IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THOMAS LAURIA, on behalf of himself and all others similarly situated,	)	
Plaintiff,	)	**Case No. 12 C 772**
v.	)	**Judge Joan B. Gottschall**
BIOSANTE PHARMACEUTICALS, INC. and STEPHEN SIMES,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. BioSante developed LibiGel, a low-dose testosterone gel that is applied to the skin on the upper arm. LibiGel was meant to treat women with hypoactive sexual desire disorder ("HSDD"), which is a form of female sexual dysfunction ("FSD"). Stephen Simes is BioSante's Vice Chairman, President and Chief Executive Officer. Plaintiffs Thomas Norgiel and Jeffrey Rennell assert that they purchased shares of BioSante at an artificially inflated price. They filed this case on behalf of themselves and others who purchased BioSante shares during the class period.

BioSante and Simes have moved to dismiss, arguing that the complaint's fraud allegations do not satisfy Federal Rule of Civil Procedure 9(b) or the pleading requirements of the Private Securities Litigation Reform Act (the "PSLRA"), 15 U.S.C. § 74u–4, *et seq*. Alternatively, they contend that their forward-looking statements are protected by the PSLRA's safe harbor, the complaint fails to allege facts that demonstrate scienter, and the plaintiffs' claim under § 10(b) of the Securities Exchange Act, 15 U.S.C.A. § 78j(b), is unavailing as they failed to establish that a defendant is directly liable under the Act.

For the following reasons, the court finds that the complaint fails to satisfy the PSLRA's pleading requirements. All of the defendants' remaining arguments turn, in whole or in part, on allegedly false and misleading statements allegedly made by BioSante or Simes. As detailed below, the court cannot ascertain which statements were allegedly misleading, the reason or reasons why each statement was misleading, and whether the plaintiffs have sufficiently alleged facts creating a strong inference of scienter. Thus, the motion to dismiss is granted, and the court will not reach the defendants' alternative arguments. The plaintiffs are given 28 days to amend their complaint if they choose to do so.

I. BACKGROUND[1]

A. The LibiGel Trials

Clinical trials typically have three phases:

- Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its short-term safety, dosage tolerance, metabolism pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness.

- Phase II usually involves trials in a small patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the drug for specific indications.

[1] The following facts are drawn from the plaintiffs' 66-page complaint and are accepted as true for the purposes of the defendants' motion to dismiss. The court has not, however, considered the numerous additional facts included in footnotes in the plaintiffs' response which are preceded by the phrase "if required to amend, [p]laintiffs would allege . . . " as it is improper to amend a complaint via a response to a motion to dismiss. *See Agnew v. Nat'l Collegiate Athletic Ass'n*, 683 F.3d 328, 348 (7th Cir. 2012). The court also notes that the facts alleged in the complaint in this case are not entirely consistent with the facts alleged in the companion shareholder derivative action which is also pending before this court. *In re BioSante Pharm. Deriv. Litig.*, 12 C 3480 (N.D. Ill.). At the motion to dismiss stage, the court accepts the facts as they are alleged; it will not attempt to reconcile the two complaints and will proceed based solely on the allegations in the complaint in the instant case.

- Phase III trials usually involve further evaluation of clinical safety and efficacy by using the drug in its final form in a larger patient population.

Compl. at ¶ 66 (Dkt. 90).

Treatment with LibiGel in a 2004 Phase II double-blind, placebo-controlled clinical trial demonstrated significantly increased satisfying sexual events in surgically menopausal women with FSD. According to the plaintiffs, BioSante's 2004 Form 10-K represented that "the Phase II trial showed 'statistically significant' results for the primary endpoints of the study. The study consisted of 46 surgically menopausal women, and was powered to determine which dose of LibiGel would have the greatest effect on women's sexual activity." *Id.* at ¶ 69. BioSante also reported a "238 percent increase from baseline ($p<0.0001$)10 in the frequency of satisfying sexual events as measured by individual patient diaries" and characterized the result as "significant versus placebo ($p< 0.05$)." *Id.* BioSante Phase II's data indicated there was "an effective LibiGel dose for the treatment of HSDD in women, and that LibiGel was well-tolerated during the course of the trial, and had a safety profile similar to that of the placebo, with no women discontinuing use due to adverse events." *Id.*

BioSante subsequently conducted three Phase III double-blind, placebo-controlled studies of LibiGel. Two studies were meant to examine efficacy, and the third was a cardiovascular and breast cancer safety study.

