NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WILLIAM T. HOEY, *on behalf of Himself and all those similarly-situated*, Plaintiff, v. INSMED INCORPORATED, WILLIAM H. LEWIS, and ANDREW T. DRECHSLER, Defendants.	Civ. Action No. 16-4323 (FLW) **OPINION**

WOLFSON, District Judge:

Lead Plaintiff Bucks County Employees Retirement Fund ("Plaintiff") brings this putative class action, on behalf of itself and all other similarly situated individuals and entities, against Insmed Incorporated ("Insmed"), a biopharmaceutical company, as well as Insmed's Chief Executive and Financial Officers, William H. Lewis ("Mr. Lewis") and Andrew T. Drechsler ("Mr. Drechsler"), respectively, alleging violations under various provisions of the applicable federal securities laws.[1] Plaintiff's action is based on Defendants'

[1] Additional named defendants in this action are Donald Hayden, Jr., Insmed's Chairman of the Board of Directors, Insmed's Directors: Alfred F. Altomari; Steinar J. Engelsen, M.D.; David W. J. McGirr; Melvin Sharoky, M.D.; and Randall W. Whitcomb, M.D. Mr. Lewis, Mr. Drechsler, and the aforementioned executives are hereinafter collectively referred to as the "Individual Securities Act Defendants." Mr. Lewis and Mr. Drechsler, who are named in Plaintiff's § 10(b) claims, are hereinafter referred to separately as the "Individual Defendants." Finally, Insmed and the individual defendants are hereinafter collectively referred to as "Defendants."

alleged misrepresentations and omissions in connection with Insmed's target drug, Arikayce, and the results of its Phase 2 Trial, which, ultimately, failed to support regulatory approval. In the instant matter, Defendants moves for dismissal of the Amended Complaint, arguing, *inter alia*, that the challenged representations are not actionable because a duty to disclose was absent, the material statements constitute permissible opinions or corporate puffery, and Plaintiff has failed to adequately plead scienter. For the reasons set forth below, Defendant's Motion to Dismiss is **GRANTED**. In lieu of dismissal, however, Plaintiff is given leave to file a Second Amended Complaint within 30 days from the date of Order accompanying this Opinion.

BACKGROUND

a. Insmed and Arikayce

The following allegations are taken from the Amended Complaint ("AC") and are assumed true for the purposes of review under Rule 12(b)(6). Insmed, a publically traded biopharmaceutical company, principally located in Bridgewater, New Jersey, specializes in the development and commercialization of inhaled therapies for patients with serious lung diseases. AC ¶¶ 17, 31. According to Plaintiff, Insmed is not profitable, as it has not developed a product for commercialization, but the company seeks regulatory approval of Arikayce, its primary drug candidate. AC ¶¶ 32, 37. Arikayce, currently a drug pending approval, is intended to treat nontuberculous mycobacterial lung disease ("NTM"), a rare, and sometimes fatal, infection, for which there is currently no approved treatment. AC ¶ 32. Arikayce is administered through a nebulizer and,

according to Insmed, Arikayce delivers amikacin, an antibiotic, directly to the lung, which may decrease toxicity to hearing, balance, and kidney function. AC ¶¶ 35-35.

b. Overview of Clinical Trials

Before a drug is marketable, regulatory agencies typically require biopharmaceutical companies, such as Insmed, to administer three separate clinical trials, wherein the drug is tested on groups of patients with the target disease. AC ¶ 39. Generally, the trials are conducted in three sequential phases, *i.e.,* Phase 1, Phase 2, and Phase 3. AC ¶ 39.

In a Phase 1 Trial, the drug is introduced to a small group of patients, and the study is designed to assess how "the drug is metabolized, the drug's safety profile, and the safe dosage range." AC ¶ 40. A Phase 2 Trial, on the other hand, involves a medium-sized group of patients, *i.e.,* 30-300, and "identif[ies] possible adverse effects and safety risks, . . . preliminarily evaluate[s] the efficacy of the drug, and . . . assess[es] dosage tolerance and optimal dosage . . . ." AC ¶ 40. Lastly, in a Phase 3 Trial, a substantial amount of patients participate, *i.e.,* 300 to 2000, and the trial typically runs for a prolonged period of time, such that the overall benefit-risk relationship of the drug can be established, adequate information for the labeling of the drug is provided, and, most importantly, the drug can be evaluated by a regulatory agency for potential approval. AC ¶ 40.

As further set forth *infra*, after discussions with the European Medicines Agency ("EMA"), Insmed submitted an application for Arikayce's regulatory approval, based solely on the results of the Phase 2 Trial data.

c. The European Process for Regulatory Approval

Europe's centralized procedure for regulatory approval permits a biopharmaceutical company to market an approved drug in all European Union ("EU") member states. AC ¶ 42. The approval process initiates with a "letter of intent" to submit a Marketing Authorization Application ("MAA"), generally no sooner than seven months before the MAA is submitted. AC ¶ 42. Upon receipt, the MAA is evaluated by the EMA's Committee for Medicinal Products for Human Use ("CHMP"), which ultimately determines whether the drug's "quality, safety, and efficacy" are adequately proven. AC. ¶ 43. Two "co-rapporteurs," representing two EU member states, are also appointed by the CHMP to lead the approval process. AC ¶ 43.

Generally, the CHMP issues a final opinion concerning the MMA within 210 days, excluding periods wherein the applicant is required to respond to the CHMP's questions by providing additional information. AC ¶ 44. On the 120th day of the application process, after the CHMP reviews preliminary assessment reports and opinions provided by the co-rapporteurs, it submits a list of questions and an overall conclusion to the applicant (the "Day 120 Questions"). AC ¶ 44. The applicant is expected to respond to the Day 120 Questions within three months; if required, however, the applicant is permitted to request an extension of an additional three months. AC ¶ 44.

Thereafter, the co-rapporteurs assess the responses to the Day 120 Questions, and, in turn, revise the preliminary assessment reports accordingly, before a list is prepared that incorporates any issues that remain. AC ¶ 45. The

revised assessment reports, including a list of outstanding issues, as well as the CHMP's recommendation, are submitted to the applicant by the 180th day of the application process, and the applicant is allotted one month to respond. AC ¶ 45. Subsequently, the applicant's replies are assessed by the co-rapporteurs, and a final report is prepared, at which point the CHMP issues a favorable or unfavorable opinion as to whether to grant the MAA. AC ¶ 45.

d. Insmed's Phase 2 Trial

On October 15, 2013, Insmed initiated a Phase 2 Trial, which was not intended to support regulatory approval for Arikayce. The study was designed as a "randomized, double-blind, placebo-controlled clinical trial," wherein a daily dosage of Arikayce was compared to a placebo in 90 adult patients with "treatment-resistant NTM lung disease." AC ¶ 46. It was also comprised of two phases: the mandatory "initial phase," which lasted 84 days, and the optional "open-label" phase, under which patients could elect to participate in, and receive, Arikayce for an additional 84 days. AC ¶ 47. The success of the Phase II Trial was measured by two metrics: (i) a "primary endpoint," defined as a statistically significant change in mycobacterial density from day 1 to day 84 of the study; and (ii) a "secondary endpoint," defined as a culture conversion, *i.e.*, a culture testing negative for mycobacteria on the last day of the initial phase. AC ¶ 48.

On March 26, 2014, Insmed revealed the results of the Phase 2 Trial. AC ¶ 49. Although the applicable data did not satisfy the primary endpoint of the study, the results were, nevertheless, statistically significant; Insmed announced

that the secondary endpoint of culture conversion was achieved: "11 out of 44 patients treated with Arikayce . . . demonstrat[ed] negative cultures by day 84," as compared to 3 of the 45 patients who received a placebo. AC ¶ 49. The FDA and EMA responded favorably to the data. On June 17, 2014, based on the results of the Phase 2 Trial, the FDA granted Arikayce with "Breakthrough Therapy Designation." [2] Additionally, following discussions with the EMA, Insmed determined that the Phase 2 trial data, alone, was sufficient to support regulatory approval from that agency. Declaration of Jonathon A. Rotenberg (dated Dec. 15, 2016) ("Rotenberg Dec."), ¶ 2, Ex. L at 209, N at 226.[3]

On August 4, 2014, in response to this feedback, Insmed indicated that it would take the following actions: (i) conduct a Phase 3 Trial; and (ii) file an MAA in Europe seeking regulatory approval for Arikayce. AC ¶ 51. On December, 14, 2014, the MAA was ultimately submitted to the EMA. AC ¶ 51.

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[2] Breakthrough Therapy Designation "is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). *See* https://www.fda.gov.forparients/approvals/fast/ucm405397.htm. (last visited August 31, 2017).

[3] Generally, when ruling on a motion to dismiss, a district court may consider matters of public record, such as filings with the Securities Exchange Commission ("SEC"). *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Thus, because Exhibits L and N of the Rotenburg Declaration are comprised of publicly filed documents with the SEC, including Insmed's Form 10-Q and Form 8-K, respectively, the Court may consider them in deciding this motion.

e. The Secondary Offering

On May 30, 2014, Insmed filed a Registration Statement with the SEC, in order to initiate a Secondary Public Offering ("SPO"),[4] the net proceeds of which were, *inter alia*, intended to fund Insmed's "efforts to obtain regulatory approvals and commercialize Arikayce . . . ."[5] AC ¶¶ 82, 83; Rotenberg Dec., ¶ 2, Ex. X. The Registration Statement was filed on a Form S-3, and offered to sell common stock in the Company on a delayed basis. AC ¶ 82. That is, the SPO was structured as a "shelf registration," in that Insmed registered securities for sale and left them on the "shelf," until it decided to conduct an offering, at a later point in time. AC ¶ 82. The Registration Statement, in relevant part, included the following description of the results of the Phase 2 Trial:

> Arikayce achieved statistical significance with regard to th[e] secondary endpoint [of the Phase 2 Trial], with 11 out of 44 patients treated with Arikayce . . . demonstrating clearance of the infecting mycobacterial organism (culture negative) at day 84 of the study as compared to 3 out of 45 patients treated with placebo . . . .
> The[] results collected from the open label phase show that 21 [out of 68 participating] patients were culture negative for NTM at Day 168. This data reflects 10 patients who were culture negative at Day 84 as well as 5 additional patients from the Arikayce arm and 6 additional patients who were initially on placebo and switched to Arikayce during the open-label phase.

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[4] An Initial Public Offering ("IPO") occurs when a corporation first offers its shares for sale on the market in order to "raise capital for future growth." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 307 n.25 (D.N.J. 2007). Likewise, an SPO, which is generally conducted for the same purpose, occurs when a corporation offers additional shares for sale to the public after its IPO. *Id.*

[5] On May 30, 2014, Insmed also filed a Prospectus on Form 424B, and on March 31, 2015, it filed an additional Prospectus Supplement. These two documents were incorporated into the Registration Statement.

AC ¶ 89. Moreover, the Registration Statement incorporated Insmed's annual report on Form 10-K, for the year ending December 31, 2014. The Form 10-K, in pertinent part, included a description of the purported safety and efficacy of Arikayce, and additionally provided information in connection with Insmed's facilities, wherein the drug Arikayce was manufactured:

> We believe that Arikayce may provide: (i) improved efficacy resulting from sustained deposition of drug in the lung and improved ability to reach the site of infection (. . . for NTM, this means enhanced uptake into macrophages, targeting NTM within these cells); [and] (ii) decreased adverse events and improved tolerability as compared with amikacin delivered intravenously . . . .
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> All sites of manufacture of Arikayce use the technology developed and optimized by us. We and all our manufacturing partners must comply with applicable regulations relating to the current good manufacturing practices (cGMP) regulations of regulatory agencies. . . . . We believe that all facilities will meet cGMP requirements for the sterile manufacturing of finished ARIKAYCE product.

