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

In re BIOSANTE PHARMACEUTICALS, INC. DERIVATIVE LITIGATION,	)	**Case No. 12 C 3480**
	)	**Judge Joan B. Gottschall**

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 transdermal testosterone gel. LibiGel was meant to treat women with hypoactive sexual desire disorder ("HSDD"), which is a form of female sexual dysfunction ("FSD"). This shareholder derivative action against BioSante's board of directors (Louis Sullivan, Steven Simes, Fred Holubow, Ross Mangano, Edward Rosenow, Stephen Sherwin, and John Potts) is based on many of the same events underlying a direct putative class action securities case captioned *Lauria v. BioSante, et al.*, 12 C 772, also assigned to this court. LibiGel's failure to perform well in Phase III efficacy trials caused BioSante's stock price to drop and is at the heart of both actions. The defendants seek to dismiss the complaint in its entirety.[1] For the following reasons, the motion to dismiss is granted, and the plaintiffs are given 28 days to amend their complaint if they choose to do so.

[1] The plaintiffs also filed a motion for leave to file supplemental authority based on the Seventh Circuit's recent decision in *Westmoreland Cnty. Emp. Ret. Sys. v. Parkinson*, — F.3d —, No. 12-3342, 2013 WL 4266586, at *4 (7th Cir. Aug. 16, 2013). The motion is granted.

I. BACKGROUND[2]

BioSante, a Delaware corporation, is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. At all times relevant to this action, BioSante's primary product in development was LibiGel, a transdermal testosterone gel for the treatment of HSDD.

The plaintiffs contend that the defendants "breached their fiduciary duty of loyalty by making or causing to be made false and misleading statements about the commercial viability, efficacy, and market potential for LibiGel." Compl. at ¶ 2. They also allege that the defendants breached their duties of oversight by "recklessly and/or negligently disregard[ing] the wrongs complained of . . . ." *Id*. at ¶ 91. Specifically, the plaintiffs assert that the defendants failed to inform shareholders that the "placebo effect" would prevent LibiGel from being approved for sale.

The placebo effect, in this context, is a function of psychological factors related to female sexual desire. Generally, women who enroll in sexual dysfunction studies are already interested in improving their sex lives. In most cases, the studies reinforce this desire by requiring participants to record their sexual experiences. As a result, placebos often perform as well as medication, and, the plaintiffs argue, a common result is that drugs designed to treat HSDD do not meaningfully outperform placebos in the treatment of female sexual dysfunction.

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[2] The following facts are drawn from the shareholder derivative complaint and are accepted as true for the purposes of the defendants' motion to dismiss. The facts alleged in the complaint in this case are not entirely consistent with the facts alleged in the complaint filed in the direct action. 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 shareholder derivative action complaint.

The plaintiffs assert that BioSante failed to structure the LibiGel trials in a manner that would minimize the placebo effect, or to inform shareholders that the manner in which the trials were conducted was likely to enhance the placebo effect. Claiming that the placebo effect destroyed the prospects of every previous effort to bring to market a drug to treat female sexual dysfunction, the plaintiffs take issue with BioSante's representations that it expected LibiGel to be the first drug approved to treat HSDD and criticize the lack of disclosures about the placebo effect.

The plaintiffs also stress that during LibiGel's Phase III clinical trials, the FDA recommended against approving Flibanserin (another treatment for female sexual dysfunction) because the placebo effect prevented Flibanserin's manufacturer from demonstrating that its medication worked. In response to the FDA's announcement about Flibanserin, BioSante issued a press release stating that "[g]iven the recommendation of the Advisory Committee [about Flibanserin], we believe that LibiGel is positioned to be the first product approved for the treatment of HSDD." *Id*. at ¶ 43.

Next, the plaintiffs point to the fact that during LibiGel's clinical trials, the American Psychological Association ("APA") revised the diagnostic manual used by psychiatrists by narrowing the definition of HSDD and its symptoms. Specifically, the APA removed "hypo" from the definition of HSDD because it incorrectly implied that "a biological deficiency of testosterone" caused HSDD. *Id*. at ¶ 70. According to the plaintiffs, the revision undermined LibiGel, which is a testosterone supplement.

