UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE DELCATH SYSTEMS, INC. SECURITIES LITIGATION	13 Civ. 3116 (LGS)
	OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Lead Plaintiff, the Delcath Systems Group, brings this putative class action on behalf of all persons or entities that purchased or otherwise acquired securities in Delcath Systems, Inc. ("Delcath" or the "Company"), from April 21, 2010 through and including September 13, 2013, seeking remedies under the Securities Exchange Act of 1934. Lead Plaintiff alleges that Defendants Delcath and its then CEO Eamonn Hobbs made material misrepresentations and omissions to shareholders, upon which Plaintiffs relied in purchasing Delcath stock. Defendants move to dismiss the Consolidated Complaint (the "Complaint") for failure to state a claim. Because the Complaint states a claim for relief under the Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder, the Motion to Dismiss is denied.

BACKGROUND

I. Facts[1]

Delcath is a specialty pharmaceutical and medical device company focused on oncology. Delcath common stock is listed on the NASDAQ. The Company had 17 employees at the end of 2009, 47 employees at the end of 2010, 80 employees at the end of 2011, and 92 employees at the end of 2012. The Company has directed all of its research efforts towards the development of

[1] For the purposes of this motion, all allegations in the Complaint are accepted as true, except as otherwise noted. The Court also considers statements or documents incorporated into the Complaint by reference, legally required public disclosure documents filed with the Securities and Exchange Commission, and matters of which the Court may take judicial notice. See Telllabs, Inc. v. Makor Issues & Rights, LTD, 551 U.S. 308, 322 (2007). Plaintiff incorporates by reference into the Complaint four analysts' reports: a Wedbush report from April 22, 2010, and three Cannacord reports from June 11, 2010, February 22, 2011, and April 12, 2011.

the "Melblez Kit," a device designed to administer high-dose chemotherapy and other therapeutic agents to treat metastatic cancer in the liver. The purpose of the Melblez Kit is to control the exposure of the high-dose therapies to the body, by isolating the circulatory system of the liver from the bloodstream, infusing the liver with melphalan, a chemotherapeutic agent, and then filtering it from the blood before returning the blood to the bloodstream. The system is intended to address the limitations of traditional treatments by permitting delivery of much higher doses of toxic treating agents to the liver while minimizing systemic exposure. The key to the Melblez Kit is the filter, which extracts the high dose of melphalan from the bloodstream in order to prevent severe side effects or death.

FDA approval is required before pharmaceuticals and devices may be marketed in the United States. The FDA requires rigorous testing to ensure that a drug is safe and effective for its intended use. Before considering approval of a drug, the FDA requires a sponsor to submit a New Drug Application ("NDA"), which contains data from clinical trials, preclinical studies, and manufacturing information that supports the product's safety and efficacy. 21 U.S.C. §355(b); 21 CFR 314.50(d). Clinical trials typically are conducted in three phases.

Phase I trials are conducted on a small number of patients to assess the tolerability and safety profile of the drug. Phase II clinical trials are conducted in a limited patient population afflicted with a specific disease in order to assess and evaluate the drug's appropriate dosages, safety profile, and preliminary efficacy. Phase III trials are large, controlled clinical trials, conducted on patients with a specific disease in sufficiently large numbers to allow the FDA to assess the efficacy and safety of the product. According to FDA regulations, the FDA must be notified no later than 15 days after the trial sponsor learns of a serious adverse experience ("SAE"), which includes any reaction that is fatal, life threatening, or that requires hospitalization.

During its Phase III trial of the Melblez Kit, Delcath used the "Clark filter," a different filter from the "Asahi filter" used during the Phase I and a portion of the Phase II testing. Before using the Clark filter in its Phase III clinical trial, Delcath had tested it in vitro -- so called "bench testing"-- but had not tested it on live subjects. In February 2010, Delcath concluded its Phase III study of the Melblez Kit. The Phase III trial was conducted under an FDA "Special Protocol Assessment" at medical centers throughout the United States. In the trial, patients were randomly assigned to one of two groups, the former receiving treatments using the Melblez Kit (the "Drug Group") and the latter control group, receiving the best alternative care, which included a doctor's choice of systemic, regional, or other appropriate therapy (the "Control Group"). Patients assigned to the Control Group were permitted to cross over into the Drug Group if they showed signs of disease progression. A majority of patients crossed over to the Drug Group. The goal, or "primary endpoint," of the study was to slow the progression of metastases in the liver. Secondary objectives included studying the response, safety, tolerability and overall survival rates for patients using the Melblez Kit.

