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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

GARY ZAGAMI, Individually and on Behalf of all Others Similarly Situated, Plaintiff,	Case No. 1:15-cv-7194 (KPF) MEMORANDUM OF LAW IN OPPOSITION TO MOTION TO DISMISS
v.	JURY TRIAL DEMANDED
CELLCEUTIX CORPORATION, LEO EHRLICH, AND KRISHNA MENON,	
Defendants.	

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I. <u>INTRODUCTION</u>

Cellceutix Corporation ("Cellceutix") is a development stage biotech company. Because it has no revenues, Cellceutix needed to constantly raise funds and convince investors that it was worth investing in. Defendants chose to do this with lies. Defendant Krishna Menon has a long history of fabricating his resume. Before the class period he falsely claimed to be involved in the development of two blockbuster drugs. He falsely claimed to be the sole inventor, rather than joint inventor, of the drug Kevetrin. He falsely claimed that two prominent scientists were on Cellceutix's advisory board. He falsely claimed to have a PhD from Harvard, a lie which he continued to make during the class period.

During the class period, new lies accumulated. Defendants lied about their Phase 1 trial for Kevetrin, misconstruing their results to portray Kevetrin as a "home run" and falsely claiming to have successfully treated a Stage 4 cancer patient. Defendants purchased the rights to Brilacidin and lied about that drug as well, exaggerating its effectiveness beyond what the science supported. Moreover, when Defendants acquired the rights to Brilacidin, they did not disclose to shareholders the serious risks that the purchase entailed, risks arising from the fact that 1) Defendants had no experience with Phase 3 trials and 2) the Phase 3 trial drastically increased Cellceutix's financing needs.

Defendants were finally called out on their lies by the short seller Mako Research. Defendants have responded by blaming everybody but themselves. They claim that Mako is part of a conspiracy to manipulate the price of Cellceutix stock. Defendants attempted to blame Plaintiff, arguing that by filing a complaint, Plaintiff drove down the price of Cellceutix stock. But Defendants cannot escape the simple fact that their stock declined because their lies were exposed.

II. <u>FACTS</u>

A. Background

Cellceutix purports to be in the business of developing innovative small molecule therapies to treat diseases with significant medical need, particularly in the areas of cancer and inflammatory disease. \P^1 18. Cellceutix was founded as EconoShares, Inc. on August 1, 2005. \P 19. On December 6, 2007 the Company acquired Cellceutix Pharma, Inc., which was founded, and owned, by Menon. *Id.* The company then changed its name to Cellceutix Corporation. *Id.* Cellceutix began development of an anti-cancer medication called Kevetrin. Kevetrin is intended to activate the gene P53. *Id.* P53 is involved in regulating cell duplication, and mutations in P53 are a common cause of cancer. *Id.* In September of 2013, Cellceutix acquired the assets of Polymedix, a bankrupt biotech company. *Id.* Among those assets were the rights to develop Brilacidin, an antibiotic, which was in Phase 2 of development at the time of Polymedix's bankrupty. *Id.*

Defendant Krishna Menon ("Menon") served as President of Cellceutix Pharma since inception in June 2007. ¶14. Following the Company's acquisition of Cellceutix Pharma in 2007, Dr. Menon served as President, Chief Scientific Officer and a director of the Company. Additionally, he serves as Chairman of the Board of the Company. *Id.* Dr. Menon, simultaneously therewith, also serves as the Chief Operating Officer at Kard Scientific, Inc. *Id.* Menon originally trained as a veterinary surgeon. Menon has also simultaneously worked for Nanoviricides, Inc., as Chief Regulatory Officer, from 2006 to the present. *Id.* Defendants failed to disclose Menon's employment with Nanoviricides in the 10-Ks filed throughout the class period. *Id.* In 1982, Menon began working at the Dana Farber Cancer Research Institute. ¶15. From 1985 to 1990, Dr. Menon was a Research Scientist at Dana Farber Cancer Research Institute. *Id.* He then worked as a Senior

¹ Unless otherwise indicated, references to ¶_ refer to the Second Amended Complaint.

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Research Scientist at In Vivo Research (Cancer), at Bayer Pharmaceuticals (Miles Laboratories) until 1993. *Id.* Dr. Menon then began a veterinary oncology and drug development consultancy practice at Eli Lilly, and one year later, became a Group Leader, Cancer In Vivo Research and Clinical Development, for Eli Lilly, where he worked in 2001. *Id.* Menon earned a PhD in Pharmacology from Kerala University, where his work focused on anti-folate therapy of various cancers. *Id.*

Defendant Leo Ehrlich ("Ehrlich") has served as the Company's Chief Executive Officer since November 5, 2010, as well as a director and CFO of Cellceutix, roles he assumed after the acquisition by Cellceutix of Cellceutix Pharma in December 2007. Id. Prior to Cellceutix's acquisition of Cellceutix Pharma, Ehrlich served as Chief Financial Officer of Cellceutix Pharma since its inception in June 2007. Id. From September 1999 to December 2008, Ehrlich served as a director of StatSure Diagnostic Systems, Inc. Id. From September 1999 to March 2005, Ehrlich was CEO of StatSure. Id. From September 1999 to March 2005, Ehrlich was also Chairman of the Board of StatSure. Id. Mr. Ehrlich was also CFO of StatSure from September 1999 to at least November 2008. Id. StatSure, which developed tests for HIV, ran large and unsustainable deficits for several years, but managed to achieve a market capitalization of over \$100 million, before defaulting on its debts in 2005. Id. The company narrowly avoided being forced into bankruptcy, but remained in default on its debts through 2008, when, with the value of its stock reduced to 30 cents per share, and its market capitalization down to \$1.2 million, it withdrew its registration with the SEC. Id. Defendants disclosed that Ehrlich was a director of StatSure, but never disclosed that he was CFO during the period of StatSure's default and dramatic decline in value. Id. Mr. Ehrlich previously practiced as a Certified Public Accountant and received his BBA from Bernard Baruch College of the City University of New York. Id.

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Cellceutix began a Phase 1 trial for Kevetrin on October of 2012, that is estimated to be complete in August of 2016. ¶20. Cellceutix also completed a phase IIb study of Brilacidin, which began in February of 2014 and ended in October of 2014. *Id.* This study compared Brilacidin with Daptomycin for the treatment of acute bacterial skin and skin and skin structure infection caused by the bacterium Staphylococcus. *Id.* Cellceutix also began a phase II study for the use of Brilacidin for the treatment of Oral Mucositis, an atrophying of the mucosal lining of the mouth due to chemotherapy or radiation. *Id.* Cellceutix has claimed that Brilacidin's antibacterial and anti-inflammatory properties contribute to the efficacy of Brilacidin in treating oral mucositis. *Id.* The phase 2 Oral Mucositis study began in May of 2015 and will end in December of 2016. *Id.*

Cellceutix participated in an "end of phase 2" meeting with the FDA in July of 2015 regarding Brilacidin for treatment of acute bacterial skin and skin structure infections or "ABSSSI". ¶21. At that meeting Cellceutix discussed the procedures for a Phase 3 trial. Defendants did not disclose this fact at the time, but instead included the disclosure in its 10-K at the end of the class period in September 2015. *Id.* At that meeting, the FDA instructed Cellceutix that to obtain approval for Brilacidin, it would be required to perform two phase 3 trials with a total of 1240 patients. ¶48. This would likely cost Cellceutix nearly \$150 million.