The defendants knew that these changes would negatively affect doctors' ability to diagnose patients with female sexual dysfunction which, in turn, would severely limit the market

for LibiGel. Thus, the defendants repeatedly explained that they were attempting to structure LibiGel's development in a way that would cause the FDA to state "that in fact female sexual dysfunction is a diagnosable condition with measurable endpoints and that women deserve an option, a therapeutic option." *Id*. at ¶¶ 71-72. They did not, however, publicly address the impact that the changes would likely have on LibiGel's market potential.

On December 14, 2011, BioSante announced that LibiGel had failed to outperform a placebo in its Phase III efficacy tests. This news caused BioSante's share price to plummet. Shareholders filed a putative class action securities case against BioSante and Simes (BioSante's Vice Chairman, President and Chief Executive Officer). *See Lauria v. BioSante Pharm., et al.*, No. 12 C 772 (N.D. Ill.). Shareholders also filed the instant action, which is a derivative action against BioSante's board of directors.

The plaintiffs did not serve a pre-suit demand on BioSante's board prior to filing this action. They assert that a pre-suit demand would have been futile because:

(1) The defendants are unwilling or unable to meet their duties as fiduciaries by filing suit themselves because they "have professional relationships with, are friends with, and have entangling financial alliances, interests and dependencies with the other defendants";

(2) The defendants had access to "the information, reports, and clinical data about LibiGel and its prospects" and nevertheless approved false and misleading statements about LibiGel's performance in clinical trials and its chances of success;

(3) "[N]one of the director defendants can exercise independent business judgment in deciding whether or not to bring and vigorously prosecute this action because they each face [a] substantial likelihood of personal liability for breaching their fiduciary duty of loyalty" and either participated in the wrongdoing or are interdependent with other defendants who acted wrongfully;

(4) As members of the Audit and Finance Committee, defendants Sullivan, Holubow, and Mangano were privy to material information not disclosed to the investing

public and were responsible for BioSante's financial and legal affairs, so are directly responsible for the breaches of fiduciary duty alleged in the complaint;

(5) Simes was privy to materially adverse information withheld from shareholders and was personally responsible for disseminating misleading information in announcements and public filings and acted "to preserve his position of control and the prerequisites thereof," including nearly $2M in compensation and will not initiate litigation that will cause him financial harm; and

(6) Any action brought by the board would expose them all to civil and potentially criminal liability so the board members all have a conflict of interest.

Id. at ¶¶ 87-102. In their federal complaint, the plaintiffs assert claims for breach of fiduciary duty (Count I), abuse of control (Count II), and unjust enrichment (Count III) against all of the defendants.

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 plaintiff's 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 plaintiff's 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).

III. ANALYSIS

The parties agree that Delaware substantive law controls as BioSante is a Delaware corporation. The defendants ask the court to dismiss the complaint with prejudice, arguing that the plaintiffs have not: (1) sufficiently pleaded demand futility; or (2) alleged a viable claim under *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 971 (Del. Ch. 1996).

A. Demand Futility

In a derivative suit, an individual shareholder sues to enforce the corporation's right to proceed against officers, directors, and third parties. *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 95-96 (1991). However, given "the basic principle of corporate governance that the decisions of a corporation — including the decision to initiate litigation — should be made by the board of directors or the majority of shareholders," most jurisdictions require a shareholder to make a pre-suit demand on the corporation's board of directors so the directors can exercise their business judgment and determine whether litigation is in the corporation's best interest. *In re Abbott Labs. Deriv. S'holders Litig.*, 325 F.3d 795, 806 (7th Cir. 2003) (quoting *Kamen*, 500 U.S. at 96).

Under the Federal Rules of Civil Procedure, a complaint in a derivative action must "state with particularity: (A) any effort by the plaintiff to obtain the desired action from the

directors or comparable authority and, if necessary, from the shareholders or members; and (B) the reasons for not obtaining the action or not making the effort." Fed. R. Civ. P. 23(b)(3); *see also Westmoreland*, 2013 WL 4266586, at *4 (federal procedural law governs the degree of detail that the plaintiff must furnish when it explains why it did not make a demand, and state substantive law governs whether those reasons are sufficient).