On April 5, 2011, Simes spoke at the Biocentury and Thomson Reuters Future Leaders in the Biotech Industry Conference. He commented on the LibiGel Phase III clinical development trials, stating:

> In terms of the market for LibiGel, there are good indications. I mentioned several times, there is nothing approved for this indication. However, in 2009 we believe

> the numbers for 2010 will come in about the same once we get the IMS data. But there were 4 million testosterone prescriptions written off label for women for this indication. And that tell[s] us in primary research that in fact if [their was] an FDA approved product, they would much prefer to use that in which the vast majority in this case, 96% of their women to the approved product [sic].
>
> We believe the market potential is at least $2 billion. Some of you know the magic there is the erectile dysfunction market in the U.S. is a $2 billion market. We think the market for women is bigger than the market for men as evidenced by certain publications that some of you might have seen over the years, with an article in the Journal of the American Medical Association in a younger population of women, 18 to 59, showing that 43% of these women reported experience in sexual dysfunction at one point or another.

Id. at ¶ 39.

On April 15, 2011, Simes presented at the Future Leaders in the Biotech Industry Conference and told attendees:

> If you look at our Phase II data, a similar dose by the way. We delivered 300 micrograms a day, which is exactly the dose shown in the past to be effective. Now in ten published Phase III [sic] studies we showed a remarkable 238% increase in the number of satisfying sexual events, which was statistically significant significantly better than placebo. We hope to repeat these data in our Phase III studies. Now we've powered the studies to show a difference of one from placebo, one sexual event from placebo, even though in this study we showed a difference of over three satisfying sexual events over placebo.
>
> Another way to look at the data, and how much we further see this, and you can see in the first month, and this is four week increments is how these are measured, an[d] it's the last four weeks of the study compared to the base line four weeks, number of the events compared to number of events. At baseline our women had about 2.5 satisfying sexual events. And of course I am compelled to say, don't ask me what a 0.5 sexual event is. However in the first month over four weeks of therapy there was an increase of 100% in the [number] of satisfying sexual events overly out [sic] of this 238% increase over the course of the three months study.

Id. at ¶ 95.

During an October 21, 2011, presentation at the BioCentury Newsmakers in the Biotech Industry Conference, Simes again commented on LibiGel, stating:

> I've chosen to concentrate on LibiGel today because it is a near-term driver, it's a near-term value producer for our Company and we have near-term data . . . . In terms of the potential markets, again we have some quite definitive numbers here. Last year in the U.S., there were over 4 million testosterone prescriptions written-off label for women. Now this is a combination of IMS reported prescriptions as well as compounded testosterone reported prescriptions in primary research . . . . We think the market potential for female sexual dysfunction in the US is over $2 billion, the magic to $2 billion is that the size of the male erectile dysfunction market [sic].

Id. at ¶ 40.

In addition, during an October 25, 2011, presentation at the BioTechnology Industry Organization Investor Forum, Simes stated:

> In terms in the market, we are very, very excited here. As you can imagine we think it's a big market, but there are some objective data. In 2010, according to IMS and other primary research there are over 4 million testosterone prescriptions written off-label for women for this indication . . . . We believe then the market for a drug for female sexual dysfunction and the market here is about $2 billion. The magic to the 2 billion is that the size of the erectile dysfunction market in the U.S.: Viagra, Levitra, and Cialis.
>
> Interestingly from published work, we think that the market for women is at least as bigger [sic] as the market for men and probably larger. And publications in JAMA and New England Journal indicate that anywhere from 30 to 50% of women report a sexual functioning issue. Happily, we have an issued patent that covers or will protect LibiGel until mid-2022, and we expect other patent activity even by the end of this year.

Id. at ¶ 41.

B. The Confidential Witness

A former BioSante employee who served as the Senior Project Manager for the LibiGel Phase III safety study from March 2008 through September 2011 is a confidential witness in this case. She stated that a typical clinical trial dropout rate ranges from 5% to 10%. She believed that the LibiGel Phase III efficacy and safety trials had unusually high dropout rates, reaching almost 20% per month in 2010-11. According to the confidential witness, this problem was

consistent throughout her time at BioSante, was a cause for concern, and was discussed by BioSante's senior management. The confidential witness was "under the impression that the dropout issue was also discussed with defendant Simes and Michael Snabes, Senior Vice President of Medical Affairs." *Id*. at ¶ 28.