B. <u>Wrongful Conduct</u>

1. Menon Lied About his Education

Menon has had a habit of falsely claiming to have received a PhD from Harvard. Prior to the Class period, Defendants' 10-K for the year ending June 30, 2009, dated October 8, 2009 falsely claimed that Menon received a PhD from Harvard. ¶24. On May 10, 2013, *Future Woman* published a profile article on Defendant Menon, for which he was interviewed. ¶22. In the article, Defendant Menon confirmed earning his PhD in Pharmacology from Harvard University. *Id*.

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Indeed, Menon falsely stated for the article: "Tom made Menon a scientist at his laboratory in Harvard. But as per Harvard's law, one should have doctorate to work there. As Menon didn't have a PhD, it was a major challenge before him. But Tom was not ready to give up. He admitted Menon as a PhD student under his guidance. And it's the time for Menon to act. He took his first PhD in pharmacology in 34 months." *Id.* Menon, in fact, never received a PhD from Harvard.

2. Defendants Exaggerate the Antibiotic Properties of their Drug Brilacidin.

During the class period, Defendants claimed that their drug Brilacidin could treat the difficult to treat "gram negative" bacteria, and could be used as an antibiotic oral rinse to treat oral mucositis. Between April 25-28 2015, Defendants displayed a poster at the 2015 European Congress of Clinical Microbiology and Infectious Diseases ("ECCMID") in Copenhagen, Denmark, which touted Brilacidin's ability to kill gram-negative bacteria such as Escherichia coli ("E. coli"). ¶25. The poster states in part that "Brilacidin has potent Gram positive activity [and] gram negative coverage". Id. In Defendants' Form 10-K for the fiscal year ending June 30, 2014, filed September 15, 2014, Defendants stated "Brilacidin and related compounds have shown antibacterial, anti-biofilm and anti-inflammatory properties in various pre-clinical studies [of oral mucositis]. We believe that the combination of these attributes contribute to the efficacy of Brilacidin in these animal models." ¶27. This statement was repeated in Cellceutix's 10Q dated November 10, 2014, filed September 30, 2014, Cellceutix's 10Q dated February 9, 2015, for the period ending December 31, 2014, and Cellceutix's 10Q dated May 11, 2015 for the period ending March 31, 2015. Id. In fact, Defendants later admitted that Brilacidin could not treat gram negative bacteria, and Brilacidin's antibiotic properties were not effective in treating oral mucositis.

3. Defendants Overhype the Prospects of Kevitrin

During the class period Kevetrin was in the very early stages of development, Phase 1 of the FDA process. According to the National Institute of Health's FAQ on clinical trials, in a Phase 1 trial "[r]esearchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects." Declaration of Jonathan Stern, Exhibit 3. Thus, Phase 1 trials are not meant to test efficacy. In order to determine whether the drug was having any effect at all, however, the Kevetrin trial measured whether Kevetrin treatments of different amounts were associated with the activation of a protein called P21. Defendants, however, could not resist the opportunity to prematurely overhype Kevetrin. They claimed that activation of P21 would reveal that Kevetrin was treating cancer. Ehrlich claimed that if P21 activation occurs "we think that we have hit a home run." ¶30. Defendants also repeatedly referred to P21 as a biomarker. ¶31-32. However, this is a misleading phrase because the term "biomarker" in a clinical trial refers to a surrogate to a clinically meaningful outcome. ¶34. Thus, by claiming that P21 activation was a biomarker, Defendants were not merely suggesting that Kevetrin was having an effect, but that it was effectively treating cancer. Defendants also claimed during the class period that they had essentially eliminated the tumor of a Stage 4 ovarian cancer patient. ¶35. In reality, however, that patient's treatment was discontinued by their doctor after tests indicated that the cancer returned. ¶36.

4. Defendants hid the Massive Risks created by Purchasing the rights to Brilacidin

On September 9, 2013, the Company issued a press release announcing the purchase of Brilacidin from PolyMedix, Inc. pursuant to an asset purchase agreement approved by the Bankruptcy Court for the District of Delaware. ¶37. However, in the 10-K dated September 30,

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2013, there was no disclosure that the acquisition of Brilacidin created a new material risk of Cellceutix's inability to fund expensive clinical trials to get Brilacidin through FDA approval, nor were such risks ever disclosed during the class period. Id. In reality, this purchase created two new substantial material risks, both due to the fact that Brilacidin was close to completing Phase II and entering Phase III of the FDA approval process. Id. First, Brilacidin massively increased the need for fundraising in the short term. Id. Defendants spent \$632,805 and \$1,509,881 for research and development expenses, in the fiscal years ending June 30, 2012 and 2013, respectively. Id. However, to obtain Phase III approval for Brilacidin, Cellceutix will be required to spend well in excess of \$100 million in research and development expenses over two to four years to complete the two phase 3 trials necessary for FDA approval. This will require greatly increased fundraising by Cellceutix, which it is unlikely to be able to complete. Id. Defendants disclosed, in their 10-K for the period ended June 30, 2015, filed September 11, 2015, that the FDA is requiring them to conform to its October 2013 guidance regarding approval for ABSSSI treatments. Id. This guidance indicates that, in order to obtain approval, Cellceutix would be required to perform two large Phase III trials. Id. In the FDA's example, these two trials would require 310 persons in each branch of a two branch trial, for 1240 individuals recruited in total. As Cellceutix admitted, in an article published by the Boston Business Journal on October 30, 2015, they will be recruiting 1400 patients for their two Phase 3 trials. By contrast, Cellceutix has only completed two clinical trials to date, with a total of 233 subjects. For purposes of comparison, Durata Pharmaceuticals recently obtained approval for Dalbavancin, an antibiotic to treat ABSSSI. Id. Dalbavancin is very similar to Brilacidin and if Brilacidin were ever approved, Dalbavancin would directly compete with it. Id. The approval process for Dalbavancin, including the phase 3 clinical trials required, was substantially the same as that required by the FDA for the approval of Brilacidin. Durata, which

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had no ongoing projects other than developing Dalbavancin, spent \$145,605,000 over four years developing dalbavancin, using two Phase 3 studies with a total of 1312 subjects. *Id.* Since its inception in 2007, Cellceutix has not been able to raise more than approximately \$30 million from investors in total. Defendants concealed the costs required to develop and obtain approval for Brilacidin and the substantial risk that Cellceutix will not be able to persuade investors to fund the \$145 million required to complete Brilacidin's phase 3 trials. *Id.*

