 9(b) if they also state the facts on which the belief is founded. Wool, 818 F.2d at 1439.

B. Statements in the IPO and Follow-on Offering

Lead Plaintiff alleges that Threshold's registration statements and prospectuses for its IPO and follow-on offering contain false and misleading statements regarding the Bari Study. First, Lead Plaintiff argues that these statements "misled investors by failing to disclose a heightened placebo effect associated with treatments for BPH, such that the Bari Study results were much less meaningful than typical non-placebo controlled studies of drugs designed to treat other conditions." Opposition at 23; SAC ¶ 66(c). In the SAC, Lead Plaintiff argues that the following information from a 1996 study should have been disclosed to investors: "In accordance to the guidelines for

evalution of BPH-findings . . . treatment which accomplishes a reduction of less than 25% must be categorized as clinically ineffective, since the placebo may account for this reduction." SAC ¶ 68. The Bari Study warned,

> This is a "proof of concept study" in which, however, a placebo arm was not used. The drawback in this design is the placebo effect that may elicit misleading results, if not properly corrected for, especially considering the small number of patients and the absence of a blind run-in period.

Mitchell Decl., Ex. C at 532. However, as the Court previously noted, the registration statements and prospectuses clearly stated that the Bari Study was "open-label," meaning that no placebo was used. Mitchell Decl., Ex. A at 48 and Ex. B. at 46. Moreover, the documents disclosed that only thirty patients were enrolled in the study and both sets of documents stated that further testing would be necessary to determine the safety and efficacy of TH-070. Id.

Next, Lead Plaintiff argues that the documents falsely stated, "The primary objective of [the Bari Study] is to determine the safety or tolerability of TH-070." Mitchell Decl., Ex. A at 3. Instead, Lead Plaintiff alleges, the Bari Study "assumed the safety of the drug based on inconclusive data from prior clinical studies." Opposition at 26. The Court previously rejected this claim noting that "even if Lead Plaintiff's allegations are proven to be true, it is not clear how this misrepresentation 'would have misled a reasonable investor about the nature of his or her investment.'" July 11, 2008 Order at 13 (quoting Kaplan, 49 F.3d at 1371). In Lead Plaintiff's SAC, he counters that the statement "was misleading because, in fact, the Bari Study had not done

anything to further demonstrate the safety of TH-070 for BPH, such that the risk of non-approval for safety reasons was no less than it had been prior to the completion of the Bari Study." SAC ¶ 70. However, as noted in the Court's previous order, this statement was not misleading, because the same paragraph of the document states, "The safety and efficacy of TH-070 for the treatment of symptomatic BPH will need to be demonstrated in subsequent trials." Mitchell Decl., Ex. A at 3. Defendants never represented that the Bari Study proved TH-070's safety, rather they cautioned that it did not.

Lead Plaintiff's SAC reiterates the contention that the documents improperly compared the results of the Bari Study to the results of Proscar, Flomax and Avodart clinical trials. Though the registration statements did not make side-by-side comparisons of the Bari Study with the Proscar, Flomax and Adovart trials, Lead Plaintiff argues that they "plainly invited investors to compare TH-070's results with those of existing drugs on the market." Opposition at 28; SAC ¶¶ 41-42, 64, 78. Further, Lead Plaintiff now asserts that the failure to warn investors "of the heightened BPH placebo effect misled investors by making these comparisons seem more favorable than they were." Opposition at 28.

Lead Plaintiff's new argument is unpersuasive. As noted in the Court's previous order, in addition to the implicit differences between the clinical study results for a drug that has already been approved by the FDA and the results of an open-label phase two trial with thirty patients for a drug that has not yet been approved, the document disclosed that Threshold had begun two

additional "randomized, placebo controlled, double blinded clinical studies." Mitchell Decl., Ex. B at 47. Nothing in Lead Plaintiff's new argument changes the Court's conclusion that the document's description of the Bari Study, together with its description of Threshold's ongoing trials, was sufficient to indicate that the results of the Bari Study were not directly comparable to the results of the clinical studies of other BPH drugs already on the market.

