

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

GOPICHAND VALLABHANENI, on behalf)
of Himself and All Others Similarly Situated,)

Plaintiff,)

v.)

Case No. 1:14-cv-01048-TWP-MJD

ENDOCYTE, INC., P. RON ELLIS,)
BETH TAYLOR, MICHAEL A. SHERMAN,)
JOHN C. APLIN, PHILIP S. LOW,)
KEITH E. BRAUER, ANN F. HANHAM,)
MARC KOZIN, PETER D. MELDRUM,)
FRED A. MIDDLETON, LESLEY RUSSELL,)
CREDIT SUISSE SECURITIES (USA) LLC,)
CITIGROUP GLOBAL MARKETS INC.,)

Defendants.)

ENTRY ON MOTION TO DISMISS

Before the Court is Defendants’ Motion to Dismiss. ([Filing No. 106.](#)) Following consolidation of this case and two others, Plaintiff, Gopichand Vallabhaneni (“Vallabhaneni”), on behalf of himself and others similarly situated, filed an Amended Complaint alleging several claims of Securities Exchange Act and Securities Act violations against Defendants, Endocyte, Inc. (“Endocyte”), Endocyte’s officers and directors, and securities underwriters. ([Filing No. 79.](#)) Specifically, Vallabhaneni alleges that Endocyte made materially untrue and/or misleading statements and omissions in the registration statement issued in connection with Endocyte’s April 2014 public offering for a potentially promising cancer treatment drug—Vintafolide—which had to cease its Phase 3 clinical trial. On March 6, 2015, Defendants filed a Motion to Dismiss all claims pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons stated below, the Defendants’ motion to dismiss is granted.

I. BACKGROUND

The following facts, taken largely from the Plaintiff's Amended Complaint, are accepted as true for purposes of the motion to dismiss and all reasonable inferences are drawn in a light most favorable to the Plaintiff. *See Tellabs, Inc. v. Makor Issues and Rights, Ltd.*, 551 U.S. 308, 321 (2007). In addition, consistent with established procedures for evaluating a motion to dismiss in a securities fraud case, the Court has considered documents referenced in the Amended Complaint and the parties' briefs.

A. Endocyte and Vintafolide

Endocyte is a biopharmaceutical company that develops targeted small molecule drug conjugates and companion imaging agents for personalized therapy in cancer and other serious diseases. The small molecule drug conjugates are designed to actively target receptors on diseased cells as opposed to healthy cells to, in theory, provide a more targeted approach to fighting diseases. The small molecule drug conjugates would enable treatment of patients with highly active drugs, delivered more frequently and at larger doses over longer periods of time than would be possible with the untargeted drug alone.

Endocyte's primary small molecule drug conjugate candidate is Vintafolide. Vintafolide consists of two parts: a molecule that targets the folate receptor expressed on various cancerous cells; and Vinblastine, a potent chemotherapy drug. Endocyte has been testing Vintafolide on several different diseases, but chose platinum-resistant ovarian cancer as its lead targeted disease for development because of the unmet need in treating this specific disease and the high percentage of patients whose tumors over-express the targeted folate receptor.

The Vintafolide treatment for platinum-resistant ovarian cancer consisted of three components used in combination. The first component of the treatment is Etarfolatide, Endocyte's

proprietary imaging agent for Vintafolide, which selectively binds to the folate receptor-expressing cells and allows computed imaging of folate receptor-expressing tumors. By using Etarfolatide, researchers could scan cancerous tumors for folate receptors to which Vintafolide could bind. The second component is the Vintafolide itself, which would bind to the folate receptor cells and selectively deliver the chemotherapy drugs to those cells. The third and final component is a proven chemotherapeutic drug Pegylated Liposomal Doxorubicin (“PLD”), which is also bound to the Vintafolide. When used by itself, PLD will kill all cells regardless of whether they are cancerous or not and, in the process, ravage healthy cells in the body. In theory, the Vintafolide treatment would solve this problem by targeting and linking only to the folate receptors found in the cancerous cells, and releasing the powerful chemotherapy drugs only in those cancerous cells, thus leaving healthy cells alone.

Before considering approval of a drug, the Food and Drug Administration (FDA) requires a sponsor to undertake a three-phase clinical investigation. 21 C.F.R. § 312.21. Phase 1 consists of a closely monitored, relatively small study (twenty to eighty volunteers) to determine the safety of the drug and, if possible, early evidence of effectiveness. *See* 21 C.F.R. § 312.21(a). Phase 2 involves further clinical research and study to determine the drug’s efficacy, short-term side effects, and risks. 21 C.F.R. § 312.21(b). Phase 2 studies are typically well-controlled, closely-monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 studies “are performed after preliminary evidence suggesting effectiveness of the drug has been obtained” and are intended to gather additional information about effectiveness and safety of the drug. 21 C.F.R. § 312.21(c). Phase 3 studies usually include several hundred to several thousand subjects.

B. Vintafolide Phase 2 Study

The Vintafolide Phase 2 study was not blinded and involved 149 patients, all of whom had ovarian cancer. The Phase 2 study patients either received PLD combined with Vintafolide or PLD alone. All patients received chemotherapeutic drugs, but only some of the patients received the targeted Vintafolide treatment. Further, as explained to investors in its 2013 Annual Report (released on March 5, 2014), patients were permitted to participate in the Phase 2 study regardless of whether their tumors over-represented the folate receptor. ([Filing No. 107-2 at 15.](#)) Endocyte's 2013 Annual Report stated that “[a]ll patients enrolled at clinical centers with nuclear imaging capabilities were scanned with our etarfolatide companion imaging agent within 28 days prior to the initiation of treatment”; but Endocyte also noted that only 113 of the 149 participants were actually scanned and that the Phase 2 study results were not solely determined based on radiologic scans. ([Filing No. 107-2 at 15, 25.](#))

In May 2010, Endocyte completed the Vintafolide Phase 2 study. A year later, in May 2011, Endocyte hired a Global Clinical Trial Manager, who is identified in the Amended Complaint solely as CW1 (the “confidential witness”). A month later, in June 2011, Endocyte presented the final analysis of the Phase 2 study at a meeting of the American Society of Clinical Oncology. Endocyte reported an 85% increase in duration of progression-free survival, a measure of how a patient lives with cancer while taking treatment but does not progress to a later stage, for patients who received the PLD in combination with Vintafolide versus those patients who received PLD alone.

Central to all of the Plaintiff's claims is the contrary opinion of a confidential witness, who asserts that the results from the Phase 2 study did *not* meaningfully measure the ability of Vintafolide to selectively target folate-receptive positive tumors in platinum-resistant ovarian

cancer. ([Filing No. 79 at ¶ 37.](#)) Specifically, the confidential witness asserts that, because imaging was not required for the Phase 2 study, it did not distinguish between patients with and without folate receptor positive tumors. As a result, the Phase 2 study measured how well people responded to treatment rather than measuring how effectively Vintafolide was attaching to only cancerous cells.

In April 2012, based on the positive Phase 2 study results, Endocyte secured a collaboration agreement with Merck Sharp & Dohme Research GmbH, a subsidiary of Merck & Co, Inc. (“Merck”). In exchange for granting Merck worldwide rights to develop and commercialize Vintafolide, Endocyte received a non-refundable upfront payment of \$120 million and a milestone \$5 million payment in 2012. In addition, Endocyte was eligible for an additional \$875 million if Vintafolide successfully achieved certain development goals. Under the agreement, Endocyte was responsible for the majority of funding and completion of the Phase 3 study, and Merck was responsible for all other development activities. In November 2012, the European Medicines Agency (“EMA”) accepted Endocyte’s applications for conditional market authorization for Vintafolide for the treatment of platinum-resistant ovarian cancer, also based on the Phase 2 study results.

C. Vintafolide Phase 3 Study Amended Protocol

In May 2011, Endocyte initiated enrollment of the Vintafolide Phase 3 study, which continued through December 31, 2013. That same month, as part of its May 13, 2011 quarterly Form 10-Q filing, Endocyte disclosed the following information regarding a meeting with the FDA, stating in relevant part,

[T]he FDA stated that, because of the difficulty in reliably determining cancer progression based on imaging studies in ovarian cancer, its office policy is to require overall survival, or OS, to be the primary endpoint for an ovarian cancer registration trial. However, the FDA stated that we may choose at our own risk, to

conduct a phase 3 trial in which progression free survival, or PFS, is the primary endpoint; provided that for such a trial to be the basis for approval, the PFS results must be very robust statistically and clinically meaningful, and the trial must be powered to demonstrate a statistically significant OS benefit.

[\(Filing No. 110-1 at 8.\)](#)

The confidential witness reports that Endocyte met with the FDA again in July 2011 to discuss the design of the Vintafolide Phase 3 study. The confidential witness attended a FDA meeting with Bing Nguyen, Endocyte's Vice President of Clinical Development, and two members of Endocyte's regulatory group. At the meeting, "[t]he FDA questioned how efficacy had been previously documented, and told Endocyte that it needed to change the imaging protocol in the Phase 3 study so that it specifically demonstrated the efficacy of Vintafolide in attaching to folate receptor positive tumors and delivering the PLD payload." [\(Filing No. 79 at ¶ 39.\)](#)

Also according to the confidential witness, Endocyte made changes to the Phase 3 protocol based on the FDA's interim recommendations, though the amended Phase 3 protocol was not approved until January 2013, nearly two years after the FDA meeting. [\(Filing No. 79 at ¶ 39.\)](#) The amended Phase 3 study required imaging of patient tumors at the beginning of the study. The patients were then categorized into three different groups: patients with no folate receptive tumors, patients with some folate receptive tumors, and patients with all folate receptive tumors. Unlike the Phase 2 study, the patients with no folate receptive tumors were eliminated from the Phase 3 study, changing the primary endpoint for the Phase 3 study to progression-free survival in patients with 100% folate receptive tumors. The Phase 3 study also differed from the Phase 2 study in that it included a placebo in order to blind the study.

