IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

CHAD A. LERNER, *

Plaintiff, *

v. **Case No.: GJH-15-2532**

*

NORTHWEST BIOTHERAPEUTICS, *
***et al.*,**
Defendants. *

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MEMORANDUM OPINION

This is a securities fraud case arising from Defendants' statements regarding the clinical trials of their cancer treatment products, "DCVax®." Lead Plaintiffs Neil Pastel and Franklin Greer ("Plaintiffs") bring this putative class action against Defendants Northwest Biotherapeutics, Inc. ("NW Bio" or "the Company") and CEO Linda F. Powers ("Powers") (collectively, "Defendants"), for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("the Exchange Act"), 15 U.S.C. §§ 78j(b), 78t, and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5. Presently pending before the Court is Defendants' Motion to Dismiss, ECF No. 26. No hearing is necessary. *See* Loc. R. 105.6. For the following reasons, Defendants' Motion to Dismiss is granted.

I. BACKGROUND

Resolving this case on a motion to dismiss, the Court takes Plaintiffs' factual allegations in the Complaint as true.[1] Northwest Biotherapeutics is a developmental-stage biopharmaceutical

[1] The Court also refers to a number of press releases and presentations attached to Defendants' Motion to Dismiss, ECF No. 26, which are referenced in and integral to Plaintiffs' Amended Complaint. *See Philips v. Pitt. Cty. Mem.*

company traded on the NASDAQ under the symbol "NWBO." ECF No. 22 ¶ 2.[2] Since the Company went public in 2001, NW Bio has "focused on developing dendritic cell cancer immunotherapies." *Id.* Dendritic cell immunotherapies work by using human dendritic cells[3] to activate the body's immune response against cancerous tumors. Plaintiffs are two individuals who purchased common stock in NW Bio between January 13, 2014 and August 21, 2015 (the "Class Period"). *Id.* ¶ 1.

A. The Drug Approval Process

Under the Federal Food, Drug, and Cosmetic Act (FDCA), persons or "sponsors" seeking to introduce a new drug[4] into interstate commerce must first obtain approval of an application filed with the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). As part of this approval process, the sponsor of the drug submits evidence and "full reports of investigations" to the FDA. § 355(b)(1). The Commissioner of the Secretary "shall issue an order refusing to approve the application" if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." § 355(d). Under this test, "substantial evidence" is defined as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the

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Hosp., 572 F.3d 176, 180 (4th Cir. 2009) (documents properly considered "so long as they are integral to the complaint and authentic").

[2] The Amended Complaint also contains numerous allegations about Defendant Powers' ties to other corporate entities, including Enron Corporation, the Toucan Group, and Cognate Bioservices. *See* ECF No. 22 at 2–3, 12–16, 33, and 39. Because these allegations are largely irrelevant to the analysis here, the Court does not delve into them with great detail.

[3] A dendritic cell is "[a] special type of immune cell that is found in tissues, such as the skin, and boosts immune responses by showing antigens on its surface to other cells of the immune system. A dendritic cell is a type of phagocyte and a type of antigen-presenting cell (APC)." NCI Dictionary of Cancer Terms, https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=44948 (last visited February 15, 2017).

[4] "Drug" is defined in the FDCA as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals . . ." 21 U.S.C. § 321(g)(1).

effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports . . ." *Id.*

The sponsor, rather than the FDA, is responsible for designing the clinical trials. ECF No. 22 ¶ 24. A sponsor generally conducts clinical trials in three phases. Phase I "includes the initial introduction of an investigational drug into humans" and determines "the metabolism and pharmacologic actions of the drug in humans." 21 C.F.R. § 312.21(a). Phase II involves studies that are "typically well-controlled," to determine the effectiveness of the drug on "patients with the disease or condition under study." § 312.21(b). Phase III includes "expanded controlled and uncontrolled trials" intended to "gather additional information about effectiveness and safety" and "evaluate the overall benefit-risk relationship." § 312.21(c).

B. Summary of Events During the Class Period

NW Bio's principal products are "DCVax®-L," an immunotherapy primarily for operable glioblastoma brain (and to a lesser extent, ovarian) cancer tumors, and "DCVax®-Direct" a newer immunotherapy for a broad array of inoperable tumors. ECF No. 22 ¶ 3. DCVax-L, NW Bio's lead product, began testing in 2005 "as an open label,[5] non-randomized Phase II study without placebo controls." ECF No. 22 ¶ 42. By May 2012, DCVax-L had reached Phase III in clinical trials. *Id.* ¶ 43. On December 13, 2013, NW Bio announced that it had registered 66 "events"[6] with the DCVax-L trial, triggering an interim review by an independent data monitoring committee.[7] *Id.* ¶ 46; ECF No. 26-6 at 4.[8] The data monitoring

[5] An "open label study" is "[a] type of study in which both the health providers and the patients are aware of the drug or treatment being given." NCI Dictionary of Cancer Terms, https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=285990 (last visited February 15, 2017).
[6] "Events" are defined as "either a tumor recurrence or a death." ECF No. 26-6 at 45.
[7] The pleadings appear to use both the acronyms "DSMB," or data safety monitoring board, *see, e.g.*, ECF No. 22 ¶¶ 52, 79; ECF No. 26-1 at 21, 23, and "DMC," or data monitoring committee, *see, e.g.*, ECF No. 22 ¶¶ 56, 78, to describe this independent entity. The Court will use "DSMB" in this Opinion.
[8] Pin cites to documents filed on the Court's electronic filing system (CM/ECF) refer to the page numbers generated by that system.

committee would first review "safety data," and subsequently review "efficacy data," once additional "events" had been registered. *See id.*; ECF No. 26-6 at 45. On March 7, 2014, NW Bio announced that "the Data Safety Monitoring Board (DSMB) has made an unblinded review of the safety data for the Company's ongoing international Phase II GBM trial, and has recommended that the trial continue as planned. The DSMB's review of the efficacy data is still pending." ECF No. 26-6 at 32.

In the second half of 2013, NW Bio also "began a 60-patient Phase I/II clinical trial with DCVax-Direct." *Id.* ¶ 49. The DCVax-Direct trial took place at MD Anderson Cancer Center in Houston, Texas, and Orlando Health in Orlando, Florida. *Id.* On May 15, 2014, NW Bio issued a press release entitled "NW Bio Announces First Data From Ongoing DCVax-Direct Trial." ECF No. 26-7 at 2. This press release described "encouraging results" from a "specific case study" involving "a sarcoma patient with a large tumor mass and multiple inoperable metastatic tumors in the lung." *Id.* The press release reported that this particular patient had received injections of DCVax-Direct, and subsequent MRI scans showed shrinkage of his tumors. NW Bio reported additional positive results about DCVax-Direct on June 11, 2014, stating that "3 case studies show no live tumor cells in injected tumors." ECF No. 26-7 at 13.