AC ¶¶ 91, 93. On March 30, 2015, Insmed issued a press release announcing the proposed SPO of 10 million shares of common stock at $20.65 per share. AC ¶¶ 84-85. On April 6, 2015, in another press release, Insmed revealed that 11.5 million shares of the Company had been sold at the aforementioned price, thereby accounting for over $223 million in net proceeds.[6] AC ¶ 86.

f. The Day 120 Questions

In the summer of 2015, Insmed received the Day 120 Questions. AC ¶ 7. Among other things, the EMA's Day 120 Questions included "Major Objections"

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[6] Plaintiff also points to various statements made by Defendants in press releases and on investor conference calls. To avoid repetition, to the extent Plaintiff's claims are based on those statements, the Court will detail them in the analysis below.

outlining certain issues in connection with the design and execution of the Phase 2 Trial, in addition to Arikayce's safety and efficacy. AC ¶ 7; Rotenberg Dec., ¶ 2, Ex. J. Specifically, the EMA noted its concern with the short duration of the study:

> There was no justification for a comparison with placebo over only 84 days . . . . There are no safety data . . . beyond 168 consecutive days and only 59 patients achieved this duration of exposure . . . . [I]t is not appropriate to ignore the fact that the applicant is promulgating continued use way beyond that supported by the safety database.

AC ¶ 54-55; Rotenberg Dec., ¶ 2, Ex. J. The EMA also included the following list of concerns with respect to the design and execution of the Phase 2 Trial: (a) the administration of Arikayce on a daily basis, as opposed to, for example, administrating Arikayce on a cyclical basis, for NTM patients was unsubstantiated; (b) the handling of contaminated samples was not accounted for; (c) various discrepancies, with respect to the number of patients who participated in the trial, were not explained; (d) sputum measurements were incorrectly reported; and (e) various external factors, some of which the EMA could not explain, likely led to false culture conversions. Moreover, with respect to Arikayce's safety, the EMA questioned whether "treatment-emergent adverse events were much more common with Arikayce" than with a placebo, AC ¶ 75, because Arikayce is "an irritant within the airways." AC ¶ 76. Finally, with respect to Arikayce's efficacy, the EMA questioned the advantages of delivering amikacin directly to the site of the NTM infection, as opposed to inhaling amikacin itself. AC. ¶ 77.

In response to the EMA's comments, Insmed amended the MAA's "proposed indication," which originally included all NTM patients, to the subset of patients who reacted most favorably to Arikayce in the Phase 2 Trial, *i.e.*, adult NTM patients with mycobacteria avium complex ("MAC"). AC ¶ 61. Insmed also conducted a *post hoc* analysis, wherein a more stringent standard of culture conversion, defined as "negative [sputum] cultures at three consecutive points in time," was applied to 47 MAC-positive patients who participated in the Phase 2 Trial. AC ¶ 63.

Despite these efforts and MMA revisions, the EMA advised Insmed that the results of the Phase 2 Trial did not support approval of Arikayce. AC ¶ 63. Insmed, in turn, withdrew its MAA on June 8, 2016, and announced that it would resubmit an application for approval after a Phase 3 Trial for Arikayce was completed. AC ¶ 176. Insmed's stock price, in response, dropped from $12.01, the closing price on June 8, 2016, to $11.02, the closing price on June 9, 2016, which totaled a loss of 8.24%. AC ¶ 193.[7] On October 14, 2016, a Withdrawal Assessment Report ("WAR") was issued, wherein the EMA included a final list of concerns and deficiencies, pertaining to the Phase 2 Trial, which ultimately supported its decision to deny approval of Arikayce. AC ¶ 11; Rotenberg Dec., ¶ 2, Ex. J.

[7] By August 15, 2016, Insmed's stock price recovered, closing at a price of $12.54 per share.

g. The Putative Class Action

On July 15, 2016, Plaintiff initiated this putative class action against Insmed for the period between March 26, 2014 and June 8, 2016, as a result of Insmed's allegedly misleading and false representations of Arikayce, the Phase 2 Trial, and Insmed's interactions with the EMA. On December 15, 2016, Plaintiff filed an Amended Complaint, asserting violations under the Securities Exchange Act of 1934 (the "Exchange Act") and the Securities Act of 1933 (the "Securities Act"). Specifically, Plaintiff's Amended Complaint consists of five Counts: (i) §§ 11 and 12(a)(2) of the Securities Act, against all named defendants (Counts I and II); (2) § 15 of the Securities Act, against Individual Securities Act Defendants as controlling persons of Insmed, to the extent that liability under §§ 11 and 12(a)(2) exist (Count III); (3) § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, against Insmed, Lewis and Drechsler (Count IV); and (4) § 20(a) of the Exchange Act, against Individual Defendants as controlling persons of Insmed under § 10(b) (Count V). *See* AC ¶¶ 99-209.

Defendants now move to dismiss the Amended Complaint, arguing that Plaintiffs have failed to state a claim under the applicable securities laws because: (a) a duty to disclose the information in dispute does not exist; (b) Insmed released the information in dispute through numerous disclosers; (c) the challenged statements are protected by the safe harbor provision of the Private Securities Litigation Reform Act of 1995 ("PSLRA") or amount to inactionable

corporate puffery; and (d) Plaintiff has failed to allege a strong inference of scienter. The motion is opposed by Plaintiff.[8]

DISCUSSION

I. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), a complaint may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quotations omitted). Under such a standard, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Indeed, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[A] complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

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[8] In the instant matter, Plaintiff requests leave to file a proposed *Sur-Reply*, or, in the alternative, a motion to strike multiple arguments and exhibits incorporated in Defendant's Reply, on the basis that Insmed allegedly mischaracterizes the record and inappropriately references corporate documents not relied upon in the Amended Complaint. Because Plaintiff's *Sur-Reply* is being considered by the Court to the resolve this motion, Plaintiff's request to strike is denied.

However, Rule 12(b)(6) only requires a "short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. The complaint must include "enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips*, 515 F.3d at 234 (citation and quotations omitted); *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. The pleading standard is not akin to a probability requirement; to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citation and quotations omitted)).

In sum, under the current pleading regime, when a court considers a dismissal motion, three sequential steps must be taken: first, "it must take note of the elements the plaintiff must plead to state a claim." *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quotations omitted). Next, the court "should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* (quotations omitted). Lastly, "when there are well-pleaded factual allegations, the court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* (quotations and brackets omitted).

"Independent of the standard applicable to Rule 12(b)(6) motions," Fed. R. Civ. P. 9(b) "imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud." *In re Rockefeller Ctr. Props. Secs. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002); *see also* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). To satisfy this heightened pleading standard, a plaintiff must state the circumstances of his alleged cause of action with "sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir. 2004)). Specifically, the plaintiff must plead or allege the "date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico*, 507 F.3d at 200 (citing *Lum*, 361 F.3d at 224). Indeed, the Third Circuit has advised that, at a minimum, Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006) (quoting *In re Rockefeller*, 311 F.3d at 216).

In addition to Rule 9(b)'s heightened pleading requirements, Congress enacted the PSLRA, 15 U.S.C § 78u, *et seq.*, to require an even higher pleading standard for plaintiffs bringing private securities fraud actions. *In re Suprema,*

438 F.3d at 276. This heightened pleading standard is targeted at preventing abusive securities litigation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) ("Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law."); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006) (identifying "ways in which the class-action device was being used to injure the entire U.S. economy" and listing examples such as "nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests, and manipulation by class action lawyers of the clients whom they purportedly represent . . .") (quotes and citations omitted).

The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). First, under 15 U.S.C. § 78u-4(b)(1), the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007) (construing 15 U.S.C. § 78u-4(b)(1)). Second, the complaint must, "with respect to each act or omission alleged to violate this chapter, 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).

Both provisions of the PSLRA require facts to be pled with "particularity." *Avaya*, 564 F.3d at 253. This particularity language "echoes precisely Fed. R.

Civ. P. 9(b)." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999); *see* Fed. R. Civ. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake."). Indeed, although the PSLRA replaces Rule 9(b) as the pleading standard governing private securities class actions, the rule's particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u-4(b)(1) of] the PSLRA." *Avaya*, 564 F.3d at 253 (citations omitted). This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *In re Advanta*, 180 F.3d at 534 (quotations marks omitted).

II. Statements Regarding Arikayce's Efficacy

a. Claims under Section 10(b) of the Exchange Act

The private right of action under Section 10(b) and Rule 10b-5 "creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market." *Burlington*, 114 F.3d at 1417. In relevant part, Rule 10b-5 makes it unlawful for an individual "[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 . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5(b). To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, the plaintiff must allege: "(1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation." *Gold*

v. Ford Motor Co., 577 F. App'x 120, 122 (3d Cir. 2014) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)).

Here, Defendants argue, among other things, that Plaintiff fails to state a claim for securities fraud because: (a) Plaintiff has not adequately alleged the requisite elements of falsity or scienter; and (b) the challenged statements are forward looking or constitute permissible expressions of opinion and corporate puffery. Under Section 10(b) and Rule 10b-5, a misrepresentation or omission of fact is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision, and there is a "substantial likelihood that the 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 (1988) (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 440, 449 (1976)); *see also Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000). Importantly, to be actionable, a statement or omission must have been materially misleading at the time it was made; liability cannot be imposed on the basis of subsequent events. *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002).

Additionally, because materiality is a mixed question of law and fact, "[o]nly if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Shapiro v. UJB Financial Corp.*, 964 F.2d 272, 280 n. 11 (3d Cir. 1992) (citation omitted). The Third Circuit has warned

that the task of determining materiality can be especially difficult when the statement at issue contains "soft" information, *i.e.*, statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward looking statements, such as projections, estimates, and forecasts. *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 642 (3d Cir. 1989).

However, regardless of whether a piece of information is material, Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Indeed, "[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014) (quoting *Basic*, 485 U.S. at 239 n. 17). Rather, "[d]isclosure 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 (quoting 17 C.F.R. § 240.10b-5(b)); *see also City of Edinburgh*, 754 F.3d at 174; *Burlington*, 114 F.3d at 1432 (3d Cir. 1997) ("[P]ossession of material nonpublic information alone does not create a duty to disclose it.").

Additionally, according to the Supreme Court's decision in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, when the alleged misleading statement at issue is an opinion or a belief, whether that statement is 'misleading' "depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective." 135 S. Ct. 1318, 1327 (2015). Although *Omnicare* examined claims under Section 11 of the Securities Act of 1933, these principles are "not unique to §11." *Id.* at 1330. Rather, "[t]hey inhere,

too, in much common law respecting the tort of misrepresentation," *id.*, and are therefore arguably applicable to claims under Section 10(b) as well. *See In re Merck & Co.*, No. 05-1151, 2015 U.S. Dist. LEXIS 62983, at *65 n. 7 (D.N.J. May 13, 2015) (finding *Omnicare*'s analysis of misleading opinions, instructive, to some extent, on the viability of claims regarding misleading opinions under Section 10(b)).

As the Supreme Court observed:

> The Restatement of Torts, for example, recognizes that '[a] statement of opinion as to facts not disclosed and not otherwise known to the recipient may' in some circumstances reasonably 'be interpreted by him as an implied statement' that the speaker 'knows facts sufficient to justify him in forming' the opinion, or that he at least knows no facts 'incompatible with [the] opinion.' When that is so, the Restatement explains, liability may result from omission of facts—for example, the fact that the speaker failed to conduct any investigation—that rebut the recipient's predictable inference.

