

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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GARY ZAGAMI, Individually and on Behalf	)	)
of all Others Similarly Situated,	)	)
	)	)
	)	<b>Case No. 1:15-cv-7194 (KPF)</b>
Plaintiff,	)	)
	)	)
	)	)
v.	)	<b>ORAL ARGUMENT REQUESTED</b>
	)	)
	)	)
CELLCEUTIX CORPORATION, LEO	)	)
EHRlich, AND KRISHNA MENON,	)	)
	)	)
Defendants.	)	)
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**DEFENDANTS’ REPLY MEMORANDUM OF LAW IN SUPPORT OF  
THEIR MOTION TO DISMISS SECOND AMENDED COMPLAINT**

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**TABLE OF CONTENTS**

*Preliminary Statement* .....1

**I. THRESHOLD ISSUES** .....3

**A. Improper Venue** .....3

**B. Deficient PSLRA Early Notice**.....4

**C. Judicial Notice & Scierter Generally** .....4

**II. THE SAC FAILS TO STATE A SINGLE ACTIONABLE CLAIM**.....5

**A. Count A: Plaintiff’s claim regarding Dr. Menon’s Ph.D. fails because the information is immaterial and no reasonable investor could rely on the article**.....5

**B. Count B: Defendant had no duty to announce a correction to the article**.....6

**C. Count C: Defendants never stated Brilacidin was effective against E. coli**.....6

**D. Count D: Plaintiff mischaracterizes Defendants’ scientific opinions and statements**.....7

**E. Count E: Plaintiff’s claim regarding a clinical trial protocol (specifically, using P21 as a biomarker) is foreclosed by Kleinman**.....8

**F. Count F: Defendants’ press release did not state Kevetrin “stopped the cancer”** .....9

**G. Count G: Defendants have no duty to disclose the alleged nondisclosed risks yet again** .....9

**III. THIS COURT SHOULD NOT GRANT LEAVE TO AMEND**.....10

**TABLE OF AUTHORITIES****Cases**

<i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 663-64 (2009) .....	3
<i>Ashland Inc. v. Morgan Stanley &amp; Co.</i> , 652 F.3d 333, 337-38 (2d Cir. 2011).....	6
<i>Greenhouse v. MCG Capital Corp.</i> , 392 F.3d 650, 661 (4th Cir. 2004) .....	5
<i>In re IBM Sec. Litig.</i> , 163 F.3d 102, 107 (2d Cir. 1998).....	6
<i>In re Livent Inc. Noteholders Sec. Litig.</i> , 151 F. Supp. 2d 371, 404 (S.D.N.Y. 2001).....	7
<i>In re MedImmune, Inc. Sec. Litig.</i> , 873 F.Supp. 953, 966-67 (D.Md.1995) .....	8
<i>Kleinman v. Elan Corp., plc</i> , 706 F.3d 145, 154-55, 156 (2d Cir. 2013) .....	8, 9
<i>Nanopierce Techs., Inc. v. Southridge Capital Mgmt. LLC</i> , 2003 WL 22882137 (S.D.N.Y. Dec. 4, 2003) .....	5
<i>Podany v. Robertson Stephens, Inc.</i> , 350 F.Supp.2d 375 (S.D.N.Y. 2004).....	10
<i>S.E.C. v. Boock</i> , No. 09 CIV. 8261(DLC), 2010 WL 2398915 (S.D.N.Y. June 15, 2010).....	4
<i>Stratte-McClure v. Morgan Stanley</i> , 776 F.3d 94, 106-07 (2d Cir. 2015) .....	10
<i>Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.</i> , 2005 WL 1322721 (S.D.N.Y. June 1, 2005) .....	4
<i>Tellabs, Inc. v. Makor Issues &amp; Rights, Ltd.</i> , 551 U.S. 308, 322 (2007).....	4, 7, 10
<i>United States v. AVX Corp.</i> , 962 F.2d 108, 115 (1st Cir. 1992).....	7

***Preliminary Statement***

This case underscores the dichotomy between securities class actions, which serve an important purpose in protecting classes of investors harmed through corporate malfeasance, and misguided lawsuits that have been filed without basis in fact, or for an improper purpose. The hallmarks of the former, of course, are consistency in the core legal theories of liability, factual allegations that are supported by an identifiable or, at a minimum, facially reliable, source, and fraud claims that are not only theoretically possible or conceivable, but plausible. In stark contrast, this lawsuit has none of these hallmarks.