1. Tests for Demand Futility Under Delaware Law

Delaware courts recognize three tests for determining if a demand on a board of directors would be futile. First, the *Aronson* test applies if a shareholder is challenging a specific decision made by the board of directors. *Aronson*, 473 A.2d at 814. Under *Aronson*, shareholders must "make a pre-suit demand of the board of directors, unless 'under the particularized facts alleged, a reasonable doubt is created that: (1) the directors are disinterested and independent [or] (2) the challenged transaction was otherwise the product of a valid exercise of business judgment." *Westmoreland Cnty. Emp. Ret. Sys.*, 2013 WL 4266586, at *4 (quoting *Aronson*, 473 A.2d at 814). "[I]f either prong is satisfied, demand is excused." *Id*. (quoting *Brehm v. Eisner*, 746 A.2d 244, 256 (Del. 2000)).

Second, *Rales v. Blasband*, 634 A.3d 927, 934 (Del. 1993), applies to claims based on allegedly deficient board oversight, such as the failure to prevent the company from making inaccurate statements. Under *Rales*, a pre-suit demand is unnecessary if the complaint's allegations create a reasonable doubt that at the time the complaint was filed, the board of directors could have properly exercised independent and disinterested business judgment in responding to a demand. *Id*. at 934. This turns on whether the plaintiff alleged particularized facts showing that: "(1) the conduct at issue makes any of the directors 'interested' and, if so,

whether other directors were compromised in their ability to act independently of the interested directors; or 2) at least half of the directors face a sufficiently substantial threat of personal liability as to the conduct alleged in the complaint to compromise their ability to act impartially on a demand." *In re Abbott Depakote S'holder Derivative Litig.*, No. 11 C 8114, 2013 WL 2451152, at *5 (N.D. Ill. June 5, 2013) (quoting *Desimone v. Barrow*, 924 A.2d 908, 928 (Del. Ch. 2007)).

If a company's articles of incorporation include an exculpatory provision immunizing directors from liability for a breach of the duty of care, the plaintiff must also plead particularized facts showing that a majority of the board breached their duties of loyalty or acted in bad faith. *Id*. at *6. To satisfy this burden, a plaintiff must allege that the directors intentionally acted against the corporation's interests, willfully violated the law, or demonstrated a conscious disregard for their duties. *Id. (citing In re Walt Disney Co. Deriv. Litig.*, 906 A.2d 27, 67 (Del. 2006)).

Third, when a plaintiff alleges that directors knowingly failed to exercise their oversight duties, the Delaware Supreme Court's opinions in *In re Walt Disney Co. Deriv. Litig.* and *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 367 (Del. 2006), control. These cases allow plaintiffs to avoid a pre-suit demand if their complaint "allege[s] inactivity coupled with specific 'red flags' suggesting that the company's internal controls are inadequate and that these inadequacies give rise to substantial risk of illegal activity occurring." *In re Abbott Depakote S'holder Deriv. Litig.*, 2013 WL 2451152, at *6. However, if plaintiffs allege "that a majority of the directors served when the illegal conduct occurred [and] knew the company was committing illegal acts and did nothing to remedy the situation, demand futility should be analyzed under the

standard set forth in *Aronson*." *Id*. (citing *In re Abbott Labs. Deriv. S'holders Litig.*, 325 F.3d at 806).

2. The Plaintiffs' Allegations

The defendants contend that the *Rales* standard applies because the plaintiffs have alleged that BioSante's officers or BioSante itself – not the board of directors – made the alleged misrepresentations, so based on the complaint, the board made errors of omission.[3] They then assert that the allegations supporting this theory are insufficient. The plaintiffs discuss the tests generally but do not specify which one applies. However, they appear to be hedging their bets, as they argue that the board faces a substantial likelihood of personal liability (relevant for *Rales*) and that the board's actions were not an exercise of valid business judgment (relevant for *Aronson*).