Omnicare, 135 S. Ct. at 1330 (quoting Restatement (Second) of Torts § 539 at 85, Comment a at 86, Comment b at 87 (1976) (citations omitted)). These principles are consistent with the Third Circuit's admonition that when evaluating Section 10(b) claims, courts must examine allegedly misleading statements in context, to determine whether they were indeed misleading. *See City of Edinburgh*, 754 F.3d at 167. Furthermore, the Third Circuit has deemed determinative that "[o]pinions are only actionable under securities laws[, including Section 10(b),] if they are not honestly believed and lack a reasonable basis." *Id.* at 170.

Similarly, under the PSLRA, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge

that the statement was false or misleading." *In re Aetna Sec. Litig.*, 617 F.3d 272, 278-79 (3d Cir. 2010). The PSLRA's definition of "forward-looking statement" includes*, inter alia*, "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." *Id.* at 279 (citing 15 U.S.C. § 78u-5(i)(1)). This safe harbor for forward-looking statements overlaps with the Third Circuit's "bespeaks caution" doctrine, adopted in *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357 (3d Cir. 1993). Under this doctrine, "cautionary language, if sufficient, renders the alleged [forward-looking] omissions or misrepresentations immaterial as a matter of law." *Id.* at 371. Under both the PSLRA and the bespeaks caution doctrine, cautionary language must be extensive, specific, and directly related to the alleged misrepresentation to provide a safe harbor. *See In re Aetna*, 617 F.3d at 282; *Id.* at 371-72.

In addition, like forward-looking statements, opinions, and beliefs, a defendant may not be held liable for an alleged misrepresentation that consists of nothing more than vague and nonspecific expressions of corporate optimism. *In re Advanta*, 180 F.3d at 538. Such statements "constitute no more than 'puffery' and are understood by reasonable investors as such." *Id.* (quoting *Burlington*, 114 F.3d at 1428 n. 14). Thus, if a false or misleading statement is "too vague to ascertain anything on which a reasonable investor might rely," it is inactionable as corporate puffery. *In re Aetna*, 617 F.3d at 284.

Here, Defendants argue that Plaintiffs have failed to adequately allege that Defendants' statements are materially false or misleading. Plaintiffs, on the other

hand, contend that Defendants misled investors by making statements concerning (a) the Phase 2 Trial's rate of conversion; (b) Insmed's reaction to the Day 120 Questions; (c) the safety, efficacy, and durability of Arikayce; (d) the nature of Insmed's interactions with the EMA; and (e) Arikayce's prospects of approval. The Court will assess each set of allegedly false and misleading statements, in turn.

i. Statements Concerning the Phase 2 Trial's Conversion Rate

First, Plaintiff contends that the following statement, concerning the Phase 2 Trial's rate of conversion, is false and misleading: "Arikayce did achieve statistical significance with regard to the clinically relevant key secondary endpoint of culture conversion, *with 11 out of 44 patients treated with Arikayce* . . . demonstrating negative cultures by day 84 of the study as compared to 3 out of 45 patients treated with placebo . . . ." Plaintiff's Opposition to Defendant's Motion to Dismiss ("Pl.'s Opp'n"), at 11; AC ¶¶ 126-128. Plaintiff reasons that this statement is actionable, because Insmed "fail[ed] to disclose the misleading assumptions upon which [the aforementioned] figures were based." Pl.'s Opp'n, at 1, 11. For example, Plaintiff submits that "that the [study's rate of conversion] included five patients who tested negative for NTM at the start of trial," and "Insmed had defined culture conversion as a negative test for NTM at a single point in time," a definition more lenient than the one promulgated in the American Thoracic Society/Infectious Disease Society of America Guidelines. Pl.'s Opp'n, at 11-12. The Court, however, is not persuaded by Plaintiff, because

Insmed was not obligated to disclose this information, which relates to the study's design and structure.

Numerous courts around the country have found that a study's alleged flaws or shortcomings need not be disclosed to a reasonable investor, on the basis that such information is not material. For this reason, "courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review." *Sanofi Secs. Litig. v. Meeker*, 87 F. Supp. 3d 510, 541 (S.D.N.Y. 2015); *see, e.g.*, *In re MELA Sciences, Inc. Secs. Litig.*, No. 10-8774, 2012 U.S. Dist. LEXIS 144150, at *13-14 (S.D.N.Y. Sept. 19, 2012); *Fort Worth Employers' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 231 (S.D.N.Y. 2009); *Johnson v. Pozen Inc.*, No. 07-599, 2009 U.S. Dist. LEXIS 12765, at *19 (M.D.N.C. Feb. 19, 2009); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-1030, 2005 U.S. Dist. LEXIS 24452, at *7 (D. Colo. Oct. 20, 2005); *In re Alkermes Sec. Litig.*, No. 03-12091, 2005 U.S. Dist. LEXIS 25826, at *16 (D. Mass. Oct. 6, 2005); *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 37 (D. Mass. 1997).

The district court's decision in *Padnes. v. Scios Nova Inc* is instructive. No. 95-1693, 1996 U.S. Dist. LEXIS 22858 (N.D. Cal. Sept. 18, 1996). The court rejected an argument by plaintiffs in that case, identical to that raised here. More specifically, the plaintiffs claimed that a summary of a clinical study for approval was materially misleading by omission, because the defendants allegedly failed to disclose the study's serious "design defects." *Id.* at *14. The plaintiffs maintained that the study's flaws required disclosure, which, among other

things, included the metric utilized for determining its outcome. *Id.* at *14-15. The district court, however, was not persuaded, and ultimately held that "where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study," regardless of whether the study is "imperfect." *Id.* at *16. In other words, the company was not obligated to "include exhaustive disclosures of procedures used," in discussing the results of the study, because the "securities laws do not impose a requirement that companies report only information from optimal studies . . . . " *Id.*

In the instant matter, the allegations concerning Defendants' alleged omissions, as pled in the Amended Complaint, do not state a legally valid claim, because they amount to an attack on the methodology of the Phase 2 Trial. To be clear, Plaintiff does not argue that Insmed inaccurately reported the results of the study after it concluded. Nor does Plaintiff contend that Insmed adjusted the study's underlying design or methodology, after the raw data was unblinded, in order to conceal or manipulate its results in favor of demonstrating Arikayce's efficacy. Rather, Plaintiff, in the Amended Complaint, alleges that the reported rate of conversion transforms into a statement that is materially false and misleading when accounting for the flawed methodology under which it was determined. *See* AC ¶ 129 (stating that Insmed's statements pertaining to the study are actionable because they failed to disclose that the "Phase 2 NTM Trial was deeply flawed . . . ."). Indeed, Plaintiff essentially argues that the reported rate of conversion was artificially inflated, because the study included

individuals who tested negative for NTM on the first day of trial. That is, if a different metric were utilized—one, for example, which excluded negative day 1 cultures—Plaintiff concludes that Insmed could have accurately calculated the study's real rate of conversion: "Although Insmed reported that patients receiving Arikayce during the Phase 2 NTM trial had shown a culture conversion rate of approximately 30%, the true rate of culture conversion was just 8.5%." AC ¶ 6. Thus, Plaintiff's allegations attempt to establish the falsity of Insmed's statements with regard to the results of the Phase 2 Trial, by attacking its underlying methodology. However, as noted above, courts throughout the country have consistently rejected this approach; Insmed's alleged omissions with regard to the design and structure of the Phase 2 Trial, therefore, fail to serve as a basis for a legally valid claim under the Exchange Act. *See In re Rigel Pharms., Inc. Secs. Litig.*, *Inter-Local Pension Fund GCC/IBT v. Deleage*, 697 F.3d 869, 878 (9th Cir. 2012) (finding that "statements concerning statistical results of a clinical trial may [not] be considered false or misleading under Rule 10b-5 because [of] the statistical methodology that produced those results . . . ."); *In re Mela*, 2012 U.S. Dist. LEXIS 144150, at *5, 39 (rejecting that the theory that "defendants made material omissions regarding [a] clinical trial by failing to reveal the trial's several flaws and deviations" which allegedly allowed for the "false enhancement of the reported accuracy rate of" the medical device in dispute); *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 567 (E.D. Pa. May 8, 2009) ("Plaintiffs' allegations regarding Defendants' statements [about the Phase 3 Trial] amount to disagreements over the proper methodology and conduct of

clinical studies. These allegations are not sufficient to establish falsity for purposes of a Rule 10b-5 claim."); *Padnes*, 1996 U.S. Dist. LEXIS 22858, at *17 ("The fact that plaintiffs disagree with the . . . defendants about the import of the [data in dispute] does not make defendants' summaries of the study false or misleading.").[9]

ii. Statements Concerning Insmed's Reaction to the Day 120 Questions

Next, Plaintiff alleges that the Phase 2 Trial's definition of culture conversion, *i.e.*, a single negative culture on treatment, was deemed insufficient for the purpose of proving Arikayce's efficacy. Pl.'s Opp'n, at 12-13. Plaintiff contends that, in the Day 120 Questions, the EMA allegedly required an application of a sustained definition of culture conversion, one under which a patient's sputum sample is tested after treatment had elapsed for three months. *Id.* at 12. Because the EMA expressly identified a standard for culture conversion which Insmed allegedly never applied, Plaintiff maintains that each of the following statements, made by Defendants in August 2015 in a press release and investor calls, are materially false and misleading: (a) "I would say that we feel we are well prepared to respond [to the Day 120 Questions], as there were no surprises with respect to the topics that the Agency asked us to address"; and (b) [t]o date, we have not unearthed anything that is of material concern to us

[9] Likewise, in the Amended Complaint, Plaintiff highlights other deficiencies in connection with the trial's design and execution in order to undermine its results and to establish the falsity of Defendants' statements concerning the results of Phase 2 Trial. AC ¶¶ 52-81. The Court, however, finds that these statements do not require disclosure, as further discussed *infra*.

about the . . . clinical impact of Arikayce." *Id.* However, Plaintiff has failed to adequately allege the falsity of these statements by complying with the heightened pleading standard of Rule 9(b).

As a threshold issue, the Court notes that Plaintiff does not support the allegations of fraud by citing to the Day 120 Questions, but rather, it solely relies upon various portions of the WAR—which the EMA issued after the class period. Moreover, the WAR and Day 120 Questions are provided to an applicant at different junctures of the application process, and they each serve different functions. For instance, the Day 120 Questions are submitted during the application process, and, in that connection, they do not provide a decision as to the approvability of a target drug; to the contrary, these particular questions constitute one part of an ongoing discussion between the applicant and the EMA. That is, the Day 120 Questions require a response from the applicant, which, in turn, is reviewed by the EMA, prior to its ultimate decision to grant or deny approval. A conclusive finding, on the other hand, is contained in the WAR, wherein the EMA provides a final determination as to the approval of a target drug. The publication of the WAR, therefore, signifies the end of the application process.

Here, the WAR, upon which Plaintiffs relies in alleging fraud, was issued in June 2016—significantly after Insmed made the statements which form the basis of Plaintiff's securities fraud claim. Nonetheless, Plaintiff attempts to circumvent this timing issue by arguing that Insmed was aware of the need to apply a specific definition of culture conversion, which it allegedly ignored, upon

receipt of the Day 120 Questions. Although a copy of the Day 120 Questions is not included as an exhibit to the Amended Complaint, the WAR contains a summary, in bullet point form, of the most significant concerns raised by the EMA in the Day 120 Questions. In that section of the WAR, titled "Summary of reasons for the Major Objection at D120," the EMA, admittedly, questions the application of the Phase 2 Trial's culture conversion definition; however, the EMA's critique in that context is insufficient to support Plaintiff's theory of falsity.