Defendants have pointed out that the original and first amended complaints (Dkts. 1, 10) were not the product of a reasonable inquiry because, among other reasons, the allegations were copied from an article by an anonymous, first-time and admittedly biased author using the pseudonym “Mako Research,” within hours of its posting online. Dkt. 39-1 (“*Cellceutix: Empty Office, Unviable ‘Science’, Misleading Disclosures, 96% Downside*”); Mem. at 7-9.<sup>1</sup> After many months and being granted leave to amend to file a third complaint, Plaintiff, while keeping the premise that Cellceutix is a fraud, has jettisoned the initial unsupportable assertions at the article’s core, namely, that the Company’s offices were empty and that its leading drugs, Brilacidin, which successfully completed a Phase 2b trial, and Kevetrin, an anti-cancer drug in clinical trials at Dana-Farber and Beth Israel, were ineffective. Instead, Plaintiff cobbles together an equally unsupportable assortment of statements that he concludes are false or misleading.

Defendants cannot help but observe here that had the original complaint never been filed, it is almost unfathomable that any plaintiff or plaintiff’s law firm would realistically pursue the claims and theories that are currently alleged in the SAC. For example:

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<sup>1</sup> References to Dkt. 39-\_\_ refer to the documents attached as an Exhibit to the Declaration of Michael J. Sullivan filed in connection with Defendants’ Request for Judicial Notice (Dkt. 38) of certain documents to be considered in connection with the motion to dismiss. “Mem.” refers to Defendants’ Memorandum of Law in support of their Motion to Dismiss (Dkt. 37) and “Opp.” refers to Plaintiff’s Memorandum of Law in Opposition (Dkt. 41).

- investors were misled because an article in an obscure Indian online magazine < <http://futuremedicineonline.com/> > erroneously implied that an officer got a degree from one university as opposed to another, particularly where those investors could review Form 10-Ks that accurately reported the information (Counts A & B);
- a company committed fraud by providing accurate scientific information about one of its drugs on a poster because by doing so, it had illegally “touted” the efficacy of that drug for an indication unrelated to the drug’s current clinical trials (Count C);
- a company’s use of a clinical trial protocol (approved by Dana-Faber) to help determine whether a drug is working was fraudulent because the plaintiff disagreed with the underlying scientific opinion whether that method could or should be used (Count E); and
- a company that has no revenue, SAC ¶62, and has warned that (a) it “may not be able to successfully develop any drugs,” Dkt. 39-8, at 28, (b) it has little or “no experience conducting or supervising clinical trials,” Dkt. 39-7, at 20, and (c) its entire existence depends on “rais[ing] substantial additional capital in the future to fund our operations,” Dkt. 39-8, at 24, committed fraud when it did not tell investors that it must raise *even more capital* after acquiring a new drug, and that it had little or no “*Phase III*” clinical trial experience (Count G).

In moving to dismiss, Defendants showed that Plaintiff pleaded no actionable claims. *See* Mem. at 3-5 (chart). In Opposition, Plaintiff does five things in an effort to survive dismissal (and presumably to make his lawsuit appear legitimate to avoid potential sanctions).

*First*, Plaintiff alleges new facts in the Opposition and comes up with new explanations and legal theories that are found nowhere in the SAC. In the process, Plaintiff essentially creates fast moving targets for Defendants (which he hopes Defendants can never hit).

*Second*, Plaintiff’s counsel (on behalf of a single plaintiff) advocates startling theories that would profoundly expand corporate liability under the securities laws. For instance, taken to its logical conclusion, Plaintiff’s argument:

- as to Counts A & B (regarding Dr. Menon’s erroneous degree), would mean that every publicly traded company would have an affirmative obligation to search for every article mentioning the company, fact check it, contact the publisher to point out any errors or incorrect inferences no matter how immaterial they may seem, and then announce a correction to the article, even in cases where the company did not publicize, adopt, or place its imprimatur on that article; and

- as to Count D (regarding the operation of one of its drugs), that a plaintiff properly pleads a securities fraud claim by simply alleging that one or two of defendants' isolated sentences in a press release is inconsistent with a descriptive opinion in a Form 10-K.

*Third*, Plaintiff continues his pattern and practice of knowingly making false factual allegations<sup>2</sup> and outrageous scienter allegations, hoping that this Court will draw unsupported inferences and conclusions from them.

*Fourth*, Plaintiff either mischaracterizes Defendants' statements, or asks this Court to draw unsupported inferences and conclusions from them.