Delcath filed an NDA with the FDA on December 22, 2010. On February 22, 2011, Delcath announced that it had received a "refusal to file" letter from the FDA, refusing to accept the NDA and requesting additional information "involving manufacturing plant inspection timing, product and sterilization validations and additional safety information." On August 15, 2012, the Company announced that it had refiled its NDA with the FDA. The revised NDA proposed using a third filter, called the "Generation 2" or "Gen 2" filter, replacing the Clark filter used in the Phase III trials, which had replaced the Asahi filter used in the Phase I and Phase II trials. The Generation 2 filter had not been clinically tested, but had been bench tested. On October 15, 2012, the Company announced that the FDA had accepted its revised NDA for review.

On April 30, 2013, the FDA published its staff briefing documents in advance of a May 2, 2013, meeting of the Oncologic Drugs Advisory Committee ("ODAC"). The briefing documents stated that 7% of Phase III participants treated with the Melblez Kit died, while none of the patients in the Control Group died, and stated that "[s]ubstantial and severe toxicity was identified in all three trials with a toxic death rate of 7%." The briefing documents also revealed that 24% of the patients in the Drug Group experienced serious side effects such as heart attack and acute kidney failure. They further stated that during the Phase III trial there was "an increase in the risk of serious and fatal toxicities . . . following device modifications involving the . . . filter . . . component." Upon the release of the briefing documents, Delcath shares declined over 40%.

The FDA documents also stated that "[n]o clinical trial data have been submitted to support the safety or efficacy of this device" and that "non-clinical studies . . . did not identify factors which caused the clinically important increase in toxicity seen in the Asahi-to-Clark transition. Therefore, these non-clinical studies are insufficient alone to safely bridge the marketing of a device containing a new filter, and clinical trial safety data are necessary to support an approval…" On May 2, 2013, the FDA staff met to discuss the Melblez Kit. One participant stated:

> The clinical benefit of this antitumor activity is uncertain in light of the trend toward overall survival detriment. We must remember that antitumor activity does not always translate into clinical benefit, which is really what defines efficacy. The risks of Melblez Kit treatment are substantial and life-threatening. . . .

Another participant said:

> []Melblez Kit treatment is associated with antitumor activity. But again, as we must always remember, activity does not always mean clinical benefit. Melblez Kit treatment is associated with fatal and life-threatening adverse reactions that occur despite careful patient selection and extensive pre- and peri-procedural steps to prevent these adverse reactions from happening.

The ODAC panel agreed with the FDA Staff's concerns. Dr. Mikkael Sekeres stated:

> What's concerning about the device is that we're also seeing what is potentially a detriment in overall survival advantage of 35 percent. And as FDA has pointed out, when you add up the toxic death rate along with serious adverse events, including cerebral vascular events, myocardial infarction, and acute renal failure, it totals 24 percent of patients who either die as a result of this therapy or who have very serious complications.
>
> So we have a progression-free survival advantage of 3 months. . . . We also have a risk of causing . . . very significant [] harm or even death in almost 25 percent of these people immediately. And is that an acceptable risk/benefit analysis? I can't imagine how I would sit down with a patient and walk them through this. . .

Another ODAC member added:

> Over here, quality of life . . . would be worse after the intervention than no intervention . . . . They might have lived for another several months. And in the end, you have reduced their lifespan by 35 percent across the board . . . [T]he option which we are offering to the patient is, we're going to make your quality of life much worse and . . . your risk is increased by 35 percent of dying before the nature disease does you in.

The ODAC panel voted unanimously, 16-0, against approving the Melblez Kit. Upon that vote, Delcath shares declined another 42%. On September 13, 2013, the FDA issued a Complete Response Letter rejecting the Melblez Kit without further testing.