In its 2013 Annual Report, Endocyte disclosed a number of differences between the Phase 2 and Phase 3 studies to investors. In particular, Endocyte noted the double-blinded nature of the study and highlighted that the primary endpoint was changed in the Phase 3 study and the results

would be determined using scans. Specifically, Endocyte highlighted that the primary endpoint would be measured “based upon investigator assessment using both radiological measurements based on RECIST [Response Evaluation Criteria in Solid Tumors], as well as assessment of clinical progression.” (Filing No. 107-2 at 13.) After the Phase 3 study was terminated, Endocyte further disclosed that the Phase 3 study used an updated RECIST 1.1 protocol instead of the RECIST 1.0 protocol that was used in the Phase 2 study. (*But see* March 20, 2014 CHMP Opinion, [Filing No. 107-3 at 8](#), 45) (noting that the Phase 2 Study used RECIST 1.0 and the Phase 3 trial used RECIST 1.1.)

The confidential witness, who stopped working for Endocyte a month after the amended Phase 3 protocol was approved, reported that “with the amended protocol, everything had changed” and “it was readily apparent in the Phase 3 study using the new imaging protocols suggested by the FDA that Vintafolide was not demonstrably effective in treating platinum-resistant ovarian cancer”. ([Filing No. 79 at ¶ 41.](#)) Further, the confidential witness states that “senior Endocyte management knew, at least as early as June 2012, that the positive data from the Phase 2 study was not appearing in the Phase 3 study.” ([Filing No. 79 at ¶ 93.](#))

D. Endocyte’s 2013 Annual Report

On March 5, 2014, the start of the class period, Endocyte issued its 2013 Annual Report. Throughout the 2013 Annual Report, Endocyte touted the Phase 2 study results. For example, the 2013 Annual Report made numerous statements regarding the Phase 2 findings of progression free survival, including the following,

In the final progression free survival, or PFS, analysis . . . vintafolide increased PFS from a median of 2.7 months to a median of 5.0 months, representing an 85 percent improvement over standard therapy (p=0.031).

...

At PRECEDENT’s final PFS analysis . . . combination therapy with vintafolide and PLD increased median PFS by 85 percent over therapy with PLD alone. . . .

patients receiving vintafolide were 37.4 percent less likely to have died or have their cancer progress compared to patients receiving only PLD.

...

We believe that vintafolide and PLD is the first combination to show a meaningful improvement in PFS over standard therapy for the treatment of PROC.

...

We believe these findings continue to support the robustness of the PRECEDENT trial results, particularly in the group of FR (100%) patients.

However, Endocyte also included eighteen pages of disclaimers in the 2013 Annual Report, including the following specific disclaimers were highlighted in bold, italicized font,

We are highly dependent on the success of vintafolide, and we cannot give any assurance that we will successfully complete its clinical development, or that it will receive regulatory approval or be successfully commercialized.

...

The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the EMA, FDA or other regulatory authorities.

...

Our efforts to obtain conditional marketing authorization for vintafolide and etarfolatide from the European Medicines Agency may be unsuccessful.

...

There is a high risk that our development and clinical activities will not result in commercial products, and we may be required to invest significant additional resources in our current development and clinical programs, to the exclusion of others, before it is known whether one or more of our product candidates will receive regulatory approval or be commercially introduced.

...

We may not obtain government regulatory approval to market our product candidates or negotiate satisfactory pricing for our product candidates which could adversely impact our future profitability.

([Filing No. 107-2 at 50-53](#), 56) (emphasis in original). Endocyte also repeated its May 13, 2011 Form 10-Q disclosure regarding its meeting with the FDA, again noting the FDA's requirement that, "the PFS results must be very robust statistically and clinically meaningful, and the trial must have sufficient power to evaluate the OS benefit" in order for the Phase 3 study to support final FDA approval of Vintafolide. ([Filing No. 107-2 at 51.](#))

E. Endocyte's March 21, 2014 Press Release

On March 21, 2014, Endocyte issued a press release announcing that the European Medicines Agency and its Committee for Medicinal Products for Human Use (“CHMP”) issued “positive opinions” for the “Conditional Market Authorisations” [sic] of Vintafolide for the treatment of adult patients with platinum-resistant ovarian cancer. The press release stated, in relevant part,

These positive CHMP opinions bring Merck and Endocyte one step closer to providing a personalized approach to address a significant unmet medical need in platinum-resistant ovarian cancer

...

Today's positive CHMP opinions are an important step toward personalizing ovarian cancer management for appropriate patients, and validate our Company's focus on the development of targeted medicines and companion imaging agents designed to improve patient outcomes.

...

The applications for Conditional Marketing Authorisation [sic] for vintafolide, etarfolatide and IV folic acid were submitted based on results in platinum-resistant ovarian cancer patients who express the folate receptor on all target lesions as evaluated in the PRECEDENT Phase 2 study.

On that same day, Endocyte held a conference call with analysts and investors. During the call, Endocyte's President and CEO, Ron P. Ellis (“Mr. Ellis”), stated,

Based on the opinion which was announced today, we expect that the EMA will grant the conditional marketing authorization for the two products or the products in the 28 countries in the EU probably in two to three months. . . . We are ready to launch.... Both Merck and Endocyte have their teams in place and have been preparing for the potential arrival.

Also on March 21, 2014, Endocyte's stock value increased from \$14.64 to \$28.17. The Plaintiff alleges that Endocyte's Vice President of Manufacturing and Chemistry Manufacturing Control, Allen Ritter (“Ritter”), sold 8,000 shares of Endocyte common stock, nearly half of his holdings, the same day, earning \$264,880.00. Defendants assert that Ritter's transactions were “non-discretionary sales” made pursuant to a 10b5-1 trading plan; and they note that no other

Endocyte officers or directors are alleged to have sold any stock during the class period. ([Filing No. 110 at 13-14.](#))

F. Endocyte’s March 25, 2014 Shelf Registration Statement

Four days later, on March 25, 2014, Endocyte filed a Shelf Registration Statement, which incorporated a Preliminary Prospectus (“Registration Statement”) to offer 5,175,000 shares of common stock. Endocyte had an outsized need to raise revenue and was attempting to capitalize on the surging stock price, noting that Endocyte “[had] never been profitable and [had] incurred losses in each year since [its] inception in December 1995.” ([Filing No. 79 at ¶¶ 33, 95, 109.](#)) Among other things, the Registration Statement highlighted the CHMP’s “positive opinions” regarding Vintafolide. Specifically, the Registration Statement stated in relevant part,

CHMP Positive Opinions

On March 21, 2014, we . . . announced that the Committee for Medicinal Products for Human Use, or CHMP, of the EMA has issued positive opinions for the Conditional Marketing Authorisations [sic] of VYNFINIT® (vintafolide) . . . for the treatment of adult patients with folate receptor-positive platinum-resistant ovarian cancer, in combination with pegylated liposomal doxorubicin, or PLD.

...

The CHMP positive opinions will be reviewed by the European Commission, or EC. If approved, the EC grants a centralized marketing authorization with unified labeling that is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway. The EC usually issues a final legally binding decision within three months of a CHMP opinion.

([Filing No. 79 at ¶ 95](#), emphasis in original.)

However, the Registration Statement cautioned that “[a]ctual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market.” ([Filing No. 107-4 at 10.](#)) In addition, the Registration Statement included a section titled Risk Factors which indicated “risks and uncertainties that could differ materially from anticipated results”, both

“whether the European Commission, or EC, will approve our applications for conditional marketing authority for vintafolide” and “the results of our ongoing [Phase 3] trials”. The Registration Statement also encouraged investors to evaluate the “Risk Factors” identified in its most recent Annual Report and “incorporated [the Annual Report] by reference in [its] entirety.” (Filing No. 107-4 at 9.)

On April 2, 2014, Endocyte completed its public offering, raising approximately \$101.8 million in just over a week.

G. Termination of Vintafolide Phase 3 Study

Endocyte issued a press release on May 2, 2014, announcing that it was terminating the Vintafolide Phase 3 study based on the Data Safety Monitoring Board’s recommendation. Specifically, Endocyte made the following disclosure,

[T]he Data Safety Monitoring Board (DSMB) of the PROCEED trial has completed a pre specified, interim futility analysis and the DSMB recommended that the trial be stopped because Vintafolide did not demonstrate efficacy on the pre-specified outcome of Progression-Free Survival (PFS) in patients with platinum-resistant ovarian cancer.

The next day, Endocyte’s stock value dropped from \$17.38 to \$6.62.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal if the complaint fails to set forth a claim upon which relief can be granted. “The purpose of a motion to dismiss is to test the sufficiency of the complaint, not to decide the merits.” *Gibson v. City of Chi.*, 910 F.2d 1510, 1520 (7th Cir. 1990). Accordingly, when analyzing a Rule 12(b)(6) motion to dismiss, a court construes the complaint in the light most favorable to the plaintiff, accepts all factual allegations as true, and draws all reasonable inferences in favor of the plaintiff. *Tellabs, Inc.*, 551 U.S. at 321 (2007) (evaluating a motion to dismiss in regards to a securities fraud claim); *City of Austin Police*

Ret. Sys. v. ITT Educ. Servs., Inc., 388 F. Supp. 2d 932, 935 (S.D. Ind. 2005). When deciding a motion to dismiss for failure to state a claim in a securities fraud case, courts must consider the complaint in its entirety, as well as other sources that courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, such as documents incorporated into the complaint by reference and matters of which a court may take judicial notice. *Tellabs, Inc.*, 551 U.S. at 323.

III. DISCUSSION

The Plaintiff alleges five claims under two securities statutes, including: (A) a Section 10(b) Securities Exchange Act claim against Endocyte and its officers and directors for making misleading statements and omissions in Endocyte's public disclosures; (B) a Section 20(a) Securities Exchange Act claim against Endocyte's officers and directors based on a control theory of liability; (C) a Section 11 Securities Act claim against Endocyte for making misleading statements and omissions in Endocyte's 2014 Annual Registration Statement; (D) a Section 11 Securities Act claim against Endocyte's officers and directors and against the two underwriters for signing the Registration Statement; and (E) a Section 15 Securities Act claim against Endocyte's officers and directors under a control theory of liability. ([Filing No. 79 at 5-7](#), 17-21, 36-41.) Each claim is addressed in turn.