*Fifth*, Plaintiff merely recites his allegations and the elements of the cause of action, and concludes that is sufficient, even though the claims are speculative and implausible on their face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 663-64 (2009) ("determining whether a complaint states a plausible claim is context-specific, requiring the reviewing court to draw on its experience and common sense") (citing *Bell Atlantic v. Twombly*, 550 U.S. 544, 556 (2007)).

In the end, this Court should view the SAC for what it is: a futile effort to salvage a complaint that should never have been filed in the first place. This is particularly true given that, if the PSLRA Certifications filed by Plaintiff's counsel are even to be believed and considered non-perjurious, the initial complaint was prepared by counsel and reviewed by plaintiff in a matter of hours following the posting of the anonymous article.

## **I. THRESHOLD ISSUES**

### ***A. Improper Venue***

Since the beginning of this litigation, Defendants placed Plaintiff on notice that the complaint failed to allege and show that venue is proper. In response, Plaintiff made no changes to the paragraph in the SAC regarding venue. *Compare* Compl. ¶8 with SAC ¶10.

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<sup>2</sup> For example, Plaintiff repeats the allegation that Defendants failed to disclose Dr. Menon's employment with Nanovircides, SAC ¶14, but no such disclosure was required, *see* 17 CFR 229.401(e), because, as disclosed in that company's Form 10-K, he was employed by KARD Scientific, Inc., and held a consulting, non-executive position with Nanovircides. < [http://www.sec.gov/Archives/edgar/data/1379006/000114420414058463/v390044\\_10k.htm](http://www.sec.gov/Archives/edgar/data/1379006/000114420414058463/v390044_10k.htm) >.

In Opposition, Plaintiff now includes new allegations concerning three presentations made by the Company in New York, *see* Opp. at 13, but none of the Defendants' misstatements are alleged to have been made there or at that time. Plaintiff also argues that *SEC v. Boock* supports his position, but that case is distinguishable because the court found that "the Defendants submission of false information to the CUSIP Bureau in Manhattan is a non-trivial act that helped accomplish the securities law violations alleged by the SEC." 2010 WL 2398915 at \*3. Indeed, Plaintiff's suggestion that every publicly-traded company may be sued in any district in the United States, *see* Opp. at 13, regardless of its contacts with that district, is untenable, and would render limiting language in the special venue provision superfluous.

***B. Deficient PSLRA Early Notice***

As an officer of the court, Defendants' counsel felt compelled to bring to this Court's attention that Plaintiff had extended the class period without mentioning that change in the SAC, resulting in a deficiency in the Early Notice. While Plaintiff argues that republication typically is not necessary, he does not rebut Defendants' argument that these new claims and theories – for example, those based on a Form 10-K available *before* he filed his first amended complaint – should be barred as untimely, or otherwise would require republication because they implicate different putative class members and theories. *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").

***C. Judicial Notice & Scienter Generally***

Plaintiff's challenge to one document regarding Defendants' association with two leading scientists (Dkt. 44; Ex. 39-20) underscores the difficulty to place a court in a position to consider the facts and allegations in their entirety, *see Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007), including the outright falsity or recklessness of the allegations. Here, most

of Plaintiff's scienter allegations (including the one referenced above involving Dr. Menon's former boss) rely on the Mako Research article, which, in turn relies upon an INDIA New England article. Defendants acknowledge that they are limited at this stage in any challenge to the veracity of factual allegations or the reliability of the source, but feel compelled to point out that: (a) contrary to Plaintiff's statement, *see* Opp. at 24, the Company disclosed advisory board members in a sworn SEC filing; and (b) in a document relied upon in the SAC (¶28), the Company explained that the INDIA New England assertions were false, and "[a]fter presenting the publisher with proof he quickly removed the article and all links to it." Dkt. 39-2, at 9.<sup>3</sup>

## II. THE SAC FAILS TO STATE A SINGLE ACTIONABLE CLAIM

### A. *Count A: Plaintiff's claim regarding Dr. Menon's Ph.D. fails because the information is immaterial and no reasonable investor could rely on the article*

Even assuming: (a) Dr. Menon made the alleged misstatement and the allegation is not considered speculative – a point Defendants do not concede as the *Future Woman* article does not state that Dr. Menon was interviewed, does not state that he received a degree from Harvard, and does not include a direct quotation from him on that point; (b) the Company became aware of the article during the class period – which nowhere is alleged in the SAC; and (c) the incorrect inference regarding which university awarded him a Ph.D. is material,<sup>4</sup> Plaintiff's claim still fails because, as a matter of law, a reasonable investor was not entitled to rely blindly on the *Future*

<sup>3</sup> This Court can take judicial notice of the fact that the Company disclosed its scientific advisory board members (without necessarily having to accept the truth of the matter asserted) in a Form 8-K dated December 10, 2007, *see* < <https://www.sec.gov/Archives/edgar/data/1355250/000135525007000020/form8k.htm> >. Also, Defendants' counsel notes that it conducted a reasonable due diligence search of the INDIA New England website < <http://indianewengland.com/> > and, as the Court may itself may do, found no link to the article.