The court's inquiry begins and ends with the plaintiffs' allegations about the board's alleged malfeasance. The allegations are germane under both *Rales* and *Aronson*, so the court need not decide which test applies. The defendants argue that the plaintiffs' allegations are conclusory because the complaint merely alleges that the defendants were involved in "drafting, producing, reviewing, and/or disseminating the false and misleading statements," "approved false and misleading statements regarding LibiGel's performance in clinical trials and its

[3] It is unclear how BioSante itself (as opposed to its officers or directors) could make any representations, as a corporation can only act through its officers or agents. *See Nat'l Spiritual Assembly of Baha'is of U.S. Under Hereditary Guardianship, Inc. v. Nat'l Spiritual Assembly of Baha'is of U.S., Inc.*, 628 F.3d 837, 848 (7th Cir. 2010) ("incorporeal abstractions act through agents") (internal citations omitted). For present purposes, the court has summarized the defendants' position that BioSante took an independent action, *see* Df. Memo. at 7; Df. Reply at 2, and will not discuss it further as it does not affect the disposition of the motion to dismiss. However, the defendants should clarify this point as necessary in any later filings.

prospects for success," and "participated in, approved, and/or permitted the wrongs alleged herein to have occurred, participated in efforts to conceal or disguise those wrongs from BioSante's shareholders, or recklessly and/or negligently disregarded the wrongs" alleged in the complaint. Compl. at ¶¶ 28, 90-91.

In contrast, the plaintiffs assert that their complaint demonstrates that in the face of contrary information, the board caused BioSante to represent that LibiGel would be profitable and the first FDA approved treatment for HSDD. In support, they direct the court's attention to ¶¶ 3-9, 35-48, and 52-82 of their complaint. Paragraphs 3-9 are in the "nature and summary of the action" section of the complaint and allege, in broad-brush terms, that the defendants collectively were overly optimistic about LibiGel's potential, and failed to disclose that the changes to the definition of HSDD and the placebo effect could have a severe, negative effect on BioSante's ability to bring LibiGel to the market.

In ¶¶ 35-48, the plaintiffs generally allege that the defendants collectively promoted LibiGel by issuing positive press releases and making positive statements while concealing information indicating that there was a substantial risk that LibiGel would not be approved. They also assert that the defendants collectively did not disclose that the Phase II trial results were misleadingly positive because they were skewed by the placebo effect.

In ¶¶ 52-82, the plaintiffs allege that the defendants collectively issued a series of press releases supporting LibiGel, including one that discussed HSDD but did not disclose the "controversy surrounding the condition, which could, and ultimately did, impact LibiGel's Phase III efficacy trials," Compl. at ¶¶ 52-61. They also allege that Simes made misleading comments about LibiGel's Phase II trial results, Next, they assert that the defendants collectively were

aware of the controversy about HSDD in the medical community but did not disclose the substantial risk this posed to LibiGel's prospects for approval and its market potential. In addition, they blame the defendants collectively for failing to structure the Phase III efficacy trials to minimize the placebo effect. The plaintiffs conclude by alleging that the "defendants stated" they were disappointed in the Phase III results and provide the actual quote about disappointment, which was made by Simes, not the board as a group. *See* Compl. at ¶ 83.

Under Delaware law, general allegations that director defendants failed to make adequate disclosures about specific risks faced by the corporation are insufficient. *See In re Citigroup Inc. S'holder Deriv. Litig.*, 964 A.2d 106, 134 (Del. Ch. 2009). Instead, a plaintiff must point to "an actual disclosure that was misleading or any statement that was made misleading as a result of an omission of a material fact." *Id*. For example, in *In re Citigroup*, the court held that the allegation that the board "abdicated its fiduciary duties by not disclosing information on the fair value of [financial instruments]" and "abdicated its fiduciary duties . . . to ensure the integrity of [the corporation's] financial statements and financial reporting process, including earnings press releases and financial information provided to analysts and rating agencies" were insufficient. *Id*. In support, the *In re Citigroup* court explained that these allegations did not suggest that the director defendants prepared the financial statements or were directly responsible for the alleged misstatements or omissions. *Id*.

The allegations here are similarly vague. Essentially, the plaintiffs assert that the individual directors must have known about the placebo effect, the change to the definition of HSDD, and alleged flaws with the Phase II clinical study that made it look misleadingly positive. They then conclude that the directors were responsible for a failure to disclose these damning

facts about LibiGel, which would have caused investors to abandon ship before the release of the poor Phase III efficacy trial results.