The pertinent language from the WAR is as follows: "There is no comparison vs. placebo beyond day 84. The maximum possible duration of therapy was 168 days. There was no plan to follow-up patients for efficacy beyond 28 days post-treatment. The 12 months follow-up was planned to capture safety data; no data were reported from this visit." Rotenberg Dec., ¶ 2, Ex. J. Although the EMA, when making its comments in the 120 Day Questions, was dissatisfied with the trial's definition of culture conversion, and, in turn, demanded a stronger showing of Arikayce's efficacy, this comment, alone, does not translate into a "requirement" that Insmed test patient sputum samples after stopping treatment for three months nor did EMA direct Insmed to follow any specific protocol. *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) ("Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them.") (internal citation omitted). The summary, as provided in the WAR, fails to include any language from which I can conclude that an application of a specific definition of culture conversion

was required and that Insmed purposefully disregarded that requirement, despite representing that it was complying with the EMA's direction. Accordingly, this section of the WAR fails to support Plaintiff's allegations of falsity.

Nevertheless, Plaintiff references portions of the WAR in the Amended Complaint, wherein the EMA expressly provides for a "sustained" definition of culture conversion, in demonstrating Arikayce's efficacy. AC ¶ 60. The cited language from the WAR states, in pertinent part:

> The only reliable way to assess the effect of treatment with [Arikayce] is to document sustained [culture conversion] at a time point long after cessation of inhaled therapy. Sustained [culture conversion] should be the primary endpoint in any study intended to support approval for treatment of NTM. Sustained [culture conversion] was not a primary or secondary endpoint in [the Phase 2 Trial] and no assessment of sputum culture was planned beyond 28 days post-study treatment. The secondary endpoint of conversion to negative culture was defined in the protocol as negativity at a single time point.
>
> Sputum culture conversion on treatment is not regarded as a reliable endpoint nor does it have any known predictive capacity for eradication of [mycobacteria] (i.e. to predict sustained negativity after stopping all treatment). [Insmed] is advised that the primary endpoint for any future EU submission should be sustained [culture conversion], which should be determined when at least 3 months have elapsed after stopping all . . . treatment.

Rotenberg Dec., ¶ 2, Ex. J. According to Plaintiff, this language demonstrates that Insmed was required to apply a specific definition of sustained culture conversion, *i.e.,* a negative sputum sample after three months of treatment have elapsed, and that Insmed had no intention of following this direction, despite stating, *inter alia*, that is was "well prepared to respond" to the Day 120 Questions. AC ¶ 161. Although a sustained definition for conversion was provided in this portion of the WAR, this merely shows that the EMA's position

was adopted at a later point in time—after the class period. More to the point, this language fails to support that, prior to making the statements in dispute, Insmed was aware that the EMA imposed a specific definition for demonstrating Arikayce's efficacy. Indeed, the EMA's comments relate to Insmed's *post hoc* analysis; the paragraph which precedes the above quoted language states, in relevant part: "The applicant provided a revised [clinical study report] during the procedure that included a *re-analysis* of the primary and several secondary endpoints," and, therefore, demonstrates that the observations upon which Plaintiff relies, pertain to Insmed's reevaluation of the data, which did, in fact, apply a more stringent, albeit insufficient, definition of culture conversion. Rotenberg Dec., ¶ 2, Ex. J (emphasis added). Accordingly, this section of the WAR also cannot support allegations of falsity.[10]

Despite the date upon which the WAR was issued, Plaintiff, in a footnote, advances the following argument: "The contention that the [Amended Complaint] relies upon issues identified in the WAR, published after the end of the Class Period, is a red herring." Pl's Opp'n, at 13, n.3. For support, Plaintiff, in a conclusory fashion, avers that "Defendants undoubtedly knew about the design, execution, and findings of the Phase 2 Trial," and that the "EMA notified Insmed about the issues in the WAR no later than the Day 120 Questions—and in some instances, earlier." *Id.* Plaintiff surmises that Insmed was aware of the required

[10] In addition to Plaintiff's pleading deficiencies, the Court notes that Insmed's comments in connection with the Day 120 Questions are inactionable as statements of opinions under the applicable securities laws, as further described *infra*.

definition of culture conversion prior to making the statements in dispute, because, in the WAR, the EMA states as follows:

> It was *already communicated* to the applicant that the pre-defined primary endpoint for this study was inappropriate and the CHMP [the committee for medicinal products for human use] has since recommended an appropriate primary endpoint for the ongoing Phase 3 study based on confirmed [sustained culture conversion] rates. Specifically, the CHMP notified the Company in the scientific advice on the ongoing Phase 3 study . . . that achieving 3 negative cultures while on LAI was not an acceptable primary efficacy endpoint.[11]

Rotenberg Dec., ¶ 2, Ex. J (emphasis added). Based on this language, Plaintiff presumes that the inadequacy of the trial's definition for conversion was communicated to Insmed by the summer of 2015. However, this argument is also unconvincing. Plaintiff's argument fails to take into account that the need to apply a sustained definition of culture conversion could have been decided and communicated to Insmed after the results of the *post hoc* analysis were reviewed, but before the WAR was published. Indeed, Insmed submitted the *post*

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[11] To be clear, in arguing that the Day 120 Questions expressly required that Insmed apply a sustained definition for culture conversion, Plaintiff solely relies on the above quoted language. However, that language, as further discussed *infra*, is insufficient to support such a contention, particularly since Plaintiff's allegations are subject to the heightened pleading standard of Rule 9(b). Accordingly, for the purposes of this motion, the Court will not presume that the concerns in the WAR were communicated to Insmed "no later than" the summer of 2015, upon receipt of the Day 120 Questions. Pl.'s Opp'n, at 13. Nor will the Court examine the sixty-one page WAR in order to determine exactly when Insmed became aware of the information; that burden lies with Plaintiff. *Doeblers' Pa. Hybrids, Inc. v. Doebler*, 442 F.3d 812, 820 n.8 (3d Cir. 2006) ("Judges are not like pigs, hunting for truffles buried in the record.") (internal quotations and citations omitted). However, because the Court will grant leave to amend, Plaintiff will have an opportunity to correct this deficiency by identifying portions of the WAR, to the extent they exist, demonstrating that Insmed knew of a need to apply a specific sustained definition for culture conversion by the summer of 2015.

hoc analysis in December 2015 and the WAR was issued in June 2016. Accordingly, a six-month period existed after the challenged statements were announced, wherein the EMA could have informed Insmed as to the need to apply an alternative endpoint. Absent any other allegations to the contrary, the Court cannot conclude, based on the pleadings, that the EMA's position was communicated prior to, or even during, the summer of 2015, as Plaintiff alleges. *See* Fed. R. Civ. P. 9(b) ("In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."); *In re Burlington*, 114 F.3d at 1417 (explaining that the Rule 9(b) requirement is to be "rigorously applied in securities fraud cases.") (citations omitted). In that regard, the fact that the EMA conveyed a need for sustained culture conversion before June 2016 — when the WAR was issued — is not sufficient to establish that Insmed was aware of this requirement during the applicable time period, particularly under the heightened pleading standard of Rule 9(b). *See Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013) ("The 'circumstances constituting fraud' must be 'state[d] with particularity.'" (citing Fed. R. Civ. P. 9(b) (alteration in original)); *see also Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 581-86 (S.D.N.Y. 2016); *Sanofi*, 87 F. Supp. 3d at 539-42; *Corban v. Sarepta Therapeutics, Inc.*, No. 14-10201, 2015 U.S. Dist. LEXIS 42688, at *9 (D. Mass. Mar. 31, 2015).

Moreover, to the extent that Plaintiff argues that Defendants should have disclosed the content of the Day 120 Questions, the Court notes that the law with respect to this issue is clear: a biopharmaceutical corporation need not

share a regulatory agency's response or criticism to a trial and its results if it does not constitute a final determination. *See, e.g., Sanofi*, 87 F. Supp. 3d at 541-42; *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995); *In re Genzyme Corp.*, No. 09-11299, 2012 U.S. Dist. LEXIS 44336, at *10 (D. Mass. 2012); *City of Pontiac Gen. Employees' Ret. Sys. v. Stryker Corp.*, 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012); *Monk v. Johnson & Johnson*, No. 10-4841, 2011 U.S. Dist. LEXIS 145554, at *13 (D.N.J. Dec. 19, 2011); *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 902 (N.D. Ill.) *aff'd sub nom. Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001). As stated above, a conclusion as to whether a target drug is granted or denied approval is not provided in the Day 120 Questions. Rather, the EMA's comments, as provided therein, are intended to elicit a response from the applicant, which is then considered before a final determination is issued. Insmed, therefore, was not under an obligation to disclose its contents.

iii. Insmed Did Not Create a Duty to Disclose

Finally, Plaintiff, who concedes that a corporation is generally not obligated to disclose matters of trial methodology and regulatory commentary, argues that Insmed created such a duty through its own statements. Pl.'s Opp'n, at 11, 14. More specifically, Plaintiff contends that Insmed was required to disclose "issues with the Phase 2 Trial's safety and efficacy findings, as well as the significant flaws in the trial's design and execution," simply because Insmed "made numerous statements about" Arikayce's safety and efficacy. Pl.'s Opp'n, at 14. I disagree.

Here, Insmed did not create a duty to disclose information concerning the Phase 2 Trial. Plaintiff merely asserts that, because "significant concerns" were raised in the Day 120 Questions, which substantially decreased the probability of approval, Insmed was required to disclose these issues when it spoke positively about the results of the Phase 2 Trial and Arikayce's efficacy. *See, e.g.*, AC ¶ 52. However, as already noted, the Day 120 Questions are not the agency's final determination; instead, their primary purpose is to facilitate a discussion between the EMA and applicant, and the information gathered from this process is further considered by the EMA before deciding approvability. In that connection, district courts have found that a biopharmaceutical corporation is not required to disclose a regulatory agency's inconclusive findings, even if they undercut that corporation's position, merely because the drug was described favorably or its strength was touted. *See, e.g.*, *In re Amarin Corp. PLC Secs. Litig.*, No. 13-6663, 2016 U.S. Dist. LEXIS 55568, at *35 (D.N.J. 2016); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 U.S. Dist. LEXIS 79823, at *38 (E.D. Pa., Mar. 15, 2007); *Gen. Partner Glenn Tongue v. Sanofi*, 816 F.3d 199, 211-12 (2d Cir. 2016); *In re EDAP TMS S.A. Secs. Litig.*, No. 14-6069, 2015 U.S. Dist. LEXIS 121960, at *30-31 (S.D.N.Y. Sept. 14, 2015). As succinctly explained by the court in *In re Medimmune, Inc. Sec. Litig.,* 873 F. Supp. 953 (D. Md. 1995):

> Nor . . . does it matter that one or more FDA staffers may have questioned [the corporate defendant] or its affiliates about the study design during the review process. *Mere questioning by the FDA imposed no duty upon Defendants 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. Questions may emanate from one or more staffers in random or sporadic fashion. Many, if not all, questions presumably get answered in the process. Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions. Where mere disclosure of a question might cause the company's stock to decline in value, the eventual answer to the question might cause it to rise once again. Investors who sold that stock when the FDA's question was asked but before the company's answer was given might have legitimate cause for concern when a satisfactory answer came forth and the stock's price began to climb again.