<sup>4</sup> Contrary to Plaintiff's assertion, Opp. at 16-17, Defendants do not suggest that a misstatement regarding educational background could never be material. Rather, to extent the Court need reach this issue, Defendants argue that in these particular circumstances, this case is like *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 661 (4th Cir. 2004), where a CEO's false representation that he had obtained a college degree was ruled to be immaterial as a matter of law because it did not alter the large body of information about the company available to investors. The cases Plaintiff relies upon involve circumstances vastly different and undoubtedly more troubling to investors. In fact, in *Nanopierce Techs., Inc. v. Southridge Capital Mgmt. LLC*, 2003 WL 22882137 at \*4 (S.D.N.Y. Dec. 4, 2003), the "background" found to raise a question of materiality involved a failure to disclose in SEC filings that an officer entered into a "consent decree permanently enjoining him from committing further securities violations and temporarily barring him from practicing before the SEC." That is a far cry from the Plaintiff's allegation here.



*Woman* article to make an investment decision, as the securities laws require a minimal due diligence, such as looking at the Company's Form 10-Ks readily available on the internet, which contained the accurate information. *Ashland Inc. v. Morgan Stanley & Co.*, 652 F.3d 333, 337–38 (2d Cir. 2011) (no reliance if, through minimal diligence, truth would have been discovered).

***B. Count B: Defendant had no duty to announce a correction to the article***

Plaintiff's related theory that Mr. Ehrlich had a duty to correct the inaccurate inference in the article fails for its breadth, *see supra* at p. 2, and for many of the above reasons. *See* Mem. at 16-17. To the extent a duty even existed, Defendants not only "cease[d] making false statements," Opp. at 16, but included accurate information in Form 10-Ks during the class period, thereby correcting the former under the maxim *expressio unius est exclusio alterius*.<sup>5</sup>

***C. Count C: Defendants never stated Brilacidin was effective against E. coli***

Plaintiff's allegation that forms the basis for this claim is that Defendant falsely "told investors that [Brilacidin] was effective against gram-negative bacteria." Opp. at 17; SAC ¶¶25-26 (Company "touted Brilacidin's ability to kill gram-negative bacteria"). But nowhere have Defendants ever made this statement. Plaintiff's sole support for this allegation is the characterization and unwarranted inference he now asks the Court to draw that Defendants "touted" the "efficacy" by including a small chart (within a more comprehensive poster) about the drug's operation in one of many peer-reviewed posters on display at an international conference. Dkt. 39-15.<sup>6</sup> In such circumstances, this Court need not credit the allegation and the

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<sup>5</sup> Indeed, Plaintiff's claim appears to be nothing more than an improper end run to impose liability for the mistaken information the Company included in 2009. *See In re IBM Sec. Litig.*, 163 F.3d 102, 107 (2d Cir. 1998) (defendant is liable only for those statements made during the class period and a plaintiff cannot surmount this hurdle by claiming a "duty to correct" misstatements that extend into the class period).

<sup>6</sup> Plaintiff displays either an astounding lack of knowledge (given that it is the basis of one of his claims) or intransigence in challenging Defendants' description of the scientific posters on display at the largest international forum for the presentations of research in the fields of clinical microbiology and infection as being "peer reviewed." *See* Opp. at 17. Although not integral to Defendants' argument, this Court may take judicial notice of this fact as there should be no dispute regarding its brochure, which states at page 12: "Since its initiation, ECCMID has grown

claim fails. *In re Livent Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 404 (S.D.N.Y. 2001) (court need not accept conclusory characterizations); *United States v. AVX Corp.*, 962 F.2d 108, 115 (1st Cir. 1992) (“reviewing court is obliged neither to ‘credit bald assertions, periphrastic circumlocutions, unsubstantiated conclusions, or outright vituperation,’ [] nor to honor subjective characterizations, optimistic predictions, or problematic suppositions”) (citations removed).<sup>7</sup>

Plaintiff also has not pleaded a strong inference of scienter because there are “plausible, nonculpable explanations for the defendant’s conduct,” namely, the decision to include comprehensive scientific data in a poster at an international conference. *Tellabs*, 551 U.S. at 324.