II. Allegedly Misleading Company Statements

The Complaint identifies alleged misstatements and omissions that fall into two categories. The first category consists of overly optimistic statements regarding the likelihood of FDA approval for the Melblez Kit ("FDA Approval Statements"), primarily in light of the Phase III trial results and the Company's proposal in the 2012 NDA to use the clinically untested Gen 2 filter. The FDA Approval Statements include the following:

- On June 15, 2010, Mr. Hobbs answered "yes" to the question whether "progression free survival [rather than overall survival] primary end point [is] enough for potential FDA approval."

- On December 22, 2010, the Company announced the filing of its first NDA with the FDA, and said, "Priority review is granted by the FDA to those products that address significant unmet medical needs or have the potential to provide significant improvement compared to marketed products. With the strength of our Phase III data, we believe that our application meets the FDA's criteria for priority review."
- On March 14, 2011, Mr. Hobbs stated at a conference that, despite the FDA's refusal to file letter, the Company believed it was "in good shape to weather the current bump in the road that [it] received with the FDA, which amounts [it] believes to be a slight delay in FDA approval."
- On August 15, 2012, the Company press release again stated, "Based upon the strength of our Phase 1, 2 and 3 data, along with the limited treatment options available for patients with unresectable melanoma metastases in the liver, we believe that our application meets the FDA's criteria for priority review."
- The same August 15, 2012, press release stated, "We also believe including our Generation 2 filter in the CMC module represents the fastest regulatory review path for the Generation 2 system . . ."

The second group of alleged misstatements addresses the safety and efficacy of the Melblez Kit based on the Phase III trial data (the "Phase III Results Statements"). The statements are alleged to be misleading because Defendants praised the Melblez Kit as a treatment option, and touted the Phase 3 results in particular, but failed to disclose the toxicity shown in the Phase 3 results. Specifically, the Complaint alleges that Defendants failed to disclose that the Drug Group suffered (1) a 24% SAE rate, which was a higher rate than for other available treatments, and (2) a 7% mortality rate, which was a higher rate than that in the Control Group. The Phase III Results Statements include the following:

- On April 21, 2010, after the completion of the Phase III trial, but before submitting its first NDA, the Company issued a press release entitled "Delcath Phase III Trial Results Exceed Primary Endpoint Expectations." The press release stated, in part:

> Comparing treatment with the Delcath PHP System™ with melphalan to Best Alternative Care (BAC) . . . the statistical analysis revealed that the PHP patients had a statistically significant longer median [hepatic progression-free survival] of 214 days compared to 70 days . . . .

The April 21, 2010, press release also included the following statements by Mr. Hobbs:

> We believe that these data support that the Delcath PHP System may provide a significantly better treatment option for patients suffering from melanoma metastases in the liver…. With the treatment arm having a median [hepatic progression-free survival] of more than three-fold that of the control arm, we easily exceeded our expectations of clinical trial success.

- On June 5, 2010, the Company quoted Mr. Hobbs in a press release saying that the Phase III trial "supports our belief that chemosaturation via PHP has potential life-extending benefits as a treatment for patients suffering with terminal, metastatic disease in the liver."
- During a July 29, 2010, earnings call, Defendant Hobbs stated that the Company did a "deep dive" into its data and came away "very, very comfortable, even more comfortable that we had a very robust trial with excellent data."
- On September 23, 2011, the Company issued a press release stating that "12 months of data and extended survival for a significant percentage of the treated patients confirm our belief that chemosaturation may provide a significantly better option than the few treatments presently available . . . ."
- During a November 7, 2011, earnings call, Mr. Hobbs stated that "[b]ased on the new data that has been entered and monitored to-date, our team is gaining more and more confidence about the quality and quantity of the additional safety data being collected . . . ."
- In the Company's 2010 Form 10-K, filed on March 8, 2011, and in its 2011 and 2012 10-Ks,

the Company stated that "[t]he side effects caused by the drug used in our clinical trials, melphalan, are similar to the side effects associated with delivery of melphalan by traditional methods."

- In its Form 10-K for 2011, filed on March 6, 2012, the Company stated, "Our Phase III clinical trial demonstrated that the Delcath chemosaturation system is capable of extracting on average 72% of the chemotherapy agent administered to the liver."
- On March 13, 2013, the Company filed its 10-K for the year 2012, which stated that "[t]he chemotherapeutic agent remaining in the bloodstream after filtration is a fraction of the infused drug, resulting in manageable toxicities. . . ."