Defendants also failed to disclose the material risk of their undertaking a Phase 3 study because none of Defendants' officers had experience in obtaining Phase 3 approval, until admitting to it in the Form 10-K filed September 11, 2015, when they stated that "[w]e have not previously conducted a Phase 3 or later stage clinical trial such as the Phase 3 clinical trials planned for our most advanced drug candidate." ¶38. This omission was material and should have been disclosed in Defendants 10-Ks that were filed in September of 2013 and 2014 because Defendants inexperience with Phase 3 trials raised a material risk with respect to the hiring of personnel, Defendants' ability to realistically budget for, and manage, the clinical trials, the likelihood of future investors agreeing to raise capital, and whether Defendants would make mistakes in the drug development process due to their inexperience. *Id.*

C. <u>The Truth is Revealed</u>

On August 6, 2015, *SeekingAlpha.com* published a report by the short seller Mako Research on the Company ("Mako Report"). ¶39. The Mako Report asserts that Defendant Menon did not earn his PhD in Pharmacology at Harvard University as claimed. ¶40. The Mako Report asserts that Brilacidin is not effective in treating gram negative bacteria. ¶41. The Mako Report also asserts that P-21, being used to evaluate the effectiveness of Kevetrin, is not a valid biomarker, noting that recent evidence has shown that P21 activity does not correlate with cancer prognosis.

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¶42. The Mako Report went on to state that "Cellceutix has made misleading claims about cancer regression from patients who discontinued the trial" and stated that Cellceutix's claim to have caused tumor elimination in a patient in the Phase 1 trial appeared to be misleading. ¶43. On this news, shares of Cellceutix fell \$0.73 per share or approximately 30% from its previous closing price to close at \$1.71 per share on August 6, 2015. ¶44.

The following day, Cellceutix issued a press release responding to the allegations in the Mako Report, but in doing so contradicted, and confirmed as false, several of Defendants' previous statements that Mako had identified as false. ¶45. Defendants admitted "Brilacidin is for treating gram positive infections such as acute bacterial skin and skin structure infections (ABSSSI) caused by Staphylococcus aureus, including methicillin-resistant strains (MRSA), and was not developed for the treatment of Gram-negative infections. ... [and] Brilacidin is not designed for use against Gram negatives." Id. This contradicts prior statements that Brilacidin is effective against both gram positive and gram negative bacteria. Id. Cellceutix's press release also stated "While patients with oral mucositis are at risk of infection through open ulcers, the disease is not caused by infection. Accordingly, brilacidin's efficacy in oral mucositis is not based on its antibiotic properties. Rather, it is based on its immunomodulatory properties. Indeed, positive data from reliable animal models of oral mucositis (without evidence of concomitant bacterial infection) support an immunomodulatory², rather than antimicrobial, mechanism of action." ¶46. This contradicts Defendants' previous statements that Brilacidin's efficacy in treating oral mucositis is due in part to its purported antibacterial properties. Cellceutix's press release also admitted that a cancer patient who was earlier described as having achieved significant tumor reduction due to treatment with Kevetrin was discontinued from the trial at a physician's recommendation because her cancer

² "Immunomodulary" refers to the property of altering (i.e. modulating) the immune system's functioning.

had returned. ¶47.

On September 11, 2015, Defendants issued a Form 10-K for the period ending June 30, 2015. That form 10-K disclosed that Defendants do not have experience with Phase 3 clinical trials. ¶48. "We have not previously conducted a Phase 3 or later stage clinical trial such as the Phase 3 clinical trials planned for our most advanced drug candidate [Brilacidin]." *Id.* The 10-K also revealed that during the meeting with the FDA, it was determined that Cellceutix would be required to perform two Phase 3 ABSSSI studies that met the FDA Guidance issued in October 2013. *Id.* This guidance requires that each wing of each study have at least 310 individuals, for a total of at least 1240 individuals enrolled across both studies. *Id.* Defendants later disclosed to the Boston Business Journal that in fact the two studies would have a total of 1,400 patients. *Id.* As noted above, a similar set of studies cost Durata Pharmaceuticals \$145,605,000. *Id.* Therefore, when the 10-K was released, investors learned that a Phase 3 trial would require the raising of drastically more money, and that Defendants were not experienced in conducting such trials. *Id.* Over the following three trading days, shares of Cellceutix fell \$.29 per share or approximately 15.5% from its previous closing price to close at \$1.58 per share on September 15, 2015. ¶49.

III. <u>ARGUMENT</u>

A. Legal Standard

Motions to dismiss are generally viewed with disfavor. *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 178 (S.D.N.Y. 2010). When evaluating the Complaint, the Court must accept all facts alleged therein as true and must draw all inferences in favor of plaintiffs. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 692 (2d Cir. 2009). The factual allegations need only "be enough to raise a right to relief above the speculative level," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

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To state a claim under §10(b) of the Exchange Act, a plaintiff must allege that the defendant, in connection with the purchase or sale of a security, made a materially false or misleading statement or omitted a material fact, with scienter, and that reliance on defendant's statements caused injury to the plaintiff. *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt. LLC*, 595 F.3d 86 (2d Cir. 2010). As this case arises under the PSLRA, Plaintiff must specify each allegedly false statement, the reasons why the statement is misleading, and, if made on information and belief, state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4. Scienter may be established by showing either: "(1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 586 (S.D.N.Y. 2011) (internal citations omitted).

B. Defendants' "Jurisdictional" Arguments are Baseless and Not Jurisdictional

Defendants argue that this case should be dismissed for two reasons that defendants refer to as "jurisdictional." As a preliminary matter, neither of these issues is jurisdictional. It is blackletter law that "venue is not jurisdictional." *Johnson v. Bryson*, 851 F. Supp. 2d 688, 704 (S.D.N.Y. 2012). As to early notice, in the only case cited by Defendants where a court found notice to be deficient, the court did not suggest that the deficiency was jurisdictional, and did not even dismiss the case, but instead instructed the Plaintiff to republish notice. *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, No. 05 CIV. 1898 (SAS), 2005 WL 1322721, at *2 (S.D.N.Y. June 1, 2005). If the concern were jurisdictional, it could not be remedied by reissuing the notice.