A. Section 10(b) Securities Exchange Act Claim

1. Heightened Pleading Standard

Along with the standards of Rule 12(b)(6), plaintiffs alleging a Section 10(b) claim must also satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *In re HealthCare Compare Corp. Secs. Litig.*, 75 F.3d 276, 280-81 (7th Cir. 1996); *City of Austin*, 388 F. Supp. 2d at 935 (S.D. Ind. 2005). Unlike a notice pleading, where it is sufficient that the court be able to identify some set of facts under

which plaintiffs could prevail, Rule 9(b) requires that the alleged fraud be pled in detail, stating with particularity the circumstances constituting fraud. *City of Austin*, 388 F. Supp. 2d at 935. This heightened pleading requirement responds “to the great harm to the reputation of a business firm or other enterprise a fraud claim can do.” *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007). Accordingly, a plaintiff claiming fraud “must do more pre-complaint investigation to assure that the claim is responsible and supported, rather than defamatory and extortionate.” *Id.* Therefore, the complaint must provide “the who, what, when, where, and how” of the alleged fraud. *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990).

In addition to the particularity requirements of Rule 9(b), the PSLRA further raises the pleading standard in securities fraud cases. *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 594 (7th Cir. 2006) (*vacated and remanded on other grounds*) (“Makor I”). Specifically, the PSLRA additionally requires that the complaint “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).

Congress enacted the PSLRA as a check against abusive litigation by private parties. *See Schleicher v. Wendt*, 529 F. Supp. 2d 959, 969 (S.D. Ind. 2007) (“Congress passed the PSLRA in response to perceived abuses in which issues of securities would be sued based on little more than a significant drop in their stock prices after announcing bad news”); *Lawrence E. Jaffe Pension Plan v. Household Int’l, Inc.*, No. 02 C 5893, 2004 WL 574665, *4 (N.D. Ill. Mar. 22, 2004) (“[t]he rule serves to (1) protect defendants’ reputations from harm, (2) minimize ‘strike suits’ and ‘fishing expeditions’, and (3) provide notice of claims to adverse parties”); H.R. Conf. Rep. No. 104-369, at 31 (1995) (noting abuses in securities litigation, including “the routine filing of lawsuits against

issuers of securities and others whenever there is a significant change in an issuer's stock price, without regard to any underlying culpability of the issuer"). Accordingly, the heightened pleading standards of the PSLRA are intended to "further increase plaintiffs' pre-complaint duty to investigate and further discourage claims of so-called *fraud by hindsight*". *Schleicher*, 529 F. Supp. 2d at 969 (emphasis added).

In addition to the more specific pleading standard, the PSLRA also imposes a substantially higher standard of pleading scienter. Specifically, the PSLRA requires that the complaint must, "with respect to each act or omission . . . 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) (emphasis added). As applied to securities fraud claims, the "required state of mind" is an "intent to deceive, manipulate, or defraud". *Higginbotham v. Baxter Int'l Inc.*, 495 F.3d 753, 756 (7th Cir. 2007).

A complaint will survive a motion to dismiss only if a reasonable person would deem the inference of scienter "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc.*, 551 U.S. at 324 (2007); *Makor Issues and Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 705 (7th Cir. 2008) ("Makor II") ("[t]he plaintiff must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference"). If the complaint fails to meet the PSLRA standard, the court shall, on the motion of any defendant, dismiss the complaint. 15 U.S.C. § 78u-4(b)(3)(A); *City of Austin*, 388 F. Supp. 2d at 936.

2. Legal Standard for a Section 10(b) Securities Exchange Act Claim

Section 10(b) of the Securities Exchange Act makes it unlawful for any person,

[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may

prescribe as necessary or appropriate in the public interest or for the protection of investors.

15 U.S.C. § 78j(b). One such rule, SEC Rule 10b-5, makes it unlawful for any person,

(a) [t]o employ any device, scheme, or artifice to defraud, (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. To establish a violation of Rule 10b-5, a plaintiff must prove that: (1) the defendant made a material misrepresentation or omission; (2) the defendant acted with fraudulent intent (“scienter”); (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) the plaintiff relied upon the misrepresentation or omission; (5) and the false statement proximately caused the plaintiff’s economic damages. *Caremark, Inc. v. Coram Healthcare Corp.*, 113 F.3d 645, 648 (7th Cir.1997), *Plumbers*, 673 F. Supp. 2d at 731 (this needs to be a full cite). At issue in the pending motion to dismiss are the first and second elements.

3. Materially Misleading Statements and Omissions

Endocyte successfully argues that dismissal of the Plaintiff’s Section 10(b) claim is appropriate because Plaintiff has failed to sufficiently allege that the challenged statements and omissions are not materially misleading, and several of the challenged statements are immaterial opinion statements and are subject to the PSLRA’s safe harbor provision.

a. Adequately Pleaded

The Plaintiff’s Section 10(b) claim is problematic because his central allegation, that Endocyte continued to promote the Phase 2 study data after the FDA expressed concern regarding how efficacy was determined, is solely supported by the vague and uncorroborated testimony of a single confidential witness. The Seventh Circuit has reacted strongly against reliance on

confidential witnesses in securities fraud cases, noting that allegations from such witnesses are to be steeply discounted. *Higginbotham*, 495 F.3d at 757 (7th Cir. 2007). (“[i]t is hard to see how information from anonymous sources could be deemed ‘compelling’ or how we could take account of plausible opposing inferences. Perhaps these confidential sources have axes to grind. Perhaps they are lying. Perhaps they don’t even exist.”).

Accordingly, if a plaintiff supports an allegation based on the testimony of a confidential source, the plaintiff must describe the source “with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged”. *Makor I*, 437 F.3d 588, 596 (7th Cir. 2006) (*vacated and remanded on other grounds*); *City of Sterling Heights Gen. Emps.’ Ret. Sys. v. Hospira Inc.* (“Hospira”), No. 11 C 8332, 2013 WL 566805, *17 (N.D. Ill. Feb. 13, 2013) (noting, however, that the complaint need not provide the “name, rank, and serial number for each of these sources.”). When the testimony of a confidential witness is supported by an adequate description of a witness’ job title, duties, and duration, and when the testimony is also used to *corroborate* allegations established by other sources, the testimony is typically considered to be adequately supported. *See, e.g., Makor II*, 513 F.3d 702 at 711-12; *Hospira*, 2013 WL 566805 at *17 (concluding that the confidential witness’ testimony was adequately supported wherein the testimony corroborated the allegations “rather than ... allege[d] a basis for misleading nature of the statements that is otherwise absent from the [c]omplaint”).

However, when a confidential witness’ testimony is not adequately described and is not used to corroborate allegations from other sources, the testimony is discounted. *See, e.g., Higginbotham*, 495 F.3d at 757 (“[a]llegations from confidential witnesses must be discounted rather than ignored. Usually, that discount will be steep”); *Plumbers*, 673 F. Supp. 2d 718 at 737

(concluding that a confidential witness' testimony was "inconsistent, uncorroborated, and vague" and was therefore a "wholly inadequate basis" for establishing material omissions by the defendants); *City of Austin* 388 F. Supp. 2d at 943-45 (S.D. Ind. 2005) (discounting confidential witnesses' testimony when the plaintiff did not sufficiently explain how the witnesses would be in a position to know about the alleged misconduct and when the plaintiff did not provide dates to explain when the witnesses gained knowledge of the alleged misconduct).

Central to all of the Plaintiff's claims are the allegations made by the Plaintiff's sole confidential witness, who served as Endocyte's Global Clinical Trial Manager from May 2011 (a month after Endocyte completed the Phase 2 study) until February 2013 (a month after the Phase 3 amended protocol was approved and fifteen months before Endocyte announced that it was terminating the Phase 3 study). According to the confidential witness, Endocyte knew that the Phase 2 study was flawed and that the Phase 3 study was not demonstrating efficacy but Endocyte continued to disclose the opposite to investors.

The confidential witness asserts that, because "imaging was not performed to scan for folate receptor positive tumors", the Phase 2 study "did not distinguish between patients with and without folate receptor positive tumors" which created "inconsistency in how progression-free survival, the primary endpoint for the trial, was determined." ([Filing No. 79 at ¶ 37.](#)) In support, the confidential witness asserts that, in the July 2011 meeting the FDA "questioned how efficacy had been previously documented, and told Endocyte that it needed to change the imaging protocol in the Phase 3 study so that it specifically demonstrated the efficacy of Vintafolide in attaching to folate receptor positive tumors and delivering the PLD payload." ([Filing No. 79 at ¶ 39.](#)) Despite the FDA's questioning of the Phase 2 study, the Plaintiff asserts that Endocyte repeatedly promoted

the Phase 2 results and the “positive opinions” for provisional marketing approval made by the European Medicine Agency’s CHMP, thereby misleading investors all along the way.

In addition, according to the confidential witness, “it was readily apparent in the Phase 3 study using the new imaging protocols suggested by the FDA that Vintafolide was not demonstrably effective in treating platinum-resistant ovarian cancer”. ([Filing No. 79 at ¶ 41.](#)) And, “senior Endocyte management knew, at least as early as June 2012, that the positive data from the Phase 2 study was not appearing in the Phase 3 study.” ([Filing No. 79 at ¶ 93.](#))

The problem with this testimony, which lays the foundation for all of the Plaintiff’s claims, is that it is wholly uncorroborated by other evidence or testimony in the Amended Complaint. The Seventh Circuit has made clear that when a confidential witness’ testimony is not adequately described and is not used to corroborate allegations from other sources, the testimony is to be “steeply” discounted.