In addition, the confidential witness observed that investigators at investigative sites associated with the LibiGel trials received relatively expensive gifts from BioSante, such as iPads and iPhones, that did not comply with regulations restricting the value of gifts. She also noted that Simes was authorized to make decisions about patient eligibility to participate in the safety trial. Specifically, questions about a patient's eligibility to enroll in the Phase III trial safety trial would occasionally arise. Certain BioSante executives brought these eligibility questions to Simes, who decided whether to enroll the patient in the study.

C. The Basis of HSDD & the Placebo Effect

The plaintiffs claim that BioSante was aware of significant disagreements in the scientific community regarding FSD and took advantage of investors by inaccurately claiming that insufficient testosterone levels caused HSDD and failing to disclose the "controversial nature of diagnosing and treating HSDD." *Id*. at ¶ 55. According to the plaintiffs, the source of female sexual dysfunctions such as HSDD are unknown. They assert that medical and pharmaceutical communities disagree about whether HSDD is a physiological or psychological issue or a combination of both. They also contend that because HSDD has a psychological aspect, a greater number of women participating in clinical trials who receive a placebo report a greater perceived improvement in their HSDD condition than would be the case when testing drugs for other conditions. The plaintiffs call this the "placebo effect."

The plaintiffs also point out that the American Psychiatric Association decided to remove HSDD from the diagnostic manual used by psychiatrists because, among other things, it believed that the word "hypoactive" incorrectly implied that a testosterone deficiency caused the disorder. In addition, they allege that the defendants "undoubtedly were aware of the controversial nature of the HSDD condition within the medical community." *Id*. at ¶ 53. In support, they note that before HSDD was removed from the diagnostic manual, BioSante entered a Special Protocol Assessment agreement with the FDA.[2] They assert that Simes knew it was important to get this agreement with the FDA because BioSante believed that "it was important to get the FDA on record as saying that in fact female sexual dysfunction is a diagnosable condition with measurable endpoints and that women deserve an option, a therapeutic option." *Id*.

D. The Phase III Results

In December of 2011, BioSante announced the results of the two Phase III LibiGel efficacy trials. The trials were unsuccessful. Indeed, in one of the studies, participants receiving a placebo had a more favorable response than participants using LibiGel. The plaintiffs allege that BioSante failed to structure the trials properly and thus did not adequately address the placebo effect. Specifically, the plaintiffs allege that BioSante should have required participants to keep a weekly diary, not a daily diary, based on a study that concludes that daily diaries may skew data.

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[2] A Special Protocol Assessment "constitutes an agreement between the FDA and the drug developing entity (the 'sponsor') that, if the sponsor follows the procedure agreed upon in the protocol and the drug proves efficacious, then it will be approved. This bypasses some potentially lengthy and costly procedures for New Drug Applications (NDAs)." *In re Cell Therapeutics, Inc. Class Action Litig.*, No. 2:10-CV-00414-MJP, 2011 WL 444676, at *1 (W.D. Wash. Feb. 4, 2011); *see also* CANCER CLINICAL TRIALS: PROACTIVE STRATEGIES 99-100 (Stanley P.L. Leong, ed.) (2007).

In a conference call in December of 2011 immediately following the release of the Phase III efficacy trial results, Simes stated:

> At this point, we can only speculate about the reasons for the placebo effect including the effect of the daily administration of the product, and the daily recording of the events by each subject as well as the monthly visits and various reminders that our investigators send out to their subjects.
>
> With all of these actions by and with the subjects participating in these trials, we believe that even those in the placebo group were thinking more and more about their sexual drive, and therefore their sexual activity and desire increased even without increased level of testosterone . . . . Whether in fact and we are just asking the question, we don't have an answer whether in fact, most of the efficacy or most of the benefit from that is the women's own reaction to being treated as opposed to the testosterone because at least in our two trials, testosterone did not seem to be indicative of [efficacy] . . . . But unfortunately it is not [that] LibiGel did not work, the problem is that both arms work equally well and it's an interesting situation, however I am told by others that in other areas for example depression as many as 50% of depression trials fail because of placebo event and this is something that is a major issue for our industry so, truly there is no treatment arm because the women in our study were well taking [sic] care of in both arms and so there is truly no treatment arm and we have suffered the consequences of that.