1. Venue is Proper in this District

When evaluating venue, the Second Circuit has held that the Court is not limited to the four corners of the Complaint, but if the Court does not hold an evidentiary hearing, and instead relies

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on the pleadings and affidavits³ submitted by the parties, dismissal is improper where the Plaintiff makes a prima facie showing of venue. *Gulf Ins. Co. v. Glasbrenner*, 417 F.3d 353, 355 (2d Cir. 2005). The Second Circuit has specifically held that the same standard of review applies in a motion to dismiss for improper venue as a motion to dismiss for lack of personal jurisdiction. *Id.* Therefore, following the Second Circuit's holding regarding the standards for evaluating personal jurisdiction, the court should take as true facts that are "either uncontested or appear from the plaintiff's papers and affidavits", unless the Court holds an evidentiary hearing. *CutCo Indus., Inc. v. Naughton*, 806 F.2d 361, 363 (2d Cir. 1986); *see also Williams v. Preeminent Protective Servs., Inc.*, 81 F. Supp. 3d 265, 269 (E.D.N.Y. 2015) ("Where, as here, the Court relies solely on the submissions of the parties in ruling on the motion, plaintiff's satisfy that burden by pleading facts sufficient to demonstrate a prima facie showing of jurisdiction or venue by way of the complaint's allegations, affidavits, and other supporting evidence, which are evaluated in the light most favorable to them.").

For lawsuits under the Exchange Act, "[a]ny suit or action to enforce any liability or duty created by this chapter or rules and regulations thereunder, or to enjoin any violation of such chapter or rules and regulations, may be brought in any such district or in the district wherein the defendant is found or is an inhabitant or transacts business." 15 U.S.C.A. § 78aa (West). The Complaint states that a significant portion of Defendants' actions and the subsequent damages took place in New York. ¶10. Cellceutix traded on the OTC Pink Market, which is headquartered in New York. ¶ 13, Declaration of Jonathan Stern Exhibit 1. When the target of a securities fraud is a stock that is traded on the OTC Market, venue is proper in the Southern District of New York. *S.E.C. v. Boock*, No. 09 CIV. 8261(DLC), 2010 WL 2398915, at *3 (S.D.N.Y. June 15, 2010). In

³ In the alternative, the matters addressed in the documents attached to the Declaration of Jonathan Stern are judicially noticeable, as set forth in the accompanying request for judicial notice.

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addition, as one Court has held, when the Defendant corporation "was a publicly traded company on the NASDAQ National Market and the alleged misstatements were widely disseminated and defrauded a nationwide class, plaintiffs could theoretically have brought suit under section 27 in any district in the United States." *In re Geopharma, Inc.*, No. 04 CIV. 9463 (SAS), 2005 WL 1123883, at *1 (S.D.N.Y. May 11, 2005). Cellceutix has also made investor presentations in New York on September 9, 2013, September 9, 2014, and May 21, 2015. Declaration of Jonathan Stern, Exhibit 2, *see also* Declaration of Michael Sullivan, Exhibit 14, referencing the 2013 presentation. By marketing CTIX stock to investors, Defendants committed "non-trivial" acts in furtherance of their fraudulent scheme in New York. *Greenwood Partners v. New Frontier Media Inc.*, No. 99 CIV. 9099 WK, 2000 WL 278086, at *6 (S.D.N.Y. Mar. 14, 2000). Therefore, venue here is proper.

2. There is No Requirement that the PSLRA Early Notice be Republished

Defendants argue that the PSLRA early notice must be republished because the Second Amended Complaint extended the class period. However, Defendants have virtually no authority for this proposition. Indeed, the only case they cite notes that "previous courts have addressed the question of whether a new notice need be issued when the class period is amended-and have generally answered that question in the negative" *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, No. 05 CIV. 1898 (SAS), 2005 WL 1322721, at *2 (S.D.N.Y. June 1, 2005). And the Court's conclusion in *Bombardier* is correct. "Courts, however, disfavor republication of notice under PSLRA when a class period is extended beyond the period contained in the first-filed securities class action." *Turner v. ShengdaTech, Inc.*, No. 11 CIV. 1918 TPG, 2011 WL 6110438, at *3 (S.D.N.Y. Dec. 6, 2011). *Bomardier* ordered republication because the Amended Complaint included a new class of securities, specifically distinguished that situation from extending the class

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period, which didn't warrant republication, and rather than dismiss the complaint, the Court simply ordered republication. *Bombardier Inc.*, 2005 WL 1322721, at *2-3.

C. <u>The Complaint Identifies Material False Statements</u>

1. The Complaint Alleges the Falsity of the Claim that Menon attended Harvard

The Complaint alleges that Menon falsely told Future Woman Magazine that he received a PhD from Harvard. ¶22. That article quoted Menon, who was interviewed for the article, and contained a detailed (and false) story of how Menon came to receive a PhD from Harvard. *Id.* Exhibit 10 to the Declaration of Michael Sullivan (Docket No. 39-10). The Complaint also alleges that Ehrlich, as CEO, had a duty to correct the Company's pre-class-period statements that Menon received a PhD from Harvard. This is a violation of Item 401(e)(1) of Regulation S-K, which requires disclosure of the qualifications of directors. 17 C.F.R. § 229.401. Defendants acknowledge that Menon did not attend Harvard and that, before the class period, Defendants falsely claimed that Menon received a PhD from there. Instead, Defendants argue, with respect to the Future Woman article, that Menon was not the "maker" of the statement, and with respect to the duty to correct allegation, that Defendants corrected the misstatement before the class period by removing the inaccurate information from Defendants' annual report.

The Complaint plausibly alleges that Menon was the "maker" of the statement that appeared in "Future Woman." The Second Circuit has held that a defendant can be liable for a misstatement disseminated by an analyst report where the complaint establishes that the defendant "intentionally fostered a mistaken belief concerning a material fact that was incorporated into reports." *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000) (internal quotes and brackets omitted). There is no reason this precedent should not apply equally to media reports. The

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Complaint properly establishes a plausible inference that Menon intentionally fostered the false claim that he went to Harvard. The Future Woman article quoted Menon and stated that it was based on an interview of him. It not only stated that Menon had attended Harvard, it also told a detailed story about how Menon came to attend Harvard, stating that Thomas Frei, of the Dana Farbert Institute, admitted Menon to Harvard as a PhD student so that Menon would be eligible to work at the lab. ¶22, n.1. It is hard to imagine where this story would come from if not Menon himself, as the article does not state that Frei was interviewed. Nor does it quote Frei. It is certainly a plausible inference that during the interview, Menon provided this information to Future Woman. Therefore, at the pleading stage, there is no basis to reject this allegation on the basis of Janus. Janus Capital Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 131 S. Ct. 2296, 180 L. Ed. 2d 166 (2011), see U.S. S.E.C. v. Geswein, 2 F. Supp. 3d 1074, 1080 (N.D. Ohio 2014) ("Whether or not Geswein possessed 'ultimate authority' over the allegedly false statements, their content, or how they were communicated; whether Geswein is the 'maker' because he signed Diebold documents or signed Sarbanes-Oxley certifications; and the extent of Geswein's involvement in the preparation of press releases, all require fact-intensive discovery."). Defendants claim that this statement is inapplicable because Menon did not, subsequent to the release of the Future Woman Report, place his "imprimatur" on the report. But the case they rely on, *Elkind*, held that third party statements are attributable to corporate officers either "where management intentionally fosters a mistaken belief concerning a material fact" or where they place there imprimateur on a statement. Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 164 (2d Cir. 1980); see also Novak v. Kasaks, 216 F.3d at 314 (interpreting *Elkind*).