In August 2014, NW Bio reported an update on the testing of DCVax-L. NW Bio stated that "55 patients who were not eligible to enroll in the trial due to unusually rapid tumor recurrence were included in a compassionate use 'Information Arm'[9] and are showing encouraging survival times." On March 27, 2015, the Company reported that these Information Arm patients were demonstrating "promising survival data." ECF No. 26-8 at 2. The Company

[9] "For patients who cannot participate in a clinical trial of an investigational drug, but have a serious disease or condition that may benefit from treatment with the drug, FDA regulations enable manufacturers of such drugs to provide those patients access to the drug under certain situations, known as 'expanded access.'" U.S. National Library of Medicine, *What is "Expanded Access?*, https://www.nlm.nih.gov/services/ctexpaccess.html (last visited February 17, 2017).

stated, "[a]s reflected in these data, both Rapid-Progressor Patients and Indeterminate Patients (as well as the Pseudo-Progressor Patient) treated with DCVax-L in the Company's Information Arm are surviving substantially longer than would be expected . . ." *Id.* Also during this time period, NW Bio made several statements about modifications to the primary DCVax-L Phase III trial, including the addition of 36 more patients and increasing the number of events that would be counted in the statistical analysis from 110 to 248, which would strengthen the statistical basis of the trial. ECF No. 26-7 at 18–19.

C. NW Bio's Public Statements

Plaintiffs allege Defendants made false and misleading representations and omissions in thirteen statements about DCVax[10] over the Class Period (January 13, 2014–August 21, 2015) (the "Class Period"). They are, in relevant part, as follows:

1. NW Bio presented a "Corporate Overview" at the Biotech Showcase conference. In the presentation, NW Bio represented that DCVax had a ">80% response rate" and showed "Median PFS [progression free survival] & OS [overall survival] extended by 1-1/2 years or more beyond results with SOC [standard of care]." ECF No. 22 ¶ 50.
2. On March 7, 2014, NW Bio issued a press release titled, "NW Bio Receives Recommendation to Continue With Phase III GBM Brain Cancer Trial Based On Data Safety Monitoring Board's Safety Review," which stated that the Data Safety Monitoring Board had made an "unblinded review of the safety data … and recommended that the trial continue as planned. The DSMB's review of the efficacy data is still pending." *Id.* ¶ 51.

[10] The March 27, 2015 statement, referenced in the Amended Complaint, ECF No. 22 ¶ 82, actually references a press release *and* an investor presentation, bringing the total to fourteen statements. ECF No. 22 ¶ 82. However, for ease of analysis, the Court will address these statements as one, as the Amended Complaint makes no distinction between them. *Id.* Additionally, "statement," as used here, refers to the press release or presentation as a whole, rather than the individual phrases or omissions within each statement, unless otherwise specified.

3. On March 28, 2014, NW Bio issued a press release addressing its Phase III trial for DCVax-L. The press release stated:

> The Company has created a significant cushion or buffer for achieving this p value of 0.05 by designing its trial to a level of 0.02 rather than designing to the exact 0.05 level. Having this cushion makes the Company's trial design more likely for the trial to succeed. . . .The Company has consistently reported throughout the trial that it is designed to the 0.02 level.

Id. ¶ 54.

4. On April 1, 2014, NW Bio filed its 2013 annual report on Form 10-K stating:

> The interim analysis will be conducted by an independent Data Monitoring Committee, or DMC, with assistance from the independent clinical research organization . . . As we also announced the DMC's interim analysis of efficacy data remains outstanding. . . . In clinical trials to date, our DCVax treatments have been achieving what we believe to be striking results.

Id. ¶ 56.

5. On May 15, 2014, NW Bio issued a press release announcing anecdotal data from a patient in the DCVax-Direct Trial. The press release stated:

> Northwest Biotherapeutics … today provided an initial patient case study, showing signs of tumor necrosis (tumor death) and initial tumor regression . . . "We are excited to see signs of DCVax-Direct mobilizing the immune system to fight the tumors in these patients with advanced metastatic cancer, even while we are still so early in this ongoing trial and while patients are only part way through their treatments," commented Linda F. Powers, CEO of NW Bio.

Id. ¶ 59.

6. On May 27, 2014, NW Bio issued a press release claiming a positive initial response in the DCVax-Direct trial. The press release stated:

> Northwest Biotherapeutics … today provided a summary of initial data to date in its ongoing Phase I/II clinical trial of DCVax-Direct for all types of inoperable solid tumors. The Company reported

> that over 50% of the patients who have completed at least half of the 6 treatments in the trial are already showing preliminary signs of cancer cell death, tumor shrinkage and/or stabilization . . . [going on to report various results from the trial].

Id. ¶ 61.

7. On June 11, 2014, NW Bio issued another press release touting preliminary responses to the DCVax-Direct trial. The press release stated:

> [I]n the ongoing Phase I/II clinical trial of DCVax-Direct for all types of inoperable solid tumors, all 9 out of 9 patients who have received 4 of the 6 planned injections are showing tumor cell death, tumor shrinkage, substantial immune cell accumulation in their tumors and/or stabilization . . . "These early glimpses are indicating an increasingly encouraging picture – especially the absence of any live tumor cells in 3 of the patients who have received 4 of the 6 planned injections of DCVax-Direct," commented Linda Powers, CEO of NW Bio.

Id. ¶ 63.

8. On August 11, 2014, NW Bio issued a press release entitled "NW Bio Obtains Approvals for Enhancements of Phase III Trial of DCVax®-L for GBM Brain Cancer" indicating that it was going to add 36 patients to the Phase III DCVax-L trial for a total of 348, and would more than double the events (disease progression or death) that the trial would measure from 110 to 248. The press release stated:

> [NW Bio] announced today that, following a 9-month process of regulatory submissions and reviews by regulators in the US, UK and Germany, it has obtained regulatory approvals to make certain enhancements to its ongoing Phase III clinical trial of DCVax-L Glioblastoma multiforme (GBM) brain cancer. The enhancements will allow the statistical analysis of trial results to take account of a major new variable which has been identified in GBM research . . . By increasing the number of "events" counted, the statistical basis of the trial, which is already quite strong, will be further strengthened.

Id. ¶ 69.

