UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GARY ZAGAMI, Individually and on Behalf of all Others Similarly Situated, Plaintiff, v. CELLCEUTIX CORPORATION, LEO EHRLICH, AND KRISHNA MENON, Defendants.	**Case No. 1:15-cv-7194 (KPF)** **ORAL ARGUMENT REQUESTED**

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF
THEIR MOTION TO DISMISS SECOND AMENDED COMPLAINT

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Defendants Cellceutix Corporation ("Cellceutix" or the "Company"), Leo Ehrlich, and Krishna Menon ("Individual Defendants," and together with the Company, the "Defendants") respectfully submit this Memorandum of Law in support of their Motion to Dismiss Plaintiff's Second Amended Complaint ("SAC") pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(3) & (6) and 15 U.S.C. § 78u-4(b)(1), (2), (4).[1]

Introduction

The SAC [Dkt. 32] adopts the premise and assertions of a sensational article posted on the internet by a first-time, anonymous and admittedly biased author (specifically, a short seller of the Company's stock)[2] who claims that Cellceutix, an emerging biotech, is instead a sham company, without legitimate purpose, run out of an empty office building, with ineffective drugs currently in clinical trials, and with executives who not only associate with, but are themselves, fraudsters. *See* Ex. 1. Not surprisingly, the securities fraud allegations in the SAC – an overwhelming majority of which are gleaned from that sensational article – are uncorroborated and conclusory in nature, ask this Court to draw inference upon unjustified inference, and, most fundamentally, are refuted both by specific documents relied upon in the SAC itself and in the Company's Securities and Exchange Commission ("SEC") filings that Plaintiff represented to this Court his counsel had reviewed prior to filing. In this light, it is perhaps equally unsurprising that Plaintiff profoundly misunderstands Defendants' leading drugs in clinical trials, the underlying biological properties of those drugs, and the operation of the clinical trials themselves.

[1] Contemporaneous with this filing, Defendants have filed both a Request for Judicial Notice of certain documents to be considered in connection with the motion to dismiss, and an accompanying Declaration of Michael J. Sullivan, dated February 10, 2016. All references to "Ex. __" herein are to exhibits attached to that Declaration.

[2] Short sellers operate by buying a security speculating that the price will decrease, and, as one New York court has observed, "have an obvious motive to exaggerate the infirmities of the securities in which they speculate." *See In re Longtop Financial Technologies Limited Securities Litigation*, 910 F.Supp.2d 561, 577-78, (S.D.N.Y. Nov. 14, 2014).

Defendants will not and need not engage in a back and forth with Plaintiff about the efficacy of its drugs or the parameters of its clinical trials. As courts have long recognized, that is up to research scientists and the Food and Drug Administration ("FDA"), with any future safety and efficacy determination based upon, among other things, the results of multiple clinical trials. Nor will Defendants address each instance of unsubstantiated "smoke" Plaintiff attempts to create by alleging a history of bad acts by Company officers. No matter how hard Plaintiff's counsel may try to dress up the third complaint filed in this matter, there is no "fire," and the SAC falls woefully short of stating any actionable securities fraud claims against Defendants.

Summary of Argument

Because the SAC was not, in Defendants' view, the product of a reasonable inquiry into the law or the facts, this Court can choose among any number of theories to reject every one of Plaintiff's claims and dismiss this securities class action lawsuit in its entirety.

As a threshold matter, the SAC is deficient for two jurisdictional reasons.

First, the SAC fails to allege sufficient facts to show that venue is proper in this District. While the SAC includes a boilerplate conclusion that venue is proper, it is not clear why this is so, as the Company is not incorporated or headquartered in New York, the Company (as a clinical stage biopharmaceutical company) does no business here, no misrepresentations are alleged to have taken place here, and the primary time "New York" is mentioned in the SAC is in the address of Plaintiff's law firm.

Second, through the sole and undeniable neglect and delay of Plaintiff and his counsel, the PSLRA early notice in this case is now deficient because the SAC purports to lengthen the class period and add additional claims arising during that extended period. This is unfair to class members who were not properly notified, and to Defendants, particularly because the "new"

claims are based on information and documents that were available and represented to have been reviewed by Plaintiff's counsel before filing an amended complaint months ago and before being appointed to represent the putative class. Plaintiff could have brought these claims earlier, and failing that, either raised this procedural deficiency, or taken steps to cure it, yet did nothing.

To the extent this Court reviews the allegations in Count I of the SAC, it will find that none states a claim for relief under the securities laws. To assist the Court in consideration of their motion to dismiss, the chart below summarizes Plaintiff's seven allegedly materially false or misleading statements issued during the class period, *see* SAC ¶¶22-38 (Claims A-G), and Defendants' primary arguments why each should be dismissed:

Alleged Misstatement	**Reason Why Plaintiff's Allegations Are Insufficient, Defendants' Statement Is Not False Or Misleading, And Does Not State A Claim**
A. In May 2013, Dr. Menon Made False Claim of Earning Ph.D at Harvard (SAC ¶¶22-23; Defs.' Mem. at pp. 14-16)	1. Plaintiff improperly attributes article and content (including its inference that he earned his Ph.D from Harvard) to Dr. Menon 2. Alleged misstatement is immaterial because no reasonable investor would view correct information as having significantly altered the "total mix" of information 3. Although Company made an error in its 2009 Form 10-K, Company correctly reported that Dr. Menon earned his Ph.D from Kerala University in its Form 10-Ks in 2010, 2011, 2012, 2013, and 2014 (before and during the class period) 4. Even assuming material, no reasonable investor could rely on inference in article and would have duty to review public SEC filings on that point, which would have disclosed the correct information 5. No loss causation because (a) corrected information was already in public domain, and (b) insufficiently pleaded loss correlation
B. Ehrlich Failed to Correct False Harvard Claim (SAC ¶24; Defs.' Mem. at pp. 16-17)	1. Although 2009 Form 10-K contained inaccurate information, Company corrected the error in its 2010 Form 10-K, and thereafter reported correct information in its Form 10-Ks 2. No duty to correct existed because inaccurate information was immaterial, but, even assuming a duty existed, correction had already been made in its Form 10-Ks 3. Plaintiff alleges no facts supporting a strong inference of scienter regarding Mr. Ehrlich's purported failure to correct the information

Alleged Misstatement	**Reason Why Plaintiff's Allegations Are Insufficient, Defendants' Statement Is Not False Or Misleading, And Does Not State A Claim**
C. Defendants Falsely Claimed that Brilacidin Was Effective against Gram Negative Bacteria (SAC ¶¶25-26; Defs.' Mem. at pp. 17-20)	1. Allegation that Company "touted Brilacidin's ability to kill gram-negative bacteria" mischaracterizes Defendants medical poster, and is unsupported by the accompanying text 2. Allegation that Company claimed "efficacy" for gram negative bacteria is unsupported by the accompanying text, and refuted by Form 10-Ks 3. Company properly disclosed all material information about Brilacidin in Form 10-Ks, including that it was in clinical trials to treat acute bacterial skin and skin structure infections ("ABSSSI"), caused by either drug-sensitive or drug-resistant strains of Staphylococcus aureus (gram positive) bacteria, through its anti-biotic properties 4. Plaintiff alleges no particularized facts showing misrepresentation was material, or supporting a strong inference of scienter, or that there was a legitimate corrective disclosure
D. Defendants Falsely Claimed Antibiotic Properties of Brilacidin Were Effective in Treating Oral Mucositis ("OM") (SAC ¶¶27-28; Defs.' Mem. at pp. 20-22)	1. Allegation mischaracterizes Defendants' statement, and is unsupported by the accompanying text 2. Allegation fundamentally misunderstands drug properties: antibiotic (antibacterial) properties cannot treat oral mucositis ("OM"), which is caused by inflammation; drug's antibiotic properties, however, could treat *lesions*, which are caused by infection that often accompany OM 3. Company properly disclosed all material information about Brilacidin-OM in Form 10-Ks, including that it was in clinical trial to treat OM, an inflammation, through its anti-inflammatory properties 4. Plaintiff alleges no particularized facts either showing alleged misrepresentation would be material, or supporting a strong inference of scienter, or that there was a legitimate corrective disclosure
E. Defendants Falsely Claimed P21 was a Biomarker in Clinical Trial for Kevetrin (at Dana-Faber Cancer Institute) (SAC ¶¶29-34; Defs.' Mem. at pp. 22-24)	1. Allegation mischaracterizes Defendants' Form 10-K statements, which says "potential biomarker" 2. Allegation displays misunderstanding of clinical trials: parameter of trial – the selection of a "biomarker" to measure biological process – was approved by Dana-Farber and is part of medical research and clinical trial itself and therefore not actionable 3. Alleged misrepresentation that p21 is a "biomarker" or "potential biomarker" is medical opinion, which is not actionable, and will be shown by future research and thus would be subject to safe harbor for forward looking statements 4. Plaintiff alleges no facts supporting either a strong inference of scienter, or a legitimate corrective disclosure