The Complaint also properly alleges that Ehrlich failed to correct Menon's false claim to have received a PhD from Harvard. The Second Circuit has recognized a duty to correct false

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statements under Section 10(b). *Overton v. Todman & Co., CPAs, P.C.*, 478 F.3d 479, 487 (2d Cir. 2007). Defendants argue that they did correct the inaccurate information by stating that Menon received a PhD from Kerala University, and by ceasing to falsely claim that he received a PhD from Harvard. But there is not merely a duty to cease making false statements when a party realizes that they are false. There is also a duty to *correct* the false statements, and Defendants never affirmatively corrected the false statement during the class period that Menon did not go to Harvard. Defendants have also suggested that the truth was "on the market" because Cellceutix's SEC filings ceased claiming that Menon received a PhD from Harvard. But the Cellceutix SEC filings never actually denied that Menon received a PhD from Harvard. Therefore, shareholders would not have been on notice that Menon had not received one.

Moreover, the misstatement was material. "[W]hen presented with a Rule 12(b)(6) motion, 'a complaint may not properly be dismissed ... on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (*citing Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir.1985)). This Court has held that when a corporate officer fails to properly disclose their background, whether that information is material is not to be resolved on a motion to dismiss. *Nanopierce Techs., Inc. v. Southridge Capital Mgmt. LLC*, No. 02 CIV. 0767 (LBS), 2003 WL 22882137, at *4 (S.D.N.Y. Dec. 4, 2003)). The Northern District of Illinois recently found that a Defendant made a materially misleading omission by concealing that an officer was associated with Stratten Oakmont, the notorious boiler room co-founded by the "Wolf of Wall Street" Jordan Belfort. *Kelsey v. Allin*, No. 14 C 7837, 2016 WL 825236, at *3 (N.D. Ill. Mar. 2, 2016. Defendants cite a Fourth Circuit case to argue that an officer lying about their education is immaterial.

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However, the Court did not hold such fraud is always immaterial. "[W]e do *not* hold as a matter of law that a key manager's education could *never* be material." *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 658 (4th Cir. 2004). And the court in *MCG* held that in context, MCG's omission was immaterial because there was virtually no other issue with MCG's public statements. Here, by contrast, Menon was a serial fabulist about his reputation. Menon misrepresented his role in working on blockbuster drugs at Ely Lily. ¶52. Menon also exaggerated his role in the invention of Kevetrin. ¶54. *Greenhouse* itself cited other cases where courts have found misstatements regarding Defendants' resume to be material. *SEC v. Physicians Guardian Unit Inv. Trust*, 72 F.Supp.2d 1342 (M.D.Fla.1999); *SEC v. Suter*, No. 81 C 3865, 1983 WL 1287 (N.D.Ill.1983).

2. The Complaint Alleges the Falsity of the Claim that Brilacidin was Effective Against Gram Negative Bacteria

The Complaint alleges that by claiming that Brilacidin has "coverage" of gram negative bacteria, Defendants falsely told investors that it was effective against gram-negative bacteria such as Escherichia coli ("E. coli"). ¶ 25. Defendants claim that the poster containing this information was peer reviewed and accepted for presentation and display at the European Congress of Clinical Microbiology and Infectious Diseases in ("ECCMID"). That claim appears nowhere in the Complaint. Defendants have provided no evidence for this claim, but even if they had, such factual assertion is a matter outside the Complaint, and may not be considered on a motion to dismiss. *Chandler v. Coughlin*, 763 F.2d 110, 113 (2d Cir. 1985).

Defendants' arguments against the falsity of this misstatement are nonsensical. Defendants assert that the Complaint's use of the word "tout" to describe their misstatement is inaccurate. Why this would be grounds to dismiss the complaint is unclear. Defendants assert that their stating that Brilacidin has "gram negative coverage" does not mean that it is effective against gram negative bacteria. But this argument is nonsensical. In this context the term "coverage" can only refer to

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Brilacidin's effectiveness. The poster is titled "Results". Beneath the title is a sentence that reads "Brilacidin has *broad* spectrum in vitro antimicrobial activity". The poster also prominently features a chart touting Brilacidin's positive results on E. coli, which is a gram negative bacteria. ¶ 25.

Defendants also argue that the statement is not false because Brilacidin's Phase 2 clinical trial was focused on gram positive bacteria. But that does not mean that Brilacidin was not also effective against gram negative bacteria. Nor does the poster cite the Phase 2 trial as the source of the results. So a reasonable investor would have believed that Brilacidin was effective against gram negative bacteria. Defendants note that this claim was made in connection with Defendants' claim about oral mucositis, but it is not clear what relevance this has to the motion to dismiss. Defendants also claim that this misstatement was immaterial, but if Brilacidin was potentially effective against gram negative bacteria, such as E. coli, it would be significantly more valuable. Therefore, it is material to investors.

3. The Complaint Alleges the Falsity of the Claim that Brilacidin's Antibiotic Properties Were Effective in Treating Oral Mucositis

Defendants alleged, throughout the class period, that "Brilacidin and related compounds have shown antibacterial, anti-biofilm and anti-inflammatory properties in various pre-clinical studies. We believe that the combination of these attributes contribute to the efficacy of Brilacidin" in treating oral mucositis. ¶27. In their August 7 press release, however, Defendants admitted that Brilacidin's anti-inflammatory properties were the basis for its claim that it had a positive clinical impact on oral mucositis. ¶28. Instead, the press release clarified that Oral Mucositis leads to open ulcers, which sometimes leads to bacterial infections, and the antibiotic properties can treat those infections. ¶46. But stating that Brilacidin can treat infections that can come from open unlcers that can come from oral mucositis is a far cry from stating that it can treat oral mucositis.

In the motion to dismiss, Defendants try to get out of this clear contradiction by claiming that while Brilacidin's antibiotic properties cannot treat oral mucositis, those antibiotic properties

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are instrumental in treating lesions caused by infections that accompany oral mucositis. But defendants do not have that quite right. As stated in their August 7 press release, Defendants state that it is the lesions (open ulcers) that cause the infections, not the other way around. Therefore, when Defendants point to a presentation that states that the antibacterial properties of oral mucositis treat the lesions, that is not accurate either – it treats one of the possible effects of the lesions. By analogy, if someone had a cut from a knife that was infected, and a doctor applied antibacterial ointment and stitched the wound, nobody would say the ointment treated the cut. It is the stitches that treated the cut. The ointment treated the infection. Defendants object that Brilacidin's antibiotic properties could not have possibly treated oral mucositis because oral mucositis is not caused by bacterial infection. But this argument amounts to an objection that investors should have seen through defendants fraud because they misrepresented basic science. But it would be unfair to place the burden of catching corporate officers' scientific lies on shareholders, rather than placing the burden on officers to not lie about science.