Documents submitted by Defendants that were publicly filed or relied upon in the Complaint contradict the Complaint and show that the Company did disclose the mortality rate and SAE rates in the Drug Group and that the investing public was aware of those disclosures. Defendants did not present evidence, however, to contradict the Complaint's allegations that Defendants failed to disclose: (1) that "the side effects caused by the Melblez Kit during the clinical trial . . . surpassed [those by] other available treatments" and; (2) that "none of the patients in the [Control Group] died." One physician on the ODAC panel stated that the level of toxicity experienced by patients in the Drug Group was "unprecedented as far as the amount of toxicity," in comparison to the amount of toxicity associated with "many therapies that do not have good options," which presumably were administered to those receiving the best alternative care in the Control Group. Another ODAC member expressed concern that the Melblez Kit caused "significant toxicity compared to the other available treatment in Europe and in United States."

III. Scienter

The Complaint alleges scienter based on inferences from the facts summarized above. The Complaint also includes alleged statements made by confidential witnesses about the Company's decision not to test the Gen 2 filter on humans before proposing it to the FDA as the Melblez Kit filter in the 2012 revised NDA. Confidential Witness One ("CW1") was a research development technician at Delcath from 2010 to 2013. He stated that employees from the Quality and Regulatory departments expressed frustration to CW1 that Defendant Hobbs did not conduct additional trials using the Gen 2 filter prior to submitting the NDA to the FDA. CW1 further stated that internal regulatory staff recommended that additional trials be undertaken on the Gen 2 filter, but that management would not consider it and "tried to pull a fast one over the FDA."

Confidential Witness Two ("CW2") was a Senior Director of Global Reimbursement and Health Economics for Delcath from May 2010 to April 2011. CW2 worked at the New York headquarters and reported to the Executive Vice President ("EVP") of Global Sales, who, in turn, reported to CEO Hobbs. CW2 told a number of EVPs that the Company should conduct additional trials using the Gen 2 filter, but was told by the EVP of Regulatory Affairs that CW2 would have to raise the issue with Defendant Hobbs because "everything we did had to get the CEO's blessing."

Confidential Witness Three ("CW3") was a Senior Manager of Regulatory Affairs at Delcath from March to October 2012. CW3 stated that the Company should have conducted a new trial to test the Gen 2 filter because it was such a substantial change, but that Defendant Hobbs would not agree given the cost and time required. CW3 also said that Hobbs would not want to conduct a new trial for fear of investor reactions. Confidential Witness Four ("CW4") expressed similar concerns about the decision not to test the Gen 2 filter on humans.

IV. Defendants' Cautionary Statements

Defendants' 10-K filings with the SEC included page-long warnings about the risk of FDA approval. Those cautionary statements fell under the heading "Risks Related to FDA and Foreign Regulatory Approval" and disclosed the risk that the FDA may not "deem [the] product candidate to be adequately safe and effective," may not "find the data from preclinical studies . . . and clinical trials to be sufficient to support a claim of safety and efficacy," and that the FDA may "interpret data from preclinical studies . . . and clinical trials significantly differently than [the Company did]." On a conference call with investors on May 8, 2012, Mr. Hobbs also disclosed the various risks to FDA approval of the Gen 2 filter in the NDA, stating that while the Company hoped for speedy approval, the FDA could say, "We will require additional clinical data for Gen Two approval. . ." Mr. Hobbs further added that it would be "counterproductive to even venture a guess which way the FDA is going to go."

V. Reliance and Loss Causation

Plaintiff purchased Delcath stock between April 21, 2010 and September 13, 2013. The price of Delcath stock fell from to $1.39 to $.832 per share when the FDA released its briefing materials on April 30, 2013. The price fell to $.4443 on May 3, 2013, one day after the ODAC voted 16-0 against approval of the Melblez Kit. Delcath shares fell to $.34 per share on September 13, 2013, after Mr. Hobbs had been terminated and the FDA issued its Complete Response Letter rejecting the Melblez Kit. The Complaint alleges that Lead Plaintiff, in purchasing shares of Delcath on the NASDAQ, relied on the allegedly misleading statements and omissions made by the Defendants.

LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(6), "[t]o survive a motion to dismiss, a complaint must plead 'enough facts to state a claim to relief that is plausible on its face.'" ECA,

Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 196 (2d Cir. 2009) (quoting Ruotolo v. City of New York, 514 F.3d 184, 188 (2d Cir. 2008)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

To allege a violation of Section 10(b) and Rule 10b–5, a plaintiff must plead the elements of the claim: "(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . .; (5) economic loss; and (6) loss causation[.]" Kleinman v. Elan Corp., 706 F.3d 145, 152 (2d Cir. 2013).

"Any complaint alleging securities fraud must satisfy the heightened pleading requirements of the PSLRA and Fed. R. Civ. P. 9(b) by stating with particularity the circumstances constituting fraud." ECA, Local 134, 553 F.3d at 196. "A securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). Allegations of fraud may be "too speculative even on a motion to dismiss," particularly when premised on "distorted inferences and speculations." Id. at 104 (internal quotation omitted).

"The PSLRA expanded on the Rule 9(b) standard, requiring that 'securities fraud complaints specify each misleading statement; that they set forth the facts on which [a] belief that a statement is misleading was formed; and that they state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Anschutz Corp. v. Merrill Lynch & Co., 690 F.3d 98, 108 (2d Cir. 2012) (alteration in original) (quoting Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 345 (2005)). "To prove liability against a corporation, of

course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation." Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 195 (2d Cir. 2008).

DISCUSSION

The issue on this motion is whether the Complaint sufficiently pleads three of the six elements of securities fraud, namely, a material misrepresentation or omission, scienter and loss causation. The Complaint is sufficient as to the Phase III Results Statements. The Complaint is not sufficient, however, as to the FDA Approval Statements, because those statements were future oriented, statements of corporate optimism, and therefore were not false and misleading.

I. Material Misrepresentations or Omissions

A. Phase III Results Statements

A statement or omission is materially misleading when there is "a substantial likelihood that the disclosure of the omitted [or corrected] fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available" to the market. Matrixx Initiatives, Inc. v. Sircusano, 131 S. Ct. 1309, 1318 (2011) (internal quotations omitted). "[It] bears emphasis that § 10(b) and Rule 10b–5 do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements [] made, in the light of the circumstances under which they were made, not misleading." Id. at 1321 (internal quotations omitted). The "total mix" standard "does not mean that pharmaceutical manufacturers must disclose all reports of adverse events." Id. "The question remains whether a reasonable investor would have viewed the nondisclosed information as having significantly altered the total mix of information made available." Id. (emphases in original) (internal quotations omitted).

The Complaint sufficiently alleges two material omissions that caused at least some of the Phase III Results Statements to be misleading until the FDA disclosed the missing facts in their briefing documents on April 30, 2013. First, the Company disclosed data regarding the number and percentage of SAEs in the Drug Group, but did not disclose comparable information for the Control Group.[2] This omission, combined with the statement that the Melblez Kit caused side effects "similar" to those caused by traditional treatment methods, is sufficient to allege that investors were misled about the safety of the Company's product. Second, the Company disclosed the 7% mortality rate from treatment in the Drug Group, but not that there were zero deaths from treatment in the Control Group. This omission also is sufficient to allege that investors were misled about the safety of the Melblez Kit. The alleged omissions were materially misleading because, based on the allegations in the Complaint, there was a substantial likelihood that the disclosure of the data "would have been viewed by the reasonable investor as having significantly altered the total mix of information made available" to the market. Matrixx Initiatives, 131 S. Ct. at 1318.[3] (internal quotations omitted).

Pharmaceutical companies need not disclose "isolated reports of illnesses suffered by users." In re Carter–Wallace, Inc. Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998). Thus, in Kleinman, the Second Circuit held that defendant's failure to disclose a fact about "dose response" was not misleading when defendant had not previously made any statements about dose response. 706 F.3d at 153-54. However, when a pharmaceutical company makes

[2] Given that investors knew the number of participants in the Drug Group, the fact that the Company did not use the precise 24% calculation employed by the FDA is unimportant to this discussion, as investors were able to analyze the rates of specific SAEs on their own.