9. Also on August 11, 2014, NW Bio issued a press release announcing an update on the DCVax-L "information arm." The press release stated:

> During 2011 and 2012, in addition to conducting the trial, the Company also treated 55 GBM patients with DCVax-L on a compassionate basis in an "Information Arm" outside of the Phase III trial . . . The 55 patients were not eligible for the Phase III trial because they were either definitely or potentially "rapid progressors": patients with such an aggressive form of GBM that their tumor was already re-growing during the 6 weeks of daily radiation . . . "Rapid progressors" have a much shorter life expectancy, in the range of 7 to 10 months, and generally are not expected to respond much to any treatments. . . . According to initial analyses, the median Overall Survival for all 55 patients is 18 months; the median Overall Survival for the 43 patients is a little over 19 months. The Company is in the process of further analyses of the data on these patients.

Id. ¶ 71.

10. On December 10, 2014, Defendant Powers spoke at the Oppenheimer 25th Annual Health Conference. At the conference, Defendant Powers stated:

> So our DCVax Phase III trial for brain cancer is our lead program. It underwent a major expansion across the U.S. and in Europe. We had a safety-only evaluation . . . by the Data Safety Monitoring Committee. Very importantly, in the latter part of the year we had some regulatory enhancements to the trial, which allow us to add some factors to the statistical analysis at the end of this trial. . .
>
> Also very exciting in September we released information about 55 patients who had not been enrolled in the Phase III trial because they were too sick to meet the eligibility criteria. . . . And that data when we released it, showed that these patients who normally wouldn't be expected to only have survival in the 7 to 10 month range had survival in the 18 -19 months range. So the patients who are even too sick to be in the trial really were getting a major benefit from the treatment. That was a very encouraging set of additional data this year.

Id. ¶ 76.

11. On January 12, 2015, Defendant Powers made a verbal investor presentation at the BioTech Showcase 2015 conference. She stated:

> In terms of efficacy, again, we are still in clinical trials, we have to see how the further trials read out, there's no guarantees, but we've seen up 'til now has been quite encouraging. These are extensions of the time to disease progression, progression free survival, and extensions of overall survival in the realm of years . . .
>
> We will be sometime this year conducting the first interim analysis for efficacy. That will be conducted by the Data Monitoring Committee.
>
> Up to now, the assessments have only been safety, so this will be the first assessment for efficacy. . . . The results [in compassionate use program] were quite striking. . . . those patients typically live seven to ten months. And in our group there, they were at the time, in the 18 month range.

Id. ¶ 78.

12. On March 17, 2015, NW Bio filed its annual report with the SEC for Fiscal Year 2014 on Form 10-K, stating:

> We anticipate that the Phase III trial will reach its first interim analysis for efficacy during 2015.
>
> [The annual report also discussed the "information arm" program, stating]: "In parallel with the Phase III trial of DCVax-L for GBM, we accepted a total of 55 patients into an "Information Arm" outside of the trial, who failed to meet the eligibility requirements for the trial. . . As we have reported, a significant extension of survival compared with expected survival times has been seen to date in these Information Arm patients, including the 19 confirmed rapid progressors.

Id. ¶ 80.

13. Finally, On March 27, 2015, NW Bio issued a press release and published an investor presentation "repeating the [alleged] misrepresentations and omissions regarding the 'information arm'" described in the March 17, 2015 report. *Id.* ¶ 82.

D. Events Prompting Plaintiffs' Discovery

Plaintiffs allege that "the truth" about DCVax was revealed through a number of partial disclosures in online news articles and a clinical hold issued by the FDA on August 21, 2015.

First, on June 19, 2014, *TheStreet.com* published an article by contributor Adam Feuerstein, which reported that "[t]he prestigious MD Anderson Cancer Center issued a stern rebuke to Northwest Biotherapeutics for making promotional, unjustified claims about results from an ongoing clinical trial of an experimental cancer vaccine known as DCVax-Direct." ECF No. 26-8 at 189. The article contained several comments by Dr. Aman Buzdar, the vice president of clinical research at MD Anderson, where the DCVax-Direct trial was being conducted. ECF No. 26-8 at 189. Dr. Buzdar said, "I have read the information that the company has put in the public domain. It is extremely unusual and inappropriate . . . the company is trying to create tremendous hype about its product." *Id.* Dr. Buzdar criticized NW Bio's clinical approach utilizing local injections as weak, stating, "it is a tremendous leap to say that this is a real response." *Id.* Subsequently, "shares of NW Bio common stock dropped to $7.18 on June 29, 2014, a decline of $1.79 from the prior day close of $8.97, on very heavy volume." ECF No. 22 ¶ 66.

Second, on July 7, 2014, *SeekingAlpha.com* published an article by Richard Pearson, "an independent stock analyst and journalist," ECF No. 22 ¶ 67, which claimed that NW Bio hired a social media promotion form which used "fictitious" authors. ECF No. 26-9 at 2. The article stated: "Northwest Bio has been the subject of a massive promotional campaign which has seen the stock price soar. In some cases, authors have used fictitious identities and fake credentials within healthcare or finance. In fact they are simply paid writers." *Id.* The article further explained that "[s]ince mid 2012, Northwest has made use of an IR and 'social media' stock

promotion firm called MDM Worldwide. Shortly after Northwest began paying MDM, the bullish articles began to appear from these fake authors." *Id.* After this article was published, "NW Bio shares fell on heavy volume an additional $0.43, or over 6%, to close at $6.71 per share on July 7, 2014." ECF No. 22 ¶ 68.

Finally, on August 21, 2015, the FDA issued a clinical hold on further trial recruitment for DCVax-L. ECF No. 22 ¶ 85. According to Plaintiffs, "the FDA does not put a clinical hold on investigational studies unless there is a situation that cannot be rapidly remedied." *Id.* ¶ 86. Following the issuance of the hold, NW Bio shares dropped "22% on heavy volume to close at $6.96 per share on August 21, 2015." ECF No. 22 ¶ 87. This lawsuit followed.

E. Procedural History

Plaintiffs filed the instant Complaint on August 26, 2015, alleging violations of Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t, and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5. ECF No. 1. Defendants filed their Motion to Dismiss for Failure to State a Claim on April 12, 2016. ECF No. 26. Plaintiffs filed a Response in Opposition on June 13, 2016. ECF No. 28. Defendants filed a Reply on July 28, 2016. ECF No. 29. The Motion to Dismiss is now ready for review.