The misrepresentation is material because antibiotics are subject to special programs by the FDA that make it more efficient to obtain marketing approval, and as a result of Defendants' misstatements a reasonable investor might have believed that Brilacidin was eligible for those benefits if approved for the treatment of oral mucositis. ¶28 Defendants ague that this misstatement was not material because Brilacidin for Oral Mucositis received a fast track designation. This argument is flawed for several reasons. First, Defendants rely on matters outside the pleading for the truth of the matters asserted. This is improper. *See* Opposition to Request for Judicial Notice, filed concurrently herewith. Second, the Complaint identifies other benefits that potential antibiotic treatments are eligible for, including priority review and an extension of marketing exclusivity. ¶28, n.2.

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4. The Complaint Alleges the Falsity of the Claim that Kevetrin's Activation of P21 was Clinically Meaningful

The Complaint alleges that Defendants falsely claimed that P21 was a "biomarker" for cancer, which means that activation of P21 would be clinically meaningful. Defendants sometimes used the phrase "potential biomarker" but elsewhere referred to P21 simply as a biomarker. ¶¶31-33. The Complaint alleges that biomarker has a specific meaning in the medical community – it is a surrogate for a clinically meaningful outcome. ¶34. And it is clear that this is exactly what Defendants intended to convey. For instance, one 8-K on September 24, 2014 stated that "[t]he biomarker p21 increased in 6 of 14 patients at relatively low doses of Kevetrin and we expect a higher percentage of p21 expression when the data is evaluated from higher doses. Another tumor marker, CEA, was decreased and the tumor size remained stable over 4 months in a pancreatic carcinoma patient." The implication of referring to "another tumor marker" is that P21 is a marker to indicate tumor size. In an interview, when asked about the expectations regarding the "P21 biomarker" Ehrlich stated "[i]f p21 activity is shown, we think that we have hit a home run ". ¶30.

Defendants mischaracterize what the complaint really alleges. The Complaint does not fault the Dana Farber institute for examining P21 activation. Instead, the Complaint faults Defendants for claiming that activation of P21 is an indication that Kevetrin is an effective cancer treatment. Therefore, it is simply not relevant that Dana Farber approved the use of P21 as a trial parameter. Defendants cite to a listing of the Kevetrin trial on clinicaltrials.gov to show that Dana Farber selected the "P21 Biomarker" but that very web page shows that the data was submitted by Cellceutix, not Dana Farber. Defendants argue that the Court should not second guess trial parameters, but that is not what the Complaint does – it questions Defendants' characterization of the significance of those parameters. Defendants argue that a reasonable interpretation of scientific

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data cannot be an actionable false statement, citing *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013), but Defendants never explain how their use of the term "biomarker" was based on any interpretation of data at all, let alone a reasonable one. Defendants also assert that the statement is subject to the PSLRA's safe harbor but do not explain how 1) use of the word potential is per se subject to the safe harbor, 2) Defendants included any meaningful cautionary language.

5. The Complaint Alleges the That Defendants Misrepresented the Clinical Outcome of a Patient in a Clinical Trial

The Complaint alleges that Defendants misleadingly presented one patient's results in the Kevetrin Phase 1 trial. Defendants reported "the near complete disappearance of a metastatic lesion in the spleen of a Stage 4 ovarian cancer patient who was enrolled in the Company's Phase 1 clinical trial of anti-cancer drug candidate Kevetrin." ¶35. A reasonable investor would have concluded that this press release indicated that, as of the time it was issued, the Kevetrin treatment was apparently successful.

Defendants assert that they disclosed the allegedly withheld information, but this is inaccurate. While Defendants are correct that they did disclose that the patient had an elevated CA125 count, what they did not disclose, until after the class period, was that the CA125 count was so high that it caused the patient's physician to discontinue treatment, indicating that the treatment was stopped because it wasn't working. Merely disclosing that the patient had an elevated CA125 count did not dispel the false impression that Kevetrin had effectively stopped the cancer. Defendants also argue that this statement was subject to the PSLRA safe harbor, but the complaint alleges that the statements were false because the patient was already sick and the treatment with Kevetrin had failed at the time the false statements were made.

6. The Complaint Properly Alleges that Defendants Failed to Disclose Material Risks Posed by the Purchase of Rights to Brilacidin

Cellceutix's purchase of Brilacidin created two significant uncertainties for its business. First, because of the high cost of completing Brilacidin's two required Phase 3 trials, Cellceutix's fundraising needs substantially increased. Second, the risk of failing a Phase 3 trial was increased because nobody at Cellceutix had experience running a Phase 3 trial. Failure to disclose a material trend or uncertainty is actionable under 10(b)(5). *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 102 (2d Cir. 2015). This requirement stems from 17 CFR § 229.303 ("Item 303"). Instruction 3 of Item 303 states that disclosure "shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

Given that the acquisition of Brilacidin quickly increased Defendants' financing needs, they had an obligation to disclose that fact under Item 303. Defendants argue that they adequately disclosed the risk of the need to raise additional funding. But the Complaint alleges not merely that Defendants needed to raise additional funding, but that their funding needs were greatly increased by the purchase of a drug that was almost at Phase 3. It is the increase in funding needs, in particular the great magnitude of that increase, that was required to be disclosed, and neither the increase, nor its magnitude, was disclosed. *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 122 (2d Cir. 2012) (issuer's disclosure of a negative trend of increasing customer complaints violated Item 303 where issuer failed to disclose specific facts describing the trend and uncertainties and their potential impact, *even where* issuer could not determine with precision what that impact would be); *In re Facebook, Inc. IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 487, 510-11 (S.D.N.Y. 2013) (disclosure of worrisome mobile trend inadequate where "Facebook

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used generalized and indefinite terms...when describing the impact [the trend] could have had on the Company's revenues and financial results. Such terms fail to constitute sufficient disclosure where Facebook *knew* of the certainty of the trends in mobile usage.").

Defendants argue that their disclosures regarding their total lack of experience in conducting Phase 3 trials were adequate because in 2013 they disclosed that they had no experience at all conducting clinical trials, and in 2014, after hiring individuals with experience conducting clinical trials, but not Phase 3 trials, they disclosed that they had "limited" experience conducting clinical trials. But this is inadequate. In 2014, with a Phase 3 trial imminent, reasonable investors would not have known that their hiring of people with clinical trial experience included no individuals with Phase 3 experience. The lack of phase 3 experience posed a serious risk, as Defendants acknowledged in their 2015 10-K, filed on the last day of the class period. But this belated disclosure could not remedy the harm caused by failing to disclose this information in 2014. Defendants' reliance on the bespeaks caution doctrine is superfluous, because the entire issue is whether Defendants' disclosures were sufficient under Item 303.