More troubling is that the confidential witness’ allegations are not pled with the specificity required by Fed. R. Civ. P. 9(b) or the PSLRA. Rule 9(b) requires that the alleged fraud be pled in detail, stating with particularity the circumstances constituting fraud. *City of Austin*, 388 F. Supp. 2d at 935. Therefore, the complaint must provide “the who, what, when, where, and how” of the alleged fraud. *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990).

Based on the vague testimony of the confidential witness, it is impossible to determine from the complaint what exactly the FDA questioned in regard to the Phase 2 study or how severe that questioning actually was. For instance, without further explanation, it is unclear why the FDA allowed the Vintafolide study to proceed to Phase 3 trials and continue for another three years, if the FDA was as concerned by the Phase 2 study data and design as the confidential witness suggests. Indeed, in the absence of a more specific description of the FDA’s questioning, the

opposite inference is more plausible: that the FDA's concerns were not as severe and the study was not as flawed as the confidential witness suggests. *See, e.g., In re Sanofi Secs. Litig.* ("Sanofi"), 87 F. Supp. 3d 533, 544-45 (S.D.N.Y. 2015) ("[h]ad the FDA at any point concluded that there were serious defects in study design that would render the study incapable of producing valid evidence of safety and effectiveness, it had authority to issue a clinical hold . . . to protect human subjects from exposure to flawed and therefore scientifically worthless studies"); 21 C.F.R. § 312.21(c) (Phase 3 studies "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained").

In addition, based on the vague testimony of the confidential witness, it is impossible to determine when Endocyte knew that the Phase 3 trials would not, or were not, demonstrating efficacy. The confidential witness makes two allegations in this regard. Specifically, the confidential witness asserts that "it was readily apparent in the Phase 3 study using the new imaging protocols suggested by the FDA that Vintafolide was not demonstrably effective in treating platinum-resistant ovarian cancer" and that "senior Endocyte management knew, at least as early as June 2012, that the positive data from the Phase 2 study was not appearing in the Phase 3 study." ([Filing No. 79 at ¶ 41](#), ¶ 93.) However, neither statement is supported by any corroborating facts. In the absence of more detail, these allegations are suspicious, given the fact that the confidential witness stopped working for Endocyte in February 2013, only one month after the Phase 3 amended protocol was approved (January 2013) and fifteen months before the Phase 3 study was terminated (May 2014). How either the confidential witness or Endocyte knew that the Phase 3 study was not demonstrating efficacy during the first month under the amended protocol (or seven months before the new protocol was even approved, in June 2012) is entirely unexplained in the Amended Complaint. Without more detail, it is impossible to determine how

either the confidential witness or Endocyte knew that efficacy was not demonstrated at such an early stage of the Phase 3 study given the double-blinded¹ nature of the study. *Compare City of Austin* 388 F. Supp. 2d at 943-45 (S.D. Ind. 2005) (discounting confidential witnesses' testimony when the plaintiff did not sufficiently explain how the witnesses would be in a position to know about the alleged misconduct and when the plaintiff did not provide dates to explain when the witnesses gained knowledge of the alleged misconduct); *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711(PKC), 2013 WL 2399869, *19 (S.D.N.Y. May 29, 2013) (“[w]here plaintiffs contend defendants have access to contrary facts, they must specifically identify the reports or statements containing the information”).

These are critical pleading omissions that go to the heart of the Plaintiff's case. If the Phase 2 study was not as fatally flawed as the confidential witness asserts, or if the Defendants did not have advanced knowledge that the Phase 3 study was either futile from the start or not producing positive results, Plaintiff's case falls apart. Accordingly, without more detail of the “who, what, when, where, and how” of these critical facts, the confidential witness' testimony cannot alone support an inference of fraudulent conduct by the Defendants. *DiLeo*, 901 F.2d at 627; *Plumbers*, 673 F. Supp. 2d at 731; *Plumbers*, 673 F. Supp. 2d at 737 (concluding that a confidential witness' testimony was “inconsistent, uncorroborated, and vague” and was therefore a “wholly inadequate basis” for establishing material omissions by the defendants). Thus, the Court finds that Plaintiff's Section 10(b) claim is not adequately pleaded.

¹ In a double-blind study, patients and investigators are not told which patients receive placebo and which receive the trial drug, in an attempt to avoid biases that might arise from differential care or treatment. *See Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711(PKC), 2013 WL 2399869, *7 (S.D.N.Y. May 29, 2013) (citing *Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials* (May 2001)).

b. Materially Misleading

Plaintiff's Section 10(b) claim does not sufficiently plead materially misleading statements or omissions. Whether a fact is material and whether a statement omitting the fact is misleading are closely intertwined. *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 903 (N.D. Ill. 2001). The more important a fact would be to investors, the more likely its omission will mislead them. *Hospira*, No. 11 C 8332, 2013 WL 566805, *17 (N.D. Ill. Feb. 13, 2013); *Anderson*, 140 F. Supp. 2d at 903. An omitted fact is material when there is "a substantial likelihood that disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1998); *Searls v. Glasser*, 64 F.3d 1061, 1066 (7th Cir. 1995). In assessing whether a plaintiff has sufficiently pleaded false or misleading statements with the requisite particularity, the Court must not consider allegations in "isolation" but must instead consider the complaint in its entirety. *Tellabs, Inc.*, 551 U.S. at 322-23 (2007); *Hospira*, 2013 WL 566805 at *17. The plaintiff bears the burden of establishing the materiality of the omitted information, and a determination that an omission was immaterial is an "insuperable bar to relief" and warrants dismissal of the complaint. *Plumbers*, 673 F. Supp. 2d at 733-34 (S.D. Ind. 2009).

Importantly, even material omissions are not, in and of themselves, sufficient to state a claim for securities fraud. *Anderson*, 140 F. Supp. 2d at 903. Indeed, federal securities law do not create an affirmative duty to disclose any and all material information; and disclosure is not required simply because it may be relevant or of interest to a reasonable investor. *In re Sanofi*, 87 F. Supp. 3d at 527. Instead, an omission is actionable only when disclosure of information is "necessary in order to make statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b); *Anderson*, 140 F. Supp. 2d at 903 ("[i]f

omitting the fact would make the statement so incomplete as to be misleading, the company must disclose it”); *Stransky v. Cummins Engine Co.*, 51 F.3d 1329, 1331 (7th Cir. 1995) (“[i]f one speaks, he must speak the whole truth”).

Further, Plaintiff must demonstrate that Endocyte had a duty to disclose the omitted information. *See Anderson*, 140 F. Supp. 2d at 903 (“[m]erely mentioning a topic . . . does not require the company to disclose every tangentially related fact that might interest investors, only those that are sufficiently important”). *See also Higginbotham* 495 F.3d at 760 (“[s]ilence is not “fraud” without a duty to disclose”); *Stransky*, 51 F.3d at 1331 (“[m]ere silence about even material information is not fraudulent absent a duty to speak”); *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1202 (1st Cir. 1996) (“[t]he proposition that silence, absent a duty to disclose, cannot be actionably misleading, is a fixture in federal securities law”).

In addition, a plaintiff must establish that a statement or omission was false or misleading “when made”, based on the defendant’s knowledge at the time the statement was made or the omission occurred; and the plaintiff may not establish “fraud by hindsight” by suggesting that a prior statement or omission was false because it “conflicts with the current state of facts”. *Plumbers*, 673 F. Supp. 2d at 740, 744-45 (concluding that defendants did not have a duty to disclose material information that they did not have possession of at the time an allegedly false statement was made).

The theory of Plaintiff’s Section 10(b) claim is that Endocyte continued to promote the Phase 2 study data even after the FDA questioned how efficacy was determined in the study. Plaintiff alleges that Endocyte misled investors by repeatedly touting the Phase 2 results and the “positive opinions” for provisional marketing approval made by the European Medicine Agency’s

CHMP, while withholding knowledge that the Phase 2 study was flawed and the Phase 3 study would not demonstrate Vintafolide's efficacy.

The Court has previously determined that Plaintiff has not sufficiently pled that the FDA questioned the Phase 2 study so severely as to suggest Vintafolide was obviously ineffective, or that the Defendants had knowledge that the Phase 3 study was futile from the start. However, even assuming the FDA's interim criticism of the Phase 2 study design was as severe as the Plaintiff suggests, numerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology.² Indeed, such courts frequently reason that interim FDA feedback is not material because dialogue between the FDA and pharmaceutical companies remain ongoing throughout the licensing process, rendering such criticism subject to change and not binding in regards to ultimate licensing approval.³ Further, even in the absence of FDA interim criticism, several courts have similarly concluded that a defendant pharmaceutical company does not have a duty to reveal potential flaws to study design or data analysis methodology, nor does the defendant have to adhere to the highest research standards, so long as the study's findings and methods are reasonable and are described

² See, e.g., *Sanofi*, 87 F. Supp. 3d 510, 539-42 (S.D.N.Y. 2015) (concluding that the defendant did not have a duty to disclose that a study did not conform to the FDA's preferred methodology and that the FDA required more convincing data of efficacy based on the methodology used, when the defendants disclosed the methodology used to investors); *In re MELA Scis., Inc. Secs. Litig.*, No. 10 CV 8774(VB), 2012 WL 4466604, at *1, 13-14 (S.D.N.Y. Sept. 19, 2012) (concluding that the defendant did not have a duty to disclose FDA criticism regarding study methodology when the defendant did not guarantee FDA approval; and noting that, despite earlier FDA criticism, the FDA ultimately approved the drug); *Fort Worth Emp'rs Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 231 (S.D.N.Y. May 8, 2009) (concluding that the defendant did not have a duty to disclose that a study design did not reflect the FDA's preferences when there was no evidence that the FDA would delay final approval for that reason).

³ The Court recognizes that there are cases where courts have reached the opposite conclusion, requiring disclosure of FDA interim criticism and concerns. Many of these cases offer little in the way of distinguishing facts or reasoning other than to highlight either "extremely negative" criticism by the FDA or a "guarantee" of FDA approval by the defendant pharmaceutical company. See, e.g., *In re Delcath Sys., Inc. Secs. Litig.*, 36 F. Supp. 3d 320, 335-36 (S.D.N.Y. June 27, 2014) (concluding that the defendant had a duty to disclose "extremely negativ[e]" FDA criticism of a study design); *In re Viropharma, Inc. Secs. Litig.*, No. CIV.A. 02-1627, 2003 WL 1824914, * (E.D. Pa. Apr. 7, 2003) (concluding that the defendant had to disclose contrary conclusions regarding efficacy, though the court did not clearly identify which FDA conclusions required disclosure).

accurately.⁴ Two cases are particularly instructive in this regard. *See Sanofi*, 87 F. Supp. 3d 510; and *Abely*, No. 12 Civ. 4711(PKC), 2013 WL 2399869 (S.D.N.Y. May 29, 2013).

In *Sanofi*, the plaintiffs argued that the defendant should have disclosed the FDA’s interim criticisms regarding study design which ultimately, after continued drug testing, contributed to the FDA’s decision not to approve the drug. *Sanofi*, 87 F. Supp. 3d at 519-523, 531-34. In particular, the plaintiffs asserted that the defendant pharmaceutical company did not disclose that the FDA repeatedly criticized the single-blind study design in private meetings with the defendant and the FDA demanded a higher showing of efficacy for final approval as a result of the defendant’s decision not to change the study’s methodology. *Id.* In light of the non-disclosure, the plaintiffs challenged several statements by the defendant that the defendant “expect[ed]” and “anticipat[ed]” FDA approval of the drug while the studies were ongoing as misleading. *Id.* at 531-34, 539.

Nevertheless, the *Sanofi* court held that the defendants did not have a duty to disclose the FDA’s interim feedback to investors. *Id.* at 534, 539, 541 (“[t]he FDA feedback specific to the Lemtrada clinical trials was part of an ongoing conversation with the agency that defendants had no affirmative legal duty to disclose”). The court noted that the FDA never stated that it would refuse to approve the drug based on the defendant’s chosen single-blind design but instead required a higher burden of proof following Phase 3 testing in order to demonstrate efficacy. *Id.* at 533, 545 (“[t]he interim feedback, viewed in real time, was about methodology and process, not about the FDA’s eventual decision”). Further, the court noted that the FDA allowed the study to proceed to Phase 3 testing despite its criticisms regarding the study’s design. *Id.* at 533, 544-45 (“[h]ad the

⁴ *See, e.g., Kleinman v. Elan Corp.*, PLC, 706 F.3d 145, 153-55 (2nd Cir. 2013) (concluding that the defendant did not have a duty to disclose the full methodology for calculating data results so long as the methodology was reasonable, even when the methodology deviated from the original study design and was not the most rigorous available); *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711(PKC), 2013 WL 2399869, *2-3, 6-9 (S.D.N.Y. May 29, 2013) (concluding that a defendant did not have a duty to disclose that its study results disclosed only positive data and withheld negative data, when the defendants generally disclosed the methods for its data analysis).

FDA at any point concluded that there were serious defects in study design that would render the study incapable of producing valid evidence of safety and effectiveness, it had authority to issue a clinical hold . . . to protect human subjects from exposure to flawed and therefore scientifically worthless studies”) (citing 52 Fed. Reg. 8798). In particular, the court noted that Phase 3 testing may be performed only after preliminary evidence suggesting effectiveness of the drug has been obtained and can only be taken after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests. *Id.* at 533-34 (quoting 21 C.F.R. § 312.21(c)).

In addition, the *Sanofi* court held that the statements were not misleading because the plaintiffs had not pleaded any facts to suggest that the defendant did not honestly consider FDA approval to be forthcoming. *Id.* at 531. The court noted that the defendant continued to fund the studies, contradicting any competing inference that the defendant believed the study to be fatally flawed and did not expect FDA approval. *Id.* at 531, 544. The court reasoned that “[t]here is no inconsistency between a pharmaceutical company executive’s concern about adverse events and the possibility of a negative FDA reaction to a proposed drug, and his sincere optimism that the FDA was likely to approve the drug.” *Id.* at 532.

In *Abely*, the plaintiff challenged the design and data analysis of all three phases of a drug study. *Abely*, 2013 WL 2399869 at *2-3, 8-9. The plaintiff asserted that the defendant pharmaceutical company “data-min[ed]” and “cherry-picked” Phase 1 study results for evidence of potential efficacy and disclosed only the positive data, thereby misleading investors into overestimating the efficacy of a tested drug. *Id.* Nevertheless, the *Abely* court concluded that the plaintiff’s criticisms of the study’s methodology did not allege material misstatements or omissions. *Id.* at *15. The court further noted that “[p]ublic statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest

research standards, provided that its findings and methods are described accurately.” *Id.* at *6. Further the plaintiff did not allege that the methodology was inaccurately described to investors but instead argued that the methodology should not have been used. *Id.* at *14-15 (“plaintiff alleges that, at most, the defendants did not engage in best practices in the design and conduct of the Phase 2 study, but such allegations are insufficient to allege material misstatements or omissions.”).

The facts here are nearly identical to those in *Sanofi* and *Abely* and much of the same reasoning applies. Similar to *Sanofi*, the Plaintiff has not pled that the FDA’s questions were so “extremely negative” to suggest that the FDA would not approve Vintafolide because of the Phase 2 study design. Despite questions the FDA may have had regarding the Phase 2 results, the FDA permitted the Vintafolide testing to proceed to the Phase 3 study, suggesting that the FDA’s concerns were not as severe as the Plaintiff asserts. As indicated by the applicable regulations, Phase 3 testing may only be performed “after there have been positive Phase 2 results sufficient to satisfy both business and *regulatory* interests”. 21 C.F.R. § 312.21(c) (emphasis added); *Sanofi*, 87 F. Supp. 3d at 533-34. As the *Sanofi* court noted, if the FDA had serious concerns about the study design, the FDA could have issued a clinical hold to prevent a “scientifically worthless stud[y]”. *Id.* at 533, 544-45; 52 Fed. Reg. 8798. All these facts imply that “[t]he interim feedback, viewed in real time, was about methodology and process, not about the FDA’s eventual decision”. *Id.* at 533, 545. Further, as in *Sanofi*, Endocyte continued to fund the Phase 3 studies for almost three years after the FDA meeting, undermining any inference that Endocyte knew that the Phase 3 study was futile from the start and would never demonstrate Vintafolide’s efficacy. *Id.* at 531-33, 544 (“[t]here is no inconsistency between a pharmaceutical company executive’s concern about adverse events and the possibility of a negative FDA reaction to a proposed drug, and his

sincere optimism that the FDA was likely to approve the drug); *Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 153 (2nd Cir. 2013) (noting that, because Phase 3 trials can only proceed after sufficient Phase 2 results, a defendant's statements regarding drug efficacy are likely honestly believed when made after a drug study advances to Phase 3 testing).

To the extent the Plaintiff alleges that Endocyte had a duty to disclose alleged flaws in the Vintafolide studies regardless of the severity of the FDA's questioning, the Court notes that "[p]ublic statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest research standards, provided that its findings and methods are described accurately." *Abely*, 2013 WL 2399869 at *6. Instead, where a study's methods are reasonable and the defendant has accurately described those methods, even if only minimally, a defendant pharmaceutical company does not have to adhere to the highest research standards, disclose all potentially relevant information or findings, or reveal potential flaws to study design or data analysis methodology. *See, e.g., Kleinman*, 706 F.3d at 153-55 (concluding that the defendant did not have a duty to disclose the full methodology for calculating data results so long as the methodology was reasonable, even when the methodology deviated from the original study design and was not the most rigorous available); *Abely*, 2013 WL 2399869 at *14-15 (noting that allegations that the defendants did not engage in best practices in the design and conduct of a drug study are insufficient to allege material misstatements or omissions); *In re Medimmune, Inc. Secs. Litig.*, 873 F. Supp. 953, 966-67 (D. Md. 1995) (noting that "[m]edical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results" and that a defendant, therefore, does not act with reckless disregard to the validity of study results simply because a regulatory authority expresses preference for a different methodology).

Notably, the Plaintiff did not plead any facts to suggest that Endocyte's disclosures regarding study methodology were "inaccurate". Instead, the complaint states that, on the first day of the class period, Endocyte publically disclosed the differences between the Phase 2 and Phase 3 Vintafolide studies in its 2013 Annual Report. ([Filing No. 107-2 at 15.](#)) Endocyte highlighted that, unlike the Phase 2 study, the Phase 3 study was double-blinded, used different assessment criteria to determine efficacy, and used scans on all enrolled patients. *Id.* Under the facts alleged, Endocyte did not have a duty to disclose anything more. *See also Higginbotham*, 495 F.3d at 759 ("[t]he securities laws do not require firms to disclose information that is already in the public domain").

The closest the Plaintiff comes to challenging the inaccuracy of the disclosed methodology is the allegation that Endocyte did not disclose, until after the Phase 3 study was terminated, that Endocyte used an updated version of the RECIST protocol in the Phase 3 study. However, the Plaintiff provides no facts or explanation to demonstrate how disclosure of this fact would have been viewed by the reasonable investor as having "significantly altered the total mix of information made available." *Basic Inc.*, 485 U.S. at 231-32; *Searls*, 64 F.3d 1061, 1066. The Amended Complaint does not explain the difference between the two RECIST protocols, how the difference impacted the Phase 3 study results, or how such a disclosure would have been relevant to a reasonable investor's decision to purchase Endocyte stock.

Plaintiff has not pleaded that Endocyte made any "guarantees" that the FDA would approve the drug, which might otherwise require additional disclosures. *See Medimmune*, 873 F. Supp. at 964 ("[m]ere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable."). Instead, the opposite is true, as Endocyte provided numerous disclaimers during the class period, in both its 2013 Annual Report and its March 25, 2014 Shelf

Registration statements ([Filing No. 107-2 at 50-53](#), 56) (“The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the EMA, FDA or other regulatory authorities”); ([Filing No. 107-4 at 10](#)) (“Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market”).

In sum, Plaintiff has not pled any facts to distinguish it from the long line of cases wherein interim FDA criticism regarding study design was considered part of an ongoing dialogue and was, therefore, determined to be immaterial to investors. *See, e.g.*, *Medimmune*, 873 F. Supp. at 966 (“[m]ere questioning by the FDA imposed no duty upon [d]efendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers’ questions as they arose. Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process”); *Sanofi*, 87 F. Supp. 3d at 533, 545 (“[t]he interim feedback, viewed in real time, was about methodology and process, not about the FDA’s eventual decision”). Accordingly, the Court finds that Plaintiff has not sufficiently pled any material statements or omissions.

c. Puffery and Opinion Statements

The Plaintiff’s Section 10(b) claim is also problematic because several of the challenged statements are opinions which are not actionable as a matter of law. Courts frequently consider “loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker that no reasonable investor could find them important to the “total mix of information available” to be immaterial as a matter of law. *Silverman v. Motorola, Inc.*, No. 07 C 4507, 2008 WL 4360648, *9 (N.D. Ill. Sept. 23, 2008). Treating such statements as not

actionable reflects the policy that “[p]eople in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; *subject to what current data indicates*, they can be expected to be confident about their stewardship and the prospects of the business that they manage” *Shields v. Citytrust Bancorp. Inc.*, 25 F.3d 1124, 1129-30 (2d Cir. 1994) (emphasis added); *Silverman*, 2008 WL 4360648 at *9. In particular, vague statements about industry leadership, unquantified growth, and expressions of optimism are generally considered “puffery” and are not actionable.⁵

The Second Circuit articulates a compelling test for assessing opinion statements challenged under Section 10(b), treating subjective statements of opinion as actionable only if the “defendant’s opinions were both false and not honestly believed when they were made.” *Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 153 (2nd Cir. 2013). Under this test, plaintiffs are required to allege with particularity provable facts to demonstrate that the statement of opinion was both objectively and subjectively false.” *Id.*

Plaintiff asserts that the Supreme Court’s recent decision, *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015), only requires that a plaintiff plead that the defendant lacked a “reasonable basis” for making the statement of opinion. However, the Court is not persuaded that *Omnicare* somehow lessened the pleading standard for opinion statements, as the term “reasonable basis” is only mentioned in the concurring opinion. *See Id.* at 1334-1335 (Scalia, J., concurring). Instead, the *Omnicare* majority opinion makes clear that a plaintiff challenging an omission in a defendant’s statement of opinion “must identify *particular* (and material) facts going to the basis of the issuer’s opinion-facts about the inquiry the issuer did

⁵ *Searls*, 64 F.3d 1061 at 1066-67 (concluding that “indefinite predictions of growth are better described as puffery rather than as material statements of fact”).

or did not conduct or the knowledge it did or did not have”. *Id.* at 1332 (emphasis added). Nevertheless, giving the Plaintiff the benefit of the doubt, this Court evaluates the challenged opinion statements based on whether Endocyte was “reasonable” and “honestly believed” the statements when made.

Endocyte identifies three opinion statements which Plaintiff alleges as materially misleading. Plaintiff challenges two statements from the 2013 Annual Report: “We believe that vintafolide and PLD is the first combination to show a meaningful improvement in PFS over standard therapy for the treatment of PROC”; and “We believe these findings continue to support the robustness of the PRECEDENT trial results, particularly in the group of FR (100%) patients”. Plaintiff argues that Endocyte did not have a reasonable basis for making these statements, given what Endocyte allegedly knew about the flawed Phase 2 study and the futility of the Phase 3 study when the 2013 Annual Report was released. However, as already discussed, Plaintiff has not adequately pleaded sufficient facts to support either of those allegations, and he cannot demonstrate that Endocyte lacked a reasonable basis for making these statements or did not honestly believe them when the statements were made in the 2013 Annual Report. These opinion statements were therefore not materially misleading.

The third challenged opinion statement was made by Endocyte’s President and CEO, Ron P. Ellis during a conference call two weeks after the 2013 Annual Report was released, which states as follows,

Based on the opinion which was announced today, we expect that the [European Medicines Agency] will grant the conditional marketing authorization for the two products or the products in the 28 countries in the EU probably in two to three months. . . . We are ready to launch. We have, both Merck and Endocyte have their teams in place and have been preparing for the potential arrival.

At first blush, this opinion statement might rightly be considered “puffery” and not actionable as a matter of law. *See, e.g., Silverman*, 2008 WL 4360648 at *9-10 (concluding that statements that a company was “upbeat” and “confident” about its “competitive” and “compelling” new products were so broad as to be immaterial). However, even when substantively evaluated, it is clear that the Plaintiff has not pleaded sufficient facts to suggest that Mr. Ellis lacked a reasonable basis for making the statement or that he did not honestly believe the statement at the time of the conference call. This is due to the fact that the Plaintiff again relies on the insufficiently pleaded theory that Mr. Ellis and Endocyte were withholding knowledge that Vintafolide would never prove efficacious. *Cf. Id.* (noting that statements that a new product was “on track” could be material if the defendants had access to facts suggesting that the opposite was true). The Court finds that this opinion statement is not materially misleading for the same reason as the other opinion statements.

Absent sufficiently detailed and reliable pleadings that Endocyte had knowledge that was contrary to these statements, Endocyte and its officers and directors were “not required to take a gloomy, fearful or defeatist view of the future” but were instead “expected to be confident about their stewardship and the prospects of the business that they manage” within the bounds of the information that they actually had when the statements were made. *Shields*, 25 F.3d at 1129-30 (2d Cir. 1994).

d. Safe Harbor for Forward-Looking Statements

Finally, Plaintiff’s Section 10(b) claim is problematic because at least one of the challenged statements was forward-looking and is not actionable under the PSLRA’s safe harbor provision. The PSLRA provides a safe harbor for class actions based on a forward-looking statement, so long as the statement meets one of the following criteria: (1) the statement is identified as a forward-

looking statement and is accompanied by “meaningful cautionary statements identifying important factors that could cause actual results to differ”; (2) the statement is “immaterial”; or the statement was not made “with actual knowledge” that the statements was false or misleading. 15 U.S.C. § 78u-5(c)(1). Forward-looking statements include statements (1) containing a projection of revenues or other financial items; (2) of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer; (3) of future economic performance; or (4) of the assumptions underlying or relating to the aforementioned statements. 15 U.S.C. § 78u-5(i)(1). “Because [forward-looking statements] are by definition only predictions, not guarantees, the standard is particularly stringent.” *Anderson*, 140 F. Supp. 2d at 904, (noting that such statements are rarely actionable and are “typically considered a safe harbor”).

Endocyte argues that Mr. Ellis’ statement regarding expected conditional marketing authorization from the European Marketing Agency is not only an inactionable opinion but is also subject to the safe harbor provision. Other courts have found similar statements regarding regulatory approval to be forward-looking because they address what a defendant expects to occur in the future, and this Court agrees. *See, e.g., In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015); *Kovtun v. VIVUS, Inc.*, No. C 10-4957 PJH, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012) (“[p]rojections about the likelihood of FDA approval are forward-looking statements”).

The Court finds the statement to be subject to the safe harbor provision because Endocyte included meaningful cautionary language. To be effective, cautionary language “must be substantive and tailored to the specific future projections, estimates or opinions” that are alleged to be misleading. *Harden v. Raffensperger, Hughes & Co.*, 65 F.3d 1292, 1404 (7th Cir. 1995).

“To determine whether cautionary language is meaningful, courts must first identify the allegedly undisclosed risk and then read the allegedly fraudulent materials – including the cautionary language – to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.” *In re Delcath Sys., Inc. Secs. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014). Nevertheless, the PSLRA’s safe harbor provision does not require that the cautionary language list every factor but only the “important factors that could cause actual results to differ materially from those in the forward-looking statement.” *Silverman*, 2008 WL 4360648 at*12; *Harris v. Ivax Corp.*, 182 F.3d 799, 807 (11th Cir. 1999). Further, “failure to include the particular factor that ultimately causes the forward-looking statement not to come true will not mean that the statement is not protected by the safe harbor.” *Id.*

Endocyte provided numerous public disclaimers during the class period in both its 2013 Annual Report and its March 25, 2014 Shelf Registration statements. (*See, e.g.*, [Filing No. 107-2 at 50-53](#), 56) (“The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the EMA, FDA or other regulatory authorities”; “Our efforts to obtain conditional marketing authorization for vintafolide and etarfolatide from the European Medicines Agency may be unsuccessful”); ([Filing No. 107-4 at 10](#)) (listing “whether the European Commission, or EC, will approve our applications for conditional marketing authority for vintafolide” under the heading “risks and uncertainties that could differ materially from anticipated results”.) This cautionary language was substantially tailored to the risks associated with European Marketing Agency marketing approval. *See Sanofi*, 87 F. Supp. 3d at 536 (holding that cautionary language stating that a regulatory authority such as

the FDA could deny or delay approval of a drug “conveyed substantive information about the risk that ultimately materialized” and was therefore “not mere boilerplate”).

In addition, this statement is subject to the safe harbor provision because Plaintiff has not pleaded that Defendants had “actual knowledge” that the statements were false when made. To avoid the safe harbor provision a plaintiff must sufficiently plead that the defendant had “actual knowledge” of falsity and not merely indifference to the danger that a statement is false. 15 U.S.C. § 78u-5(c)(1); *Makor II*, 513 F.3d 702, 705 (7th Cir. 2008); *Anderson*, 140 F. Supp. 2d at 904, 906 (concluding that the plaintiffs had failed to demonstrate that the defendant had no reasonable basis for predicting a continued growth trend).