Medimmune, 873 F. Supp. at 966 (emphasis added). Contrary to Plaintiff's contention, therefore, the Day 120 Questions fail to trigger a duty to disclose, because the concerns or issues, as expressed therein, are reassessed by the EMA at a later point in time when Insmed has provided more information. Indeed, Insmed was not barred from expressing an opinion as to Arikayce's efficacy or safety, even if the EMA "was not convinced" of those aspects of the drug by Day 120 of the application process. *Id.* at 955. Nor was Insmed required to disclose the contents of that document merely by touting the strength of Arikayce, because the Day 120 Questions are not conclusive findings of the EMA. Fatally, Plaintiff's allegations of falsity are not based on Insmed's internal emails or other studies; for example, there are no allegations that Insmed contradicted, or doubted, the opinion which it represented to investors concerning Arikayce. Accordingly, to the extent that they stem from the Day 120 Questions, Plaintiff's allegations fail to support a duty to disclose; accordingly falsity has not been sufficiently pled.[12]

[12] Plaintiff contends that Insmed's alternative argument purportedly based on the "truth on the market defense," is rarely an appropriate basis to dismiss a

iv. Statements Concerning Insmed's Interaction with the EMA and Arikayce

Finally, Plaintiff avers that materially false statements were included or announced in Insmed's press releases and investor conferences. These statements, challenged by Plaintiff, can be separated into three categories, with the first group related to Insmed's representation of the Phase 2 Trial, as well as Arikayce's safety, efficacy, and durability: (a) "there is . . . a very thorough process . . . that ensure[s] that there is no corruption of [sputum samples]"; (b) "[w]e are encouraged by . . . durable culture conversions"; (c) [w]e have data for all of these areas that shows the drug is safe and effective in my judgment"; [13] (d) "Why do I get comfortable that [Arikayce's] clinical risk is digestible"; (e) "the deeper we dive into the data, the more evident it is to us and to the clinicians that [Arikayce] had a significant impact"; and (f) "But my enthusiasm flows from the fact that most of the data that would give you insight into whether this is

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§ 10b claim. Pl.'s Opp'n, at 16-17. Admittedly, this defense requires a fact intensive analysis not suitable for consideration on a motion to dismiss but rather, should be resolved at a later juncture of litigation, *i.e.,* summary judgment motion or trial. *See, e.g., Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000) ("The truth-on-the-market defense is intensely fact-specific and is rarely an appropriate basis for dismissing a § 10(b) complaint for failure to plead materiality."). The Court, however, need not engage in such an inquiry here, as I have already determined that as pled, Insmed was under no obligation to disclose the alleged flaws with the Phase 2 Trial or the content of the Day 120 Questions. *See e.g.*, *Amarin*, 2015 U.S. Dist. LEXIS 84080, at *35 n.16 (the defendant's truth on the market defense was not reached, because the challenged statements were not actionable in the first instance); *In re Cisco Sys. Secs. Litig.*, No. 11-1569, 2013 U.S. Dist. LEXIS 53137, at *48 (N.D. Cal. Mar. 29, 2013).

[13] Plaintiff, in its brief, omits the portions of Mr. Lewis's statements wherein he clearly indicates that he was merely expressing an opinion.

going to work points in the positive direction." Pl.'s Opp'n, at 13-14; AC ¶¶ 130, 134, 150, 172.

The next group of statements pertain to Insmed's interactions with the EMA, and Insmed's subjective interpretation of the EMA's feedback after the conclusion of the Phase 2 Trial: (a) "[w]e greatly appreciate the collaborative and supportive interactions we have had with the EMA"; (b) "I think we took [the EMA's] guidance, listened to it very carefully, and I would characterize [them] as being very enthusiastic"; (c) "I think Europe finds this to be an exciting drug. There was open enthusiasm among the [EMA] about the findings that we presented to them"; (d) "w[e] are pleased with our dialogue to date with both the EMA and the FDA"; (e) "we feel like we're doing exactly what [the EMA] asked." Pl.'s Opp'n, at 14; AC ¶¶ 133, 140, 143, 144, 145.

The final group includes statements made by Insmed to express its positive belief as to Arikayce's regulatory approval: (a) "I think one of the nice things about this company two and a half years ago when I had the privilege to talk to the board and to look at the opportunity was, I saw an approvable drug, bottom line"; (b) "[b]ut our expectation is that between the [Phase 2 NTM Trial] data set and the promise of the report of [the phase 3 NTM clinical trial] next year, coupled with all of our CF study data, we should be in a good place to secure a label in Europe based on the data sets we currently have in hand." AC ¶¶ 150, 154. Plaintiff submits that this category of statements is materially false and misleading, because, the WAR identified issues pertaining to the structure, execution, and results of the Phase 2 Trial, all of which led to the disproval of

Arikayce. AC ¶ 151. The Court will examine each group of allegedly false and misleading statements made by Insmed.

As articulated by the Third Circuit, material representations contrasted with statements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism, "constitute no more than 'puffery' and are understood by reasonable investors as such." *In re Aetna*, 617 F.3d at 283 (internal quotations and citation omitted). In the same vein, "[a] representation is immaterial if the statement at issue is too vague to be actionable," and, in turn, cannot form the basis of a claim for securities fraud. *Id.* (internal quotations and citations omitted).

"[A]lthough questions of materiality have traditionally been viewed as particularly appropriate for the trier of fact, complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so unimportant that courts can rule them immaterial as a matter of law at the pleading stage." *Id.* (internal citation omitted). Therefore, in challenging an expression of opinion, a plaintiff must adequately allege that the disputed statement is "not honestly believed and lack[s] a reasonable basis." *City of Edinburgh*, 754 F.3d at 170; *Fait v. Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011) (holding that subjective statements under the securities law are subject to liability if they are "both false and not honestly believed when they were made" (citing *Va. Bankshares v. Sandberg*, 501 U.S. 1083, 1095 (1991)).[14]

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[14] Plaintiff maintains that the Supreme Court's decision in *Omnicare,* a case involving §11, has implicitly overruled the standard under which an opinion can

As a preliminary matter, the Court finds that each of these challenged representations is inactionable because it is an opinion, corporate puffery, or forward looking. In fact, the individual defendants who made those statements introduce or conclude with phrases such as "I believe" or "in my judgment," which in this Court's view, establish that the information provided in those challenged remarks constitutes that individual defendant's subjective belief. In that connection, without more, Plaintiff fails to properly allege that these statements are false for the purposes of § 10(b). Plaintiff's § 10(b) claim based on these statements, therefore, fails on this basis alone. Nevertheless, in the interest of completeness, the Court will examine each category of statements.

First, Plaintiff maintains that Insmed unreasonably represented that the sputum samples did not contain residual Arikayce, by citing to the following language from the WAR: "The possibility that residual amikacin in sputa interfered with culture results seems likely but the extent to which this may have

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be challenged, as set forth by the Third Circuit in *City of Edinburgh*. Plaintiff argues that, under *Omnicare,* a statement of opinion is actionable if it is either false *or* lacks a reasonable basis. Pl.'s Opp'n, at 21-22. I am, however, is unpersuaded by this contention. The Third Circuit has expressed reluctance in finding that *Omnicare*'s standard applies to § 10b claims. *See OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 493 n.11 (3d Cir. 2016); *In re Amarin Corp. PLC Sec. Litig.*, No. 16-2640, 2017 U.S. App. LEXIS 8970, at *16 (3d Cir. May 23, 2017). Absent any guidance to the contrary, I will apply the standard as set forth by the Third Circuit in *City of Edinburgh*, the same approach taken by other courts within this district, subsequent to the *Omnicare* decision. *See e.g.*, *In re Hertz Global Holdings, Inc. Sec. Litig.*, No. 13-7050, 2017 U.S. Dist. LEXIS 65156 at *37 (D.N.J. Apr. 27, 2017); *Lovallo v. Pacira Pharms., Inc.*, No. 14-6172, 2015 U.S. Dist. LEXIS 155759, at *40, (D.N.J. Nov. 18, 2015). Regardless, even if *Omnicare* were to govern here, Insmed's statements of opinion would still not be actionable, because Plaintiff has failed to sufficiently plead that Insmed lacked a reasonable basis for its representations, as further discussed *infra*.

influenced the applicant's conclusions on efficacy cannot be gauged." Rotenberg Dec., ¶ 2, Ex. J; AC ¶ 173. However, this comment, alone, is insufficient to support Plaintiff's claim, because, as evidenced by the language itself, a definitive conclusion with respect to the reliability of Insmed's testing method was not reached. Rather, although the EMA expressed a concern with regard to the process implemented by Insmed, the agency could not determine whether the data on Arikayce's efficacy was unreliable in that context. Indeed, there are no allegations that Insmed had doubted the integrity of its process for testing sputum cultures in, *inter alia*, any internal analysis or correspondence. To the contrary, as pled, Insmed had a reasonable basis for making the statements in dispute. For example, during the Phase 2 Trial, Insmed prevented residual Arikayce from obscuring the study's results by implementing a system under which sputum samples were placed in a centrifuge, which, in turn, produced a "pellet" of mycobacterium for testing. *See* AC ¶ 172; SEC Form 10-Q, 460-62. Accordingly, the EMA's inconclusive language, as contained in the WAR, is insufficient to establish that Insmed's opinion was materially false or unreasonable, particularly since Insmed implemented a methodological system aimed at preserving cultures for testing. *Medimmune*, 873 F. Supp. at 966 (finding that the defendants were not required "to trim back their opinions as to the efficacy" of the target drug, where the FDA did not conclusively find that it was inefficacious).

The remaining comments in the first group of statements, relating to Arikayce's durability, safety, and efficacy, are also inactionable because they

represent Insmed's subjective interpretation of the Phase 2 Trial data. *See Pfizer*, 754 F.3d at170 ("Interpretations of clinical trial data are considered opinions." (citing *Kleinman*, 706 F.3d at 153)); *Sanofi*, 87 F. Supp. 3d at 543-44 (finding that the defendants' "subject[ive] assess[ment of] the clinical trial results and descr[iption of] them as encouraging" were inactionable as "unambiguous[] statements of opinion."); *Gillis*, 197 F. Supp. at 595 (holding that the defendant's subjective interpretation of the results of a clinical study were statements of opinion, and not actionable under the applicable securities laws); *In re Adolor*, 616 F. Supp. at 567. Plaintiff, once again, references the WAR's findings, and argues that, because the trial was fundamentally flawed and failed to demonstrate the safety or efficacy of Arikayce, Insmed lacked a reasonable basis for its public representations. AC ¶ 152; Pl.'s Opp'n, at 13-14. However, this contention is unavailing because, for one, Plaintiff fails to provide specific allegations wherein Insmed was informed about any concerns with respect to the trial, at a time before the statements in dispute were announced to investors. Indeed, the WAR, upon which Plaintiff solely relies for support was published at a later date, and therefore, it cannot serve as a basis for undermining Insmed's position with respect to the results of the Phase 2 Trial. *Gillis*, 197 F. Supp. at 598 ("That [a regulatory agency] ultimately disagreed with defendants' interpretation of the data does not render their subjective assessments false or misleading.") (internal citation omitted); *see Medimmune,* 873 F. Supp. at 966-67 (discussing that a reasonably held opinion that is later proven wrong is, nevertheless, not actionable). As pled, these particular statements were made

during conferences held by Insmed on March 24, 2015, even prior to the receipt of the Day 120 Questions, and on December 1, 2015, after the Day 120 Question but before the WAR was published by the EMA on June 8, 2016.