D. <u>The Complaint Demonstrates Scienter</u>

The complaint alleges numerous bases for Menon's scienter. First, the Complaint notes that Menon has a history of lying to investors. This is relevant because a pattern of deceptive behavior "demonstrates a high degree of sciener." *U.S. S.E.C. v. E. Delta Res. Corp.*, No. 10-CV-310 SJF WDW, 2012 WL 3903478, at *8 (E.D.N.Y. Aug. 31, 2012); *In re Symbol Techs., Inc. Sec. Litig.*, No. 05-CV-3923 DRH AKT, 2013 WL 6330665, at *10 (E.D.N.Y. Dec. 5, 2013) ("prior misconduct establishes a pattern of culpable conduct on the part of Symbol and its management which supports a strong inference of scienter."). Menon has lied about his role in developing commercially successful drugs, ¶52, his role in the creation of Kevetrin, ¶54, and his

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receiving a PhD at Harvard. ¶53. The Cellceutix website also falsely claimed that Dr. Emil Frei and Har Gobind Khorana, were scientific advisors of the Company. ¶55. Defendants claim that Frei and Khorana were founding shareholders of the company, relying on a stock transfer report purporting to show that. However, Defendants have not provided any justification for why such a document would be judicially noticeable, particularly to demonstrate the truth of the matter asserted, and even if Khorana and Frei were shareholders, that does not make them scientific advisors. Menon failed to disclose to Cellceutix investors his role at another pharmaceutical company, Nanoviricides, in violation of SEC regulations and the securities laws. This omission violates Item 401(e)(1) of Reg. S-K, which required Cellceutix to "describe the business experience during the past five years of each ... executive officer ...including: each person's principal occupations and employment during the past five years." Menon also made contradictory statements about his health and reasons for resigning from Nanoviricides. ¶56. The Complaint also shows that Menon had motive to commit fraud, because he was using Cellceutix stock to settle the various lawsuits against him. Defendants claim that such motives are generally possessed by most officers or directors. But most officers and directors do not try to freeze out their co-inventors and placate them with company stock after being sued.

Defendants argue that it was improper to rely on the Mako Report to establish scienter, but the Southern District has repeatedly held that it is appropriate to rely on short seller reports in formulating a complaint, and that the reliability of such a report is not a question for a motion to dismiss. *McIntire v. China MediaExpress Holdings, Inc.*, 927 F. Supp. 2d 105, 123 (S.D.N.Y. 2013); *Ho v. Duoyuan Glob. Water, Inc.*, 887 F. Supp. 2d 547, 563 (S.D.N.Y. 2012); *see also In re China Educ. Alliance, Inc. Sec. Litig.*, No. CV 10–9239, 2011 WL 4978483, *4 (C.D.Cal. Oct. 11, 2011). Defendants' claim that Plaintiffs failed to provide witness interviews or attach

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evidentiary documents to their complaint, but there is no authority for the proposition that Plaintiffs are required to do so. Defendants cite to authority that indicates that sources relied upon in a complaint must have been likely to know the relevant facts. But the complaint sets forth just such a basis. The allegation that Menon exaggerated his role in the creation of drugs at Ely Lily was based on an India New England article that cited to interviews with people who worked on the drugs that Menon claimed to have worked on. ¶52. The allegations that Frei and Khorana were not really advisors for Cellceutix was derived from interviews of Frei and Khorana conducted by India New England. ¶55. Defendants do not identify a single inadequately sourced allegation, but instead merely conclusorily allege that the Complaint mirrors the Mako Report.

The complaint properly alleges Ehrlich's scienter. The Complaint alleges that Ehrlich violated Regulation FD. "Regulation FD requires an issuer, to make public material information disclosed to security market professionals or holders of the issuer's securities who are reasonably likely to trade on the basis of that information." *S.E.C. v. Siebel Sys., Inc.*, 384 F. Supp. 2d 694, 696 (S.D.N.Y. 2005). Defendants claimed that the Complaint does not so demonstrate, but Defendants wholly ignore most of the illegal statements. Most egregiously, Ehrlich reassured an investor nervous about the price of Cellceutix stock that Cellceutix was "catching up" and that events would be made public in the coming weeks that Menon hoped would "show the potential of CTIX". ¶52. Defendants argue that Ehrlich's reassurances that various trials or the NASDAQ listing are still "on track" are not material, but it is of course material to an investor to learn that no delays have arisen since the last public status report on a corporate project. Finally, Defendants argue Ehrlich did not violate Regulation FD because "Dr. Alexander had disclosed the same information previously (which then was posted on the Company's website)." Defendants neither clarify what information is being referred to or where on the website this information appears. It

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appears that Defendants are referring to Ehrlich's disclosure that patients in "cohort 10" has been dosed. Ehrlich refers to a statement by "Dr. Alexander" that "cohort 10" was starting, but there is no evidence that Dr. Alexander had made public that cohort 10 had already been dosed.

The Complaint also alleges that Ehrlich's scienter can be inferred from his artful description of his tenure at StatSure Diagnostic Systems. While Defendant did disclose being a director of Statsure, and holding various positions including CFO, he omitted the fact that he was in fact the CFO through the company's total failure. ¶64. The Complaint also shows Ehrlich's scienter through his support of Menon's lies. Ehrlich claimed that Menon had an "unparalleled track record of taking a compound from the chemist's bench to FDA approval." ¶63. Of course, Menon had no track record of obtaining FDA approval. Ehrlich continued to defend the claims that Frei and Khorana were advisors of Cellceutix after the lie had been exposed. *Id*.

"High level corporate officers who signed the SEC filings containing the company's financial statements have a duty to familiarize themselves with the facts relevant to the core operations of the company." *In re Winstar Commc'ns*, No. 01 CV 3014, 2006 WL 473885 at *7 (S.D.N.Y. Feb. 27, 2006). Therefore, when a misstatement involves such "core operations", courts take this fact as providing additional support for scienter. *New Orleans Employees Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 14, n. 3 (2d Cir. 2011). In this case, the fraud undoubtedly related to core operations of the company. The allegations relate to 1) the efficacy of Brilacidin, 2) the efficacy of Kevetrin, and 3) the cost and risk of a phase 3 trial for Brilacidin. As the Complaint notes, Cellceutix is a development stage biotech company without any revenues. ¶62. Essentially all of Defendants' business is the development of drugs. Therefore, these statements go to the very foundations of Defendants' operations.