II. STANDARD OF REVIEW

Defendants "may test the adequacy of a complaint by way of a motion to dismiss under Rule 12(b)(6)." *Maheu v. Bank of Am., N.A.*, No. 12-CV-508, 2012 WL 1744536, at *4 (D. Md. May 14, 2012) (citing *German v. Fox*, 267 F. App'x 231, 233 (4th Cir. 2008)). To overcome a Rule 12(b)(6) motion, a complaint must allege enough facts to state a plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when "the plaintiff pleads

factual content that allows the Court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

In evaluating the sufficiency of the Plaintiffs' claims, the Court accepts factual allegations in the Complaint as true and construes the factual allegations in the light most favorable to the Plaintiff. *See Albright v. Oliver*, 510 U.S. 266, 268 (1994); *Lambeth v. Bd. of Comm'rs of Davidson Cty.*, 407 F.3d 266, 268 (4th Cir. 2005). However, the Complaint must contain more than "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." *Nemet Chevrolet, Ltd v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009). The court should not grant a motion to dismiss for failure to state a claim for relief unless "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *GE Inv. Private Placement Partners II v. Parker*, 247 F.3d 543, 548 (4th Cir. 2001) (citing *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 249–50).

Several heightened pleading standards apply to this litigation. First, in claims "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) requires "that a plaintiff alleging fraud must make particular allegations of the time, place, speaker, and contents of the allegedly false acts or statements." *Adams v. NVR Homes, Inc.*, 193 F.R.D. 243, 249–50 (D. Md. 2000); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (describing the "who, what, when, where, and how of the fraud claim").

Second, the Private Securities Litigation Reform Act ("PSLRA") imposes "additional pleading requirements on plaintiffs in securities fraud actions." *Shah v. GenVec, Inc.*, No. CIV.A. DKC 12-0341, 2013 WL 5348133, at *9 (D. Md. Sept. 20, 2013). The PSLRA requires

Plaintiffs to "specif[y] the statements alleged to have been misleading and the reasons why they were misleading" and to "support a reasonable belief that the statements were in fact misleading." *Id.* (citing *Teachers' Retirement System of LA v. Hunter*, 477 F.3d 162, 174–75 (4th Cir. 2007). "These heightened pleading standards exist because Congress recognized the potential for abuse in the securities fraud context, including 'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers.'" *Plymouth Cty. Ret. Ass'n v. Primo Water Corp.*, 966 F. Supp. 2d 525, 538 (M.D.N.C. 2013) (citing *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006)). Accordingly, the Court should "be vigilant in preventing meritless securities fraud claims from reaching the discovery phase of litigation." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 623 (4th Cir. 2008).

III. ANALYSIS

The first count of Plaintiffs' Amended Complaint alleges violations of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b–5, 17 C.F.R. § 240.10b–5. ECF No. 22 at 43. Section 10(b) prohibits "any person" from "us[ing] or employ[ing], 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 [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Its implementing regulation, SEC Rule 10b–5, provides:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
> (a) To employ any device, scheme, or artifice to defraud,
> (b) To 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) To 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 state a claim under § 10(b), the complaint must set forth facts showing:

> (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation (that is, the economic loss must be proximately caused by the misrepresentation or omission).

Shah, 2013 WL 5348133, at *10 (citing *Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). Defendants contend that Plaintiffs' Amended Complaint fails to satisfy the first, second, and sixth of these pleading requirements. Upon review of the pleadings, arguments, and relevant case law, the Court finds that Plaintiffs have failed to establish an actionable misrepresentation or omission. Even assuming that Defendants' statements could be considered false or misleading, Plaintiffs have failed to establish a strong inference of scienter as required under the PSLRA.

A. Actionable Misrepresentation or Omission

To establish a misleading statement or omission, the amended complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1).

As an initial matter, the challenged statement or omission must be "'*factual*,' *i.e.*, 'one that is demonstrable as being true or false'; it 'must be *false*, or the omission must render public statements *misleading*;' and 'any statement or omission of fact must be *material*.'" *Shah*, 2013

WL 5348133, at *11 (quoting *Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4th Cir. 1999)) (emphasis in original). "While opinion or puffery will often not be actionable, in particular contexts when it is both factual and material, it may be actionable." *Longman*, 197 F.3d at 683 (4th Cir. 1999); *see also Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1091–96 (1991) (under certain circumstances, opinions demonstrably true or false); *In re PEC Sols., Inc. Sec Litig.*, 418 F.3d 379, 388 n.6 (4th Cir. 2005) (describing PSLRA's "safe harbor" provision for "forward looking statements).

A statement or omission is "material" if there is a "substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact." *Shah*, 2013 WL 5348133, at *12 (citing *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 387 (4th Cir. 2005)). "Ultimately, the inquiry is whether, read as a whole, the statements or omissions would have misled a reasonable investor about the nature of the securities." *Shah*, 2013 WL 5348133, at *12 (citing *Recupito v. Prudential Securities, Inc.*, 112 F. Supp. 2d 449, 455 (D.Md. 2000) (internal citations omitted).

As described above, Plaintiffs point to various press releases and presentations that contained alleged false or misleading statements or omissions. *See* ECF No. 22 ¶ 50 (Jan. 13, 2014 Biotech Showcase presentation), ¶ 51 (Mar. 7, 2014 press release), ¶ 54 (Mar. 28, 2014 press release), ¶ 56 (Apr. 1, 2014 Annual Report on Form 10-K), ¶ 59 (May 15, 2014 press release), ¶ 61 (May 27, 2014 press release), ¶ 63 (June 11, 2014 press release), ¶ 69 (Aug. 11, 2014 press release), ¶ 71 (additional Aug. 11, 2014 press release), ¶ 76 (Dec. 10, 2014 remarks of Ms. Powers at Oppenheimer 25th Annual Health Conference), ¶ 78 (Jan. 12, 2015 investor

presentation by Ms. Powers at BioTech Showcase), ¶ 80 (Mar. 17, 2015 Annual Report on Form 10-K), ¶ 82 (Mar. 27, 2015 press release and Mar. 27, 2015 investor presentation).