[3] The Complaint also asserts that Defendants made a material omission in failing to disclose the reason it included the Gen 2 filter in its NDA, namely, that "the Clark filter had clearly failed to generate approvable results." The Clark filter was used only in the Phase III trials. Thus, the alleged failure to disclose the comparable rates of mortality and SAEs in the Drug Group and Control Group also could be described as an alleged failure to disclose that the Phase III trial failed "to generate approvable results." Accordingly, statements regarding the inclusion of the Gen 2 filter are considered as part of the Phase III Trial Statements and omissions.

statements about its product, the company is required to disclose information that would render those statements not misleading. See City of Livonia Employees' Ret. Sys. v. Wyeth, 07 Civ. 10329, 2010 WL 3910265 (S.D.N.Y. Sept. 29, 2010) (finding that the Plaintiff adequately alleged that omissions were material where SAEs were not reported).

Defendants suggest that the Control Group mortality data was not misleading or that it was immaterial since Defendants disclosed the 7.5% mortality rate in the Drug Group, which was within the range for the FDA-approved drug melphalan of 3% to 10%. However, at this stage of the litigation, Defendants' truthful but allegedly incomplete disclosures were misleading, because the Complaint alleges that insufficient facts were disclosed to allow a reasonable investor to make an accurate assessment of the disclosures that were made. "Statements of literal truth can become, through their context and manner of presentation, devices which mislead investors." Kleinman v. Elan Corp., 706 F.3d at 153 (internal quotation marks and citation omitted).

Defendants similarly argue that the FDA, and therefore Plaintiffs, place undue weight on the significance -- i.e., the materiality -- of the omitted facts. The allegedly omitted facts about the relative toxicity of Defendants' product, however, were critical to the FDA's conclusion that the risk of harm outweighed the potential benefit of the Company's product, and that it should not be approved. Defendants seem to argue that this is a misinterpretation of data akin to that in Kleinman. The court in Kleinman held that the failure to disclose plaintiff's alleged characterization of the control group was not actionable when defendant's competing interpretation was reasonable. Id. at 154. The Court also held that disagreement with the method of statistical analysis applied to data gathered from a trial does not render statements misleading. Id. at 154-55. The defendant in Kleinman disclosed the negative data at issue, and then attempted to explain it away by applying statistical analysis the plaintiff believed was misleading.

The allegations here do not involve differing interpretations of disclosed data, but rather data that was not disclosed. Defendants' alleged omissions more closely resemble the failure to disclose adverse events in Matrixx than the failure to disclose differences in methodology and interpretation in Kleinman. In Matrixx, the company made positive statements about projected revenue growth, which, assuming the facts in the complaint to be true, were misleading without disclosures about adverse events caused by the company's leading drug. Matrixx, 131 S. Ct. at 1323. Similarly here, Defendants made statements about their Phase III trial results, which given the allegations in the Complaint, were misleading without the disclosure of additional facts that would cast those results in a more negative light.

Defendants argue that they sufficiently disclosed significant risks of SAEs for patients receiving melphalan with the Melblez Kit by disclosing that SAEs in the Drug Group were "similar" to those experienced by patients treated with melphalan by "traditional means." This argument is incorrect. Defendants' statement potentially gave the false impression that not only the types of side effects, but also the rates of SAEs, were similar for the two groups and potentially misled investors.

B. The FDA Approval Statements

The Complaint alleges that the Company made misstatements about the likelihood of FDA approval. The FDA Approval Statements are not actionable under the PSLRA's "safe harbor provisions" and the judicially created "bespeaks caution" doctrine, because no reasonable investor could have been misled into thinking that the risk of FDA's denial did not exist. The alleged omission regarding the Gen 2 filter is not actionable, because the Company adequately disclosed the relevant information regarding inclusion of the Gen 2 filter in the NDA and the risks involved with its inclusion.