Dismissal of the Plaintiff’s Section 10(b) claim is appropriate because the allegations are not adequately pleaded, the challenged statements and omissions are not materially misleading, and several of the challenged statements are immaterial opinion statements and subject to the PSLRA’s safe harbor provision. As such, the Court finds that Plaintiff has failed to sufficiently allege a material misstatement or omission.

4. Scienter

Dismissal of the Plaintiff’s Section 10(b) claim is also appropriate because the Plaintiff has not sufficiently pleaded a strong inference of scienter or “guilty state of mind”. The PSLRA requires that the complaint must, “with respect to each act or omission . . . 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) (emphasis added). As applied to securities fraud claims, the “required state of mind” is an “intent to deceive, manipulate, or defraud”. *Higginbotham*, 495 F.3d at 756 (7th Cir. 2007).

A complaint will survive a motion to dismiss only if a reasonable person would deem the inference of scienter “cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Tellabs, Inc.*, 551 U.S. at 324; *Makor II*, 513 F.3d at 705 (7th Cir. 2008) (“[t]he plaintiff must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference”). When making this consideration, the court must take into account “plausible opposing inferences”, including nonculpable explanations for the defendant’s conduct. *Tellabs*, 551 U.S. at 323-24 (“[t]he inference that the defendant acted with scienter need not be irrefutable . . . or even the most plausible of competing inferences. . . . Yet the inference of scienter must be more than merely reasonable or permissible—it must be cogent and compelling, thus strong in light of other explanations”); *Makor II*, 513 F.3d at 705 (“[s]o first the inference must be cogent, and second it must be as cogent as the opposing inference, that is, the inference of lack of scienter”).

To establish the requisite scienter, a plaintiff bears the burden of either alleging facts that provide a strong inference of “motive and opportunity to commit fraud” or alleging strong circumstantial evidence of “conscious misbehavior or recklessness”. *Lawrence E. Jaffe Pension Plan v. Household Int’l, Inc.*, No. 02 C 5893, 2004 WL 574665, *4 (N.D. Ill. Mar. 22, 2004). The Plaintiff alleges scienter based on three theories: that one of Endocyte’s officers engaged in insider trading during the class period; that Endocyte had a motive to raise capital to support its struggling business; and that Endocyte’s officers and directors had knowledge of the futility of the Phase 3 studies based on the FDA interim criticism and their positions of control within the company.

a. Insider Trading

Trading by insiders during the class period, by itself, does not raise an inference of scienter. *Silverman v. Motorola, Inc.*, No. 07 C 4507, 2008 WL 4360648, *13 (N.D. Ill. 2008). Instead, a

sale of stock must be suspicious in scope and timing to support an inference of scienter. *Id.* In general, an unusual pattern of insider stock sales can provide circumstantial evidence of scienter. *City of Austin*, 388 F. Supp. 2d at 950-51. However, the key concept is that the trading was “unusual.” *Id.* at 951 (S.D. Ind. 2005) (“[t]he trading must be unusual, well beyond the normal patterns of trading by those defendants before it will be found probative of scienter”).

For instance, heavy sales by an insider during the class period could be evidence of motive. *Anderson*, 140 F. Supp. 2d at 910. In contrast, retention of significant holdings of stock during the class period weighs against an inference of scienter. *See, e.g., Higginbotham*, 495 F.3d at 759 (finding a lack of scienter when the plaintiffs did not allege that the defendants’ stock sales were “abnormally high” during the class period); *Silverman*, 2008 WL 4360648 at *13 (finding a lack of scienter when the plaintiffs did not demonstrate unusual scope or timing of defendant stock sales during the class period); *Rombach v. Chang*, 355 F.3d 164, 171-72 (2nd Cir. 2004) (noting that the absence of defendant stock sales demonstrated that the defendants “shared the pain” when the stock price fell, thereby negating an inference of scienter).

Here, Plaintiff alleges that “Ritter, sold 8,000 shares of Endocyte common stock, nearly half of his holdings, the same day, earning \$264,880.00.” The Defendants assert that Ritter’s transactions were “non-discretionary sales” made pursuant to a 10b5-1 trading plan; and the Defendants note that no other Endocyte officers or directors are alleged to have sold any stock during the class period. ([Filing No. 110 at 13-14.](#)) Even disregarding the Defendants’ explanation, the Plaintiff has not pleaded sufficient facts to suggest that the stock sale by only one of Endocyte’s officers was “unusual”. Without such additional facts, the Plaintiff cannot establish scienter based solely on the fact that Ritter sold some stock during the class period.

b. Raise Capital

Similarly, the Plaintiff cannot establish a strong inference of scienter based on its allegation that Endocyte had a motive to raise capital for a financially struggling company. A plaintiff cannot establish scienter by alleging motives that are common to most corporate officers, such as the desire for the corporation to appear profitable or the desire to raise stock prices or raise capital. *See, e.g., Rombach v. Chang*, 355 F.3d 164, 177 (2nd Cir. 2004). Similarly, a plaintiff cannot establish scienter based on routine corporate management. *City of Austin*, 388 F. Supp. 2d at 950; *see also Hospira Inc.*, No. 11 C 8332, 2013 WL 566805, *26 (N.D. Ill. Feb. 13, 2013) (“allegations that executives attended [routine] meetings or received reports on a problem do not exclusively support an inference of scienter”); *Schleicher*, 529 F. Supp. 2d at 972 (S.D. Ind. 2007).

Here, the Plaintiff alleges that Endocyte had an outsized need to raise revenue and used the allegedly flawed Phase 2 study and the “positive opinions” made by the European Medicine Agency’s CHMP to secure a collaboration agreement with Merck to raise over \$101.8 million through a stock sale. According to the Plaintiff, these actions suggest that the Endocyte was motivated to hide the alleged flaws in the Phase 2 study from investors. However, the allegation that a corporation and its officers were motivated by the desire to raise capital is precisely the sort of scienter pleading that courts have routinely rejected. *See, e.g., Rombach*, 355 F.3d at 177; *Abely*, 2013 WL 2399869 at *20; *Regeneron*, 2005 WL 225288 at *23.

c. Core Operations

Finally, the Plaintiff cannot establish a strong inference of scienter based on the allegation that Endocyte had knowledge of Phase 3 design futility based on their positions of control and acted in reckless disregard for the truth. Reckless disregard for the truth is sufficient to meet the scienter requirement, but recklessness is still a more demanding standard than even serious or

inexcusable negligence. *City of Austin*, 388 F. Supp. 2d at 948; *Schleicher*, 529 F. Supp. 2d at 968. The Seventh Circuit defines “reckless conduct” in regards to securities fraud as, “an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” *Makor II*, 513 F.3d at 704 (“[w]hen the facts known to a person place him on notice of a risk, he cannot ignore the facts and plead ignorance of the risk”); *In re Sanofi Secs. Litig.*, 87 F. Supp. 3d 510, 529 (S.D.N.Y. 2015) (“plaintiffs can establish recklessness by adequately alleging that defendants knew facts or had access to non-public information contradicting their public statements and therefore knew or should have known they were misrepresenting material facts”).

In this regard, the Plaintiff once again repeats his theory that Endocyte’s officers and directors knew or recklessly turned a blind eye to flaws in the Phase 2 study design. The closer the alleged misstatement or omission is related to a business’ “core operations” or “key products” the more reasonable it may be to infer that senior management was aware of a problem regarding those situations. *See, e.g., Makor II*, 513 F.3d at 709, 711. Nevertheless, the plaintiff must still allege actual knowledge of the problem by the defendant and cannot rely on allegations of “some second-hand belief that such knowledge existed.” *Id.* (concluding that, in the absence of any allegation that a defendant had actual awareness of material information or any allegation that the confidential witness communicated with the defendant, a strong inference of scienter could not be established based on the defendant’s implied knowledge); *Silverman*, 2008 WL 4360648 at *13-14 (concluding that, in the absence of allegations that problems were communicated to the upper level management, a strong inference of scienter could only be established to corporate executives and not to managers that were unconnected to the key product at issue). However, as discussed throughout this opinion, the Plaintiff has insufficiently pleaded that the Phase 2 study was actually

fatally flawed or that the Defendants had advance knowledge that the Phase 3 study was futile from the start and Plaintiff cannot establish scienter for this reason.

Accordingly, dismissal of the Plaintiff's Section 10(b) claim is warranted.

B. Section 20(a) Securities Exchange Act Claim

Plaintiff's Section 20(a) claim depends on the Plaintiff's underlying Section 10(b) claim, which is insufficiently pleaded; accordingly, the Plaintiff's Section 20(a) claim must also be dismissed. Section 20(a) of the Securities Exchange Act provides a basis for holding individuals and businesses liable for acts of securities fraud if they control other individuals or businesses that violate the securities laws. Specifically, the statute states in relevant part,

Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable.

15 U.S.C. § 78t(a). Unlike a Section 10(b) claim, a Section 20(a) claim does not have either a scienter requirement or a heightened pleading requirement. In order to establish a Section 20(a) claim, a plaintiff must allege a primary securities violation and must allege that each of the defendants exercised general control over the corporation's operation or possessed the power or ability to control the specific transaction or activity upon which the primary violation was predicated, whether or not that power was exercised. *Hospira Inc.*, No. 11 C 8332, 2013 WL 566805, *28 (N.D. Ill. Feb. 13, 2013). Courts have found control adequately pleaded when the defendants are senior executives in a company or when the defendants individually signed an SEC filing.

Liability under section 20(a) must be based on an underlying violation of the securities laws or the rules promulgated under them. *City of Austin.*, 388 F. Supp. 2d at 951. Because the

Plaintiff has failed to adequately plead a violation of Section 10(b), the Section 20(a) claim must also be dismissed under Rule 12(b)(6) for failure to state claim upon which relief can be granted.

C. Section 11 Securities Act Claim

The Plaintiff has insufficiently pled either a material statement or omission or in the Registration Statement, therefore, dismissal of the Section 11 claims are also warranted.