The statements can be grouped into five categories for analysis: (i) initial and on-going data from the DCVax-Direct Phase I/II clinical trial, (ii) the design of the DCVax-L Phase III trial, (iii) the Data Safety Monitoring Board ("DSMB") interim analysis of the DCVax-L Phase III trial, (iv) the "information arm" or "compassionate-use" study using DCVax-L, and (v) the efficacy of DCVax products in general.

i. Initial and On-Going Data from DCVax-Direct Phase I/II Clinical Trials

Plaintiffs allege that Defendants' statements made in the May 15, 2014 press release, May 27, 2014 press release, and June 11, 2014 press release regarding the Phase I/II clinical trial of DCVax-Direct were materially false and misleading. ECF No. 22 ¶¶ 59, 61, 63. In particular, Plaintiffs argue that "the results touted by Defendants had not been substantiated by trial investigators" and the "anecdotal patient" had been "cherry-picked." ECF No. 22 ¶ 60. Plaintiffs further claim that "the statements omitted that signs of necrosis or tumor death were just as likely caused by needle trauma as a response to the vaccine," *id.* ¶ 62, and "the statements omitted that the preliminary results actually failed to establish a response as defined by industry-standard RECIST [Response Evaluation Criteria in Solid Tumors] criteria." *Id.* ¶ 64. Plaintiffs also object that "the results were too preliminary and too anecdotal to suggest anything about the actual effects of DCVax-Direct." *Id.* ¶ 62.

However, Plaintiffs fail to adequately plead how the lack of substantiation by "trial investigators" or "fail[ing] to establish a response as defined by industry-standard RECIST criteria" made Defendants' statements untrue or amounted to misleading omissions. Specifically, Plaintiffs' allegations do not explain how these shortcomings are not merely "the difference

between two permissible judgments, but rather the result of a falsehood." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) (citing *In re GlenFed, Inc. Securities Litigation,* 42 F.3d 1541, 1549 (9th Cir. 1994)). Simply alleging that defendants "should have used different statistical methodology" in their clinical trials is not sufficient to allege falsity. *In re Rigel Pharm.*, 697 F.3d at 878. Plaintiffs do not allege that Defendants falsely or inaccurately reported their conclusions; rather they seem to merely disagree with Defendants' methodology for reaching those conclusions. Indeed, "where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. . . The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal." *Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996); *see also In re MedImmune, Inc. Sec. Lit.*, 873 F. Supp. 953, 966 (D. Md. 1995).[11]

Plaintiffs' allegations relating to certain omissions suffer from similar deficiencies. As the Supreme Court has stated, "it bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 44 (2011). "Disclosure of an item of information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Resnik v. Swartz,* 303 F.3d 147, 154 (2d Cir. 2002). Thus, the alleged omission that "signs of tumor necrosis were just as indicative of needle trauma [as indicative of response to treatment]," is not actionable. Defendants were under no duty to disclose every variable that could potentially contribute to the

[11] Moreover, as Defendants point out: "trial investigators—the doctors treating the patients at the medical centers involved in the clinical trial—*never* substantiate trial results, much less preliminary results. The evaluation of trial results is done by the product sponsor, together with statisticians, safety experts, and other independent expert advisors." ECF No. 26-1 at 38 (emphasis in original) (citing ECF No. 26-9 at 101, FDA, Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance 25 (1996) ("The *sponsor* should utilize appropriately qualified individuals to . . . verify the data, to conduct statistical analyses, and to prepare the trial reports.") (emphasis added)).

shrinking of a patient's tumor. "Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44. Additionally, Plaintiffs misconstrue and embellish the statements by Dr. Buzdar in their Opposition. ECF No. 28 at 50; ECF No. 26-8 at 189. Dr. Buzdar did not state that the positive effects of NW Bio's clinical trials were "probably" caused by needle trauma, ECF No. 28 at 50; but rather, he identified it as a possibility, stating that "there have been many studies in which tumors are injected locally -- the injections could consist of anything -- and you see tumor regression because of necrosis caused by inflammation." ECF No. 26-8 at 189. Hence, Plaintiffs' claims of falsity are based on speculation.

Additionally, Plaintiffs' contention that the anecdotal patient had just been "cherry-picked" is conclusory and does not demonstrate falsity. *See Carpenters Pension Trust Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (noting that "plaintiffs asserting claims under Rule 10b–5 must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so."). The May 15, 2014 press-release expressly states it was only describing one sarcoma patient in a specific case study. *See* ECF No. 26-7 at 2 (stating that "[t]he specific case study announced today involves a sarcoma patient with a large tumor mass and multiple inoperable metastatic tumors in the lung" and describing results of injections as "encouraging"). Plaintiffs have not demonstrated how this is misleading. Rather, the "clear import," *In re Rigel*, 697 F.3d at 880, of these statements is that the case study focused on one patient, and results were "encouraging." *See Shah*, 2013 WL 5348133, at *14 (noting that "soft expressions of optimism" are not actionable misrepresentations). Additionally, Plaintiffs' contentions that the "the results were too preliminary and too anecdotal to suggest anything about the actual effects of DCVax-Direct" are belied by the statements themselves. The press

releases unequivocally state that "the trial is still at an early stage, with many of the patients only part way through the treatment regimen." ECF No. 26-7 at 2.

Plaintiffs' claims regarding the initial and on-going data from the DCVax-Direct Phase I/II Clinical Trials are not actionable and therefore will be dismissed.

ii. Design of DCVax-L Phase III Trial

Plaintiffs next claim that Defendants' statements made in the March 28, 2014 press release and August 11, 2014 press release regarding the design of the DCVax-L Phase III trial were materially false or misleading. ECF No. 22 ¶¶ 54, 69. Plaintiffs first object to Defendants' measurement of statistical significance:

> Although a p-value of 0.05 in each of two trials is considered to be the standard measure of statistical significance when a sponsor substantiates efficacy with two well-controlled clinical trials, as is the typical course, the FDA does not consider a p-value of 0.05 to be the de facto measure of statistical significance where, as here, a sponsor intends to seek approval on the basis of only a single Phase III clinical trial.

ECF No. 22 ¶ 55. Plaintiffs also allege that "the change in trial size was not an 'enhancement,' but rather an attempt to move the goalposts in light of a lack of promising evidence from the trial as specified." ECF No. 22 ¶ 70.

Again, Plaintiffs fail to move their Complaint from mere disagreement to actionable misrepresentation or omission. The fact that "the FDA does not consider a p-value of 0.05 to be the de facto measure of statistical significance," ECF No. 22 ¶ 55, does not render Defendants' representations false or misleading. *See DeMarco v. DepoTech Corp.*, 149 F.Supp.2d 1212, 1225 (S.D. Cal. 2001) ("Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim."); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 568 n.15 (E.D. Pa. 2009) (finding no "false or

misleading" statement where plaintiffs' statistician identified what he believed were problems with a defendant's statistical analysis of a clinical trial, and plaintiffs merely alleged a disagreement about "how to conduct and analyze a study").