Id. at ¶ 60.[3] BioSante also issued a press release stating that the Phase III efficacy trials failed to meet the co-primary or secondary endpoints, expressing "disappointment" in the results, and noting that BioSante would "be analyzing the best path forward for the study given the results reported today." *Id*. at ¶ 106. On December 15, 2011, in response to the release of the Phase III efficacy trials, BioSante's stock dropped from $1.64 per share to close at $0.48 per share, for a one-day decline of over 77% on volume of nearly 50 million shares.

[3] The court assumes that the phrase "the problem is that both arms work equally well" refers to the fact that LibiGel is applied topically to the upper arm. If LibiGel and the placebo had comparable results, both arms would work equally well. If this assumption is incorrect, the parties should advise the court in one of their subsequent filings.

The plaintiffs' complaint alleges violations of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5, against BioSante and Simes (Count I). It also alleges violations of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against Simes (Count II).

II. LEGAL STANDARD

For purposes of a motion to dismiss, the court takes all facts alleged in the complaint as true and draws all reasonable inferences from those facts in the plaintiffs' favor, although conclusory allegations that merely recite the elements of a claim are not entitled to this presumption of truth. *Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011). A motion to dismiss should be granted if the plaintiff fails to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The factual allegations in a complaint must "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555–56. The complaint must also offer "enough facts to raise a reasonable expectation that discovery will reveal evidence" that supports the plaintiffs' allegations. *Id*. at 556.

Allegations of fraud are subject to a heightened pleading standard. Fed. R. Civ. P. 9(b). This means the plaintiffs must, at a minimum, provide the time, place, and content of the alleged false representations, the method by which the representations were communicated, and the identities of the parties to those representations. *Slaney v. Int'l Amateur Athletic Fed'n*, 244 F.3d 580, 597 (7th Cir. 2001); *see also Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 569 (7th Cir. 2012) ("[T]he plaintiff must allege the who, what, when, where, and how of the alleged fraud.") (internal quotations omitted).

In addition, under the PSLRA's pleading standards, a securities fraud complaint must: (1) "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"; and (2) "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)(1)-(2).

III. ANALYSIS

A. Rule 9(b) and The PSLRA

The court's consideration of the motion to dismiss begins and ends with Rule 9(b) and the PSLRA's pleading requirements. BioSante contends that the fraud allegations in the complaint are insufficient because they consist of "large blocks of text from Defendants' public filings, press releases, conference calls and speeches" which the plaintiffs characterize as "false and misleading." Dkt. 95 at 4. In their response, the plaintiffs state that the bolded and italicized sections of the 14-page section of the complaint entitled "false and misleading statements issued during the class period" (not the entire section) form the basis of their fraud claim.

It appears that the plaintiffs intend the court and the defendants to parse through their complaint in an attempt to: (1) locate reasons why the plaintiffs believe that the italicized/bolded statements are misleading; and (2) find specific facts corresponding to those statements that "giv[e] rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(1)-(2). These supporting details might be in the sections of the complaint labeled "false and misleading statements issued during the class period," "the truth regarding the

failed trials is revealed," "scienter allegations." They could be elsewhere in the lengthy complaint as well.

The salient point is that the court cannot ascertain which allegations are meant to match up with the italicized/bolded portions of the complaint. As one of the court's colleagues noted when dismissing a similarly confusing complaint:

> The net effect of the pleading's format is to leave the reader — whether Defendants or the court — jumping from page to page in an attempt to link the alleged statements to the background that supposedly makes them false or misleading. Even this activity might be tolerable if the statements themselves were clearly identified, but . . . they are not. Rather, it is frequently difficult to discern where the supposedly challenged statements end and the context or characterization [of the statements] begins.

Conlee v. WMS Indus.,Inc., No. 11 C 3503, 2012 WL 3042498, at *4 (N.D. Ill. July 25, 2012).

The italics/bolding system described in the plaintiffs' response to the motion to dismiss further adds to the confusion as the complaint contains words that appear to be italicized and bolded for emphasis. For example, the plaintiffs allege:

> On June 21, 2010, BioSante issued a press release entitled "BioSante Pharmaceuticals Says FDA Advisory Committee Recommendation Against Flibanserin had No Impact on LibiGel®." Flibanserin was Boehringer Ingelheim's 2010 attempt to treat HSDD in pre-menopausal women via daily doses of dopamine and norepinephrine. BioSante claimed that the "FDA Advisory Committee recommendation against flibanserin has no impact on LibiGel" because LibiGel was not subject to the same ***safety*** concerns that had prevented flibanserin approval. However, contrary to the impression given by BioSante's press release, the FDA did not reject flibanserin ***solely*** on safety issues — in fact, the FDA ***also rejected*** flibanserin for ***failing to demonstrate an improvement in desire beyond that of the placebo***. And as discussed earlier, LibiGel was equally vulnerable to a high placebo effect. Consequently, BioSante's press release was materially false and misleading, further stating, in part:
>
> > "There are important scientific differences between the way LibiGel and flibanserin work on the body, and differences in their clinical development programs," stated BioSante President and