Additionally, the Court notes that Insmed's opinion with regard to the strength of Arikayce was substantiated by the surrounding circumstances. For instance, Insmed decided to seek approval for Arikayce, after discussions with the EMA, based solely on the results of the Phase 2 Trial; additionally, the FDA granted Insmed with breakthrough therapy designation. Rotenberg Dec. ¶ 2, Ex. N. And, finally, Insmed's decision to conduct a *post hoc* analysis, and its initiation of a Phase 3 Trial after regulatory denial is telling. Phase 3 Trial, which, to date, is still in progress, presumably requires an allocation of significant time and resources, and further evidences that Insmed genuinely believes in its product. *Sanofi*, 87 F. Supp. 3d at 544 ("Defendants' substantial investment of money and personnel in [its drug's] clinical trials over a several-year period is hard to square with the premise that defendants understood that the study design was fatally flawed or that the results made [its drug] dead on arrival."); *Gillis*, 197 F. Supp. 3d at 589 ("[D]efendants' continued investment of time and resources into developing [its drug] . . . suggests that they honestly believed approval was still attainable.)." Accordingly, these particular statements, which appear reasonably grounded and honestly believed, cannot be used to support Plaintiff's allegations that Insmed mislead investors.

Likewise, Plaintiff fails to state a claim under the second subset of statements, wherein Insmed merely described the EMA as, *inter alia*,

"collaborative and supportive," as well as "enthusiastic" about the results of the trial. Based on Plaintiff's pleadings, it appears that "support" and "enthusiasm" were expressed by the EMA during the applicable time period. In fact, Insmed, following discussions with the EMA, was confident in submitting an MAA based solely on the Phase 2 Trial, which was not initially intended to support regulatory approval. That decision, which was made after Insmed's discussions with the EMA, is suggestive of Insmed's positive interactions with that agency. These representations, therefore, cannot serve as a basis for Plaintiff's securities claims. *Gillis*, 197 F. Supp. 3d at 589 (holding that the challenged statements were statements of opinion, because they did not "address[] existing objective facts," but rather "express[ed] [the defendants'] views, either as to the FDA's actions and communications, or as to [its drug's] prospects."); *Kleinman*, 706 F.3d at 153 ("We have also held that words like 'encouraging' are the type of 'expressions of puffery and corporate optimism' that do not generally 'give rise to securities violations.'") (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004))).

Lastly, the third group of statements, with respect to Arikayce's approvability, are both forward looking and inactionable as corporate puffery. For instance, the statement, given by Mr. Lewis during Insmed's first investor conference in March of 2015, reads, in pertinent part: "I think one of the nice things about this company two and a half years ago when I had the privilege to talk to the board and to look at the opportunity was, I saw an approvable drug, bottom line." Pl.'s Opp'n, at 14; AC ¶ 50. This statement suffers from the same

flaw in Plaintiff's previous arguments; in demonstrating falsity, Plaintiff references concerns which were raised after the fact. And, more to the point, a reasonable investor would not rely on this statement. Indeed, it clearly embodies the opinion of Mr. Lewis, and amounts to nothing more than a "gut feeling" stemming from a vaguely described interaction with Insmed's corporate board, at a time before conducting a Phase 2 Trial. Statements of this kind are a paradigm of corporate puffery, and, therefore, they cannot serve as the basis for § 10(b) liability. *Vallabhaneni v. Endocyte, Inc.*, No. 14-1048, 2016 U.S. Dist. LEXIS 673, at *47 (S.D. Ind. Jan. 4, 2016) ("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." (internal citation omitted)); *Lopez v. CTPartners Exec. Search, Inc.*, 173 F. Supp. 3d 12, 28 (S.D.N.Y. 2016) (holding that statements which are "so broad and nebulous as to not provide any specific or concrete guarantee" are not relied on by reasonable investors); *Medimmune*, 873 F. Supp. at 964 ("Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable.").[15]

[15] Plaintiff also argues that, during an investor conference, Mr. Lewis misrepresented the reason for Insmed's delay in responding to the Day 120 Questions. Pl.'s Opp'n, at 15. Specifically, Plaintiff contends that, "[w]hen directly asked by an analyst whether Insmed's request for additional time to respond to the EMA's Day 120 Questions was due to 'any surprises in those questions, Mr. Lewis responded that Insmed had sought the additional time in order to include the trial's one-year-follow-up data . . . ." *Id.* However, in actuality, Plaintiff maintains that the delay was caused by Insmed's *post-hoc* analysis, and its decision to narrow the MMA for a specific subset of NTM patients. Although that

Likewise, Mr. Lewis's representation that Insmed was in a "good place to secure a label in Europe," based on "the data sets we currently have on hand," is a forward-looking statement.[16] AC ¶ 154. Under the PSLRA, forward-looking statements are broadly defined to include, *inter alia*, "statement(s) of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." 15 U.S.C.A. § 78u-5(i)(1). Significantly, these statements encompass those such as the one above, wherein a defendant expresses the likelihood of approval by a regulatory agency, *i.e.*, the EMA. *Bauer v. Eagle Pharms., Inc.*, No. 16-3091, 2017 U.S. Dist. LEXIS 76247, at *24 (D.N.J. May 19, 2017) ("[S]tatements relating to anticipated FDA approval . . . are 'statement[s] of the plans and objectives of management for future operations, including plans or objectives relating to the products.'" (internal citation omitted)); *Kovtun v. Vivus, Inc.*, No. 10-4957, 2012 U.S. Dist. LEXIS 139548, at *34 (N.D. Cal. Sept. 27, 2012) ("Projections about the likelihood of FDA approval are forward-looking statements. They are

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may be factually accurate, what Plaintiff fails to sufficiently allege, pursuant to the heightened pleading standard, is that the delay was not caused by the need to provide one-year-follow-up data to the EMA or any other reasons. *See* Fed. R. Civ. P. 9(b). In other words, the fact that Insmed conducted a *post hoc* analysis does not necessarily mean that Insmed did not have any other bases to request a delay. Thus, these conclusory allegations fail to show that Mr. Lewis' statement in this regard was false.

[16] While Plaintiff contends that the safe harbor is inapplicable to this statement because Plaintiff's allegations of fraud are based upon omissions, I disagree. Plaintiff cannot transform the alleged misrepresentations into omissions simply by alleging that Defendants failed to disclose that the allegedly misleading fact was untrue. *See Johnston v. HBO Film Mgmt.*, 265 F.3d 178, 193 (3d Cir. 2001).

assumptions related to the company's plan for its product, and as such fall under the PSLRA's safe harbor rule."); *Gillis*, 197 F. Supp. 3d at 585 (holding that statements pertaining to FDA approval "are classically forward-looking, as they address what defendants expected to occur in the future." (internal citations omitted)). Accordingly, Mr. Lewis's statement, which anticipates regulatory approval, clearly falls within the ambit of the PSLRA's safe-harbor.[17]

Next, having determined that the challenged statement is forward-looking, the Court must assess whether it was appropriately accompanied by cautionary language. *See Avaya*, 564 F.3d at 256. In that connection, "[a] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has

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[17] Plaintiff also argues that the majority of Insmed's opinions are actionable, because they combine present and future statements, such that they are not truly forward-looking under the PSLRA. Pl.'s Opp'n, at 20. In so arguing, however, Plaintiff only provides the aforementioned statement as an example; accordingly, the Court's analysis is confined to Mr. Lewis's projection of regulatory approval. Although the present portion of a future looking statement is not entitled to the safe harbor, the statement did not violate the applicable law, as Plaintiff contends, merely because Mr. Lewis referenced "data sets" which Insmed currently "ha[d] on hand." *Avaya*, 564 F.3d at 255. For one, it is of no significance here that such data provided the basis for Mr. Lewis's representation, because "any statement of the assumptions underlying or relating to" a forward-looking statement are encompassed by the safe harbor. *Id.* (internal quotations and citation omitted). In other words, Mr. Lewis's representation is not transformed into a non-forward looking statement, because the data sets, *i.e.*, present information, are what "ma[de] the future projection [of approval] attainable." *Id.* To hold otherwise would effectively render the PSLRA's safe harbor meaningless. *Id.* ("Such an assertion [of current fact] is necessarily implicit in every future projection."). Mr. Lewis's statement, in this regard, is protected by the PSLRA. *Id.* at 255-56 (holding that the defendant's assurance that it was currently "on track" to meet its projected financial goals was forward-looking); *Bauer*, 2017 U.S. Dist. LEXIS 76247, at *24 (finding that the defendant's representation of approval was not actionable by virtue of its reference to present discussions with the FDA.).

risks will ordinarily be inadequate to prevent misinformation." *Id.* (internal quotations and citation omitted). Instead, "[t]o suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge." *Id.* (internal quotations and citation omitted).

Here, contrary to Plaintiff's contentions, Insmed has satisfied this obligation under the applicable securities law. Specifically, in a Form 10-K for the year ending 2015, Insmed explicitly states, in a paragraph titled "**RISK FACTORS**," that "risks and uncertainties could cause actual results to differ materially from those expressed or implied by forward-looking statements . . . ." ("Rotenberg Dec."), ¶ 2, Ex. S. Insmed then provides, *inter alia*, the following list of warnings, throughout various portions of the remainder of the document: (a) "[t]here can be no assurance . . . that results from the [Phase 2 Trial] will be sufficient to obtain full or conditional marketing approval"; (b) "[i]f major objections raised during the review procedure are not subsequently resolved, it may impact our ability to obtain an approval without submission of additional study data"; and (c) "[t]here is little or no precedent for clinical development and regulatory expectations for agents to treat NTM; as a result we may encounter challenges developing clinical endpoints . . . and may need to reevaluate our surrogate endpoints . . . . ." Rotenberg Dec., ¶ 2, Ex. S. Accordingly, Insmed's cautionary language is specifically tailored to the concerns which impacted the regulatory approval process. Indeed, the EMA concluded that the Phase 2 Trial, alone, was insufficient for the purposes of granting approval, and raised major

objections throughout the application process which ultimately culminated in the commencement of a Phase 3 Trial, under which a sustained definition of culture conversion is applied—the very issue which Plaintiff raises in the Amended Complaint. *Bauer*, 2017 U.S. Dist. LEXIS 76247, at *28 (finding that the defendant's warnings were appropriately cautionary, because they warned of "the risks that came to fruition and form the basis of Plaintiffs' complaint"); *Sanofi*, 87 F. Supp. 3d at 536 ("These statements conveyed substantive information about the risk that ultimately materialized. As such, they were meaningful cautionary language, not mere boilerplate."). Accordingly, Insmed's representations in this context are forward-looking statements under the PSLRA.[18]

The Court finds that, in total, Plaintiff has failed to plead falsity as to the challenged representations made by Defendants. In that connection, Plaintiff's § 10(b) claim fails on this basis alone. However, Plaintiff also fails to plead scienter.

III. Scienter

[18] Even if Insmed's cautionary language is inadequate, Plaintiff has failed to sufficiently allege that "the [challenged] statement was made with actual knowledge of its falsehood," as is required under the PSLRA. 15 U.S.C. § 78u-5(c)(1). Indeed, as further discussed *infra*, the facts, as pled in the Amended Complaint, do not support that the Individual Defendants acted with scienter. Thus, Plaintiff's arguments with respect to Mr. Lewis's projection of regulatory approval fail on this basis as well. *Avaya*, 564 F.3d at 259 ("This scienter conclusion provides a ground for dismissing Shareholders' claims relating to the forward-looking statements, one that would apply even assuming defendants' cautionary language was inadequate.") (citing 15 U.S.C. § 78u-5(c)(1)).