Alleged Misstatement	Reason Why Plaintiff's Allegations Are Insufficient, Defendants' Statement Is Not False Or Misleading, And Does Not State A Claim
F. Defendants Misrepresented Kevetrin Patient Results (SAC ¶¶35-36; Defs.' Mem. at pp. 24-25)	1. Alleged misstatement reproduced in SAC is incomplete 2. Complete reproduction of press release shows Defendants accurately reported patient's result (including alleged nondisclosed information), and therefore Plaintiff's claim does not plead a plausible omission 3. Plaintiff alleges no facts supporting either a strong inference of scienter with regard to this particular statement, or loss causation
G. Defendants Failed to Disclose Material Risks of Lack of Funding and Lack of Phase III Clinical Trial Experience (SAC ¶¶37-38; Defs.' Mem. at pp. 25-28)	1. Company disclosed risks of raising capital in in "Risks" section of Form 10-Ks in 2013, 2014, and 2015 2. Company disclosed lack of clinical trial experience in "Risks" section of Form 10-Ks in 2013, 2014, and 2015 3. Alleged undisclosed risks were disclosed consistently in Company press releases in cautionary language disclaimer for forward looking statements, including in ones relied upon in SAC and others claimed to have been reviewed by Plaintiff's counsel prior to filing complaints 4. Plaintiff alleges no facts supporting either a strong inference of scienter with regard to this particular statement, or loss causation

Notably, Plaintiff fails in the SAC to allege particularized facts supporting the fraud, as required by the heightened pleading standards of Rule 9(b), and a strong inference of scienter, that is, an intent to deceive, manipulate or defraud, as required by the Private Securities Litigation Reform Act of 1995 ("PSLRA").[3] Plaintiff likewise fails to plead loss causation because the opinion article posted anonymously online is not a corrective disclosure, and because any correlation between the alleged misrepresentations and loss is implausible on its face.

Count II also should be dismissed against Individual Defendants because the SAC fails to state a primary violation in Count I.

[3] Plaintiff does not allege scienter on a claim-by-claim basis, but rather includes a generalized section near the end of the pleading. *See* SAC ¶¶ 51-67; *but see* 15 U.S.C. § 78u–4(b)(2) (complaint must plead scienter "with respect to each act or omission alleged"). Defendants discuss the PSLRA's requirement of a strong inference of scienter as it may apply to individual claims, but also include a stand-alone discussion to address Plaintiff's general allegations.

BACKGROUND

A. Parties

Cellceutix is an emerging clinical stage biopharmaceutical company, with clinical trials underway involving infectious disease and anti-cancer drugs, including at Harvard Cancer Center's Dana-Farber Cancer Institute ("Dana-Farber") and Beth Israel Deaconess Medical Center ("Beth Israel"). SAC ¶2.[4] The Company is incorporated in Nevada and headquartered in Beverly, MA. SAC ¶13. As of June 30, 2015, the Company had 14 employees. SAC ¶58; Ex. 9 (2015 Form 10-K), at 18. The Company maintains an internet website at http://cellceutix.com, and trades over the counter under the symbol "CTIX." SAC ¶13; Ex. 9 (2015 Form 10-K), at 4.

Krishna Menon and Leo Ehrlich are both officers of Cellceutix. SAC ¶14, 15. Mr. Ehrlich is Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors. SAC ¶15; Ex. 4 (2010 Form 10-K), at 18. Mr. Ehrlich also serves as a media contact for the Company. *See, e.g.*, Ex. 2 at 9.

Dr. Menon is the Company's President, Chief Scientific Officer and Director. SAC ¶14; Ex. 4 (2010 Form 10-K), at 36. In 1982, Dr. Menon worked at Harvard's Dana-Farber, and, two years later, earned his Ph.D in Pharmacology from Kerala University in India. SAC ¶15; Ex. 4 (2010 Form 10-K), at 36. He also served as a research scientist at Dana-Farber from 1985 to 1990, before moving to the corporate sector. SAC ¶15. His corporate work included work at Bayer Pharmaceuticals and Eli Lilly, SAC ¶15, the latter of which honored him with the "President's Recognition Award" in 1999 for his contributions. Ex. 4 (2010 Form 10-K), at 36.

This Court appointed Gary Zagami as Lead Plaintiff to represent a putative class consisting of persons "who purchased or otherwise acquired Cellceutix securities between May 10, 2013 and August 6, 2015, both dates inclusive." Compl. ¶1; Am. Compl. ¶1; Order [Dkt. 25];

[4] Details regarding all of the Company's clinical trials are publicly available at < https://clinicaltrials.gov/ >, a service of the U.S. National Institutes of Health, of which this Court can take judicial notice. Fed. R. Evid. 201.

PSLRA Early Notice [Dkt. 11-1, 15-1]; *but see* SAC ¶1 (extending class period). Mr. Zagami resides in California, and purchased stock on June 26, 2015 (2000 shares at $2.75), on July 6, 2015 (1000 at $2.08) and on July 20, 2015 (2000 shares at $3.45). *See* PSLRA Cert. for Am. Compl. [Dkt. 10-1]. He consequently suffered losses of approximately $9,000. *See* Ex. 17 (CTIX Historical Prices). Defendants are not aware of any other identifiable plaintiffs.

B. Anonymous Article Attacking Cellceutix Posted On-line

On August 6, 2015, an article entitled "Cellceutix: Empty Office, Unviable 'Science', Misleading Disclosures, 96% Downside," authored by an anonymous short seller using the pseudonym "Mako Research," was posted on the website *Seeking Alpha*. Ex. 1.[5] Defendants believe the placement of this article is part of an emerging and well-publicized securities manipulation scheme by short sellers targeting small companies like Cellceutix.[6]

The principal assertions in the article are: (1) Cellceutix is a "sham" company and is run out of an "empty office building," Ex. 1, at 1-3; (2) Brilacidin, the Company's drug to treat acute bacterial skin and skin structure infections and oral mucositis in cancer patients, is "without novelty or efficacy," Ex. 1 at 4-7; (3) Kevetrin, the Company's anti-cancer drug, is ineffective and has an "ineffective clinical trial design," Ex. 1 at 7-9; (4) Dr. Menon, the Company's President, did not receive a degree from Harvard as he had claimed, Ex. 1 at 9-11; and (5)

[5] The article posted on *Seeking Alpha* is not to be confused with an audit report or other traditional third party analyst's report. Instead, one New York court has described *Seeking Alpha* and its content as "a virtual bulletin board and as an open discussion forum where people can publish commentary and articles covering U.S. financial markets." *Nanoviricides v. Seeking Alpha, Inc.*, 2014 WL 2930753, at *2 (N.Y. Sup. Jun. 26, 2014). The website is "overwhelmingly comprised of posts by third-party sources and not actual reporters," *id*., and *Seeking Alpha* often compensates anonymous authors on a per-page-view model, *i.e.*, based on how many people view the posting. *See* Hoffman, Eli. "How Much Does Seeking Alpha Pay Its Contributors?" *Seeking Alpha*. 10 Apr. 2014. 21 Oct. 2015. <http://seekingalpha.com/article/2134803-how-much-does-seeking-alpha-pay-its-contributors>.

[6] For contextual purposes, this so-called "short attack" scheme is as follows: use social media to publicize favorable news about the target company to drive the stock price up, sell the stock short at the new, higher price (*i.e.*, sell shares without technically owning them), place an anonymous, negative, and sensational article about the target on websites like *Seeking Alpha* to drive the price down, use social media to disseminate the false allegations, anticipate that plaintiff's law firms will announce investigations, thus lending validity to the attack and further driving the price down, and, finally, when the target's stock has been sufficiently decimated, buy the shares back at the new, lower price to cover shares sold at the beginning, thereby reaping significant (illegal) profits.

Company is "rotten to the core" with corrupt executives associated with fraudsters, Ex. 1, at 11-35. The anonymous author – who would stand to benefit from the stock's decrease as a short seller – encourages investors to avoid the stock, claiming it will fall to only pennies. Ex. 1, at 1.

After the article was posted on-line, Plaintiff's law firm announced an investigation and that a securities class action lawsuit may be filed, *see* Ex. 18, and the stock price fell by 30% by the end of the day. SAC ¶44; Ex. 17 (CTIX Historical Prices).

C. Securities Class Action Based on Anonymous Article

For Cellceutix, recovering from the fallout from the anonymous article and "short attack" should have been the end of the nightmare. Unfortunately, one plaintiff's law firm decided to move forward to file a securities class action lawsuit based solely on the on-line article assertions. Compl. & Am. Compl. ¶23. In fact, Plaintiff's counsel drafted the complaint, and the original plaintiff (and substitute plaintiff, a former client) reviewed and authorized its filing under the pains and penalties of perjury within hours. PSLRA Cert. for Compl. (reviewed on Aug. 6, 2015) & Am. Compl. (identical complaint reviewed on Aug. 7, 2015).

Substantively, both complaints did nothing more than to repeat many of the assertions in the anonymous article. *Accord* Ex. 18 (Early Notice).[7] The complaints contained no information beyond what was asserted in the article, and included no allegations regarding scienter.[8] The

[7] The complaints did not make a claim based on the article's assertion the Cellceutix is run out of an "empty office." This representation might have been difficult upon which to base a securities claim, but, in any event, was immediately debunked as demonstrably false, even defamatory, in the media. *See* "My visit to Cellceutix, the biotech that a short seller recently called a sham," D. Seibert, *Boston Business Journal*, Aug. 14, 2015 <http://www.bizjournals.com/boston/blog/bioflash/2015/08/my-visit-to-cellceutix-the-biotech-that-a-short.html>.

[8] Based on the obvious deficiencies (including improper venue), Defendants notified Plaintiff that the complaints were frivolous, were filed without complying with Rule 11's due diligence obligations, and should be dismissed. Plaintiff declined either to withdraw the complaint, or to undertake efforts with any reasonable diligence to file a properly-supported and –pleaded complaint, within Rule 11's safe harbor period. Defendants hereby reserve their right to pursue sanctions pursuant to Rule 11's traditional method, as well as pursuant to the mandatory review process under the PSLRA, which attaches to "any complaint" filed in the matter. 15 U.S.C. §78u-4(c)(1)&(2).

PSLRA early notice, *see* 15 U.S.C. §78u-4(a)(3)(A), advised the putative class of the allegations, claims, class period, and option to seek appointment as lead plaintiff. *See* Ex. 18.

D. PSLRA Appointment to Represent Putative Class

At a December 18, 2015, hearing, the Court appointed Mr. Zagami and his law firm (who filed the only motion for appointment, [Dkt. 14], as Lead Plaintiff and Lead Counsel. After hearing argument, the Court granted Plaintiff's counsel leave to amend and to file a third complaint in this matter. *See* Order [Dkt. 24]. After an extension of time, *see* Order [Dkt. 28]. Plaintiff filed the SAC on January 11, 2016.

APPLICABLE LAW

A. Fed. R. Civ. P. 12(b)(6)

"To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009) (pleading offering labels and conclusions or a formulaic recitation of elements of a cause of action insufficient). Although a court generally accepts as true the facts alleged in the complaint, a court need not credit allegations "that are contradicted … by facts of which the court may take judicial notice," *Hirsch v. Arthur Anderson & Co*., 72 F.3d 1085, 1095 (2d Cir. 1995), and, "[i]f ... allegations of securities fraud conflict with the plain language of the publicly filed disclosure documents, the disclosure documents control, and the court need not accept the allegations as true." *In re Optionable Sec. Litig*., 577 F.Supp.2d 681, 692 (S.D.N.Y. 2008). Furthermore, a court need not accept as true "conclusory statements unsupported by assertions of fact[,] or legal

conclusions and characterizations presented as factual allegations." *In re Livent Inc. noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 404 (S.D.N.Y. 2001).

B. Heightened Standards under Rule 9(b) and the PSLRA

Private securities fraud claims are subject to a heightened pleading standard in two respects. *One,* Rule 9(b) requires that the circumstances constituting fraud be alleged with particularity. Fed. R. Civ. P. 9(b). *See Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 168 (2d Cir. 2005) ("[Rule 9(b)] is applied assiduously to securities fraud. This Circuit's strict pleading requirements in securities-fraud cases were (essentially) codified in the [PSLRA]."). *Two,* the PSLRA further heightens the pleading standard and provides that "with respect to each act or omission alleged," a complaint "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 plaintiff has pled a "strong inference" of 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," and a court "must consider plausible, nonculpable explanations for the defendant's conduct." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

C. The Securities Exchange Act of 1934

Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") makes it illegal to "use or employ, in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe …." 15 U.S.C. § 78j(b). Under Rule 10b-5 one may not "make any untrue statement of a material fact or [ ] omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading ... in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5.

"To sustain a private claim for securities fraud under Section 10(b), 'a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *Ashland Inc. v. Morgan Stanley & Co., Inc.*, 652 F.3d 333, 337 (2d Cir. 2011) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). To show a violation under Section 20(a), plaintiff "must show a primary violation by the controlled person and control of the primary violator by the targeted defendant, and show that the controlling person was in some meaningful sense a culpable participant in the fraud perpetrated by the controlled person." *SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1472 (2d Cir. 1996).

ARGUMENT

I. AS A THRESHOLD MATTER, THE SECOND AMENDED COMPLAINT IS DEFICIENT FOR TWO JURISDICTIONAL REASONS

A. The SAC Fails To Allege Facts Showing Venue Is Proper In This District

This Court should dismiss the SAC because Plaintiff fails to allege sufficient facts showing venue is proper. *See* Fed. R. Civ. P. 12(b)(3); 28 U.S.C. §1406(a). Plaintiff bears the burden of establishing proper venue. *See Gulf Ins. Co. v. Glasbrenner*, 417 F.3d 353, 355 (2d Cir. 2005). In the SAC, Plaintiff concludes that venue is proper under "the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b) as a significant portion of the Defendants' actions, and the subsequent damages, took place within this District." SAC ¶10.

Contrary to Plaintiff's conclusory statement above, the SAC does not allege that "a significant portion of the Defendants' actions," or "subsequent damages," occurred in New York. In fact, the SAC does not allege that *any* part of the conduct complained of occurred in New

York. In addition, no damages are alleged to have taken place here as the only identifiable plaintiff, Mr. Zagami, resides in California. PSLRA Cert. to Am. Compl. at 1-1.

Nor does the SAC contain any other basis for venue in this District. Contrary to Plaintiff's conclusory allegation, the Exchange Act's specific venue provision displaces 28 U.S.C. §1391(b)'s venue provision, so Plaintiff's reliance on it is misplaced. *See, e.g., SST Global Technology, LLC v. Chapman*, 270 F. Supp. 2d 444, 452 (S.D.N.Y. 2003) ("Venue with regard to securities law claims under the Securities Exchange Act is controlled exclusively by 15 U.S.C. § 78aa, without regard to the general venue provisions of 28 U.S.C. § 1391.").

The Exchange Act's venue provision permits suit only in a district where: (1) "a defendant is found or is an inhabitant or transacts business;" or (2) where "any act or transaction constituting the violation occurred." 15 U.S.C. § 78aa(a). Again, the SAC does not allege that any defendant is found in, or is an inhabitant of, this District, or otherwise transacts business here, nor does the SAC allege that any act violating the Exchange Act occurred in this District.[9]

B. The PSLRA Early Notice In This Case Is Now Deficient

The PSLRA early notice in this case is now deficient because the SAC seeks to both lengthen the class period and add new securities claims. Specifically, the SAC purports to extend the class period from August 6, 2015, to September 11, 2015, presumably to allow it to add a new misrepresentation claim based on the Form 10-K filed on September 11, 2015, and a press release dated August 7, 2015, which otherwise would be outside the class period.

This is improper because any "new" legal claims Plaintiff seeks to include are based on documents represented to have already been reviewed and considered by Plaintiff's counsel before filing an amended complaint on September 24, 2015 [Dkt. 10], moving for Lead Plaintiff

[9] In the event Plaintiff demonstrates that venue may be proper, Defendants reserve the right to move under 28 U.S.C. §1404(a) to transfer this case. Indeed, to the extent Plaintiff's claims should proceed at all, they should go forward in Massachusetts, where Defendants, witnesses, and evidence are undeniably more available and convenient.

appointment on November 11, 2015 [Dkts. 14 & 15], and being appointed to represent the putative class on December 18, 2015 [Dkt. 25]. *See* Compl. & Am. Compl. at p. 1 (first sentence of complaint). Plaintiff has had almost five months to raise this procedural issue (or take steps to cure it), and any attempt now to change the period and add new claims is unfair to putative class members who were not notified per the PSLRA, *see Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, 2005 WL 1322721, at *2 (S.D.N.Y. June 1, 2005) ("republication is generally appropriate where an amended complaint asserts new theories or legal claims"), and to Defendants. Plaintiff and his counsel have no one but themselves to blame for either dismissal of these claims based upon their lack of due diligence, or for any costs or inefficiencies of republication of the early notice.

II. COUNT ONE OF THE SECOND AMENDED COMPLAINT FAILS TO STATE ANY CLAIMS UNDER SECTION 10(b) OF THE EXCHANGE ACT

In Court I, Plaintiff alleges seven "**MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE PERIOD,**" four of which allegedly involve an affirmative misstatement, *see* SAC ¶¶22-23, 25-34 (Claims A, C, D, E), and three of which involve an alleged failure to disclose, *see* SAC ¶¶24, 35-38 (Claims B, F, G). The SAC essentially adopts and repeats the premise of the Mako Research article, *see* SAC ¶¶39-50, but newly suggests that a point-by-point rebuttal released by the Company to that article, *see* Ex. 2, and a 2015 Form 10-K, filed by the Company on September 11, 2015, *see* Ex. 9 – both outside the class period covered by the PSLRA early notice – support several of his claims. Plaintiff also includes, for the first time, a generalized section of sensational allegations (again, mostly gleaned from the Mako Research article) purporting to show Defendants' scienter. SAC ¶¶51-68.

Each claim is discussed below, and, as noted, Defendants provide a chart, *supra* at pp. 3-5, summarizing its arguments on each.

A. Plaintiff's Claim That Dr. Menon Falsely Claimed He Earned A Ph.D At Harvard Fails To State A Claim For Five Reasons

Like the two earlier complaints filed in this matter, the SAC begins by claiming that in May 2013, Dr. Menon falsely claimed in an article that he earned his Ph.D from Harvard. *See* SAC ¶¶22-23. Plaintiff bases his claim on the following ambiguous passage in a *Future Woman* article dated May 10, 2013, in which the author writes:

> During that time, Tom Frei [Dana-Farber's physician-in-chief] was the Scientific Advisor to a company called Pfizer. He offered Menon a job in his firm as a scientist. A bachelor's degree in BVSC [Bachelor of Veterinary Science] and some work experience in Jamaica were the only plus points Menon had with him then. Menon came [*sic*] very close to while working at the firm. But within three months, Frei forced Menon to quit the job and took him to Harvard University. ***Tom made Menon a scientist at his laboratory in Harvard. But as per Harvard's law, one should have a 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.*** Foliage mechanism was the research subject of Menon.

Ex. 10 (emphasis added). Plaintiff attributes the alleged misstatement to Dr. Menon, *see* SAC ¶22, fn. 1, even though it is inferential and there is no direct quotation from Dr. Menon.

Relevant Disclosures Before and During the Class Period relating to Dr. Menon's Ph.D

Many years ago, the Company made an error in Dr. Menon's educational background in its 2009 Form 10-K, dated October 9, 2009, stating: "Two years later [after working at Dana-Farber], he earned his PhD in Pharmacology from Harvard University." Ex. 3 (2009 Form 10-K), at 52. The following year, in the Company's 2010 Form 10-K, dated October 12, 2010, the Company corrected the error, stating: "Two years later, he earned his PhD in Pharmacology from Kerala University." Ex. 4 (2010 Form 10-K) at 36. Thereafter, the Company correctly reported that Dr. Menon earned his Ph.D from Kerala University, shortly after he had worked at Harvard under Dr. Frei at Dana-Farber. *See* Ex. 5 (2011), at 52; Ex. 6 (2012), at 60; Ex. 7 (2013), at 57; Ex. 8 (2014), at 51.

Plaintiff's Alleged Misstatement Cannot Be Attributed to Dr. Menon and is Immaterial

First, Plaintiff improperly attributes the alleged misstatement to Dr. Menon and Cellceutix. This is improper because: (a) neither Dr. Menon nor the Company "made" the statement, *see Janus Capital Group v. First Derivative Traders*, 564 U.S. 135, 140 (2011) ("For purposes of Rule 10b–5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it"); (b) there is no direct quotation attributable to Dr. Menon (as in other places throughout the article); (c) the article does not even directly state he earned that degree at Harvard; and (d) there are no particularized allegations that either the Company or Dr. Menon reviewed or were aware of the *Future Woman* article, let alone somehow either adopted or placed their "imprimatur" on it. *See, e.g.*, *Elkind v. Liggett & Myers, Inc.*, 635 F.2d 156, 163-64 (2d Cir. 1980).

Second, even so, the alleged misrepresentation is immaterial as a matter of law, *see* 15 U.S.C. § 78u-4(b)(1), because no reasonable investor would view it as altering the "total mix" of information available about Dr. Menon and the Company, particularly in light of current and past Form 10-Ks showing to the contrary. *See Greenhouse v. MCG Capital Corp*, 392 F.3d 650, 661 (4th Cir. 2004) (finding CEO's misrepresentation that he had obtained a college degree, when he had in fact completed only three years, was immaterial because it did not alter the large body of information about the company's financial data and the CEO's other qualifications).

Third, it is immaterial for the additional reason that many years before the class period, the Company provided accurate information starting with its 2010 Form 10-K, and thereafter disclosed the information accurately before and during class period in Form 10-K filings. Plaintiff's allegations do not plead materiality because if information is already known to the market, the alleged misrepresentation cannot then defraud the market. *See, e.g.*, *Rodman v. Grant*

Found., 608 F.2d 64, 70 (2d Cir. 1979) (taking into account information already in the public domain or reasonably available to the shareholders).

Fourth, even assuming a reasonable investor would deem this type of information material, that investor would have had a duty to review SEC filings, which would have disclosed the correct information. *Ashland Inc. v. Morgan Stanley & Co*., 652 F.3d 333, 337–38 (2d Cir. 2011) ("An investor may not justifiably rely on a misrepresentation if, through minimal diligence, the investor should have discovered the truth.").

Fifth, loss causation has not been properly pled because (a) any alleged fraud must be new to the market, *see Joffee v. Lehman Bros., Inc.*, 410 F.Supp.2d 187, 191 (S.D.N.Y. 2006), and (b) any purported loss was far more plausibly a result of the "short attack" scheme and the announcement of an investigation by Plaintiff's counsel, *see* Ex. 18, on the same day. *Id*.; *see also In re Moody's Corp. Sec. Litig.*, Fed. Sec. L. Rep. P. 97, 618 (S.D.N.Y. Aug. 23, 2013) (plaintiffs must affirmatively "disaggregate competing causal events from economic loss").

B. Plaintiff's Allegations That Mr. Ehrlich Failed To Correct The False Claim That Dr. Menon Earned A Ph.D At Harvard Does Not State A Claim

Relatedly, Plaintiff alleges (in a single, conclusory paragraph) that Mr. Ehrlich made the same false claim regarding Dr. Menon's Ph.D in a 2009 Form 10-K, had a duty to correct it during the class period, and failed to do so. SAC ¶24. These allegations fail to state a claim.

First, to the extent Plaintiff is purporting to make a claim based on the Company's 2009 Form 10-K, it is not only outside the class period, *see In re IBM Sec. Litig*., 163 F.3d 102, 107 (2d Cir. 1998) (defendants liable only for those statements made during the class period), but outside the applicable statute of limitations and statute of repose, *see* 28 U.S.C. 1658(b).

Second, Mr. Ehrlich did not have duty to disclose and correct the alleged misstatement because it was immaterial. As noted, disclosure of this type of information would not have been

viewed by a reasonable investor as having significantly altered the "total mix" of information available about Cellceutix. *Greenhouse*, 392 F.3d at 661 (CEO's false statement about education is immaterial as a matter of law given plethora of other corporate information available).

Third, even assuming Mr. Ehrlich had a duty to disclose, he did so, first in the 2010 Form 10-K, and then later both before and during the class period. The claim thus fails to plead an omission, breach of a duty, and is implausible on its face.

Fourth, Plaintiff fails to plead with particularity concrete facts supporting a strong inference of scienter relating to Mr. Ehrlich's purported lack of disclosure, particularly given the more compelling and cogent opposing inference that it had been corrected and was immaterial.

C. Defendants Did Not State Brilacidin Was "Effective" Against Gram Negative Bacteria, Let Alone Have "Touted" It

Undoubtedly recognizing that it would be frivolous to allege that the Company's drugs are ineffective (as the article and earlier complaints did), Plaintiff now claims that Defendants made false or misleading statements about the underlying biological properties. Two of these claims are based on Brilacidin (C & D), and two are based on Kevetrin (E & F). SAC ¶¶25-36.

Relevant Disclosures During the Class Period Relating to Brilacidin

In its 2013 Form 10-K, the Company disclosed that on September 4, 2013, it purchased substantially all of the assets of Polymedix Inc, and Polymedix Pharmaceuticals, Inc. (collectively "Polymedix"). Ex. 7, at 6; SAC ¶19. Polymedix's lead product candidate was Brilacidin, which was being developed in two important respects.

One, an intravenous ("IV") formulation of Brilacidin is an antibiotic that has the potential to treat acute bacterial skin and skin structure infections ("ABSSSI") caused by either drug-sensitive or drug-resistant strains of gram positive bacteria. *See* Ex. 7 (2013 Form 10-K), at 6.

Two, an oral rinse containing Brilacidin "was shown to reduce the occurrence of severe ulcerative oral mucositis" ("OM") in animal models. *Id*. Unlike ABSSSI, OM is not an infection caused by a bacteria, but rather a painful inflammation of the mucous membrane of the mouth (*i.e.*, tissue swelling), and is a common complication of chemotherapy. *See* Ex. 15. Often times, lesions caused by infections may accompany OM, which may implicate Brilacidin's antibiotic properties. *Id.* Summarizing Brilacidin-OM's operation, the Company stated:

> Brilacidin and related compounds have shown antibacterial, anti-biofilm and anti-inflammatory properties in various pre-clinical studies. Polymedix believed [and later Cellceutix believes] that the combination of these attributes contribute to the efficacy of brilacidin in these animal models.

See Ex. 7 (2013 Form 10-K), at 6; Ex. 8 (2014 Form 10-K), at 21.

In its 2014 Form 10-K, the Company disclosed that in August 2014, Brilacidin completed enrollment in a Phase 2b clinical trial for ABSSSI infections and "[d]ata collection including other end of study procedures and work on the clinical study report will proceed through the end of the year." *See* Ex. 8, at 12. The Company also disclosed that for Brilacidin-OM, an Investigative New Drug application was submitted in September 2014 for treating certain cancer patients receiving chemotherapy. *See* Ex. 8, at 2.

Plaintiff's Allegations Mischaracterize Defendants' Statements

Plaintiff alleges that the Company falsely "touted Brilacidin's ability to kill gram-negative bacteria." SAC ¶¶25-26; *see also id.* at p. 9 ("**Defendants Falsely Claimed that Brilacidin Was Effective against Gram Negative Bacteria**"). Plaintiff bases this claim on text in an accompanying medical poster, which he reproduces in part. SAC ¶25. This peer-reviewed poster is one of several accepted by the review committee for presentation and display at the European Congress of Clinical Microbiology and Infectious Diseases in ("ECCMID"). *See* Ex. 15.

At the outset, this claim is a bit perplexing because as noted above, it is well known that Brilacidin (the IV formulation) had completed a Phase IIb clinical trial to treat ABSSSI, caused by *a gram positive bacteria*. In fact, one exclusion criteria for the trial makes clear that patients suspected of having infections caused by gram negative bacteria are ineligible.[10] In addition, Plaintiff's sole support is poster information showing *limited activity* (or "coverage") against gram negative bacteria, and which was presented in connection with Oral Mucositis, not ABSSSI. *See* Ex. 15. Not surprising, Plaintiff's allegations fail to state a claim for five reasons.

First, the characterization, *see* SAC ¶25, that Defendants "touted" anything in the poster is an improper characterization, unsupported by the accompanying text. *See* Ex. 15.

Second, nowhere on that poster does the Company claim "efficacy" for gram negative bacteria, *see* SAC p. 9, let alone that it can "kill" it. SAC ¶25. To the contrary, the poster states that "Brilacidin has potent Gram positive activity" but only "Gram negative coverage." *See* Ex. 15. Plaintiff's allegations thus fail to plead a false statement. *Scott v. General Motors*, 46 F.Supp.3d 387, 394 (S.D.N.Y. 2014) (dismissing because "[t]he allegations of misstatements … are supported neither by plausible factual allegations nor by the quoted passages").

Third, nowhere does the SAC allege that the Company has represented that "Brilacidin is Effective against Gram Negative bacteria." SAC at p. 9 (heading). In fact, the Form 10-Ks during the class period flatly refute Plaintiff's characterization, making the allegations unsupported and conclusory, and the claim implausible. *Iqbal*, 556 U.S. at 677.

Fourth, even so, Plaintiff alleges no particularized facts under Rule 9(b) why this alleged misrepresentation constitutes a fraud, or is material. For example, the SAC does not allege that Defendants had any reason to fraudulently claim Brilacidin treats gram negative bacteria.

[10] *See* "*Efficacy and Safety Study of Brilacidin to Treat Serious Skin Infections*," < https://clinicaltrials.gov/ct2/show/NCT02052388?term=cellceutix&rank=3>.

Fifth, relatedly, even assuming Defendants made this statement and the misrepresentation were somehow material, there is nothing in the SAC to support an inference, let alone a strong one, that any of the Defendants intended to deceive by making this alleged misrepresentation. This is particularly true given that the poster was peer-reviewed and presented at a medical conference, and given the extensive body of information the Company currently discloses publicly about its drugs, any clinical trials underway, and the results from those trials.

D. Defendants Did Not State Brilacidin's Antibiotic Properties Were Effective In Treating Oral Mucositis

Along the same lines, Plaintiff alleges that the Company falsely claimed that Brilacidin's antibiotic properties were effective in treating OM. SAC ¶¶27-28. Plaintiff first points to the Company's Form 10-K description of the various drug properties at work, specifically that "Brilacidin and related compounds have shown antibacterial, anti-biofilm and anti-inflammatory properties in various pre-clinical studies." SAC ¶27 (citing Form 10-Ks). Plaintiff next points to a statement in Defendants' rebuttal to the Mako Research article, *see* Ex. 2, that Brilacidin's antibiotic properties were not effective in treating OM, to claim that Defendants' Form 10-K disclosures are false or misleading. SAC ¶28.

This claim, too, is a bit confounding because the Company has regularly disclosed that Brilacidin-OM (the oral rinse) is in clinical trial to treat oral mucositis, which is caused by an inflammation and not by bacteria. It is therefore (by definition) untreatable with antibiotics. As noted above, however, Brilacidin's antibiotic properties can be instrumental in treating lesions that are caused by infections that often accompany OM from chemotherapy. *See* Ex. 15.

In any event, Plaintiff's claim fails for many of the same reasons as the earlier claim.

First, Defendants have never stated that Brilacidin's antibiotic properties were effective in treating OM. The language relied upon by Plaintiff, *see* SAC ¶27 (reproduced *supra* at p. 18),

does not support that characterization. This language does nothing more than list the various biologic properties at work, and the sentence that follows makes clear that "the combination of these attributes contribute to the efficacy of brilacidin in these animal models." *See, e.g.*, Ex. 7 at 6; This is entirely accurate given that Brilacidin-OM may be able to treat OM through one of its properties (anti-inflammatory), and any accompanying lesions through another (antibacterial).

Second, Plaintiff also fails to plead a false or misleading statement because the Company disclosed all material information about Brilacidin in Form 10-Ks and elsewhere, including regarding its operative properties. This is confirmed by the very poster Plaintiff reproduces in support of another one of his claims regarding gram negative efficacy. Specifically, that poster concludes: "While we believe the efficacy in the OM model is primarily the result of brilacidin's immunomodulatory activities [immune system response], its antimicrobial [antibiotic] function can also play a role in treating the lesions." *See* SAC ¶25; Ex.15.

Third, Plaintiff alleges no particularized facts why this alleged misrepresentation constitutes a fraud, or is material. 15 U.S.C. §78u-4(b)(1). For example, the SAC contains no allegations that Defendants had any reason to claim that Brilacidin's antibiotic properties, as opposed to its anti-inflammatory properties, were effective in treating OM, or why that would be important. As such, it plainly fails to satisfy Rule 9(b) pleading standards.

Fourth, relatedly, even assuming Defendants made the alleged statement and the misrepresentation were somehow material, there is nothing in the SAC to support an inference of scienter, let alone a strong one, that any Defendant intended to deceive by misrepresenting which property of the drug was at work, particularly given the very specific information the Company discloses about its drugs, the clinical trials underway, and the results from those trials.[11]

[11] Presumably in an effort to paint the Company in a bad light, Plaintiff alleges in ¶28 that Brilacidin-OM "will not be eligible to receive a 'qualified infectious disease product' ["QIDP"] designation that would allow a fast-track

E. Plaintiff's Allegation That Defendants Falsely Claimed P21 Was A Biomarker In Clinical Trial For Kevetrin Is Not Actionable

Plaintiff next bases two claims on Kevetrin. SAC ¶¶25-36. The first alleges an affirmative misrepresentation regarding the biomarker approved for the trial,[12] while the second alleges a failure to disclose patient information, rendering a press release false or misleading.

Relevant Disclosures During the Class Period relating to Kevetrin

Kevetrin is a novel anti-cancer drug that "has demonstrated the potential for a major breakthrough in cancer research by exhibiting an activation of p53," which plays a crucial role in controlling cell mutations. Ex. 7 (2013 Form 10-K), at 14. In its 2012 Form 10-K, the Company disclosed that Phase 1 trials are being conducted at Dana-Farber and Beth Israel. Ex. 6, at 8.

In its Form 10-Ks, Cellceutix "identified the increased expression of p21 as a ***potential biomarker*** in [the] upcoming clinical trial for Kevetrin," on the basis that "Kevetrin significantly enhanced p21 levels compared to control which correlated with anti-tumor activity of Kevetrin." *See* Ex. 6 (2012, emphasis added), at 8; Ex. 7 (2013, same), at 15; Ex. 8 (2014, same), at 18; Ex. 9 (2015, same), at 39; *accord* SAC ¶¶31, 32. This clinical trial parameter was approved by research scientists at Dana-Faber responsible for conducting the trials.[13]

Plaintiff's Allegations regarding the Biomarker Do Not State an Actionable Fraud Claim

Plaintiff alleges that the biomarker (p21) selected and used by the Company (and, by extension, research scientists at Dana-Faber) for the Kevetrin clinical trial, *see* SAC ¶¶29-34, was improper because it "has not been shown to be correlated with improved clinical outcomes

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approval process as an anti-biotic." To the contrary, because OM is not an infectious disease (the fundamental mistake that dooms his claim), it did not require a QIDP designation, and, in fact, the FDA awarded Brilacidin a "Fast Track" designation for treating OM in November 2015. *See* Ex. 16.

[12] A biological marker or "biomarker" is a characteristic that is objectively measured and evaluated as an indicator of biologic processes, or biological responses, to a therapeutic intervention. Biomarkers are considered by the FDA for use in clinical trials of novel therapeutics because their use has the potential to facilitate the availability of safer and more effective drugs, to guide dose selection, and to enhance their benefit-risk profile.

[13] *See* Detailed Description in "*A Safety, Pharmacokinetic and Pharmacodynamic Study of Kevetrin in Patients With Advanced Solid Tumors*," < http://clinicaltrials.gov/ct2/show/NCT01664000?term=Kevetrin&rank=1 >.

for cancer." SAC ¶34. According to Plaintiff, the Company's statements "were false and misleading because Defendants claimed that P21 was a biomarker, which in the context of clinical trials that it is indicative of a clinically meaningful outcome for treatment, i.e., reduced mortality of cancer." SAC ¶34. These allegations do not state an actionable fraud claim.

First, Plaintiff's allegation is a mischaracterization of Defendants' statement in its Form 10-K filings, which do not state p21 is a biomarker but rather a "potential biomarker."

Second, Plaintiff's allegation displays a fundamental misunderstanding of the conduct of clinical trials. The selection of a "biomarker" to measure biological process was approved by Dana-Farber, and is part of medical research being conducted. *See* fn. 13, *supra*. Courts have routinely dismissed complaints that seek to question the parameters of clinical trials. *See, e.g., Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154-55 (2d Cir. 2013) ("Our job is not to evaluate the use of post-hoc analysis [as a methodology] generally in the scientific community"); *In re Keryx Biopharm. Inc., Sec. Lit.*, Fed. Sec. L. Rep. P. 97, 820 (S.D.N.Y. 2014) ("It would indeed be unjust and could lead to unfortunate consequences beyond a single lawsuit if the securities laws become a tool to second guess how clinical trials are designed and managed.").

Third, any alleged misrepresentation that p21 is a "biomarker" or a "potential biomarker" in Form 10-Ks, SAC ¶¶31, 32, a Form 8-K, SAC ¶33, or otherwise, is medical opinion, which is not actionable, *see Kleinman*, 706 F.3d at 154 (where defendant's competing interpretation of data is reasonable, there is no false statement), and is subject to PSLRA's safe harbor for forward looking statements. 15 U.S.C. § 78u-5; Ex. 12, at 5 (use of word "potential" is forward looking).

Fourth, Plaintiff does not appear to allege either a loss caused by this alleged misstatement, or anything that could be reasonably construed as a corrective disclosure, presumably because whether a p21 is a biomarker is a medical opinion that is subject to debate.

Fifth, Plaintiff's allegations fail to raise even an inference of scienter, let alone a strong one. Indeed, to the extent there is any intention to deceive, it would have to be imputed to third party scientists at Dana-Farber who share the Company's view, which is implausible.

F. Plaintiff's Claim That Defendants Failed To Disclose That A Kevetrin Patient's "cancer had returned" Is Demonstrably False

Plaintiff alleges that Defendants' statement in a January 20, 2015, press release, *see* SAC ¶35 (reproduced in part); Ex.13 (full text), regarding a Kevetrin patient's clinical stability, was "highly misleading" because Defendants failed to disclose (and later admitted on August 7, 2015) "that the patient's CA125 count was elevated," SAC ¶36, which, in turn, showed, according to Plaintiff, *see* SAC ¶36, that "the patient's [ovarian] cancer had in fact returned."[14]

Before and during the class period, the Company has reported results in the Kevetrin clinical trial. In the January 20, 2015, press release at issue, the Company reported, based on information from the hospital, that after Kevetrin treatments, scans showed that a stage 4 ovarian cancer patient's "spleen lesion to be essentially undetectable and the patient's disease to be clinically stable." Ex. 13, at 1. The press release included a direct quote by Mr. Ehrlich:

> I can't overexpress the excitement at Cellceutix regarding Kevetrin or the significance of a metastatic lesion disappearing in a later stage ovarian cancer patient," commented Leo Ehrlich, Chief Executive Officer at Cellceutix. "We don't know of any other company, regardless of specialization, albeit small molecule, immunotherapy or other, that has published an effect like that in such a hard to treat disease like metastatic ovarian cancer during a Phase 1 safety trial. The idea that a stage 4 ovarian cancer patient's disease was clinically stabilized, ***although her CA125 count was increased in the third month***, is remarkable.

Ex. 13, at 2 (emphasis added).

Plaintiff fails to allege Defendants' press release is false or misleading for three reasons.

[14] The factual allegation (in two places in ¶36) that a "patient's [ovarian] cancer had in fact returned" is grossly irresponsible, particularly given that it is the most lethal of gynecologic cancers. No such medical diagnosis could ever or should ever be ethically made (or alleged) without review of a patient's chart and history by a medical professional. This underscores not only the implausibility of Plaintiff's allegations, but the recklessness as well.

First, the passage in ¶35 of the SAC upon which Plaintiff relies is incomplete, and the text reproduced above shows that Defendants disclosed the alleged nondisclosed information, *see* SAC ¶36, namely, that the patient's CA125 count was elevated. Ex. 13, at 2. Plaintiff's claim is thus unsupported, conclusory, and fails to plead a plausible omission rendering it misleading.

Second, Defendants' statement regarding a clinical trial patient's clinical stability is subject to PSLRA's safe harbor for forward looking statements as the press release contains legitimate cautionary language. *See* Ex. 13, at 3-4; 15 U.S.C. § 78u-5.

Third, Plaintiff fails to allege any particularized facts supporting an inference of scienter, let alone a strong one, that Defendants intended to deceive by reporting the results in the release.

G. Plaintiff's Claim That Defendants Failed To Disclose Two Material Risks Is Refuted By Public Filings Represented To Have Been Reviewed By Plaintiff's Counsel[15]

Plaintiff's final claim is that the Company failed to disclose two material risks. SAC ¶¶37. *One*, Plaintiff alleges that the Company failed to disclose "Cellceutix's inability to fund expensive trials to get Brilacidin through FDA approval" in its 2013 Form 10-K, "nor were such risks ever disclosed during the class period." SAC ¶37. *Two*, Plaintiff alleges that the Company should have disclosed in 2013 and 2014 Form 10-Ks their inexperience in conducting Phase 3 clinical trials. SAC ¶38. As demonstrated below, Plaintiff's claim fails to plead a false or misleading statement because it ignores extensive disclosure of these specific risks.

Relevant Disclosures relating to Risks of Raising Capital

Clinical stage biopharmaceutical companies have no drugs approved by the FDA and conduct research to look for signals that their drugs or compounds either are working, or have the potential to treat diseases and conditions. "Competition in the pharmaceutical and

[15] As noted, Defendants object to the extent this is a new claim that relies on the Form 10-K filed on September 11, 2015. This was available to Plaintiff earlier and is outside the class period in his PSLRA early notice.

biotechnology industries is intense," Ex. 7, at 19, and these companies largely are "high risk, high reward." These considerations are explicitly discussed in the Company's Form 10-Ks.

For example, in its 2013 and 2014 Form 10-Ks, in the section entitled "**ITEM 1A. RISK FACTORS,**" the Company cautions that:

> Investing in the Company's common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this Annual Report on Form 10-K, before purchasing shares of the Company's common stock.

Ex. 7 (2013 Form 10-K), at 20. Ex. 8 (2014 Form 10-K), at 24.

The first "Risks Specific to Us" states: ***"We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.***" Ex. 7 (2013 Form 10-K), at 20 (emphasis in original); *see also* Ex. 8 (2014 Form 10-K, warning: "***We need to raise substantial additional capital in the future …, which could prevent us from fully implementing our business, operating and development plans.***"), at 24; Ex. 9 (2015 Form 10-K, same), at 19. In fact, both the 2013 and 2014 Form 10-Ks disclose that the Company does not have "resources" or "current cash balance" to complete the development and commercialization of any of its proposed products. *See* Ex. 7, at 20; Ex. 8, at 27. Regarding "the expensive trials to get Brilacidin through FDA approval," SAC ¶37, the 2014 Form 10-K specifically discloses: "[i]n the event that we cannot obtain acceptable financing, we would be unable to complete preclinical development projects, and clinical trials for Kevetrin, Prurisol, and Brilacidin"). *See* Ex. 8, at 25.

Relevant Disclosures related to Lack of Clinical Trial Experience

Only a fraction of drugs that are investigated become candidates for clinical trials. Like many other companies, Cellceutix did not always have clinical trial experience in-house, and warned potential investors of that fact. For example, in its 2013 Form 10-K, in "ITEM 1A. RISK

FACTORS," the Company stated: "We have no experience conducting or supervising clinical trials that must be performed to obtain data to submit in concert with applications for approval by the FDA." Ex. 7, at 20. After the Company added personnel, the 2014 Form 10-K discloses that "[w]e have acquired limited experience in conducting and supervising clinical trials," and cautions "[b]ecause we have limited experience [], we outsource a significant amount of the work relating to our clinical trials to third parties." Ex. 8, at 31.[16]

Plaintiff's Allegations are Unsupported and Refuted by SEC Filings

First, in light of the disclosures reproduced above, Plaintiff's allegations that Defendants made "***no*** disclosure" of the risk of an inability to fund expensive clinical trials, SAC ¶37 (emphasis added), and "failed to disclose the material risk of their undertaking a Phase 3 study" due to their inexperience, *see* SAC ¶38, are unsupported, conclusory in nature, and fail to plead any plausible omission on the part of Defendants.

Second, as a matter of law, the Form 10-K cautionary language and risk disclosures were more than sufficient to rebut any misrepresentation or omission claim under the "bespeaks caution" doctrine. *See, e.g., Halperin v. eBanker USA.COM, Inc.*, 295 F.3d 352 (2d Cir. 2010) (alleged omissions together with cautionary language would not mislead a reasonable investor).

Third, even assuming the 2013 and 2014 Form 10-K disclosures were somehow insufficient, Plaintiff fails to allege any specific facts showing an inference of strong scienter that Defendants intended to deceive by not including additional risk information, particularly given the more compelling opposing inference that they believed the existing language was sufficient.

[16] In the Form 10-Ks, the Company extensively disclosed many other specific risks including that it is "a development stage company and have no products approved for commercial sale, have never generated any revenues, and may never achieve revenues or profitability," and that "[d]evelopment of pharmaceutical products is a time-consuming process, subject to a number of factors, many of which are outside of our control. Consequently, we can provide no assurance of the successful and timely development of new drugs, and the failure to do so could cause us to cease operations." *See, e.g.,* Ex. 8 (2014 Form 10-K), at 27, 29.

III. THE SECOND AMENDED COMPLAINT DOES NOT ADEQUATELY PLEAD LOSS CAUSATION

Plaintiff devotes a section of the SAC to the Mako Research article posted on the website *Seeking Alpha*. SAC at p.17 ("**THE TRUTH EMERGES**"). To the extent Plaintiff relies on that article as a corrective disclosure for its medical claims (claims C-F), it is insufficient because that article's content is chiefly opinion regarding disclosed facts. *See Nanoviricides v. Seeking Alpha, Inc.*, 2014 WL 2930753, at *6 (N.Y.Sup. Jun. 26, 2014) (*Seeking Alpha* "is designed to give people a place to express their opinions," and readers should treat anonymous third-party content "as opinion rather than fact"); *In re Omnicom Grp. Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010) ("A negative journalistic characterization of previously disclosed facts does not constitute a corrective disclosure of anything but the journalists' opinions.").

Likewise, to the extent Plaintiff relies on the 2015 Form 10-K (claim G) to plead loss causation, it fails because the SAC allegation that the Company's stock price fell approximately 15% as a result of that filing, *see* SAC ¶49, is simply implausible given that Plaintiff's counsel filed the original class action complaint that same day, issuing an "*Equity Alert*." *See* Ex. 19; *In re Moody's Corp. Sec. Litig.*, Fed. Sec. L. Rep. P. 97, at 10 (requiring disaggregating of events).

IV. EVEN ASSUMING THE SECOND AMENDED COMPLAINT PLEADED A FRAUD, IT DOES NOT RAISE A STRONG INFERENCE OF SCIENTER

Undoubtedly in an effort to make it as confusing as possible, Plaintiff alleges a seeming laundry list of prior bad acts by Dr. Menon and Mr. Ehrlich. SAC ¶¶51-67. Even assuming Plaintiff had pleaded facts constituting any fraud against Defendants, the SAC would be insufficient nonetheless because it fails to raise a strong inference of scienter for five reasons.

First, Plaintiff's alleged examples are not accompanied by a single document, or based on a single witness interview as corroboration, and instead are gleaned mostly from the Mako Research article. They are thus conclusory in nature and implausible.

Second, at bottom, the allegations do little more than suggest that the Individual Defendants acted in their economic self-interest, or with motives that are "generally possessed by most corporate directors and officers," which is insufficient. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001); *see* SAC ¶¶ 55, 56, 57, 62.

Third, many of the allegations are circular in nature, claiming scienter based on the fraud alleged earlier in the complaint. SAC ¶¶53, 60, 63, 66, 67. This is insufficient because if the facts alleged in the Complaint are insufficient to support Plaintiffs' belief that false or misleading statements were made, those facts cannot support an inference that Defendants knew or should have known their statements were false or misleading. *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., Inc.,* 75 F.3d 801, 813 (2d Cir.1996).

Fourth, it is improper for Plaintiff to rely on the Mako Research article as a basis for the scienter allegations. Not only have New York courts admonished readers to treat those assertions as opinion, and not fact, but in addition to identifying the source, the source must be shown to have been likely to know the relevant facts. *Fraternity Fund Ltd. v. Beacon Hill Asset Mgmt. LLC*, 376 F.Supp.2d 385, 395 (S.D.N.Y. 2005); *In re NTL, Inc. Sec. Litig*., 347 F.Supp.2d 15, 23 (S.D.N.Y.2004). There is no reason to believe that the anonymous author meets that standard.

Fifth, many of Plaintiff's scienter allegations are demonstrably false or implausible on their face. The Company's point-by-point rebuttal to the article, *see* Ex. 2, explains the outright falsity or implausibility of many of these, thereby undercutting any reliance to show a strong inference of scienter. Some additional observations include but are not limited to:

- In ¶55, Plaintiff alleges the Company falsely claimed the association of "Dr. Emil Frei, director and physician-in-chief emeritus at the Dana Faber Cancer Institute, and Dr. Har Gobind Khorana, a 1968 Nobel Prize Winner" with the Company, but, in fact, they were founding shareholders of the Company, *see* Ex. 20, (Stock Transfer Agent Report) at 5-6;

- In ¶62, Plaintiff claims Mr. Ehrlich disclosed non-public information in violation of Regulation FD, but a careful reading shows no such violation occurred because, as stated by Mr. Ehrlich, Dr. Alexander had disclosed the same information previously (which then was posted on the Company's website), and providing an affirmative response that the status quo remains the same ("uplisting still on track"), or regarding a required SEC filing (without sharing content) shares no material non-public information; and

- In ¶64, Plaintiff alleges that Mr. Ehrlich "failed to disclose that in fact he was CFO [of StatSure Diagnostics Systems, Inc.] from 1999 to 2008," yet Plaintiff inexplicably omits language in the very Form 10-Ks he quotes, which states: "From October 8, 1999 to December 31, 2008, Mr. Ehrlich had been a director at StatSure Diagnostic Systems, Inc. and has held different executive officer positions at that company including CEO, President, and CFO." Ex. 7 (2013 Form 10-K), at 57.

V. COUNT TWO OF THE SECOND AMENDED COMPLAINT FAILS TO STATE A CLAIM UNDER SECTION 20(a) OF THE EXCHANGE ACT

In Count II, Plaintiff asserts claims under Section 20(a) of the Exchange Act against the Individual Defendants. Section 20(a) imposes "control person" liability, and is predicated on a primary violation of securities law, here, Section 10(b). *Rombach v. Chang*, 355 F.3d 164, 177-78 (2d Cir. 2004). Because Plaintiff fails to state a primary violation, Count II must be dismissed.

Conclusion

Courts and Congress have long recognized the extraordinary costs and burdens of baseless securities class action lawsuits, particularly to emerging companies seeking to develop novel medicines. This is one such case, and, for the foregoing reasons, Defendants respectfully request that this Court dismiss Plaintiff's SAC with prejudice.

Dated: February 10, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Michael J. Sullivan, hereby certify that on February 10, 2016, I electronically filed the foregoing document with the United States District Court for the Southern District of New York by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

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