> CEO Stephen M. Simes. "The LibiGel safety and efficacy trials are being conducted under an SPA (Special Protocol Assessment) agreement with FDA, a level of agreement that the flibanserin program did not have. BioSante also is conducting a large safety study comparing LibiGel to placebo to show cardiovascular and breast-cancer safety. ***We are pleased also by comments made by the Advisory Committee stressing the need for a product to treat this unmet medical need. Given the recommendation of the Advisory Committee, we believe that LibiGel is positioned to be the first product approved for the treatment of HSDD."***
>
> "The Advisory Committee's judgment on flibanserin has no impact on the clinical development program of LibiGel and is not relevant to the potential for FDA approval of LibiGel for the treatment of HSDD in menopausal women," said Michael C. Snabes, MD, PhD, BioSante's vice president of clinical development.

Compl. At ¶ 82 (emphasis in original).

The italized/bolded words in this paragraph are cryptic. The words "***safety***," "***solely***," and "***also rejected***" do not state an understandable claim of fraud under Rule 9(b) or the PSLRA. Perhaps the plaintiffs intended to italicize and bold the entire sentences, or merely used italics and bolding for emphasis. Either way, their complaint is deficient as the court – and BioSante – should not have to speculate about the contours of the plaintiffs' fraud claims. *See Oakland Cnty. Emps' Retirement Sys. v. Massaro*, 736 F. Supp. 2d 1181, 1187-88 (N.D. Ill. 2010) (dismissing prolix securities complaint for, among other things, the failure to allege facts adequate to support scienter).

In sum, neither Rule 9(b) nor the PSLRA allows a plaintiff to survive a motion to dismiss based on the length of a complaint alone. Instead, a plaintiff must allege facts necessary to support his fraud claim in a clear and understandable manner. Because the current iteration of the complaint fails to meet this standard, it is dismissed.

B. The Defendants' Request to Dismiss With Prejudice

The defendants contend that the court should dismiss this action with prejudice because amendment would be futile. It is true that under Delaware law, if a defendant files a motion to dismiss and the plaintiff files an answering brief opposing the motion instead of an amended complaint, a subsequent dismissal of the plaintiff's claims pursuant to the defendant's motion will be with prejudice unless "dismissing with prejudice would not be just under all the circumstances." *Braddock v. Zimmerman*, 906 A.2d 776, 783 (Del. 2006). Nevertheless, such a remedy is "drastic." *King v. VeriFone Holdings, Inc.*, 12 A.3d 1140, 1151-52 (Del. 2011). It is conceivable that the plaintiffs could correct the defects identified in this order by amending their complaint. Accordingly, in an exercise of its discretion, the court will afford the plaintiffs one opportunity to amend. *See Pugh v. Tribune Co.*, 521 F.3d 686, 698 (7th Cir. 2008) (the decision to grant leave to amend is reviewed under the abuse of discretion standard).

Consistent with this order and counsel's Rule 11 obligations, the plaintiffs may file an amended complaint within 28 days of the issuance of this order, if they choose to do so. When preparing their amended complaint, the plaintiffs should focus on the quality, not the quantity, of their allegations. They should also bear in mind that the current complaint "is disjointed as to the factual ground it covers and the statements it identifies. The amended complaint (if any) may be shorter, but it may even be longer. The key point for this case is to present the allegations in an easier-to-follow format." *Conlee*, 2012 WL 3042498, at *5 n.1.

The court also notes that it considered addressing the remaining arguments in the motion to dismiss in the hope that it would help streamline this litigation. It was unable to do so, as these arguments are necessarily based on the allegations in the complaint and, as discussed

above, these allegations are deficient. Thus, the court will allow the plaintiffs to amend and will not reach the defendants' remaining arguments at this time.

IV. CONCLUSION

For the above reasons, the defendants' motion to dismiss the consolidated class action complaint [Dkt. 94] is granted. The plaintiffs may file an amended complaint within 28 days of the date of this order.

ENTER:

/s/
JOAN B. GOTTSCHALL
United States District Judge

DATED: September 11, 2013