To the extent that the statements, as discussed above, are allegedly materially false or misleading, Plaintiff has failed to adequately plead that the Individual Defendants acted with scienter, an essential element of Rule 10b-5. "Scienter" stands for the "mental state [of] intent to deceive, manipulate or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n. 12 (1976). Under this PSLRA's pleading requirement, a plaintiff must "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Avaya*, 564 F.3d at 267 (quoting 15 U.S.C. § 78u-4(b)(2)). The scienter standard requires a plaintiff to allege facts giving rise to a "strong inference of "either reckless or conscious behavior." *Advanta*, 180 F.3d at 534-35. Courts must weigh the "plausible nonculpable explanations for the defendant's conduct" against the "inferences favoring the plaintiff." *Tellabs,* 127 S. Ct. at 2510. A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 2504-05; *see id.* at 2510 ("The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the most plausible of competing inferences" (internal quotation marks omitted)).

"[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences . . . . A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference." *Tellabs,* 551 U.S. at 323-29 (emphasis in original). "While [courts] [] aggregate the allegations in the complaint to determine whether [they] create[] a

strong inference of scienter, plaintiffs must create this inference with respect to each individual defendant in multiple defendant cases." *Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007) (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 603 (7th Cir. 2006) *rev'd on other grounds*, 551 U.S. 308 (2007)).

In arguing that the Individual Defendants acted with scienter, Plaintiff underscores the following: (1) Mr. Lewis and Mr. Drechsler, two high level officers, were likely aware of the trial's shortcomings, because the viability of Insmed depended on the success of Arikayce; (2) Mr. Lewis personally attended two co-rapporteur meetings, and likely had access to the Day 120 Questions, wherein the EMA presumably informed Insmed about the issues with the design and structure of the Phase 2 Trial; (3) Insmed was motivated to conceal the issues with the Phase 2 Trial, and maintain a positive perception of Arikayce, in order for patients to enroll in, and raise funding for, a Phase 3 Trial supporting approval; and (4) Doctor Gupta, a key facilitator of the Phase 2 Trial, resigned shortly after the results of the study were announced. Although the Court will examine the totality of the inferences raised by Plaintiff, those pertaining to the Individual Defendants' motive and opportunity will be analyzed before allegations related to conscious misbehavior or recklessness. *See Avaya,* 564 F.3d at 268.

a. Motive and Opportunity

While the Third Circuit recognizes that "'motive and opportunity' may no longer serve as an independent route to scienter" in the wake of *Tellabs's*

instructions to consider the Complaint in its entirety, particularized allegations regarding motive and opportunity may, in combination with other allegations, support a strong inference of scienter. *Avaya*, 564 F.3d at 268; *see also Tellabs*, 551 U.S. at 323-29. In that connection, because Insmed was allegedly dependent on the success of Arikayce, Plaintiff avers that the Individual Defendants, to continue operating, strived "to maintain the illusion of positive phase 2 results," such that they could raise capital for, and complete enrollment in, a Phase 3 Trial. Pl.'s Opp'n, at 26-27 n.28. However, the Fourth Circuit rejected an identical argument raised in *Cozzarelli v. Inspire Pharms., Inc.*, holding that: "[i]t is improbable that [a pharmaceutical corporation] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure." 549 F.3d 618, 627 (4th Cir. 2008). This reasoning is persuasive: Insmed, surely, realized that it could not indefinitely maintain a false impression of the trial's results, particularly since the EMA was required to issue a final decision as to approvability on the 210th day of the application process. *See, e.g.*, *Gillis*, 197 F. Supp. 3d at 600 ("Moreover, by its nature, [the defendants] purported scheme could not have continued in perpetuity. Defendants would have known that their efforts [in connection with] feigning likely FDA approval would be revealed, in relatively short order, upon the FDA's rejection of [their product]."); *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446-47 (S.D.N.Y. 2006) ("[T]he tenuous plausibility of the [defendant's] alleged scheme substantially weakene[d] the overall strength of plaintiffs' scienter allegations[,] . . . [where defendants] must have . . . realized that . . . [the public would] quickly uncover the scheme.").

The implausibility of this type of motivation is further heightened by Plaintiff's failure to allege why Insmed engaged in a scheme to defraud investors, despite the high risks associated with such an activity. Even Plaintiff, for example, concedes that, during the applicable time period, the Individual Defendants did not engage in insider trading by selling their stock in this allegedly doomed investment. Although not determinative, courts have consistently weighed this fact against an inference of scienter. *See, e.g.*, *In re Mela*, 2012 U.S. Dist. LEXIS 144150, at *15 ("[N]o defendant sold [the company's] shares . . . during the class period. This is inconsistent with an intent to commit fraud."); *Nat'l Junior Baseball League v. PharmaNet Dev. Group, Inc.*, 720 F. Supp. 2d 517, 558 (D.N.J. 2010) ("[T]he fact that [the individual defendants] did not sell any [of the company's] stock during the Class Period tends to negate scienter."); *Turner v. MagicJack VocalTec, Ltd.*, No. 13-0448, 2014 U.S. Dist. LEXIS 13293, at *11 (S.D.N.Y. Feb. 3, 2014) ("That three of the four individual Defendants, all high-ranking executives at the Company, did not sell stock during the Class Period . . . rebuts an inference of scienter."); *In re N. Telecom Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders . . . is inconsistent with an intent to defraud shareholders."). In fact, after the Day 120 Questions were received, the Individual Defendants actually increased their holdings in the company; on February 1, 2016, Mr. Lewis purchased over 50,000 shares of Insmed, totaling $667,000.[19] Thus, based on

[19] While the stock purchase was executed pursuant to a 10b5-1 trading plan, which effectively removed any discretion from Mr. Lewis, the trading plan,

the pleadings, the Individual Defendants were not intending to deceive the public by misrepresenting the results of the Phase 2 Trial, but instead honestly believed in the strength of Arikayce in discussing its results.

Finally, the remaining motives alleged by the Amended Complaint are innocuous. For instance, Plaintiff maintains that Insmed likely concealed the issues with Arikayce so patients would enroll in the Phase 3 Trial; however, the desire to conduct a successful study, upon which regulatory approval is sought, applies to all pharmaceutical companies and corporate officials. Therefore, this general allegation is insufficient for Plaintiff to meet its burden under the law. *Avaya*, 564 F.3d at 278 ("[M]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud." (internal quotations and citation omitted)); *SC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004) ("In every corporate transaction, the corporation and its officers have a desire to complete the transaction, and officers will usually reap financial benefits from a successful transaction. Such allegations alone cannot give rise to a 'strong inference' of fraudulent intent.") (internal quotation omitted). Likewise, for this same reason, Insmed's secondary offering, in which it raised $331 million for a Phase 3 Trial, also fails to support a strong inference of scienter. *In re Mela,* 2012 U.S. Dist. LEXIS 144150, at *15 ("To the extent the PSAC relies on [the defendant corporation's] capital raised

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nevertheless, was implemented subsequent to the summer of 2015, when the Day 120 Letter was received by Insmed.

during the Class Period, the Court also finds this inadequate to support an allegation of intent to commit fraud." (internal citations omitted)); *Geiger v. Solomon-Page Group, Ltd.*, 933 F. Supp. 1180, 1189-90 (S.D.N.Y. 1996) ("[A] company issuing its stock to the public always has a generalized motive to ensure the success of the issue and to raise as much money as possible . . . . Allegations of these interests are not of themselves sufficient allegations from which a strong inference of fraudulent intent may be drawn."). Because these allegations of motive are applicable to any corporation seeking to commercialize an investigational drug, Plaintiffs have failed to adequately plead motive.

b. Conscious Misbehavior or Recklessness

Next, the Court turns to Plaintiff's allegations of scienter concerning the Individual Defendants' alleged conscious misbehavior or recklessness. "The standard for 'conscious misbehavior or recklessness' requires misrepresentations to be 'so recklessly made that the culpability attaching to such reckless conduct closely approaches that which attaches to conscious deception.'" *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 622 (E.D. Pa. 2009) (quoting *In re Digital Island Sec. Litig.*, 357 F.3d 322, 332 (3d Cir. 2004)). "Conscious misbehavior involves 'intentional fraud or other deliberate illegal behavior.'" *In re Radian*, 612 F. Supp. 2d at 613 (quoting *In re Advanta*, 180 F.3d at 535). Recklessness involves "not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to

the defendant or is so obvious that the actor must have been aware of it." *In re Advanta*, 180 F.3d at 539.

In the instant matter, Plaintiff claims that the fraud relates to the "core business" of Insmed. That is, because "Insmed did not have any approved drugs and its near-term profitability was dependent upon EMA approval of Arikayce," Mr. Lewis and Mr. Drechsler, Insmed's key officials, were likely aware of the fundamental flaws with the Phase 2 Trial. Pl.'s Opp'n, at 24; AC ¶183. Moreover, Plaintiff, in a footnote, briefly argues that the resignation of Dr. Gupta, the Phase 2 Trial's lead doctor, shortly after its results were announced by Insmed, further "provides additional circumstantial evidence that Defendants were aware of the trial's significant problems." Pl's Opp'n, at 26 n.26.

The Court will first address Plaintiff's "core business" allegation. "While it is true that false or misleading statements by key executives regarding a company's lead product or core business practices will weigh in favor of finding a strong inference of scienter, [courts] will not make such an inference 'absent particularized allegations showing that defendants had ample reason to know of the falsity of their statements.'" *City of Roseville Employees' Ret. Sys. v. Horizon Lines, Inc.*, 686 F. Supp. 2d 404, 423 (D. Del. 2009). In that connection, Plaintiff contends that Mr. Lewis was likely aware of the flawed definition of culture conversion, because he attended two co-rapporteur meetings, as stated during an investor conference on November 6, 2014: "In this case, I personally attended both of the co-rapporteur meetings, one in Poland with the Polish authorities and the other in England. Those are our two co-rapporteurs coming into this

application process." Pl.'s Opp'n, at 24; AC ¶ 144. Plaintiff additionally reasons that the Individual Defendants likely had access to the Day 120 Questions, wherein issues concerning the definition of culture conversion were raised. Neither of these allegations are sufficient to create the requisite strong inference of scienter.

To begin, Plaintiff fails to provide details with respect to the dates on which the meetings took place, or the discussions, if any, which transpired between Mr. Lewis and the co-rapporteurs. In fact, based on the allegations, as pled in the Amended Complaint, the meetings could have plausibly occurred before the conclusion of the Phase 2 Trial, such that the EMA's concerns were not among either meeting's topics of conversation. The Court, therefore, cannot infer that Mr. Lewis was aware of the study's allegedly inadequate definition of culture conversion before the disputed representations were made, based upon his attendance of two meetings, the purposes of which Plaintiff has not adequately pled. *Coyne v. Metabolix, Inc.,* 943 F. Supp. 2d 259, 273 (D. Mass. 2013) ("Plaintiff in this case makes no allegations regarding any particular meeting that Defendants attended or any specific discussions that occurred at any meeting. There is no way, from the allegations in the operative complaint, to infer what defendants knew or when."); *Nat'l Junior Baseball League*, 720 F. Supp. 2d at 556 (Plaintiff cannot rely on th[e core purpose] doctrine when it has failed to allege other individualized allegations that [the individual defendants] had

knowledge of the facts at issue.").[20] Nor can the Court infer that the Individual Defendants were aware of the alleged flaws with the trial, based on the allegation that they likely had access to the Day 120 Questions. In that regard, Plaintiff fails to adequately support such a theory with specific allegations that the EMA conditioned regulatory approval on the application of a specific definition of culture conversion in the Day 120 Questions. Indeed, as discussed above, the summary of the Day 120 Questions provided in the WAR did not include a requirement of "sustained" culture conversion. Thus, Plaintiff has failed to adequately allege scienter on this basis.