With respect to the use of the word "enhancement" to the trial size, "Section 10–b is not concerned with such subtle disagreements over adjectives and semantics." *See In re Merrill Lynch Auction Rate Sec. Litig.*, 704 F. Supp. 2d 378, 392 (S.D.N.Y. 2010) ("semantic distinction [between 'routinely' and 'systematically'] is not persuasive"); *In re Xinhua Fin. Media, Ltd. Sec. Litig.*, No. 07 Civ. 3994(LTS)(AJP), 2009 WL 464934, at *8 (S.D.N.Y. Feb. 25, 2009) ("soft adjectives are nothing more than puffery"). Moreover, Plaintiffs do not sufficiently explain how "tak[ing] account of a major new variable" and "increasing the total number of patients from 312 to 348" cannot truthfully be described as "enhancements," rather than Plaintiffs' preferred description of "attempt to move the goalposts."

Thus, claims related to the design of the DCVax-L Phase III Trial are dismissed.

iii. Interim Analysis of DCVax-L Phase III Trial by DSMB

Plaintiffs next allege that Defendants' statements made in the March 7, 2014 press release, April 1, 2014 annual report on Form 10-K, and December 10, 2014 Oppenheimer 25th Annual Health Conference regarding the interim analysis by the DSMB were materially false or misleading. ECF No. 22 ¶¶ 54, 56, 76. Plaintiffs allege that "the review of efficacy data by the DSMB was not pending and would easily have been completed" and Defendants "omitted that the Company did not need a formal interim analysis to make a ballpark assessment of efficacy." ¶ 52. Plaintiffs further state that "the assertion that the analysis remained 'outstanding' falsely implied that it was in the process of being completed, when in fact it was either completed and buried, or the DSMB had been directed not to complete it." *Id.* ¶ 57. Plaintiffs also claim, with

respect to the January 12, 2015 remarks, that "the interim review was not scheduled to commence in 2015 but in fact had commenced in 2013 and required only a few weeks to complete." *Id.* ¶ 79.

It first bears noting that Plaintiffs cite to a December 13, 2013 press release which explicitly states, "The Company does not participate in the interim analysis process or the assessment, and both the Company and the clinical trial sites remain completely blinded." ECF No. 26-6 at 5. Thus, it is unclear from the Complaint how Plaintiffs attribute the alleged shortcomings of the safety board review to Defendants given their stated lack of involvement. But more importantly, Plaintiffs rely on the unfounded "expert" opinion of Dr. Richard A. Guarino for their contention that "there is absolutely no reason why an interim analysis could not be completed within a few weeks." ECF No. 22 ¶ 47. Plaintiffs may not substitute factual allegations with the speculation of their expert witness. *See Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285–86 (5th Cir. 2006) ("allowing plaintiffs to rely on an expert's opinion in order to state securities claims requires a court to 'confront a myriad of complex evidentiary issues not generally capable of resolution at the pleading stage.' In addition, considering such opinions might require ruling on the expert's qualifications."); *DeMarco v. DepoTech Corp.*, 149 F.Supp.2d 1212, 1222 (S.D. Cal. 2001) ("Conclusory allegations and speculation carry no additional weight merely because a plaintiff placed them within the affidavit of a retained expert.").

The gravamen of Plaintiffs' objections regarding the interim review by DSMB appears to be that it took too long, or that Defendants somehow delayed announcing conclusive results, or concealed the results altogether. But "Defendants, like any other company wishing to publicly discuss the results of a scientific study, had to make a judgment as to which specific bits of

information about the study and its conclusions to disclose." *Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996); *see also In re Human Genome Scis. Inc. Sec. Litig.*, 933 F. Supp. 2d 751, 761 (D. Md. 2013) (noting that "[w]hile it is possible to infer that . . . executives deliberately omitted facts . . . in order to hoodwink investors, it is just as plausible, indeed more so, to infer that they only offered vague details about the study because it was ongoing."). Plaintiffs here do not "plead facts sufficient to explain why the defendants' summaries [or lack thereof] of the study were false or misleading." *In re Rigel*, 697 F.3d at 979. Plaintiffs' additional argument that Defendants were trying to "bury" interim efficacy results is undercut by the record itself. A review of the record in its entirety leaves as the only reasonable inference that the data monitoring committee had reviewed only *safety* data from the Phase III trials, not *efficacy* data. ECF No. 22 at 34 ("We had a safety-only evaluation . . . by the Data Safety Monitoring Committee"); 35 ("Up to now, the assessments have only been safety, so this will be the first assessment for efficacy"). Plaintiffs do not establish how Defendants deliberately withheld or concealed information with respect to the interim review.

Accordingly, Plaintiffs' claims related to the Interim Analysis of the DCVax-L Phase III Trial by the DSMB are dismissed.

iv. Compassionate Use or Information Arm Study

Plaintiffs further challenge Defendants' statements made in the August 11, 2014 press release, March 17, 2015 annual report on Form 10-K, March 27, 2015 press release, and March 27, 2015 investor presentation regarding the "information arm" or "compassionate use" program. ECF No. 22 ¶¶ 71, 80, 82. Plaintiffs argue that Defendants "omitted mention that the results were significantly biased by the uncontrolled nature of the 'information arm' trial design," and "the reported results were further inflated by improper classifications that excluded certain 'rapid

progressors.'" *Id.* ¶¶ 72, 81. Plaintiffs also object to Defendant Powers' statements about the compassionate use program made at the December 10, 2014 Oppenheimer Conference, including her remarks: "That was a very encouraging set of additional data." ECF No. 22 at 34.

Plaintiffs' opinion that Defendants should have disclosed all the ways in which the results may have been biased does not establish a securities violation. *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009) ("While it may be desirable to eliminate biases to the maximum extent possible . . . [m]edical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols.") (internal citations omitted). Moreover, a compassionate use trial, by definition, is the use of a medical product outside of a clinical trial.[12] The press releases and presentations concerning the compassionate use or information arm study made quite clear that these subjects were a special group of patients "too sick to meet the eligibility criteria." ECF No. 22 at 34. Plaintiffs have not sufficiently articulated how Defendants statements about this program constitute an actionable misrepresentation or omission.

Plaintiffs' contention that "NW Bio excluded from that tabulation five patients who died within ten weeks of surgery" again amounts only to their disagreement with the design of the study and relies on the conjectures of Plaintiffs' expert, Dr. Guarino. ECF No. 22 at 33. Furthermore, Defendants were not obligated to take a pessimistic view with regard to the results, so long as they were reported accurately. *See also Kleinman v. Elan Corp.*, 706 F.3d 145, 153 (2d Cir. 2013) ("We have also held that words like 'encouraging' are the type of "expressions of

[12] "Expanded access, sometimes called 'compassionate use,' is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by FDA). FDA is committed to increasing awareness of and knowledge about its expanded access programs and the procedures for obtaining access to human investigational drugs (including biologics) and medical devices." *Expanded Access (Compassionate Use)*, FDA, http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm (last visited February 14, 2017).

puffery and corporate optimism" that do not generally "give rise to securities violations.") (citing *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)); *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011) (noting that subjective statements can be actionable only if the "defendant's opinions were both false and not honestly believed when they were made.").