1. Pleading Standard

Several circuits have concluded that the heightened pleading standards of Rule 9(b) applies to a Section 11 claim that is premised on fraud, as alleged elsewhere in the complaint. *See, e.g., Rombach v. Chang*, 355 F.3d 164, 171-72 (2nd Cir. 2004) (noting that a Section 11 claim is often premised on the same course of conduct as a simultaneously plead Rule 10b-5 claim; and applying a heightened pleading standard to a Section 11 claim when the plaintiff challenged a registration statement as “misleading”, “untrue”, and “materially false” in the complaint); *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1278-79 (11th Cir. 2006) (“[i]t would strain credulity to claim that Rule 9(b) should not apply in this allegation: The defendant is a no good defrauder, but, even if he is not, the plaintiff can still recover based on the simple untruth of the otherwise fraudulent statement.”). *See also Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1332 (2015) (this should be a short cite) (noting that a plaintiff challenging an omission in a defendant’s statement of opinion “must identify *particular* (and material) facts going to the basis of the issuer’s opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have”) (emphasis added). However, the same courts have found the heightened pleading standards do not apply to claims against underwriter defendants when the claims sound in negligence. *See, e.g., Rombach*, 355 F.3d at 178.

It does not appear that the Seventh Circuit has been presented with the question. However, there is evidence that the Seventh Circuit would apply a heightened pleading standard in similar circumstances. Indeed, the Seventh Circuit has noted that when “[a] claim that sounds in fraud” – in other words, one that is premised upon a course of fraudulent conduct – can implicate Rule 9(b)’s heightened pleading requirements.” *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507-08 (7th Cir. 2007) (this should be a short cite) (concluding that claims of interference with economic and fiduciary relationship and civil conspiracy were subject to Rule 9(b) heightened pleading standards when the plaintiff’s complaint and motion to dismiss brief repeatedly referenced fraud and made clear that a theory of fraud pervaded the entire case). *See also Sears v. Likens*, 912 F.2d 889, 892-93 (7th Cir. 1990) (dismissing a Section 15 Securities Act claim sounding in fraud for failing to meet the heightened pleading standard of Rule 9(b)).

Regardless whether this Court views the Plaintiff’s Section 11 claim through the lens of Fed. R. Civ. P. 8 or 9(b), the Court finds that Plaintiff has not sufficiently pled the requisite material misstatement or omission to survive dismissal.

2. Legal Standard for a Section 11 Securities Act Claim

To establish a violation of Section 11 of the Securities Act of 1933, a plaintiff must prove that a defendant’s registration statement contained an untrue statement of material fact or omitted a material fact required to be stated therein or necessary to make the statements therein not misleading. 15 U.S.C. § 77k(a). “Section 11 thus creates two ways to hold issuers liable for the contents of a registration statement—one focusing on what the statement says and the other on what it leaves out.” *Omnicare, Inc.*, 135 S. Ct. at 1323. The statute sets forth five groups of people who may be liable for the misrepresentation: (1) every person who signed the registration statement; (2) every person who was a director or partner in the issuer at the time of the filing; (3)

every person who is named in the registration statement as being a director or partner; (4) every person who has certified any part of the registration statement; and (5) any underwriter of the security. 15 U.S.C. § 77k(a). Unlike a Section 10(b) claim, there is no state of mind element to a Section 11 claim. *Omnicare, Inc.*, 135 S. Ct. at 1323, 1327; *Wagner*, 464 F.3d at 1277 (noting that liability under Section 11 is “virtually absolute, even for innocent misstatements”).

3. Materially Misleading Statements and Omissions

For the same reasons that the Plaintiff has failed to adequately plead a misstatement or omission to carry his Section 10(b) claim, the Plaintiff has also failed to do so for his Section 11 claim. In an apparent attempt to avoid the heightened pleading standard of Fed. R. Civ. P. 9(b), the Plaintiff has carefully separated his Securities Act claims from his Securities Exchange Act claims in his Amended Complaint. (See [Filing No. 79 at 5-7](#), 17-21, 36-41.) In addition, the Plaintiff also made a brief disclaimer at the beginning of his Securities Act pleadings, “expressly exclud[ing] any allegations of knowledge or scienter, and any allegation that could be construed as alleging fraud or intentional or reckless misconduct. The Securities Act claims are rooted exclusively in theories of strict liability and negligence.” (See [Filing No. 79 at ¶ 29](#).)

Nevertheless, it is clear that the omission that Plaintiff claims was materially omitted from the Registration Statement, is the same omission that the Plaintiff claims was materially omitted from the Defendants’ other disclosures. Specifically, the Plaintiff alleges that Endocyte knew that the Phase 2 study was fatally flawed and the Phase 3 study was futile from the start. Therefore, the “positive opinions” for provisional marketing approval made by the European Medicine Agency’s Committee for Medicinal Products for Human Use were “untrue” because Endocyte knew that the Committee would never actually approve Vintafolide for marketing. The Court has addressed at length, why these allegations are insufficiently pleaded. Even under Rule 8 pleading

standards, the Court's conclusion remains the same. Plaintiff has not plausibly pleaded that Defendants knew the Phase 2 study was fatally flawed or that the Phase 3 study was futile from the start. Accordingly, the Court finds dismissal of the Plaintiff's Section 11 claims to be appropriate.

D. Section 15 Securities Act Claim

Finally, because Plaintiff's Section 15 claim depends on Plaintiff's underlying Section 11 claim, which is insufficiently pleaded, Plaintiff's Section 15 claim must also be dismissed. Section 15 of the Securities Act of 1933 imposes liability on those who "control" persons liable under other provisions of the Act.

Every person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77l of this title, shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person had no knowledge of or reasonable ground to believe in the existence of the facts by reason of which the liability of the controlled person is alleged to exist.

15 U.S.C. § 77o. Because Plaintiff has failed to adequately plead a Section 11 claim, the Section 15 claim must also be dismissed.

E. Leave to Replead

With much consternation, the Court concludes that dismissal of the Plaintiff's claims should be without prejudice. Fed. R. Civ. P. 15 directs that courts should "freely" grant leave to amend a pleading "when justice so requires". Fed. R. Civ. P. 15(a)(2). Nevertheless, courts are instructed to deny leave to amend "[w]here the problems with a claim are substantive rather than the result of an inadequately or inartfully pleaded complaint [and] an opportunity to replead would be futile". *In re Sanofi Secs. Litig.*, 87 F. Supp. 3d at 548-49 (concluding that it would be futile to allow the plaintiffs an opportunity to re-plead their securities fraud claims when the challenged

statements were not false or misleading as a matter of law). It is futile to allow an amended pleading in the absence of showing that such evidence actually exists. *See Schleicher*, 529 F. Supp. 2d at 969 (noting that the heightened pleading standards of the PSLRA are intended to “further increase plaintiffs’ pre-complaint duty to investigate and further discourage claims of so-called fraud by hindsight”).

The Plaintiff’s claims all rely on the same theory and the same vague and uncorroborated testimony of a single confidential witness. Without more factual detail to demonstrate that the Phase 2 study was fatally flawed and that Endocyte had advanced knowledge that the Phase 3 study was futile from the start, none of the Plaintiff’s claims can survive dismissal.

In a foot note, Plaintiff states that if any portion of its Complaint were dismissed, it requests leave to replead pursuant to Fed. R. Civ. P. 15. (Filing No. 41 at 43.) Endocyte notes that this cursory request provides no indication that a second amended complaint would survive another motion to dismiss. However, the Court presumes Plaintiff would not request leave unless he believed otherwise. Therefore, to avoid dismissal with prejudice Plaintiff must demonstrate sufficient facts exist to justify an amended pleading, consistent with this Order. If the Plaintiff does not present such facts within 28 days, dismissal will be changed to with prejudice and final judgment will be entered. If sufficient facts are stated, Plaintiff will be granted leave to file a Second Amended Complaint.

IV. CONCLUSION

For the reasons set forth above, the Court **DISMISSES without prejudice** the Plaintiff’s Amended Complaint ([Filing No. 107](#)). The Plaintiff is allowed up to **Monday, February 1, 2016** to demonstrate sufficient facts exist to justify an amended pleading, consistent with this Order. If the Plaintiff does not present such facts by that time, dismissal will be changed to with prejudice.

SO ORDERED.

Date: January 4, 2016



TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

DISTRIBUTION:

Judy L. Woods
BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP
jwoods@beneschlaw.com

Mario Garcia
BRATTAIN MINNIX GARCIA
mgarcia@brattainminnix.com

Scott D. Gilchrist
COHEN & MALAD LLP
sgilchrist@cohenandmalad.com

Angela M. Liu
DECHERT LLP (Chicago)
angela.liu@dechert.com

Carl E. Volz
DECHERT LLP (Chicago)
carl.volz@dechert.com

David H. Kistenbroker
DECHERT LLP (Chicago)
david.kistenbroker@dechert.com

Joni S. Jacobsen
DECHERT LLP (Chicago)
joni.jacobsen@dechert.com

Christopher G. Scanlon
FAEGRE BAKER DANIELS LLP (Indianapolis)
chris.scanlon@FaegreBD.com

Daniel E. Pulliam
FAEGRE BAKER DANIELS LLP (Indianapolis)
daniel.pulliam@faegrebd.com

Paul A. Wolfla
FAEGRE BAKER DANIELS LLP (Indianapolis)
paul.wolfla@faegrebd.com

Kim E. Miller
KAHN SWICK & FOTI
kim.miller@ksfcounsel.com

Craig J. Geraci, Jr.
KAHN SWICK & FOTI
craig.geraci@ksfcounsel.com

J. Ryan Lopatka
KAHN SWICK & FOTI, LLC
j.lopatka@ksfcounsel.com

Agnes Dunogue
SHEARMAN & STERLING LLP
agnes.dunogue@shearman.com

Adam S. Hakki
SHEARMAN & STERLING, LLP
ahakki@shearman.com

Charles C. Hayes
SWEENEY HAYES LLC
charleshayes.atty@gmail.com