Next, the Court will examine Plaintiff's contention that scienter is supported by Dr. Gupta's resignation, shortly after the results of the Phase 2 Trial were announced. Pl.'s Opp'n, at 26 n.28. Within this circuit, "a defendant's resignation could constitute a 'piece to the scienter puzzle' if the resignation both takes place within a couple of months of the announcement of the errors committed and is accompanied by an extraordinary corporate punishment measure, *e.g.,* denial of severance payment." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 347 (D.N.J. 2007); *see also City of Roseville Employees' Ret. Sys. v. Horizon Lines, Inc.*, 442 Fed. App'x 672, 679 (3d Cir. 2011). Significantly, Plaintiff fails to adequately allege an extraordinary corporate punishment against

[20] The non-binding case upon which Plaintiff relies is not applicable here. *See In re Enzymotec Secs. Litig.*, No. 14-5556, 2015 U.S. Dist. LEXIS 167403 (D.N.J. Dec. 14, 2015). Although that court applied the core purpose doctrine, the plaintiff, there, specifically demonstrated in the pleadings that the individual defendants were aware of the alleged facts, and acted with scienter, through the suspicious timing of their stock trades.

Dr. Gupta. To the contrary, rather than "sudden[ly] resign[]," as Plaintiff alleges, Insmed's Form 8-K demonstrates that Dr. Gupta transitioned to a "new role as Special Advisor to the CEO," under which she assisted Mr. Lewis "in evaluating important science and development matters related to Arikayce . . . ." AC ¶ 184; Rotenberg Dec., ¶ 2, Ex. J; *See Genesis Bio—Pharmaceuticals, Inc. v. Chiron Corp.*, 27 F. App'x 94, 99-100 (3d Cir. 2002) (holding that, on a motion to dismiss, a court need not accept a plaintiff's allegations which are contradicted by properly considered documents). Moreover, even if Dr. Gupta's resignation was not amicable, Insmed's Form 8-K also demonstrates that she voluntarily left the company in the fall of 2014, before Insmed made the statements upon which Plaintiff relies in support of his securities claim. Thus, Plaintiff has also failed connect Dr. Gupta's resignation to the actions of the Individual Defendants; a finding of scienter on this basis, therefore, is inappropriate.[21] Plaintiff has failed to allege scienter.

Accordingly, because Plaintiff has failed to allege the elements of falsity and scienter, Plaintiff's § 10(b) claim (Count IV) is dismissed. Likewise, Plaintiff's

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[21] Plaintiff further argues that an inference of scienter has been pled, because Insmed, in response to the Day 120 Questions, conducted a *post hoc* analysis and narrowed Arikayce's target group of patients. Pl.'s Opp'n, at 26. The Court, however, declines to impute liability from Insmed's response to the EMA's commentary, because that allegation, without more, does not show that Defendants acted with a strong inference of scienter. Moreover, the Court notes an inconsistency in Plaintiff's argument; on one hand, Plaintiff maintains that the Day 120 Questions required Insmed to reanalyze the trial data under a new definition of culture conversion, but, at the same time, Plaintiff inconsistently contends that scienter is inferable from Insmed's *post hoc* analysis wherein a more stringent definition of culture conversion is utilized. In any event, Plaintiff's allegations, viewed collectively, do not establish that Insmed's response to the Day 120 Questions demonstrates scienter.

claim under § 20(a) of the Exchange Act (Count V) is also dismissed. *Mill Bridge V, Inc. v. Benton*, No. 8-2806, 2010 U.S. Dist. LEXIS 135375, at *71 (E.D. Pa. Dec. 21, 2010) ("Section 20(a) establishes a derivative cause of action in which liability 'is premised on an independent violation of the federal securities laws.'") (quoting *In re Rockefeller*, 311 F.3d at 211).

IV. The Securities Act

Plaintiff maintains that the registration statement and prospectus, filed in connection with Insmed's SPO, are in violation of §§ 11 and 12(a)(2) of the Securities Act. Pl.s Opp'n, 27-30. Plaintiff reasons that the prospectus, which incorporates the registration statement, contains three statements that are materially false or misleading, because Insmed omitted material information with respect to the Phase 2 Trial. *Id.* at 29. In particular, these statements relate to Arikayce's efficacy, safety and facilities wherein the drug is manufactured: (a) "Arikayce achieved statistical significance with regard to this secondary endpoint, with 11 out of 44 patients treated with Arikayce . . . demonstrating clearance of the infecting mycobacterial organism (culture negative) at day 84 of the study . . . ."; (b) We believe that Arikayce may provide: (i) improved efficacy . . . [and] (ii) decreased adverse events and improved tolerability as compared with amikacin delivered intravenously . . . ."; and (c) We believe that all facilities will meet [the current good manufacturing practices] requirements for the sterile manufacturing of finished Arikayce product. AC ¶¶ 89, 91, 93. The Court, however, finds that these statements are insufficient to support a claim under

the Securities Act, largely for the same reasons that Plaintiff's claims under the Exchange Act fail.

Under "Section 11 of the Securities Act, 15 U.S.C. § 77k," Congress "create[d] a private cause of action in cases in which a registration statement either contains an untrue statement of material fact or omits a material fact that is required or necessary to make the other statements therein not misleading. *Klein v. General Nutrition Cos.*, 186 F.3d 338, 342 (3d Cir. 1999). Similarly, "§ 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), creates a private cause of action against any person who offers or sells a security by means of a prospectus or oral communication which either contains an untrue statement of material fact or omits a material fact necessary to make the other statements therein not misleading." *Id.* Moreover, the Third Circuit has explained that the Securities Act requires "an undisclosed fact be material at the time of offering in order for liability to attach." *Id.* In that connection, the materiality requirement is satisfied where "'there is a substantial likelihood that a reasonable [investor] would consider [a fact] important in deciding how to [act].'" *Id.* (quoting *In re Trump*, 7 F.3d at 369).[22]

[22] As a threshold issue, Insmed contends that the heightened pleading standard of Rule 9(b) is applicable to Plaintiff's allegations under the Securities Act, because they are premised upon the same course of conduct in support of Plaintiff's claims under the Exchange Act. *See, e.g.*, Cal. *Pub. Emples'. Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 163 (3d Cir. 2004). Plaintiff, on the other hand, contends that his claims under the Securities Act sound in negligence, and, therefore, are subject to the less demanding pleading requirements of Rule 8, as set forth in *Twombly* and *Iqbal*. The Court, however, need not resolve this dispute on this motion, because Plaintiff's allegations, as further discussed *supra*, fail to

Here, the reasons as to why Plaintiff fails to state a legally sufficient claim under the Exchange Act are equally applicable to the claims brought under the Securities Act. Indeed, Plaintiff, once again, fails to adequately allege that Insmed was aware of the EMAs concerns, before making representations which Plaintiff challenges under the law. To begin, Plaintiff argues that the statements contained in Insmed's prospectus are actionable because it fails to disclose the following information: (a) "Insmed was utilizing an unreasonably expansive definition of culture conversion" which artificially inflated its true rate; (b) "[R]esidual amounts of Arikayce in patients' sputum samples likely interfered with culture results, leading to false culture conversions"; (c) "Insmed had not adequately studied or documented the possible advantages of using liposomal amikacin for inhalation" or that the "Phase 2 NTM Trial . . . raised serious concerns about the safety of the drug . . ."; and (d) "the product quality of Arikayce was unsatisfactory . . . ." AC ¶¶ 90, 92, 94. However, the prospectus, wherein these statements are included, was filed in March of 2015, before Insmed received the Day 120 Questions or the WAR was published. Significantly, Plaintiff does not identify, in the Amended Complaint, any other document or communication in which the EMA could have informed Insmed of these concerns. Plaintiff, therefore, has failed to adequately demonstrate that Insmed's statements in the prospectus were materially false at the time they were made.[23]

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support a legally valid claim under the Securities Act, even if Rule 8(b) pleading standard were applicable.

[23] Plaintiff, in a few conclusory sentences, argues that the Registration Statement "negligently omitted . . . existing issues with the trial, which . . . should

Nevertheless, Plaintiff argues that, "[e]ven if Defendants were somehow ignorant of [the aforementioned concerns], their knowledge is irrelevant to the Securities Act claims, which allege negligent omissions." Pl.s Opp'n, at 29-30. However, this contention is without merit, because, for one, the EMA's communications serve as the basis upon which Plaintiff argues that the prospectus is materially false by omission. *See* AC ¶¶ 90, 92, 94 (noting that the EMA made various determinations, with respect to Insmed's definition of culture conversion, in addition to Arikayce's efficacy, safety, and quality, which were required to be disclosed in the prospectus). Clearly, to succeed on this claim, Plaintiff must demonstrate that Insmed was aware of the content, as provided in the Day 120 Questions or WAR, before it filed the prospectus in March of 2015, or at the very least, that Insmed knew, internally, that the Trial 2 Phase had significant issues.

Additionally, more to the point, the challenged representations are protected by the PSLRA, because they constitute statements of opinion. *See* AC ¶¶ 91 ("We believe that Arikayce may provide . . . ."), and 93 ("We believe that all facilities will meet . . . ."). In order for liability to attach, therefore, Plaintiff must show that these opinions lack a reasonable basis by, for example, identifying

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have been discussed by Defendants pursuant to Item 503" of Regulation S-K. Pl.'s Opp'n, at 30. In particular, that provision requires a "discussion of the *most significant factors* that make the offering speculative or risky." 17 C.F.R. § 229.503(c) (emphasis in original). This is not sufficient to allege falsity. Assuming that a duty to disclose existed, Plaintiff has failed to adequately plead that Insmed was aware of any trial shortcomings, during the applicable time period, particularly since the Registration Statement was filed before the EMA's Day 120 Questions—the first communication alleged by Plaintiff wherein the agency expressed concerns with the trial.

evidence that contradicted Insmed's position before the prospectus was filed. Plaintiff has not made this showing here; accordingly, the Court finds that Plaintiff has failed to state a claim under §§ 11 and 12(a)(2) of the Securities Act. Those claims (Counts I and II) are dismissed. Likewise, Plaintiff's claim under § 15 of the Securities Act (Count III) is also dismissed. *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 533 (S.D.N.Y. 2005) ("There can be no secondary liability under section 15 unless a primary violation has been properly pled under section 11 or section 12" of the Exchange Act") (internal citation omitted)).[24]

[24] The parties also dispute whether: (a) Plaintiff's Securities Act claims are time barred; and (b) personal jurisdiction exists over named defendant Steinar J. Engelsen ("Mr. Engelsen"), a director of Insmed. I note that these arguments are made in short footnotes in the parties' briefings. Therefore, for the purposes of this motion to dismiss, the parties have failed to adequately address these issues, and the Court declines to discuss them here. Indeed, Plaintiff's claims are dismissed without prejudice. Should Plaintiff re-plead and Defendants move to dismiss for a second time, Defendants may assert these defenses with proper citations to the record and case law.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is **GRANTED**. Plaintiff's Complaint is dismissed **WITHOUT PREJUDICE**. Plaintiff is given leave to file a Second Amended Complaint within thirty days from the date of the Order accompany this Opinion, in accordance with the dictates of this Opinion.

DATED: February 15, 2018

/s/ Freda L. Wolfson
Freda L. Wolfson
U.S. District Judge