Thus, Plaintiffs' claims involving the Compassionate Use or Information Arm Study will also be dismissed.

v. Efficacy of DCVax Products

Finally, Plaintiffs object to Defendants' statements made at the January 13, 2014 BioTech Showcase and, to a lesser extent, the January 12, 2015 BioTech Showcase regarding the efficacy of DCVax products in general. ECF No. 22 ¶¶ 50, 78. Plaintiffs claim that "neither DCVax-L nor DCVax-Direct had demonstrated an 80+% response rate in any well-designed clinical trial," and "neither DCVax-L nor DCVax-Direct had demonstrated a 1-1/2 year extension in median overall survival or progression free survival over standard of care in any well-designed clinical trial." ECF No. 22 ¶ 50. Plaintiffs further state that "NW Bio had no evidence from well-controlled trials showing any 'extensions of the time to disease progression, progression free survival, and extensions of overall survival in the realm of years." *Id.* ¶ 79.

These claims are either flawed or suffer from a lack of clarity. If, for example, Plaintiffs are alleging that NW Bio falsely reported a greater-than-80% response rate for DCVax, Plaintiffs may have stated a claim. However, in their Opposition, Plaintiffs merely explain that "these representations were misleading not because of what they affirmatively stated, but because of the adverse interim Phase III results they omitted." ECF No. 28 at 40. Plaintiffs fail to show how this is an actionable omission, as they do not adequately plead facts demonstrating that an interim *efficacy* analysis took place or what such analysis revealed. Indeed, the only reasonable inference

with respect to these allegations, as stated, is that Plaintiffs disagreed with Defendants' methodology, interpretation of the data, or expressions of optimism. In that regard, they fail to allege how these statements are false or misleading. *See Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996) (holding that "[t]he fact that plaintiffs disagree with the . . . researchers and with defendants about the import of the . . . data does not make defendants' summaries of the study false or misleading."); *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 631 (S.D.N.Y. 2008) (noting that "'corporate officials need not present an overly gloomy or cautious picture' so long as 'public statements are consistent with reasonably available data.'"); *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007) (stating that allegations in securities fraud claims "that are conclusory or unsupported by factual assertions are insufficient.").

Plaintiffs additionally object to the following statement from Defendant CEO Powers: "In terms of efficacy, again, we are still in clinical trials, we have to see how the further trials read out, there [are] no guarantees, but [what] we've seen up 'til now has been quite encouraging." ECF No. 22 ¶ 78. This is quite unlike the defendant's statement in *In re Medimmune, Inc.*, cited by Defendants, ECF No. 26-1 at 27, in which the company Vice President stated: "There's absolutely no question about efficacy," in regards to defendant's drug Respivir. There, the Court held:

> It is one thing to declare enthusiasm "about the results from this study and the implications for preventing this serious illness," . . . [or] that a high dose of Respivir "significantly reduced the severity of RSV and significantly reduced the frequency of RSV related hospitalizations." It is quite another thing to make a statement that falls into the second category of arguably false or misleading statements, *i.e.* that Respivir was unquestionably efficacious.

In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 967 (D. Md. 1995). Here, Defendants did not represent that DCVax was "unquestionably efficacious," nor do Plaintiffs allege that the reported results in the presentation were false.

Therefore, the Court cannot find that Plaintiffs have stated a claim with respect to the efficacy of DCVax Products.

B. Scienter

Even assuming that the Court were to consider some of Defendants' statements false or misleading, Plaintiffs have failed to establish scienter, which provides an independent grounds for dismissal. The PSLRA's heightened pleading standard requires Plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007). The "strong inference" standard of the PSLRA "unequivocally raised the bar for pleading scienter." *Id.* (internal citations omitted). The Supreme Court and Fourth Circuit have made clear "that an inference of scienter can only be strong—and compelling, and powerful—when it is weighed against the opposing inferences that may be drawn from the facts in their entirety." *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 624 (4th Cir. 2008) (citing *Tellabs, Inc.*, 551 at 324).

Thus, a complaint will survive "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* In resolving this inquiry, "[a] court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 885 (4th Cir. 2014) (citing *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). Hence,

"when the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed." *Cozzarelli*, 549 F.3d at 624 (4th Cir. 2008). Additionally, "if the defendant is a corporation, the plaintiff must allege facts that support a strong inference of scienter with respect to at least one authorized agent of the corporation, since corporate liability derives from the actions of its agents." *Proter v. Medifast, Inc.*, No. CIV.A. GLR-11-720, 2013 WL 1316034, at *9 (D. Md. Mar. 28, 2013) (citing *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 184 (4th Cir. 2007)). Plaintiffs have not met that heavy pleading burden here.

Plaintiffs' allegations of scienter have three permutations. First, they argue that Defendants had "actual knowledge" of the alleged misleading statements and omissions "by virtue of [Powers'] position at NW Bio" and because "Powers unquestionably had full knowledge of the details of NW Bio's internal affairs." ECF No. 22 ¶¶ 108, 109. Second, Plaintiffs make the additional argument in their Opposition that Defendants "recklessly ignored" the "material adverse information held from investors." ECF No. 28 at 41–44. Third, Plaintiffs contend that "[m]isleading stock promotion played a central role in this scheme [to defraud]" because Defendants had a "unique financial motive" to sell NW Bio shares in order "to confer windfalls upon [Powers'] private companies." ECF No. 22 at 12; *see also* ECF No. 28 at 44.

Plaintiffs' first argument fails because a defendant's position of control in a company, without more, is insufficient to establish scienter. Courts have routinely held that corporate executives' access to information and internal affairs is not enough to demonstrate scienter under the PSLRA. *See In re Criimi Mae, Inc. Sec. Litig.*, 94 F. Supp. 2d 652, 661 (D. Md. 2000) (finding no scienter of executives based on their positions of control and summarizing cases); *In re Peritus Software Servs., Inc. Securities Litig.*, 52 F. Supp. 2d 211, 228 (D. Mass. 1999)

(holding that allegations that defendants held executive and managerial positions and had access to non-public information were insufficient to establish scienter). Rather, Plaintiffs must show "additional detailed allegations establishing the defendants' actual exposure" to the subject of the fraud. *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 890 (4th Cir. 2014). Here, Plaintiffs do not sufficiently allege how Defendant Powers, as CEO and Principal Financial Officer, had knowledge that representations made about the clinical trials were "false" or "misleading."

Plaintiffs' second argument does not fare better. Plaintiffs contend that Defendants "recklessly ignored" the "truth" about DCVax-L and DC-Vax-Direct. ECF No. 28 at 41–44. The Fourth Circuit makes clear that "[r]eckless conduct sufficient to establish a strong inference of scienter" must be "severe," *Ottmann v. Hanger Orthopedic Grp., Inc.*, 353 F.3d 338, 344 (4th Cir. 2003), or "so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 181 (4th Cir. 2009). To bolster this argument, Plaintiffs rely on the opinion of Dr. Buzdar, who claimed NW Bio's press releases were "extremely unusual and inappropriate," ECF No. 26-8 at 189; and Plaintiffs further claim that "Defendants received by early 2014 information from an interim efficacy analysis but to this day have refused to disclose this 'incoming trial data' to investors." ECF No. 28 at 43. Neither Dr. Buzdar's unsubstantiated conjectures in an online posting, nor Plaintiffs' unsupported assertion, demonstrates that Defendants engaged in "an extreme departure from the standard of ordinary care." *Cf. Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 149 (3d Cir. 2004) (dismissing securities fraud claim where plaintiffs had not alleged how

confidential sources "obtained the information they allegedly possessed," or whether "their supposed knowledge was first or second hand.").

Plaintiffs' reliance on *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 609 (4th Cir. 2015) is unpersuasive. In that case, also a drug-development securities fraud action, the Fourth Circuit found that plaintiffs had established scienter. In so finding, the court pointed to several concerning representations made by defendants, including their mischaracterization of "the risk of submitting the new drug application supported only by a single, one-week study providing scant evidence of durability of effect." *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 609–10 (4th Cir. 2015). The court also noted that the FDA had issued "a recommendation against approval [of the drug]," but Defendants had not disclosed this to investors. *Id.* Additionally:

> According to the plaintiffs' allegations, although the defendants knew that the FDA expected two successful efficacy studies demonstrating durability of effect to support regulatory approval of Northera, none of the defendants' statements to investors addressed this critical expectation. After the defendants met with FDA officials in December 2010 to discuss submission of the new drug application based only on Study 301, the defendants instead informed investors that the FDA had "agreed" that Chelsea could submit its new drug application for Northera "without the need for any further efficacy studies."

Id. The case *sub judice* is distinguishable. Unlike in *Zak*, Plaintiffs here do not allege that Defendants concealed an adverse recommendation from the FDA. They do not claim that Defendants mischaracterized a risk, constituting extreme departure from the standard of ordinary care. They do not allege that Defendants manufactured a "blessing" or "approval" by the FDA. *See In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 809 (C.D. Cal. 2011) (finding scienter where defendant biopharmaceutical company had claimed FDA "blessed" their study design). Plaintiffs' allegations here simply do not establish a strong inference of scienter as required by

the PSLRA. *See In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012) ("in cases where we have found the pleading standard satisfied, the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or were at least warned by others that this was so"); *In re Human Genome Scis. Inc. Sec. Litig.*, 933 F. Supp. 2d 751, 761 (D. Md. 2013) (finding no scienter, stating "[b]ecause the above statements are all factually accurate, albeit with a positive spin, scienter would have to be inferred from the company's omission of more specific details about the study . . .")

Finally, Plaintiffs unsuccessfully attempt to raise a "strong inference of scienter" based upon Defendants' "unique financial motive to inflate NW Bio's stock price." Specifically, they allege that "NW Bio operated as a fiefdom for the personal benefit of Powers," and "[b]ecause the lavish benefits that NW Bio conferred upon Cognate, Powers, and her Toucan Group of companies far exceeded the Company's assets, NW Bio had to repeatedly tap the public markets." ECF No. 28 at 45. Even if that were true, it does not follow that "defendant acted with the required state of mind" to defraud investors. *Tellabs, Inc.*, 551 U.S. at 321 (2007). "A strong inference of fraud does not arise merely from seeking capital to support a risky venture. Indeed, the motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud." *Cozzarelli*, 549 F.3d at 627 (4th Cir. 2008). That Defendants may have wished to raise capital for other business ventures does not, on its own, establish fraudulent intent. *See Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 891 (4th Cir. 2014) (noting that "[w]e decline, however, to infer fraud from financial motivations common to every company.").

To conclude, it bears noting that:

> All investments carry risk, particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the PSLRA.

Cozzarelli, 549 F.3d at 627 (4th Cir. 2008). That is all the alleged conduct amounts to here. Plaintiffs have not demonstrated how Defendants were reckless, much less deliberately misleading, and thus they fail to establish the required scienter.

C. Section 20(a) Claim

Plaintiffs' second claim in the Amended Complaint alleges a violation against Defendant Powers as a "controlling person" under Section 20(a) of the Exchange Act. ECF No. 22 at 45–46. Section 20(a) provides:

> 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 . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). A "claim for controlling person liability under section 20(a) must be based upon a primary violation of the securities laws." *Svezzese v. Duratek, Inc.*, 67 F. App'x 169, 174 (4th Cir. 2003). Thus, because Plaintiffs' claim under Section 10(b) is dismissed, their claim under Section 20(a) is dismissed as well. *See id.*; *Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 628 (4th Cir. 2008) (dismissing Section 20(a) claims as derivative of other claims).

D. Leave to Amend

As a final matter, Plaintiffs have requested leave to amend their complaint if Defendants' motion to dismiss were to be granted. ECF No. 28 at 55. Under Federal Rule of Civil Procedure

15(a)(2), courts should grant leave to amend a pleading "freely . . . when justice so requires." Fed. R. Civ. P. 15(a)(2). "Leave to amend should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or amendment would be futile." *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009). "An amendment is futile when the proposed amendment is clearly insufficient or frivolous on its face, or if the amended claim would still fail to survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6)." *El–Amin v. Blom*, Civ. No. CCB–11–3424, 2012 WL 2604213, at *11 (D. Md. July 5, 2012). Here, Plaintiffs do not explain how a second amended complaint would reconcile the infirmities of the first amended complaint, nor is the existing record lacking in volume. However, the Court finds no evidence that amendment would be prejudicial to Defendants, or any indication of bad faith on the part of Plaintiffs — and will therefore grant Defendants' Motion to Dismiss without prejudice.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is granted. A separate Order shall issue.

Date: March 31, 2017

GEORGE J. HAZEL
United States District Judge