Lead Plaintiff also reiterates his argument that Defendants misled investors when they stated that "TH-070 kills prostate cells, reducing the size of the prostate." Opposition at 28 (quoting Mitchell Decl. Ex. B at 46). However, the sentence Lead Plaintiff quotes in part states in full, "By targeting the metabolism of glucose and other processes that are essential for prostate cell viability, TH-070 kills prostate cells, reducing the size of the prostate, and therefore may provide an effective treatment for symptomatic BPH." Mitchell Decl., Ex. B at 46. As the Court noted in its previous order, this complete statement again reiterates that the testing on TH-070 was not complete and might not show that the drug was more effective than a placebo.

Finally, without providing any new facts to support his claim, Lead Plaintiff asks the Court to reconsider its decision with respect to his other allegations of falsity, which "are the same as those made by plaintiffs in the prior round of briefing." Opposition at 28. The Court has reviewed Lead Plaintiff's previous arguments and concludes that they still do not support a valid claim that the registration documents misled investors. See July

11, 2008 Order at 15-19.

The Court finds that Lead Plaintiff has failed to allege any material omission or misleading statement in the IPO and follow-on offering documents regarding the Bari Study.[3] Because Lead Plaintiff has not alleged any material misstatement or omission in the IPO or follow-on offering documents, the Court grants Defendants' motion to dismiss the claims under §§ 11 and 12(2) of the Securities Act. Because Lead Plaintiff has had an opportunity to amend these claims, this dismissal is without leave to amend.

II. Section 10(b) of the Exchange Act and Rule 10b-5

Section 10(b) of the Exchange Act makes it unlawful for any person to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b); see also 17 C.F.R.

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[3]As noted in the Court's previous order, it still finds inapposite Defendants' argument that because the publication of the results of the Bari Study disclosed the information Lead Plaintiff alleges to have been omitted, it put Lead Plaintiff on notice of his claims, therefore making his claims untimely. "[I]nvestors are not generally required to look beyond a given document to discover what is true and what is not." Miller v. Thane, 519 F.3d 879, 887 (9th Cir. 2008) (citing multiple cases). Taking all of Lead Plaintiff's allegations as true, a dispute remains whether the May, 2005 publication of the results of the Bari Study was sufficient to put investors on notice of their claims. Similarly, the question of whether the May, 2006 disclosure of the partial hold on the clinical trials put investors on notice of the allegedly misleading statements in the IPO and follow-on offering documents cannot be resolved at this stage.

Moreover, the challenged statements in the IPO and follow-on offering documents are not forward-looking and therefore are not protected under the PSLRA's safe harbor or the bespeaks caution doctrine. See 15 U.S.C. § 78u-5(c)(A)(I) ("forward-looking statements"); In re Worlds of Wonder Sec. Litig., 35 F.3d 1407, 1413 (9th Cir. 1994) (same).

§ 240.10b-5 (Rule 10b-5). To state a claim under § 10(b), a plaintiff must allege: "(1) a misrepresentation or omission of material fact, (2) reliance, (3) scienter, and (4) resulting damages." Paracor Fin., Inc. v. Gen. Elec. Capital Corp., 96 F.3d 1151, 1157 (9th Cir. 1996); see also McCormick v. Fund Am. Cos., 26 F.3d 869, 875 (9th Cir. 1994).

Some forms of recklessness are sufficient to satisfy the element of scienter in a § 10(b) action. See Nelson v. Serwold, 576 F.2d 1332, 1337 (9th Cir. 1978). Within the context of § 10(b) claims, the Ninth Circuit defines "recklessness" as

> a highly unreasonable omission [or misrepresentation], involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.

Hollinger v. Titan Capital Corp., 914 F.2d 1564, 1569 (9th Cir. 1990) (en banc) (quoting Sundstrand Corp. v. Sun Chem. Corp., 553 F.2d 1033, 1045 (7th Cir. 1977)). As explained by the Ninth Circuit in In re Silicon Graphics Inc. Securities Litigation, 183 F.3d 970 (9th Cir. 1999), recklessness, as defined by Hollinger, is a form of intentional conduct, not merely an extreme form of negligence. See Silicon Graphics, 183 F.3d at 976-77. Thus, although § 10(b) claims can be based on reckless conduct, the recklessness must "reflect[] some degree of intentional or conscious misconduct." See id. at 977. The Silicon Graphics court refers to this subspecies of recklessness as "deliberate recklessness." See id. at 977.

As stated above, Lead Plaintiff must plead any allegations of

fraud with particularity, pursuant to Rule 9(b) of the Federal Rules of Civil Procedure. In re GlenFed, Inc. Sec. Litig., 42 F.3d at 1543. Pursuant to the requirements of the Private Securities Litigation Reform Act of 1995 (PSLRA), the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

Further, pursuant to the requirements of the PSLRA, a 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). The PSLRA thus requires that a plaintiff plead with particularity "facts giving rise to a strong inference that the defendant acted with," at a minimum, deliberate recklessness. See 15 U.S.C. § 78u-4(b)(2); Silicon Graphics, 183 F.3d at 977. Facts that establish a motive and opportunity, or circumstantial evidence of "simple recklessness," are not sufficient to create a strong inference of deliberate recklessness. See 183 F.3d at 979. In order to satisfy the heightened pleading requirement of the PSLRA for scienter, plaintiffs "must state specific facts indicating no less than a degree of recklessness that strongly suggests actual intent." Id.

A. Misrepresentation or Omission of a Material Fact

Thus, to state a claim pursuant to § 10(b) of the Exchange Act, Lead Plaintiff must allege, among other things, a misrepresentation or omission of a material fact. Lead Plaintiff

claims that three sets of statements made in conference calls conducted and press releases issued between March 20, 2006 and May 11, 2006 misled investors by including positive statements about the ongoing clinical trials and omitting negative information about toxicity and efficacy problems. The Court addresses each set of statements in turn.

1. March 20 and April 5, 2006 Announcement of Completion of Enrollment in Ongoing Clinical Trials and May 10, 2006 Announcement that TH-070 Trials were on Track

Lead Plaintiff alleges that the March 20 and April 5, 2006 press releases were materially false and misleading to investors "because they announced seemingly positive news about the ongoing clinical trial of TH-070 without revealing the hidden risks to approval of the drug -- i.e., that the drug was prone to causing liver toxicity in patients and it did not work any better than a placebo in treating BPH." SAC ¶ 93. Similarly, Lead Plaintiff alleges that, on May 10, 2006, after the liver toxicity issues had been reported to the FDA and just one day before the trials were placed on clinical hold, Threshold announced its 2006 first quarter results but "made no announcement of the liver toxicity issues that had arisen in the ongoing trials of TH-070, nor did it warn of any efficacy issues that had arisen in those trials." SAC ¶ 106. Instead, the press release "trumpeted the completion of enrollment in the phase 2 and 3 trials as significant highlights of the quarter." Id.

The Court previously dismissed Lead Plaintiff's claims based on the March 20 press release because he did not allege that

Defendants had identified any SAEs at the time of the press release, and the later investigation and reporting of SAEs to the FDA were not sufficient to establish that Defendants misrepresented or omitted material facts about TH-070. Lead Plaintiff amended his original complaint now to allege that by March 20, "defendants had actual knowledge that significant liver toxicity issues had arisen in those trials." SAC ¶ 96 (emphasis original). Lead Plaintiff explains that because one SAE involving a patient with elevated liver toxicity was reported to the FDA on April 10, "the temporal proximity between that report and the announcements of the completion of the enrollment strongly supports the inference that, at the time of those announcements, defendants had actual knowledge that liver toxicity issues had erupted in the trials." Id. However, this temporal proximity allegation is no different than the one Lead Plaintiff presented in his earlier complaint. See CAC ¶ 97 ("At the time these statements were made, defendants knew about or recklessly disregarded evidence that TH-070 had significant toxicity problems that made it unlikely that the drug would fulfill its claimed promise as a significant new treatment for BPH"). Therefore, the new allegation lacks the specificity required under the PSLRA to sustain a claim.

Lead Plaintiff's SAC alleges that on April 10, Defendants also shared with the FDA "other data that we had available to us at that time across all of our studies." SAC ¶ 104. Lead Plaintiff contends that this "other data" must have included information about liver toxicity. Lead Plaintiff also asserts that by March 20, 2006, approximately eighty-five percent of the participants in

the study had completed dosing, and given that the liver toxicity issues arose within the twenty-eight day dosing period, "it is far more likely than not" that Defendants had information about the liver toxicity issues before the March 20 press release. ¶ SAC 101. Even though many of the study participants likely completed their dosing by March 20, Lead Plaintiff still has not sufficiently alleged that the liver toxicity issues should have been reported by that date. Moreover, Lead Plaintiff's own confidential sources say that three SAEs relating to liver toxicity were being discussed internally at some point in April, not March. SAC ¶ 98.

In the Court's previous order, it noted that because the test in which the SAEs occurred was a blinded, placebo-controlled study, it would not have been possible for Defendants to know by March 20 whether any incidents of liver toxicity were caused by TH-070. Lead Plaintiff argues that Defendants now admit that "certain clinical data were partially unblinded prior to the clinical hold to permit researchers to determine whether the observed elevation in liver enzymes was associated with TH-070." Motion to Dismiss at 1 n.2. Even with this admission, Lead Plaintiff has not alleged with particularity what data was unblinded, when it was unblinded, and how omitting that data in the March 20 press release was material. Therefore, the Court dismisses Lead Plaintiff's claims based on the March 20 press release.

Although his allegations regarding the March 20 press release are deficient, Lead Plaintiff has alleged additional information sufficient to support a finding that the April 5 and May 10 announcements omitted material information about the SAEs. In

particular, Lead Plaintiff has alleged that, on April 10, Threshold reported to the FDA an SAE "involving a patient with a thirty-fold elevation in liver transamine ALT levels." SAC ¶ 96 (emphasis in original). Lead Plaintiff alleges that Defendants had known about this incident of liver toxicity for some time and had conducted considerable investigation to determine that the toxicity was significant, because they elected to report the incident to the FDA even though the European study was not within the FDA's jurisdiction. SAC ¶ 102. Defendants counter that there was nothing voluntary about reporting the SAE to the FDA because 21 C.F.R. § 312.32(c) obliges them to report "any adverse experience associated with the use of the drug that is both serious and unexpected . . . as soon as possible and in no event later than 15 calendar days after the sponsor's initial receipt of the information." Considering the mandatory nature of the regulation, Defendants must have been aware of the problem at least within fifteen calendar days of April 10. Thus, it is reasonable to infer that five days earlier, at the time of the April 5 press release, information about potential liver toxicity problems was available to Defendants. Failing to disclose it would be a material omission.

There is an even stronger inference that Defendants were obliged to disclose potential liver toxicity issues by the time Threshold released its May 10, 2006 quarterly report. Not only had Defendants reported the European patient's elevated liver enzymes, but they undoubtedly had information about the severity of the SAEs that, one day later, led the FDA to place a partial hold on the

clinical trials. Therefore, the Court finds that Lead Plaintiff has adequately alleged material misstatements in the April 10, 2006 press release and May 10, 2006 quarterly report based on Defendants' failure to disclose evidence of liver toxicity in the ongoing clinical trials.

B. Requisite Mental State

As discussed above, to state a claim pursuant to § 10(b) of the Exchange Act, Lead Plaintiff must also allege that Defendants acted with "deliberate recklessness." Silicon Graphics, 183 F.3d at 977. The PSLRA requires that these allegations be plead with particularity. 15 U.S.C. § 78u-4(b)(2). Specifically, "plaintiff must plead 'a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" Zucco Partners v. Digimarc Corp., No. 06-35758, 2009 WL 57081, at *6 (9th Cir. January 12) quoting Silicon Graphics, 183 F.3d at 976. If no individual allegations are sufficient, then the Court will "conduct a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference" of scienter. Id. The parties dispute whether, assuming Lead Plaintiff has alleged false or misleading statements, he has adequately plead that Defendants acted with the requisite intent.

Lead Plaintiff's SAC alleges that, in addition to allegations of motive and opportunity to establish scienter, it relies "principally upon allegations of actual knowledge." Opposition at

13 (emphasis in original). Specifically, the SAC alleges that Defendants "knew of both the liver incidents themselves and of the market's intense focus on Threshold's clinical trials. . . ." Id. It claims that Defendants "were at least deliberately reckless to the fact that announcing the positive developments in the clinical trials would be misleading unless investors were warned of the liver toxicity events that had arisen, causing risks of delay, disruption or discontinuation of those trials." Opposition at 14.

However, actual awareness of an SAE alone does not constitute a strong inference of scienter. See In re Carter Wallace, Inc. Sec. Litig., 220 F.3d 36, 41 (2d Cir. 2000) ("Carter-Wallace's actual awareness of adverse reports while touting Felbatol's safety does not, on its own, constitute 'strong circumstantial evidence of conscious misbehavior or recklessness.'"). This is because SAEs are broadly defined and may be caused by preexisting conditions or other factors aside from the drug being tested. See C.F.R. § 312.32.

Here, however, Lead Plaintiff has alleged other facts evidencing Defendants' culpable state of mind. Specifically, Lead Plaintiff has adequately plead that Defendants knew of facts that would necessarily prevent or delay the regulatory approval or marketing of the drug and concealed those facts from the investing public. See In re Astrazeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008) ("If the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter."). At the time of the April 5, 2006, press

release, it is reasonable to infer that Defendants were deliberately reckless in failing to disclose information about potential liver toxicity problems. Further, the fact that the FDA placed a partial hold on the clinical trials one day after Defendants issued its May 10, 2006 quarterly report, lends even more support for an inference of scienter. Also, Defendants acknowledge that they un-blinded the clinical trials prior to the clinical hold. Though Lead Plaintiff has not specifically alleged the information the un-blinding uncovered, Defendants certainly cannot claim ignorance as to its content.

The Court concludes that Lead Plaintiff has adequately alleged that Defendants were deliberately reckless in releasing positive statements about TH-070 on April 5 and May 10 when they had material contrary information. Therefore, the Court denies Defendants' motion to dismiss Lead Plaintiff's Rule 10b-5 claim.

III. Section 20(a) of the Exchange Act and § 15 of the Securities Act

Both the Exchange Act and the Securities Act provide for joint and several liability for every person who, directly or indirectly, controls any person found liable under other provisions of the Acts. 15 U.S.C. § 78t(a); 15 U.S.C. § 77o. To succeed on such a claim, the complainant must first show that the controlled person violated either the Exchange Act or the Securities Act. See Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 n.15 (9th Cir. 2002).

Defendants Selick and Swearson move to dismiss the claims brought against them pursuant to § 15 of the Securities Act and § 20 of the Exchange Act on the sole basis that Lead Plaintiff has

not sufficiently plead an underlying primary violation. Because the Court dismissed Lead Plaintiff's claims under §§ 11 and 12 of the Securities Act, Lead Plaintiff has not sufficiently plead an underlying violation of the Securities Act against Selick or Swearson. Swearson is not liable under § 20(a) of the Exchange Act because Lead Plaintiff does not allege a Rule 10b-5 claim against her. SAC ¶¶ 186-190; Opposition at 29. However, as to Selick, because the Court concludes that Lead Plaintiff has adequately plead an underlying violation of the Exchange Act, the Court denies Defendants' motion to dismiss the claims of control liability under § 20(a) against him.

CONCLUSION

For the foregoing reasons, the Court grants in part Defendants' motion to dismiss (Docket No. 56). Lead Plaintiff's claims under §§ 11 and 12 of the Securities Act are dismissed as to all Defendants. Therefore, Lead Plaintiff's claims under § 15 of the Securities Act against Swearson and Selick are also dismissed. The Court denies Defendants' motion to dismiss Lead Plaintiff's Rule 10b-5 claims against Threshold and Selick. Therefore, Lead Plaintiff's claim under § 20(a) of the Exchange Act against Selick survives.

IT IS SO ORDERED.

Dated: 4/3/09

CLAUDIA WILKEN
United States District Judge