Further supportive of scienter is the very small size of the company. Batwin v. Occam

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Networks, Inc., No. CV 07-2750 CAS (SHX), 2008 WL 2676364, at *12 (C.D. Cal. July 1, 2008) (finding scienter more likely where company had "relatively small" size of 80 to 100 employees); *In re Commtouch Software Ltd. Sec. Litig.*, No. C 01-00719 WHA, 2002 WL 31417998, at *9 (N.D. Cal. July 24, 2002) ("In a company of Commtouch's modest size, it is unlikely that transactions of this scope would fly below the radar of top management"). Given the tiny number of employees, 9-14 throughout the class period, it is unlikely that Ehrlich, as CEO, or Menon, as Chief Scientific Officer, were unaware of large details of their company's operations. ¶58.⁴

E. <u>The Complaint Establishes Loss Causation</u>

Because loss causation is often a fact-intensive inquiry, it is generally inappropriate to rule on loss causation on a motion to dismiss. The Second Circuit has held that loss causation "is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss." *Emergent Capital Inv. Mgmt., LLC. v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003). Courts all over the country have agreed. For example, the Third Circuit in *McCabe v. Ernst & Young, LLP,* 494 F.3d 418, 427 n. 4 (3rd Cir. 2007) stated that "loss causation becomes most critical at the proof stage," and cited scholarly authority stating that it is normally inappropriate to rule on loss causation at the pleading stage. (internal quotation marks omitted). The Ninth Circuit held in *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1057-58 (9th Cir. 2008) that "so long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate." The *Gilead* court explained that "this is not 'a probability requirement...it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence' of loss causation." *Id.* (internal citation omitted).

The Complaint alleges that the filing of the Mako Report on Seeking Alpha caused the

⁴ The Complaint alleges that corporate scienter can be inferred from the Individual Defendants' scienter, which Defendants do not challenge. ¶68.

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price of Cellceutix to decline on August 6, 2015. ¶39, 44. This Court has recognized that a short seller's report can constitute a corrective disclosure, even when the disclosure does not contain any non-public information, but rather just a detailed analysis of publicly available information. In re Winstar Commc'ns, No. 01 CV 11522, 2006 WL 473885, at *15 (S.D.N.Y. Feb. 27, 2006). In Winstar, Asensio & Company, a short seller, issued several reports questioning Winstar's accounting practices and concluding that Winstar's existing cash flow would likely not be enough to fund its operations (the "Asensio Reports"). Id. at *15. The findings in the Asensio Reports were derived entirely from Winstar's published financials. Id. Defendants there argued that there was no loss causation because the Asensio Reports were based on public information and could not possibly be a corrective disclosure. The court disagreed and held that "the claimed ability of Asensio to arrive at its findings by an examination of the publicly reported financials does not mean that a reasonable investor could have drawn those same conclusions based on the total mix of the available information." Id. Moreover, the court held that "there is no basis to conclude, as a matter of law, that the findings in the Asensio reports were already reflected in the price of Winstar securities. In fact, plaintiffs' allegations that the price of Winstar's stock fell in the immediate wake of the issuance of those reports belies such a conclusion." Id. "While the court in In re Omnicom could point to particular articles explicitly stating that the Wall Street Journal article disclosed no new information", here the market was clearly surprised by the revelation that the VIE structure was concealing a fraud. In re Vivendi Universal, S.A. Sec. Litig., 634 F.Supp.2d 352, 372 (S.D.N.Y. 2009) ("facts available to the public are not necessarily well disseminated to the market"). To the extent that the Mako Report was based on analyses of facts in the public domain, that does not prevent it from being a corrective disclosure. "Allegations that the market reacted negatively to an opinion or speculation which in fact exposes the falsity of defendants' representations can be

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sufficient to plead loss causation." In re Winstar Commc'ns, 2006 WL 473885, at *14.

Fogarazzo v. Lehman Bros., Inc. is also instructive. There, plaintiffs sued several investment banksfor issuing falsely optimistic analyst reports about RSL Communications, Inc. 341 F.Supp.2d 274, 277 (S.D.N.Y. 2004). Essentially, in an effort to win investment banking business from RSL, the banks instructed their equities research division to issue fraudulently-positive "buy" ratings for RSL, and the equities research divisions complied. *Id.* at 281-84. This was done despite the fact that RSL was actually mired in financial woes, until it became a penny stock and was eventually delisted by NASDAQ. *Id.* at 284. RLS shareholders sued the Banks for their investment losses in RSL. The court held that loss causation was adequately pled against the Banks because: "even though [RSL's true financial condition was] available for the world to see, ... [they] affirmatively opin[ed] on the meaning of those facts the Banks obscured the logical conclusion that RSL was failing." *Id.* at 290. Indeed, just because certain facts are public, does not mean that the average investor can draw all necessary insights from those facts.

Moreover, Mako conducted their own research, contacting Harvard Student Clearing House to learn that Menon never received a PhD. ¶40. It also included scientific analysis that a reasonable investor could not be expected to conduct on their own. ¶¶42-43. For this reason, Defendants' citation to *Omnicom* is inapposite. In fact, Defendants quote *Omnicom* out of context. If Defendants' quotation is included with just the following sentence, *Omnicom* reads as follows: "[a] negative journalistic characterization of previously disclosed facts does not constitute a corrective disclosure of anything but the journalists' opinions. After all, no hard fact in the June 12 article suggested that the avoidance of the write-down was improper." *In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010). Here, by contrast, Mako points to hard facts that do much more than suggest that Defendants' conduct was improper. In addition, *Omnicom* was

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decided on summary judgment-where both parties had the opportunity for full fact discovery and to submit expert testimony concerning the impact of the alleged corrective disclosure and any confounding factors. Indeed, as indicated *supra*, courts generally agree that loss causation is better decided at the proof stage than at the pleading stage, where a complaint need only satisfy the modest pleading standards of Rule 8. As *Omnicom* was adjudicated at summary judgment, loss causation allegations survived a motion to dismiss.

As to the second disclosure date, when Defendants filed their 10-K, Defendants also complain that plaintiffs failed to disaggregate the loss caused by the 10-K and the loss caused by the Rosen Law firm filing an initial complaint. However, at the pleading stage, there is no requirement for Plaintiffs to "rule out other contributing factors or alternative causal explanations." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC,* 797 F.3d 160, 189 (2d Cir. 2015). Instead, all that is required is to "allege enough facts regarding [the] loss to support the inference that [Plaintiffs] 'would have been spared all or an ascertainable portion of that loss absent the fraud." *Id. quoting Lentell v. Merrill Lynch & Co.,* 396 F.3d 161, 175 (2d Cir. 2005).

F. <u>The Complaint States A Control Person Claim</u>

Defendants do not challenge control person liability except to claim that control person liability cannot exist because there is no primary violation. For the reasons set forth above, control primary liability, and therefore control person liability, exist.

IV. CONCLUSION

For the foregoing reasons, the motion to dismiss should be denied. If it is granted, Plaintiffs request leave to replead. Leave to amend a complaint should be liberally given, unless the Court is convinced that an amendment would be futile. *Loreley*, 797 F.3d at 191.

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Respectfully submitted,

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