The complaint, however, does not include any specific facts indicating that the directors should have been on notice that the Phase II studies were skewed by the placebo effect or, indeed, that the Phase II studies had a demonstrable, verifiable design flaw or were affected by the placebo effect. Moreover, the assumption that the Phase II studies were flawed and produced falsely positive results appears to be inconsistent with the fact that LibiGel proceeded to Phase III testing. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 344 n.15 (2008) (outlining the serial nature of clinical drug trials). The allegations in the complaint also demonstrate that the FDA did not change its requirements for the Phase III trials after the definition of HSDD was narrowed.

In addition, the plaintiffs have not alleged that the director defendants prepared the allegedly misleading statements or that they were directly responsible for the alleged misstatements or omissions. Instead, the plaintiffs generally assert that false statements and omissions were made and the director defendants were responsible. In fact, however, the only allegation tying the director defendants to a specific statement is the plaintiffs' claim that the director defendants stated they were disappointed in the Phase III results. Notably, the plaintiffs then attribute the statement about disappointment to Simes, and do not explain how the other director defendants are responsible for that statement. *See* Compl. at ¶ 83. Thus, the complaint is dismissed based on the plaintiffs' failure to show that they were not required to make a pre-suit demand.

In the interest of completeness, the court also adds that BioSante attached a copy of its certificate of incorporation to its motion to dismiss. The court can take judicial notice of BioSante's certificate of incorporation for purposes of a motion to dismiss. *See Gordon v. Goodyear*, No. 12 C 369, 2012 WL 2885695, at *6 n.2 (N.D. Ill. July 13, 2012) (collecting cases). Consistent with Delaware law, the certificate of incorporation contains a "provision eliminating or limiting the personal liability of a director to the corporation . . . for breach of fiduciary duty as a director," except for breaches of the duty of loyalty, "intentional misconduct," or "acts or omissions not in good faith or which involve a knowing violation of law." *See* Del. Code Ann. Tit. 8, § 102(b)(7).

As noted above, when a company's articles of incorporation immunize directors from liability for a breach of the duty of care and the validity of the waiver clause is not contested, a plaintiff must plead particularized facts showing that a majority (*i.e.*, at least half) of the board breached their duties of loyalty or acted in bad faith. *In re Abbott Depakote S'holder Deriv. Litig.*, 2013 WL 2451152, at *5-6. To do so, a plaintiff must allege that the directors intentionally acted against the corporation's interests, willfully violated the law, or demonstrated a conscious disregard for their duties. *Id.* The current version of the complaint fails to meet this standard as the only individualized allegations of wrongdoing are attributed to Simes. Thus, the complaint is deficient as the complaint's allegations are too general to allow the court "to reasonably conclude [that] the directors' conduct falls outside the exemption [in the articles of incorporation]." *See In re Abbott Labs. Deriv. S'holders Litig.*, 325 F.3d at 810-11.

B. *Caremark*

The defendants' second argument is that to the extent the plaintiffs are attempting to assert a corporate mismanagement claim under *In re Caremark Int'l Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996), they have failed to do so. In their response to the motion to dismiss, the plaintiffs clarify that they did not intend to assert a *Caremark* claim. Thus, the court will not address the defendants' arguments about *Caremark*.

C. The Defendants' Request to Dismiss With Prejudice

The defendants contend that the court should dismiss this action with prejudice, due to (among other things) the plaintiffs' failure to satisfy the pre-suit demand requirement or establish that making a demand would have been futile. In support, the defendants cite to Delaware law holding that 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). The plaintiffs do not challenge the application of Delaware procedural law regarding leave to amend.

The court need not opine on the applicability of this aspect of Delaware law as it finds that the plaintiffs conceivably could correct the defects identified in this order by amending their complaint. 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.

IV. CONCLUSION

For the above reasons, the plaintiffs' motion for leave to file supplemental authority [Dkt. 43] and the defendants' motion to dismiss the plaintiffs' verified consolidated shareholder derivative complaint [Dkt. 32] are 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