Under the PSLRA safe harbor, forward-looking statements that are identified as such, and "accompanied by meaningful cautionary statements," are not actionable. 15 U.S.C. § 78u—5(c)(1)(A)(i). Under the bespeaks caution doctrine, "alleged misrepresentations . . . are [deemed] immaterial as a matter of law [if] it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language. . . ." Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 357 (2d Cir. 2002). Moreover, "expressions of puffery and corporate optimism do not give rise to securities violations." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004). To determine whether cautionary language is meaningful, courts must first "identify the allegedly undisclosed risk" and then "read the allegedly fraudulent materials -- including the cautionary language -- to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." Halperin, 295 F.3d 352 at 359.

The FDA Approval Statements here are not actionable because they were forward-looking statements that fall within the safe harbor provision. The Company consistently gave warnings that the FDA might not approve the Defendants' product, and no reasonable investor could have believed that there was no risk in this regard. See id. The fact that the Defendants were wrong about obtaining FDA approval does not make the FDA Approval Statements actionable. See City of Livonia, 2010 WL 3910265, at *5. The FDA Approval Statements did not express certainty of approval. They expressed only the belief that the FDA would approve the Melblez Kit based upon the data.

Plaintiff argues that the FDA approval statements were boilerplate warnings of general risk factors that investors ignore. Nevertheless, a defendant that makes specific cautionary statements, such that no reasonable investor would have been misled about the nature of the risk, is not liable when that risk materializes, contrary to the defendant's optimistic statements.

Halperin, 295 F.3d 352 at 359. Defendants here consistently disclosed that the FDA may not "deem [the] product candidate to be adequately safe and effective," may not "find the data from preclinical studies . . . clinical trials to be sufficient to support a claim of safety and efficacy," and that the FDA may "interpret data . . . significantly differently than [the Company did]." The Company also adequately disclosed inclusion of the Gen 2 filter in the NDA, and the accompanying risks of the inclusion, on a conference call with investors, stating in detail that the FDA could deny approval for the Gen 2 filter for lack of clinical testing. Defendants, therefore, adequately disclosed the possibility of a risk that materialized when the FDA denied approval of the Melblez Kit.

II. Scienter

The PSLRA requires a plaintiff to "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)(A). "This standard requires courts take into account 'plausible opposing inferences.'" Matrixx, 131 S. Ct. at 1324 (quoting Tellabs, 551 U.S. at 323). A complaint sufficiently pleads scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. In this Circuit, a plaintiff may satisfy the scienter requirement by alleging facts that show either that "the defendants had both motive and opportunity to commit the fraud" or that offer "strong circumstantial evidence of conscious misbehavior or recklessness."[4] ATSI, 493 F.3d at 99.

[4] The Complaint fails to allege scienter under a theory of motive and opportunity, because there are no allegations that Defendants possessed unique motives not shared by all insiders of corporations. "[M]otives possessed by virtually all corporate insiders, including . . . the appearance of corporate profitability, or of the success of an investment, . . . the desire to maintain a high stock price in order to increase executive compensation, . . . or prolong the benefits of holding corporate office" are not sufficient to support an inference of scienter. Novak, 216 F.3d at 307 (Internal citations omitted). Instead, plaintiffs must allege that "defendants benefitted in some concrete and personal way from the purported fraud." Id. at 307-08. The Complaint alleges no such concrete and personal benefit.

The Complaint satisfies the second test, sufficiently alleging that Defendants consciously or recklessly failed to disclose data about the SAEs and mortality in the Control Group. "At least four circumstances may give rise to a strong inference of scienter[.]" The one that is relevant here is where a complaint sufficiently alleges that the defendants "knew facts or had access to information suggesting that their public statements were not accurate." ECA, Local 134, 553 F.3d at 199 (internal quotation omitted).

The Complaint alleges facts that would allow a reasonable person to infer scienter at least as compelling as any opposing inference. Plaintiffs can plead conscious misbehavior or recklessness by "alleg[ing] defendants' knowledge of facts or access to information contradicting their public statements." Novak, 216 F.3d at 308. Delcath was a small company that focused on the production of just one product, the Melblez Kit. Approval of that product by the FDA turned on the product's performance in clinical trials, particularly the broad based Phase III trials. The Confidential Witnesses stated that all decisions came from Mr. Hobbs, who was the Company's CEO. The Company's press releases and Mr. Hobbs' public statements evinced a familiarity with the data in the trials, including comparative data between the Drug Group and the Control Group. For example, Mr. Hobbs compared the two groups when discussing hepatic progression-free survival, stating that the Drug Group had a more than three-fold increase in hepatic progression-free survival as compared with the Control Group. Also, the Company proposed a new and relatively untested filter, the Gen 2 filter, in its revised NDA, rather than the Clark filter used in the Phase III trials, suggesting that Defendants knew that the results of its Phase III trials were not as strong as they represented in public statements. These allegations taken together raise a strong inference that Mr. Hobbs and the Company knew and/or had access to facts that contradicted their public statements regarding the safety of the Melblez Kit and the results of the Phase III trial. Accord, e.g., In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y.