***D. Count D: Plaintiff mischaracterizes Defendants’ scientific opinions and statements***

In his Opposition, Plaintiff seeks to confuse and distract the Court from the fundamental question, which is whether the statement in the Company’s Form 10-K is properly alleged to be false or misleading. SAC ¶27. It is not. In its Form 10-Ks the Company stated:

In animal models of oral mucositis, an oral rinse containing brilacidin was shown to reduce the occurrence of severe ulcerative oral mucositis by more than 90% compared to placebo. **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.**

Dkt. 39-7, at 6 (emphasis added); *see also* Dkt. 39-8, at 21.

Plaintiff’s allegation that this is false or misleading based on a subsequent statement fails for a myriad of reasons, including: (a) in context, the Form 10-K language is not inconsistent,

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in size and importance and now attracts around 10,000 participants every year. The number of submitted abstracts has risen to over 4,500 of which roughly 70% are accepted for oral, ePoster or poster presentation.” < [https://www.escmid.org/fileadmin/src/media/PDFs/4ESCMID\\_Library/3Publications/Brochure/WEB\\_Imagebrochure\\_08\\_04\\_2015.pdf](https://www.escmid.org/fileadmin/src/media/PDFs/4ESCMID_Library/3Publications/Brochure/WEB_Imagebrochure_08_04_2015.pdf) >.

<sup>7</sup> Defendants note that the very sentence Plaintiff relies upon – “Brilacidin has broad spectrum *in vitro* antimicrobial activity,” Opp. at 18 (emphasis added) – demonstrates the implausibility and speculative nature of his claim. The use of the term *in vitro* means, by definition, that the results were from a test tube experiment. How these results could be reasonably construed as an affirmative statement that the drug was effective at treating a gram negative infection *in humans* is perplexing, particularly in light of Defendants’ repeated, opposing disclosures that Brilacidin is being developed to treat particular types of gram positive infections. *See e.g.*, Dkt. 39-7, at 6.

particularly given Plaintiff's concession that the drug may help cancer patients undergoing radiation and chemotherapy with both oral mucositis and the lesions that accompany it, Opp. at 18; (b) there is no allegation in the SAC that this opinion of a scientific fact ("we believe that the combination...") did not represent true scientific expressions of the Company's view (or that of Polymedix, from whom it acquired the drug) at the time, *see In re IBM Sec. Litig.*, 163 F.3d at 109 (opinion not actionable, particularly where nothing to suggest speakers did not believe that they were accurate when made); and (c) in any event, Plaintiff has not pleaded a strong inference of scienter, because there is at least as compelling inference that Defendants did not intend to mislead investors through descriptive language regarding the combination of properties.

***E. Count E: Plaintiff's claim regarding a clinical trial protocol (specifically, using P21 as a biomarker) is foreclosed by Kleinman***

No matter how craftily Plaintiff seeks now to re-characterize his claim, *see* Opp. at 20 (Plaintiff "questions Defendants' characterization" and not the parameter), the SAC explicitly states that Plaintiff believes that P21 is not a legitimate biomarker because "P21 has not been shown to be correlated with improved clinical outcomes for cancer." SAC ¶34. But Plaintiff's disagreement with the Company – whose scientists (as well as those at Dana-Faber) believe it worthwhile to use P21 expression in a clinical trial to see if the drug is working – cannot form the basis of a securities fraud claim. That is expressly foreclosed by the Second Circuit's opinion in *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154-55 (2d Cir. 2013). *See id.* at 154 (citing *In re MedImmune, Inc. Sec. Litig.*, 873 F.Supp. 953, 966–67 (D.Md.1995) (reasonably held opinion even if later proven wrong is not actionable)).<sup>8</sup>

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<sup>8</sup> Plaintiff cites a scientific article in support of his allegation in ¶34, but this Court can take judicial notice of the existence of other studies concluding to the contrary. *See* "Relationship between p21 expression and mutation of the p53 tumor suppressor gene in normal and malignant ovarian epithelial cells" < <http://www.ncbi.nlm.nih.gov/pubmed/9816335> >; "Correlations between p21 expression and clinicopathological finding, p53 gene and protein alteration, and survival in patients with endometrial carcinoma" < <http://www.ncbi.nlm.nih.gov/pubmed/9422988> >. In addition to the collaboration and agreement of scientists at

As the *Kleinman* Court ruled, this Court must only “look to see whether the statements made were misleading or rendered misleading due to an omission,” 706 F.3d at 155, and because Defendants disclosed it was using P21 as a biomarker in the trial, that ends the inquiry.

***F. Count F: Defendants’ press release did not state Kevetrin “stopped the cancer”***

Plaintiff originally claimed that the Company’s press release is misleading because Defendants later admitted “that the patient’s CA125 count was elevated,” which, according to Plaintiff, is a “commonly accepted test for cancer recurrence.” SAC ¶36. After Defendants pointed out that it disclosed in that release that the patient’s CA125 levels were elevated and that the patient discontinued the trial, Mem. at 24-25, Plaintiff changes his theory, asking this Court to infer that Defendants gave the false impression that the drug “stopped the cancer.” Opp. at 21.

Defendants’ press release stated only that “[a]ccording to information supplied by the hospital,” “the patient’s disease to be clinically stable,” Dkt. 39-13, at 1. Nor does Plaintiff allege that any of Defendants’ factual statements in the release – most notably, “the near complete disappearance of a metastatic lesion” – were false. Furthermore, Defendants included extensive cautionary language and characterized the results (as well as the principal investigators’ interest in a presentation regarding “the safety and pharmacological effect of Kevetrin”) only “as a very optimistic sign.” *Id.* As such, it cannot be relied upon and also is foreclosed by *Kleinman*, 706 F.3d at 156, which found that allegations of positive statements with “a note of caution,” particularly where “[t]here are no actionable affirmative false statements” do not state a claim.

***G. Count G: Defendants have no duty to disclose the alleged nondisclosed risks yet again***

After recognizing a glaring and fatal deficiency in his claim – namely, that Defendants consistently have disclosed the risks of the need to raise money for clinical trials and its lack of

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Dana-Farber, the scientific difference of opinion shows that it is subject to medical debate and that the decision to use P21 therefore represents an interpretation of medical data, which is not actionable under *Kleinman*, *supra* at 154. It also defeats any claim of scienter given the compelling opposing inference that can be drawn. See Mem. at 23, 24.

clinical trial experience, Mem, at 25-27 – Plaintiff newly claims that the Company violated 17 C.F.R. §229.303 requiring the disclosure of “material events and uncertainties ... that would cause reported financial information not to be necessarily indicative of future operating results or future financial condition.” Opp. at 22-23. The fundamental problem with this new theory (and the cases he relies upon) is that, as the SAC admits in ¶62 and the Opposition admits on page 1, the Company has no revenue and must raise money simply to exist. Dkt. 39-8, at 24. There consequently is no trend or uncertainty, and it is already known to a reasonable investor that if the Company cannot raise enough money, it cannot fund its operations or pursue its drug trials. There is simply no reason for the Company to disclose this, or its lack of trial experience, again.

Plaintiff also cannot meet the heavy burden of scienter because the very case he relies upon shows that when a company takes affirmative steps to make disclosures regarding a risk, the argument is at least as compelling that it did not intend to mislead investors. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106-07 (2d Cir. 2015) (citing *Tellabs*, 551 U.S. at 324).

### **III. THIS COURT SHOULD NOT GRANT LEAVE TO AMEND**

As a last resort, Plaintiff (in his conclusion) requests leave to amend to file a fourth complaint. This argument requires little comment as Plaintiff has not provided any indication that defects identified in the SAC could be cured, nor any indication of what an amended pleading might look like. *See Podany v. Robertson Stephens, Inc.*, 350 F.Supp.2d 375 (S.D.N.Y. 2004). Indeed, beginning with the dubious PSLRA certification filed with a hastily-drawn original complaint, this case has been taking on water since its inception. This Court graciously granted leave to file a third complaint (Dkt. 24), and then an extension of time in which to do so (Dkt. 28). Defendants respectfully submit that any further amendment would be futile, and that this Court should dismiss the SAC with prejudice and let this ship go down once and for all.

Dated: March 25, 2016

Respectfully Submitted,

**ASHCROFT LAW FIRM, LLC**

/s/ Michael J. Sullivan

Michael J. Sullivan

*Counsel for Defendants*

**CERTIFICATE OF SERVICE**

I, Michael J. Sullivan, hereby certify that on March 25, 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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