2008) aff'd sub nom. State Universities Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404 (2d Cir. 2009) (strong inference of scienter from allegations that management "is reckless in dealing" with facts that "will necessarily prevent the regulatory approval or the marketing of the drug"); In re Pfizer Inc. Securities Litig., 584 F. Supp. 2d 621, 639-640 (S.D.N.Y. 2008) (allegations that defendants knew negative results of clinical studies were sufficient to allege strong inference of scienter).

Defendants argue that the Complaint at most alleges that Defendants knew of the omitted facts, but that the relevant inquiry for scienter is whether the danger of misleading investors was "so obvious that any reasonable man would be legally bound as knowing." City of Phila. v. Fleming Co., 264 F.3d 1245, 1260 (10th Cir. 2001) (internal quotations omitted). That is not the standard in the Second Circuit, which requires a plaintiff to allege that a defendant "knew facts or had access to information suggesting that their public statements were not accurate." ECA, Local 134, 553 F.3d at 199 (internal quotation omitted).

Defendants also argue that they did not have the requisite state of mind and that there is no strong inference of scienter where management honestly believes its positive view of the data from its trials, even though the FDA may have had a different interpretation. See AstraZeneca, 559 F. Supp. 2d at 470. The Complaint, however, raises a strong inference that Mr. Hobbs and the Company were at least "reckless" with regard to the omitted data. See id. ("There is also scienter if the management is reckless in dealing with . . . adverse facts."). While the FDA's disagreement with management's interpretation of data does not create a misstatement on the part of management, the disagreement may help support a strong inference of scienter. Here, the extreme negativity of the FDA and ODAC statements regarding the Phase III trial results supports, along with other allegations, that Defendants were reckless. See Novak, 216 F.3d at

308 (holding that "an egregious refusal to see the obvious, or to investigate the doubtful, may in some cases give rise to an inference of recklessness" (internal quotation and alteration omitted)).

III. Loss Causation

The Complaint adequately alleges loss causation. To plead loss causation, a plaintiff must allege that it purchased securities at an inflated price and that the price dropped once the fraud became known. See Acticon AG v. China N. E. Petroleum Holdings Ltd., 692 F.3d 34, 40 (2d Cir. 2012). The Complaint alleges that when the FDA disclosed the increased mortality and SAE rates in the Drug Group as compared to the Control Group on April 30, 2013, Delcath's stock price dropped from $1.39 to $.832 per share, and that on May 3, 2013, one day after the ODAC panel voted against approval of the Melblez Kit, Delcath's stock price dropped further to $.4443. Defendants argue that it was the FDA's rejection of the Melblez Kit and not the alleged fraud that caused the stock price to drop. This is a factual argument for a later day and does not diminish the sufficiency of the Complaint.

IV. Section 20(a) Violation

To state a claim for control person liability under Section 20(a) of the Securities Exchange Act, a plaintiff must show "(1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful sense a culpable participant in the primary violation." Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir. 1998) (internal quotations omitted). Defendants' main argument for dismissal of this claim is that, if the primary claim fails, so too must the secondary liability claim. As the Court has denied Defendants' Motion to Dismiss Plaintiff's Section 10(b) claim, and the Plaintiff has otherwise adequately alleged a control person violation, the Motion to Dismiss Plaintiff's Section 20(a) claim is denied.

CONCLUSION

For the reasons state above reasons, the Defendants' Motion to Dismiss is DENIED. The Court will issue a separate order to schedule a conference. The Clerk of the Court is directed to close the motion at Docket No. 58.

SO ORDERED.

Dated: June 27, 2014
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE