UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TERRY M. BRENNAN; RON KENNER; KEVIN KOZIATEK; VINCENT RAMPE; and DRAGON GATE MANAGEMENT LTD., individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 15-13618-FDS**
ZAFGEN, INC. and THOMAS E. HUGHES,	)	
Defendants.	)	

MEMORANDUM AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

SAYLOR, J.

This is a putative class action involving alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5. The lead plaintiffs have brought suit, on behalf of a class of similarly situated persons, against biopharmaceutical company Zafgen, Inc. and its CEO Thomas E. Hughes.[1] Plaintiffs contend that class members were harmed when they purchased Zafgen's common stock at prices that were artificially inflated by the company's materially misleading statements and omissions concerning its anti-obesity drug, Beloranib.

Before Zafgen became a public company in June 2014, it conducted a Phase II trial of Beloranib from August 2012 to May 2013 (the "ZAF-201 trial"). In the prospectus for its 2014

[1] The caption has been amended to reflect the Court's order appointing lead plaintiffs on January 7, 2016. (Docket No. 22). The previous named plaintiff was Aviad Bessler. (Docket No. 1).

initial public offering, Zafgen disclosed that two "serious thrombotic events" occurred during that trial.[2] Zafgen repeated that disclosure multiple times throughout the class period (that is, from June 19, 2014, through October 16, 2015). Zafgen also stated in its disclosures that "[serious AEs] that are not characterized by clinical investigators as possibly related to Beloranib or [serious AEs] that occur in small numbers may not be disclosed to the public" until the FDA-approval process.

In October 2015, Zafgen announced that a patient participating in the Phase III trial of Beloranib had died. After unblinding the trial two days later at the request of the FDA, the company disclosed that the patient had been receiving Beloranib, and that the drug had been placed on a clinical hold. During a conference call with analysts later that day, Zafgen disclosed, for the first time, that two "superficial" thrombotic AEs had occurred during the ZAF-201 trial, in addition to the two previously disclosed "serious" AEs. Zafgen's stock price fell 50 percent the next day, and this lawsuit followed five days later.

The complaint alleges that Zafgen's disclosures during the class period contained materially false misrepresentations and omissions because they failed to disclose that four, not two, AEs occurred during the ZAF-201 trial. It also alleges that defendants made those false disclosures with scienter, that is, with an intent to defraud or a high degree of recklessness. The complaint alleges that when defendants made the disclosures, they knew or recklessly disregarded "that there was a significant risk of thrombotic adverse events in future clinical trials of Beloranib." (Compl. ¶ 36). As evidence of defendants' knowledge of that risk, the complaint cites scientific literature and news articles that explored "a potential connection between anti-

[2] "Thrombotic adverse events refer[] to adverse events associated with the formation of blood clots." (Compl. ¶ 2 n.2). This opinion refers to adverse events as "AEs."

angiogenics, such as Beloranib, and thrombotic adverse events." (Pl. Mem. 13-14). The complaint also alleges that Hughes and other Zafgen insiders had a motive to inflate the company's stock price, as demonstrated by insider stock sales in September 2015.

Defendants have moved to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(6) and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4, for two principal reasons.[3] First, they contend that the complaint fails to set forth plausible allegations that Zafgen's disclosures contain actionable misrepresentations or omissions. Second, they contend that it fails to allege specific facts that give rise to a strong inference of scienter.[4]

As the First Circuit has stated, "[a] statement cannot be intentionally [or recklessly] misleading [under the securities laws] if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008). In other words, a complaint is insufficient under the PSLRA if it does not contain particularized factual allegations raising a strong inference that *at the time of disclosure* defendants knew (or were reckless by not knowing) that their failure to provide additional information was misleading.

Even assuming that the complaint plausibly alleges a material misrepresentation or omission, its allegations as a whole fail to clear the PSLRA's relatively high hurdle of pleading a strong inference of scienter. In hindsight, the superficial thrombotic AEs that occurred during

[3] Defendants also base their motion to dismiss on Fed. R. Civ. P. 9(b). "Of course, plaintiffs alleging securities fraud must also meet the Rule 9(b) standard for pleading fraud with particularity." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008). "The PSLRA is consistent with [the First Circuit's] prior application of Federal Rule of Civil Procedure 9(b) to securities fraud actions, a standard which is 'notably strict and rigorous.'" *Id.* at 58 n.7 (quoting *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193 (1st Cir. 1999)).

[4] Defendants also contend that they had no duty to disclose the omitted information and that the complaint fails to make adequate allegations of loss causation. (Def. Mem. 19-20).

the ZAF-201 trial perhaps took on added significance more than two years later when a patient died during the Phase III trial. However, "[p]leading fraud by hindsight, essentially making general allegations that defendants knew earlier what later turned out badly, is not sufficient." *Ezra Charitable Trust v. Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) (internal quotation marks omitted). Without the benefit of hindsight, the complaint fails to plead particularized facts demonstrating that defendants had "sufficient information *at the relevant time* to form an evaluation that there was a need to disclose" the "superficial" AEs, and to form an intent not to disclose them. *See Biogen*, 537 F.3d at 45 (emphasis added). For example, the complaint does not point to a single confidential-source allegation, internal e-mail, or any other direct evidence that would suggest Hughes knew (or was reckless in not knowing) "that there was a significant risk of thrombotic adverse events in future clinical trials of Beloranib." (Compl. ¶ 36). Moreover, the complaint's circumstantial allegations concerning scienter—a patchwork of scientific literature and unsuspicious insider sales—are insufficient to support a strong inference of defendants' "conscious intent to defraud or '[ ] high degree of recklessness.'" *ACA Fin.*, 512 F.3d at 58 (quoting *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002)).

Accordingly, and for the reasons set forth below, defendants' motion to dismiss will be granted.

I. Factual Background

Unless otherwise noted, all facts are stated as set forth in the complaint.[5]

[5] Defendants' motion to dismiss is accompanied by thirteen exhibits (Def. Exs. A-M), including SEC filings and transcripts of Zafgen conference calls. While ordinarily "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden . . . courts have made narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; [and] for documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). As plaintiffs conceded during the hearing on defendants' motion, it has become standard for courts considering motions to dismiss in securities-fraud cases to consider financial statements, SEC filings concerning insiders' stock holdings, and transcripts referred to in the complaint. *See, e.g.*, *Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc.*, 778 F.3d 228, 232 n.2 (1st Cir. 2015). Accordingly, the Court will consider the

A. The Parties and Beloranib

Zafgen, Inc. is based in Boston, Massachusetts. (Compl. ¶ 20).[6] Founded in 2005, Zafgen is a small biopharmaceutical company "dedicated to significantly improving the health and well-being of patients affected by obesity and complex metabolic disorders." (*Id.*). Defendant Thomas E. Hughes has been Zafgen's Chief Executive Officer since 2008. (*Id.* ¶ 21). Zafgen became a public company on June 19, 2014 (the first day of the class period), through an initial public offering, and its shares are traded on the NASDAQ stock exchange. (*Id.* ¶ 20). By the date of its IPO, Zafgen had approximately twelve full-time employees. (*Id.* ¶¶ 30-31).

Beloranib, an obesity therapy, is Zafgen's only product candidate in clinical development—that is, past the pre-clinical stage. (*Id.* ¶¶ 26-27). Beloranib is Zafgen's "lead product candidate . . . [,] a novel, first-in-class, twice-weekly subcutaneous, or SC, injection." (*Id.* ¶ 26). Beloranib treats "severe obesity in two rare diseases, Prader-Willi syndrome, or PWS, and hypothalamic injury-associated obesity, or HIAO, including craniopharyngioma-associated obesity; and severe obesity in the general population." (*Id.*).

The complaint alleges that lead plaintiffs Terry Brennan, Ron Kenner, Kevin Koziatek, Vincent Rampe, and Dragon Gate Management Ltd., purchased shares of Zafgen common stock during the class period, from June 19, 2014, through October 16, 2015. (*Id.* ¶¶ 1, 14-18).

B. Adverse Events During the ZAF-201 Trial

In total, Zafgen has conducted three Phase I trials, four Phase II trials, and one Phase III trial of Beloranib for different obesity-related diseases. (*Id.* ¶ 28).[7] Zafgen conducted the ZAF-

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submitted exhibits where indicated.

[6] All citations are to the amended complaint.

[7] The FDA requires any new drug to go through a series of clinical trials before it can be approved for marketing and sales. *Biogen*, 537 F.3d at 39. After a drug is tested on animals, the developer requests FDA approval to begin human testing. *Id.* If that request is approved, human testing begins and typically follows three

201 trial (Beloranib's Phase IIA proof-of-concept clinical trial) over twelve weeks and eight study sites from August 2012 to May 2013. (*Id.* ¶ 47). During the ZAF-201 trial, 160 obese patients participated, 122 of whom were treated with Beloranib. (*Id.*).

Four thrombotic AEs of varying severity occurred during the ZAF-201 trial. (*Id.* ¶ 48). Third-party clinical investigators categorized two as "superficial" AEs and two as "serious" AEs. (*Id.* ¶ 49; Def. Ex. E at 18, 31; Def. Ex. I at 5). The two serious AEs were determined to be a pulmonary embolism and deep vein thrombosis, respectively. (Compl. ¶ 49; Def. Ex. I at 5). The two superficial AEs were determined to be "superficial thrombophlebitis." (Compl. ¶ 49; Def. Ex. I at 5). All four AEs occurred in patients receiving Beloranib (as opposed to a placebo). (Compl. ¶ 49). The complaint does not allege that Beloranib caused those AEs, and to this date investigators have not determined a specific cause. (Def. Ex. I at 5).

In the spring of 2014, after the ZAF-201 trial, Zafgen began to prepare for its IPO. (Compl. ¶ 52). In its April 18, 2014, SEC Form S-1, which was signed by Hughes, the company disclosed the following concerning the ZAF-201 study:

> As severely obese patients are at an increased risk for cardiovascular disease, we measured systemic biomarkers of cardiovascular disease risk, including low density lipoprotein cholesterol, HDL, CRP, triglycerides and blood pressure in trial participants, to determine Beloranib's impact on such biomarkers. *The results of these biomarker measurements in this trial, as summarized below, suggest that Beloranib treatment does not increase the risk of cardiovascular disease and may be associated with reduced cardiovascular disease risk.*
>
> [Results]
>
> . . . .
>
> There were no deaths or any [serious AEs] deemed to be possibly, probably, or definitely related to Beloranib, although there were *two serious thrombotic*

phases of clinical trials. *Id.*; *see* 21 C.F.R. § 312.21. Each phase requires the company to test the drug on a broader population and results in more stringent monitoring and evaluation. *Biogen*, 537 F.3d at 39. "Throughout the clinical trials, the drug company must report to the FDA and to all participating physicians any serious and unexpected adverse drug experiences that occur." *Id.* (citing 21 C.F.R. § 312.32(c)(1)(i)(A)).

> *adverse events* which, while not attributed to Beloranib treatment, *may point to the utility of assessment of prior history of thrombotic events in patients enrolled in subsequent trials and added vigilance for AEs related to blood clotting during future clinical trials*. The most commonly reported TEAEs [treatment-emergent adverse events] were gastrointestinal disorders, mainly nausea, diarrhea, or vomiting, nervous system disorders, mainly dizziness, and psychiatric disorders, mainly insomnia, sleep disorder, or abnormal dreams. TEAEs were generally mild in severity and transient. Other frequently reported TEAEs were headaches and injection site bruising/itching, although the incidences were comparable to placebo and not observed to be dose-related.

(*Id.*). Zafgen repeated substantially the same disclosure in nine other filings throughout the class period. (*Id.* ¶¶ 55-62).

Accordingly, "prior to October 16, 2015, [Zafgen] had not disclosed any thrombotic adverse events in clinical trials of Beloranib other than the two [serious AEs] in the ZAF-201 trial." (*Id.* ¶ 54). However, the company also made the following disclosures in its Form S-1, Form 10-K for 2014, and Form 10-Qs for the second and third quarters of 2014 and first and second quarters of 2015:

> Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events.
>
> . . . .
>
> [Serious AEs] that are not characterized by clinical investigators as possibly related to Beloranib or [serious AEs] that occur in small numbers may not be disclosed to the public until such time the various documents submitted to the FDA as part of the approval process are made public. We are unable to determine if the subsequent disclosure of [serious AEs] will have an adverse effect on our stock price.

(*See, e.g.*, Def. Ex. E at 44-45; 51).

C. The Patient Death and Disclosure of the Two Superficial Adverse Events

In October 2015, Zafgen's share price began to drop. It opened at $34.76 on October 12 and closed at $15.75 on October 13. (Compl. ¶ 63). On the morning of October 14, Zafgen announced that a patient in its ongoing Phase III trial had died. It issued a press release stating, in relevant part, as follows:

> Zafgen recently learned of a patient death which occurred in the company's ongoing double-blind, randomized, placebo-controlled Phase 3 bestPWS study of Beloranib in Prader-Willi Syndrome, a rare genetic disorder with a high rate of mortality linked to obesity and its co-morbidities. The cause of death remains unknown at this time. According to normal practice, the event was reported to the [FDA], at which point the [FDA] initiated a discussion with the company. The company is working with the [FDA] to expedite a review and understanding of this event, and to determine implications of the event on the conduct of the trial, and anticipates providing an update as its discussions with the [FDA] progress. The thoughts of the company are with the family of the patient at this time. Zafgen remains committed to ensuring the safety of all patients enrolled in its studies.

(*Id.* ¶ 68). Zafgen did not announce the date of the patient's death or disclose whether the patient had been receiving Beloranib or a placebo. (*Id.* ¶ 69).

Two days later, on October 16, the company issued another press release, stating that it "received verbal notice late yesterday from the [FDA] that Beloranib has been placed on partial clinical hold." (*Id.* ¶ 71). That press release also stated:

> As previously reported, Zafgen learned of a death in the ongoing Phase 3 bestPWS study (ZAF-311) of Beloranib in Prader-Willi Syndrome (PWS). While the cause of death remains unknown, the patient's treatment assignment has been unblinded and it is now known that the patient was receiving Beloranib. Due to previously reported thromboembolic events in ongoing and prior clinical trials of Beloranib and the unknown nature of the death, the FDA gave verbal notice of a partial clinical hold to institute measures to ensure patient safety. Patients currently participating in the ZAF-311 study will be screened for existing thrombotic disease prior to receiving further study drug and regularly monitored through the completion of the study. Given that the study is near complete, at this time, the company expects to report top-line results in the first quarter of 2016. Similar screening and monitoring is being considered for the ongoing Phase 2b study (ZAF-203) in patients with severe obesity complicated by type 2 diabetes.

> The company now anticipates that the PWS Phase 3 clinical trial, ZAF-312, will be initiated after ZAF-311 is completed and a full assessment of the safety and efficacy of Beloranib is performed by the FDA.

(*Id.*). During an analyst conference call later that afternoon, Zafgen's chief medical officer, Dennis Kim, stated:

> In our past clinical trials, we have seen six cases of thrombotic findings of varying severity in Beloranib-treated patients[,] including three cases of pulmonary embolism/deep vein thrombosis or DVT and one case of DVT alone. The six events were seen in approximately 400 patients treated with Beloranib for a period up to one year of treatment. We've had no thrombotic events in the approximately 150 patients treated with placebo.

(*Id.* ¶ 72). Kim added that while two of the six AEs occurred in ongoing trials, four had occurred in completed trials, and all four had occurred during the ZAF-201 trial. (*Id.* ¶ 73). He stated that the two previously undisclosed AEs "came from study ZAF-201, which is the same trial [for] the two events that you're aware of. The other two events were what can be classified as minor or benign thromboembolic disease, that being superficial thrombophlebitis, which usually isn't treated except symptomatically." (Def. Ex. M. at 10).

During the same October 16 call, an analyst asked when the company learned of the patient death. (Compl. ¶ 76). Hughes answered:

> Patient confidentiality always matters[,] and just to be clear, we do not, nor should we ever find out the actual identity of this patient or of their family who is still dealing with this horrible event. So, for patient confidentiality, in order to keep people from tracking into it, we can't provide a specific date, but it was about two weeks ago[.] [T]he death we reported very promptly to [the] FDA as one would expect and that's when our dialog with them began.
>
> Question: So you found out and how quickly after you—how soon after you found out, you reported to FDA?
>
> Hughes: Well, briefly within the—we're required to do so within a week, and we certainly were well within that time horizon.

(*Id.*; Def. Ex. M at 11). After closing at $21.02 per share on October 15, Zafgen's share price

closed at $10.36 on October 16, the final day of the class period. (Compl. ¶ 75).

D. Alleged Material Misrepresentations and Omissions

The complaint alleges that defendants made three materially false misrepresentations or omissions in disclosures during the class period:

- "As severely obese patients are at an increased risk for cardiovascular disease, we measured systemic biomarkers of cardiovascular disease risk, including low density lipoprotein cholesterol, HDL, CRP, triglycerides and blood pressure in trial participants, to determine Beloranib's impact on such biomarkers. The results of these biomarker measurements in this trial, as summarized below, suggest that ***Beloranib treatment does not increase the risk of cardiovascular disease and may be associated with reduced cardiovascular disease risk.***"[8]

- "There were no deaths or any [serious AEs] deemed to be ***possibly, probably, or definitely related to Beloranib*** . . . ."

- "[A]lthough there were ***two serious thrombotic adverse events*** which, while not attributed to Beloranib treatment, may point to the utility of assessment of prior history of thrombotic events in patients enrolled in subsequent trials and added vigilance for AEs related to blood clotting during future clinical trials. The most commonly reported TEAEs [treatment-emergent adverse events] were gastrointestinal disorders, mainly nausea, diarrhea, or vomiting, nervous system disorders, mainly dizziness, and psychiatric disorders, mainly insomnia, sleep disorder, or abnormal dreams. TEAEs were generally mild in severity and transient. Other frequently reported TEAEs were headaches and injection site bruising/itching, although the incidences were comparable to placebo and not observed to be dose-related."

(*Id.* ¶ 52) (emphasis in original).

The complaint alleges that Zafgen made those statements, using substantially the same language, in the following ten disclosures, all of which were signed by Hughes: (1) the Form S-1 filed on April 18, 2014, for its IPO; (2) the Form S-1/A filed on April 28, 2014; (3) the Form

[8] The results appearing below this statement indicate that, among other things, "[l]evels of the cardiovascular disease risk marker C-reactive protein were reduced by an average of 2.5, 2.3 and 1.9 μg/ml, or 23%, 22% and 37%, respectively, for patients treated with Beloranib at 0.6 mg, 1.2 mg and 2.4 mg, respectively, compared to an average increase of 1.0 μg/ml for patients dosed with placebo ($p<0.0001$)." (*See, e.g.*, Def. Ex. B at 86).

S-1/A filed on May 2, 2014; (4) the Form S-1/A filed on June 2, 2014; (5) the Form S-1/A filed on June 5, 2014; (6) the Form 424B4 filed on June 19, 2014; (7) the Form S-1 filed on January 12, 2015, for a follow-on offering; (8) the Form S-1/A filed on January 16, 2015; (9) the Form 424B4 filed on January 23, 2015; and (10) the Form 10-K filed on March 25, 2015. (*Id.* ¶¶ 52, 55, 57, 59, 61).

The complaint alleges that those disclosures were materially false misrepresentations or omissions for the following reasons:

> Defendants were well aware of all adverse events relating to Beloranib from the ZAF-201 study. Having chosen to reveal two thrombotic adverse events that occurred in the ZAF-201 trial of Beloranib, to state that those events were not "deemed to be possibly, probably, or definitely related to Beloranib," to state that Beloranib treatment did not increase the risk of cardiovascular disease, and disclosing adverse events as minor as nausea, abnormal dreams, or itching at the injection site, defendants misled investors by failing to reveal that, in total, four thrombotic adverse events occurred in that trial among patients taking Beloranib. Defendants also failed to disclose that zero patients receiving a placebo experienced thrombotic adverse events. In the alternative, defendants omitted to disclose the material fact that they did not disclose all adverse events observed in patients taking Beloranib. By providing an extensive list of even minor adverse events—nausea, dizziness, abnormal dreams, and so on—a reasonable investor would be misled into believing that all material adverse events were revealed when, in fact, they were not.
>
> Prior to October 16, 2015, the company had not disclosed any thrombotic adverse events in clinical trials of Beloranib other than the two events in the ZAF-201 trial described above. Therefore[,] defendants misled investors by failing to disclose that there were four thrombotic adverse events that occurred in patients taking Beloranib in the ZAF-201 clinical trial.

(*Id.* ¶¶ 53-54; *see also id.* ¶¶ 56, 58, 60, 62).

According to the complaint, "all four adverse events were material for investors because the FDA considers the *frequency/rate* of adverse events in determining whether a drug is causing those adverse events." (*Id.* ¶ 49). It further alleges that stock analysts "considered the *frequency/rate* of adverse thrombotic events to be material information for investors determining

the value of Zafgen stock." (*Id.* ¶ 50). For example, after Zafgen disclosed all of the AEs in October 2015, one analyst wrote "with six events on Beloranib and none on placebo, the imbalance is worrisome, and an association between Beloranib and thrombotic events certainly seems to be emerging." (*Id.* ¶ 50(c)).

E. Scienter Allegations

The complaint alleges that "[a]t all times during the class period, defendants knew—or were reckless in not knowing—that there was a significant risk of thrombotic adverse events in future clinical trials of Beloranib." (*Id.* ¶ 36). The allegations concerning scienter essentially fall into two groups: (1) news and scientific articles that allegedly demonstrate defendants' knowledge of a causal relationship between Beloranib and thrombotic AEs and (2) allegations that defendants had a motive to mislead investors and inflate Zafgen's stock price.

1. News and Scientific Articles about Thrombotic Adverse Events

The complaint alleges that "Beloranib is different from traditional weight-loss treatments, many of which focus on appetite suppression. Instead, Beloranib is an inhibitor of the methionine aminopetidase 2 (MetAP2) enzyme, which Zafgen believes to have [] intracellular actions that lead to reduced fat biosynthesis and increased fat oxidation and lipolysis." (*Id.* ¶ 37) (internal quotation marks omitted). As Hughes noted in a 2013 article, MetAP2 inhibitors like Beloranib were originally "developed as anti-angiogenic agents for the treatment of cancer," and "in xenografted mice, high doses of Beloranib suppress angiogenesis and tumorigenesis." (*Id.* ¶ 38).[9]

The complaint alleges that "other angiogenesis inhibitors (*i.e.*, agents that suppress the [formation of new blood vessels]) have been associated with an increased risk of thrombotic side

[9] "Angiogenesis is the formation of new blood vessels." (*Id.* ¶ 38 n.6).

effects." (*Id.* ¶ 39). It alleges that the association between thrombosis and angiogenesis inhibitors like Beloranib has been demonstrated by the following scientific literature and news articles:

- The National Cancer Institute's short "fact sheet," discussing angiogenesis inhibitors, notes that "[s]ide effects of treatment with angiogenesis inhibitors can include problems with bleeding, [and] clots in the arteries (with resultant stroke or heart attack), hypertension, and protein in the urine." (*Id.*).

- A 2002 article in *Nature Biotechnology* noted that "8 out of 19 patients [in a trial for the angiogenesis inhibitor Avastin] suffered serious clotting," and "[a]lthough clotting rates were much lower in other trials . . . doctors are now taking the risk seriously." (*Id.* ¶ 40).

- A 2008 article in the *Journal of Pharmaceutical Sciences* stated that "thrombotic events, which can be fatal, have been described in patients treated with angiogenesis inhibitors," and listed eight different angiogenic inhibitors associated with thrombotic events. (*Id.* ¶ 41).

- A 2009 article in *Best Practice & Research Clinical Haematology* stated that "[m]any new biological agents with anti-angiogenic properties appear to be associated with an increased risk for thrombosis . . . ." (*Id.*).

- A 2013 study of Fumagillin, a "structural analog" of Beloranib, found that "Fumagillin may trigger cell membrane scrambling of erythrocytes, a hallmark of eryptosis[,]" and that "triggering of eryptosis [favors] the development of thrombosis." (*Id.* ¶ 42).

- A 2009 article in the *MIT Technology Review* about Zafgen (for which Hughes was interviewed) stated that "anti-angiogenic drugs such as Avastin used to treat breast, lung, and colon cancer, have unpleasant side effects—especially when used long-term—including problems with the reproductive, *cardiovascular*, and immune systems." (*Id.* ¶ 44) (emphasis in complaint).

- A March 2015 article in the *Journal of Psychosocial Nursing and Mental Health Services* about Beloranib stated that "[t]he safety of Beloranib in particular will need to be evaluated carefully. . . . Other angiogenesis inhibitor drugs have been associated with bleeding, hypertension, proteinuria, and fatal *cardiovascular events*, and angiogenesis inhibition may impair wound healing and tissue repair." (*Id.*) (emphasis in complaint).

The complaint further alleges that "[t]he significance of thrombotic risk was only heightened by the patient profile that Zafgen was targeting," because, as the company acknowledged in its disclosures, the typical adult PWS patient is morbidly obese, has an average

life expectancy of 32 years, and is already "at an increased risk for cardiovascular disease." (*Id.* ¶ 43; Def. Ex. B at 51).

2. Motive to Mislead Investors

The complaint alleges that Zafgen's executives, including Hughes, had an incentive to inflate the company's share price because "a significant portion of [their] annual compensation consist[ed] of 'option awards' and 'non-equity incentive plan compensation' (*i.e.*, 'performance-based cash bonuses')." (Compl. ¶ 33). For example, it alleges that in 2013, Hughes received $591,961 in option awards and $120,000 in performance-based cash bonuses (which were awarded, in part, based on total shareholder return and changes in the share price). (*Id.* ¶¶ 34-35). Plaintiffs also contend that because Zafgen was essentially a one-drug company (*id.* ¶ 27), defendants had a motive to "shade the truth" and "need[ed] Beloranib to succeed to keep their jobs." (Pl. Mem. 16).

The complaint also points to "heavy selling by insiders" in September 2015. (Compl. ¶ 77). Hughes sold 22,500 shares of Zafgen on September 17, and another 23,126 shares on September 18, for a total price of $1.8 million. (*Id.* ¶ 78). Had Hughes sold those shares at the closing price on October 16, he would have received $472,658. (*Id.*).[10] The complaint acknowledges that the insiders sold shares pursuant to Rule 10b-5 plans, but alleges that "[b]ecause the class period covers the entire period that Zafgen has been a public company, it is highly likely that the trading plan[s] [were] adopted during the class period." (*Id.*). It also alleges that none of the company's officers sold any shares before September 2015, and that "by selling their stock in September 2015, just weeks before the revelation of the additional adverse

[10] The complaint also alleges that chief medical officer Dennis Kim sold 40,360 shares in total on September 14, 15, and 17, chief commercial officer Alicia Secor sold 26,256 shares on September 17, and board member Avi Goldberg sold 5,000 shares on September 18. (*Id.* ¶¶ 79-81). None of those individuals are named defendants.

events surrounding Beloranib and the patient death, these executives collectively avoided losing almost $3.5 million." (*Id.* ¶ 77). The complaint alleges that Hughes owned just 11,320 shares of Zafgen after his September 2015 sales. (*Id.* ¶ 78). However, plaintiffs acknowledge that he actually retained at least 93 percent of his stock and vested options in Zafgen (based on 647,811 shares of stock and *vested* options owned before September 2015, and 45,626 shares of total stock sold in September 2015). (Def. Ex. K).[11] The other insiders all retained at least 85 percent of their stock and vested options after the September 2015 sales. (*Id.*).

II. Procedural Background

Plaintiff Aviad Bessler filed the original complaint in this case on October 21, 2015. On January 7, 2016, the Court appointed as lead plaintiffs Terry M. Brennan, Ron Kenner, Kevin Koziatek, Vincent Rampe, and Dragon Gate Management Ltd. On February 22, 2016, the lead plaintiffs filed an amended complaint on behalf of all purchasers of Zafgen's common stock during the period from June 19, 2014, through October 16, 2015. The amended complaint alleges that Zafgen and Hughes violated Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 (Count One), and that Hughes violated Section 20(a) of the 1934 Exchange Act (Count Two).

Defendants have moved to dismiss the complaint with prejudice. They contend that Count One should be dismissed under Fed. R. Civ. P. 9(b) and 12(b)(6), and the PSLRA, 15 U.S.C. § 78u-4, for two principal reasons: (1) failure to plausibly allege an actionable misstatement or omission and (2) failure to satisfy the PSLRA's requirement of pleading specific facts giving rise to a strong inference of scienter. Defendants also contend that Zafgen did not have a duty to disclose the omitted information, and that the complaint fails to make adequate

[11] If 180,000 of Hughes's options that were set to begin vesting in March 2016 were included, the percentage of shares that he retained after his sales would increase to 95 percent.

allegations of loss causation. They have moved to dismiss Count Two for failure to state an underlying Exchange Act violation.

III. Legal Standard

On a motion to dismiss a claim brought under Section 10(b) and Rule 10b-5, courts must accept plaintiffs' allegations as true. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, Congress has raised the standard of pleading for Section 10(b) and Rule 10b-5 securities fraud claims.[12]

When a plaintiff alleges misrepresentation or omission of a material fact, the PSLRA requires that the complaint "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1); *accord Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240. "A fact is material when there is 'a substantial likelihood' that a reasonable investor would have viewed it as 'significantly alter[ing] the total mix of information made available.'" *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 756 (1st Cir. 2011) (alteration in original) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988)). "A statement can be 'false or incomplete' but not actionable 'if the misrepresented fact is otherwise insignificant.'" *Id.* at 756-57 (quoting *Basic*, 485 U.S. at 238). However, "while a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead.'" *In re Cabletron Sys., Inc.*, 311

[12] "In 1995, Congress enacted legislation attempting to wrest control over securities fraud class action lawsuits from the plaintiffs' bar devoted to such litigation and confer it upon counsel for larger institutional investors. Such a measure, it was believed, would cut down on frivolous litigation as counsel for institutional investors were thought to take a more balanced cost-benefit view of such litigation. While at it, Congress raised the hurdle a plaintiff would have to jump before being permitted to present her case to a jury." *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 271 (D. Mass. 1998) (citations omitted).

F.3d 11, 36 (1st Cir. 2002) (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc)).

"The PSLRA also separately imposes a rigorous pleading standard on allegations of scienter." *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *ACA Fin.*, 512 F.3d at 58).[13] To plead scienter, the complaint must "with respect to each act or omission . . . 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). A strong inference is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314. "A complaint will survive a motion to dismiss only if it states with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent 'to deceive or defraud investors by controlling or artificially affecting the price of securities' or 'acted with a high degree of recklessness.'" *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240 (quoting *Waters Corp.*, 632 F.3d at 757). "Recklessness, as used in this context, 'does not include ordinary negligence, but is closer to being a lesser form of intent.'" *Id.* (quoting *Greebel*, 194 F.3d at 188).

In evaluating the adequacy of a complaint's scienter allegations, a court "cannot hold plaintiff to a standard that would effectively require them, pre-discovery, to plead evidence." *Mississippi Pub. Emps. Ret. Sys. v. Boston Sci. Corp. I*, 523 F.3d 75, 90 (1st Cir. 2008) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996)). However, a plaintiff may not simply rely on a "fraud by hindsight" theory of scienter. *Shaw*, 82 F.3d at 1223, *abrogated on*

[13] The materiality and scienter inquiries are linked because "[t]he question of whether a plaintiff has ple[aded] facts supporting a strong inference of scienter has an obvious connection to the question of the extent to which the omitted information is material." *Waters Corp.*, 632 F.3d at 757. "If it is questionable whether a fact is material or its materiality is marginal, that tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact." *Id.*; *accord Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 242.

other grounds by 15 U.S.C. § 78u-4(b)(2); *accord ACA Fin.*, 512 F.3d at 62. Courts should look at the complaint as a whole and weigh "competing inferences" in a "comparative evaluation" of plaintiffs' allegations and alternative inferences from those allegations. *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 314. If "there are equally strong inferences for and against scienter," then the tie goes to the plaintiffs. *Biogen*, 537 F.3d at 45 (quoting *ACA Fin.*, 512 F.3d at 59).

IV. Analysis

Distilled to its essence, the complaint alleges that defendants knew there was a significant risk of thrombotic adverse events in future clinical trials of Beloranib. It alleges that defendants actually knew of that risk when they made the allegedly misleading disclosures (failing to disclose the two superficial AEs that occurred in the ZAF-201 trial), or that they must have known of the risk because it was so obvious. Accordingly, it alleges that defendants intentionally or recklessly misled investors when they disclosed the two serious AEs that occurred during the ZAF-201 trial but failed to disclose the two superficial AEs. In addition to the claim under Rule 10b-5 (Count One), the complaint also asserts a claim against Hughes as a "control person" under Section 20(a) of the Exchange Act (Count Two).

Defendants contend that Count One should be dismissed for several reasons. Principally, they contend that the complaint's scienter allegations rely on an "implausible fraud-by-hindsight theory." (Def. Reply 10). They summarize that theory as follows: "Zafgen transparently disclosed two serious thrombotic [AEs] in the ZAF-201 trial and the need for added vigilance for AEs related to blood clotting during future clinical trials . . . but [somehow] fraudulently concealed two minor [AEs] from the same trial—all [AEs] that to this day have not been shown to have been caused by Beloranib." (*Id.*) (citations and internal quotation marks omitted).

According to defendants, the complaint does not plead sufficient facts giving rise to a strong inference of scienter under that theory; indeed, they contend, that theory is not even plausible. Defendants further contend that any inference of scienter is outweighed by a more cogent and compelling non-fraudulent inference: "The unfortunate event of a patient death prompted Zafgen to focus on a potential connection between Beloranib and thrombotic episodes and, as a part of that focus, Zafgen assessed all thrombotic [AEs] in all its completed and ongoing clinical trials." (*Id.*). They also contend that Count One should be dismissed because the complaint fails to allege an actionable misrepresentation or omission, loss causation, and a duty to disclose. They contend that Count Two should be dismissed for failure to plead a predicate Exchange Act violation.

A. Count One: Rule 10b-5 Generally

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful "[t]o 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). Pursuant to that section, the SEC has promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. To state a claim for securities fraud under Section 10(b), a plaintiff must allege: "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind;

(3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 40 (1st Cir. 2014); *accord Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240.

Defendants dispute the first, second, and sixth elements. They also contend that they had no duty to disclose the two superficial AEs. The Court will address the allegations concerning a material misrepresentation or omission before turning to the issue of scienter.

B. Allegations of Material Misrepresentations and Omissions

Under the PSLRA, a complaint must allege that a statement is false or misleading and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1); *accord Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240. As noted, the complaint alleges that defendants made three materially misleading statements in disclosures during the class period.

The first alleged misrepresentation is the following:

> As severely obese patients are at an increased risk for cardiovascular disease, we measured systemic biomarkers of cardiovascular disease risk, including low density lipoprotein cholesterol, HDL, CRP, triglycerides and blood pressure in trial participants, to determine Beloranib's impact on such biomarkers. The results of these biomarker measurements in this trial, as summarized below, suggest that ***Beloranib treatment does not increase the risk of cardiovascular disease and may be associated with reduced cardiovascular disease risk.***

(Compl. ¶ 52). The complaint does not contain any specific allegations as to why that statement is misleading. As the statement indicates, the "biomarker measurements" data was "summarized below [in the disclosure]."[14] The complaint does not include the data on which the allegedly misleading statement relies and attempts to summarize, nor does it provide reasons why that

[14] The results appearing below the statement indicate that, among other things, "[l]evels of the cardiovascular disease risk marker C-reactive protein were reduced by an average of 2.5, 2.3 and 1.9 μg/ml, or 23%, 22% and 37%, respectively, for patients treated with Beloranib at 0.6 mg, 1.2 mg and 2.4 mg, respectively, compared to an average increase of 1.0 μg/ml for patients dosed with placebo ($p<0.0001$)." (*See, e.g.*, Def. Ex. B at 86).

data, and defendants' summary of that data, were misleading. *See City of Bristol Pension Fund v. Vertex Pharms. Inc.*, 12 F. Supp. 3d 225, 237-38 (D. Mass. 2014) (concluding that defendant's assessment of trial data was not materially misleading where complaint "does not allege that defendants presented factually incorrect information about the p value"). Nor does the complaint allege with particularity why the inference "suggest[ed]" by the data was false or misleading.

The second alleged misrepresentation is the following:

> There were no deaths or any [serious AEs] deemed to be ***possibly, probably, or definitely related to Beloranib*** . . . .

(Compl. ¶ 52). That statement does not appear to be false or misleading even with the benefit of hindsight, much less when Zafgen made the disclosures before the patient death. Although the complaint alleges that the two serious AEs, the two superficial AEs, and the patient death all occurred in patients receiving Beloranib rather than a placebo, it does not allege that they were caused by or related to Beloranib. Indeed, it appears that third-party clinical investigators have not determined the cause of those events to this day.[15] At most, plaintiffs are left with the claim that the serious AEs were "possibly" related to Beloranib—which remains, at this point, a matter of conjecture.[16]

The third alleged misrepresentation is the following:

> [A]lthough there were ***two serious thrombotic adverse events*** which, while not attributed to Beloranib treatment, may point to the utility of assessment of prior history of thrombotic events in patients enrolled in subsequent trials and added vigilance for AEs related to blood clotting during future clinical trials. The most

[15] Moreover, Zafgen disclosed to investors that third-party clinical investigators, not the company, determined the severity of AEs and whether they were possibly related to Beloranib. (*See* Def. Ex. M at 10).

[16] Plaintiffs also suggest in their memorandum that defendants' press release on October 14, 2015, was misleading. In that release, Zafgen stated that "[t]he cause of death [of the patient during the "double-blind" Phase III trial] remains unknown at this time." (Compl. ¶ 68). Plaintiffs contend that the statement was misleading because it did not indicate whether the patient was being treated with Beloranib or a placebo. Setting aside the fact that the complaint does not allege with particularity why the statement is misleading, it is clear from the disclosures and press releases that Zafgen did not learn whether the patient was receiving Beloranib until the FDA ordered it to unblind the patient's treatment assignment on October 16. (Compl. ¶ 71).

> commonly reported TEAEs [treatment-emergent adverse events] were gastrointestinal disorders, mainly nausea, diarrhea, or vomiting, nervous system disorders, mainly dizziness, and psychiatric disorders, mainly insomnia, sleep disorder, or abnormal dreams. TEAEs were generally mild in severity and transient. Other frequently reported TEAEs were headaches and injection site bruising/itching, although the incidences were comparable to placebo and not observed to be dose-related.

(Compl. ¶ 52).

Defendants contend that the statement is not actionable for two reasons. First, they contend that Zafgen's failure to disclose the two superficial AEs cannot possibly be a misleading omission, because the company cautioned investors that it may not disclose all serious AEs. But that caution does not absolve the company if it later elects to disclose information; "[i]f . . . a company chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole truth." *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 26 (1st Cir. 1987); *see also In re Cabletron Sys.*, 311 F.3d at 36 ("While a company need not reveal every piece of information that affects anything said before, it must disclose facts, 'if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead.'" (quoting *Backman*, 910 F.2d at 16)). Having started down the road of disclosure, defendants cannot use the company's earlier wholesale disclaimer concerning AE disclosures as a blanket shield.

Defendants also contend that the two superficial AEs were not material to a reasonable investor, and therefore their omission is not actionable. That argument is not entirely without merit, and the questionable materiality of defendants' omission is also relevant to the issue of scienter. However, "[i]n general, the materiality of a statement or omission is a question of fact that should normally be left to a jury rather than resolved by the court on a motion to dismiss." *In re Cabletron Sys.*, 311 F.3d at 34. Accordingly, the complaint's allegation that Zafgen's failure to disclose the superficial AEs was material is sufficient under the circumstances.

In sum, the complaint appears to adequately allege at least one material misrepresentation or omission. Accordingly, the Court must determine whether the complaint as a whole pleads with particularity facts that give rise to a strong inference of scienter.

C. Allegations of Scienter

To be actionable under the PSLRA, a statement must be more than merely material and misleading; it also must have been made with the requisite scienter. *See ACA Fin.*, 512 F.3d at 58-59. "Scienter is 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Id.* (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)). "A complaint will survive a motion to dismiss only if it states *with particularity* facts giving rise to a *strong inference* that defendants acted with a conscious intent to deceive or defraud investors by controlling or artificially affecting the price of securities[,] or acted with a high degree of recklessness." *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240 (emphasis added) (citations and internal quotation marks omitted); *accord ACA Fin.*, 512 F.3d at 58-59; *see also* 15 U.S.C. § 78u-4(b)(2)(A). "It does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." *Tellabs*, 551 U.S. at 314. Instead, the court must "engage in a comparative evaluation" and weigh "competing inferences" to determine whether the inference of scienter is "cogent and compelling." *Id.* at 314, 324. A "'strong inference' of scienter 'must be more than merely plausible or reasonable—it must be cogent and *at least as compelling as any other opposing inference* of nonfraudulent intent.' In other words, where there are equally strong inferences for and against scienter, *Tellabs* now awards the draw to the plaintiff." *ACA Fin.*, 512 F.3d at 59 (citations omitted) (quoting *Tellabs*, 551 U.S. at 314).

In the First Circuit, "a plaintiff may satisfy the scienter requirement with a showing of

either conscious intent to defraud or 'a high degree of recklessness.'" *Id.* at 58 (quoting *Aldridge*, 284 F.3d at 82); *accord Greebel,* 194 F.3d at 198-201. "Recklessness in this context means 'a highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that *is either known to the defendant or is so obvious the actor must have been aware of it*.'" *Mississippi Pub. Emps. Ret. Sys. v. Boston Sci. Corp. II*, 649 F.3d 5, 20 (1st Cir. 2011) (emphasis added) (quoting *SEC v. Fife*, 311 F.3d 1, 9-10 (1st Cir. 2002)); *see also Greebel*, 194 F.3d at 188 (noting that recklessness in this context "does not include ordinary negligence, but is closer to being a lesser form of intent").[17]

"Knowingly omitting material information is probative, although not determinative, of scienter." *Mississippi Pub. Emps. Ret. Sys. I*, 523 F.3d at 87; *see also Aldridge*, 284 F.3d at 83 ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter."). However, it is well-established that "[p]leading 'fraud by hindsight,' essentially making general allegations 'that defendants knew earlier what later turned out badly,' is not sufficient." *Ezra Charitable Trust*, 466 F.3d at 6 (quoting *Gross v. Summa Four, Inc.*, 93 F.3d 987, 991 (1st Cir. 1996)). In the context of clinical drug trials, the First Circuit has stated that "defendants cannot have committed fraud if they did not know *at the time* [of the allegedly misleading disclosure] that the failure to provide additional information was misleading." *Biogen*, 537 F.3d at 48.

Scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations." *ACA Fin.*, 512 F.3d at 59; *see also Tellabs*, 551 U.S. at 310 ("[T]he

[17] "Even if plaintiffs wish to prove scienter by 'recklessness,' they still must allege with sufficient particularity, that defendants had full knowledge of the dangers of their course of action and chose not to disclose those dangers to investors." *Maldonado v. Dominguez*, 137 F.3d 1, 9 n.4 (1st Cir. 1998).

inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."). "There is no set pattern of facts that will establish scienter; it is a case-by-case inquiry." *ACA Fin.*, 512 F.3d at 66. Compelling evidence of scienter generally includes "clear allegations of admissions, internal records or witnessed discussions" that suggest that defendants were "aware that they were withholding vital information or at least were warned by others that this was so" when they made the misleading statements. *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012). Courts have "considered many different types of evidence as relevant to show scienter," including

> insider trading . . . ; closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information; evidence of bribery by a top company official; existence of an ancillary lawsuit charging fraud by a company and the company's quick settlement of that suit; disregard of the most current factual information before making statements; disclosures of accrual basis in a way which could only be understood by a sophisticated person with a high degree of accounting skill; the personal interest of certain directors in not informing disinterested directors of impending sale of stock; and the self-interested motivation of defendants in the form of saving their salaries or jobs.

Greebel, 194 F.3d at 196 (citations omitted). In addition, various other "facts and circumstances indicating fraudulent intent—including those demonstrating motive and opportunity"—may also combine to satisfy the scienter requirement. *In re Cabletron Sys.*, 311 F.3d at 39. The "presence of [contemporaneous] insider trading can be used, in combination with other evidence, to establish scienter." *Biogen*, 537 F.3d at 55. However, "[i]nsider trading cannot establish scienter on its own, but rather can only do so in combination with other evidence." *Mississippi Pub. Emps. Ret. Sys. II*, 649 F.3d at 29.

Here, the complaint alleges scienter under both an actual intent theory and a recklessness theory. Plaintiffs rely on two principal sets of allegations concerning scienter. First, the

complaint alleges that because news and science articles demonstrated a link between anti-angiogenics like Beloranib and thrombotic AEs, defendants knew or must have known of such a risk when they made the misleading disclosures. Second, it alleges that defendants had a motive to commit securities fraud, as demonstrated by "heavy" insider sales before the patient death. Plaintiffs contend that "[d]efendants do not argue they were unaware of the two omitted thrombotic [AEs] or that the failure to disclose them was unintentional. Unable to plead ignorance, [d]efendants instead argue that they cannot have been expected to realize the two omitted thrombotic adverse events were material." (Pl. Mem. 13).

As an initial matter, plaintiffs place excessive weight on defendants' concession that they knew about the superficial AEs when they made the disclosures. Indeed, that argument misses the point of the scienter analysis, at least under these circumstances. As the First Circuit has noted,

> [t]he dispute here is not about whether the facts alleged support the inference that the defendants knew of certain undisclosed facts during the class period. We addressed that type of scienter question in *New Jersey Carpenters Pension & Annuity Funds v. Biogen Idec Inc.*, 537 F.3d 35, 44 (1st Cir. 2008). Rather, the question here is whether there is a strong inference that the defendants' failure to disclose certain facts was a result of wrongful intent, or scienter, even assuming defendants knew of those facts. Answering this question involves an inquiry into the relationship between scienter and the materiality of the undisclosed information.

Waters Corp., 632 F.3d at 753. In other words, the relevant issue concerning scienter in this case is not whether defendants knew about the superficial AEs when they made the allegedly misleading disclosures. It is undisputed that they did know. Rather, the issue is whether defendants' choice not to disclose the superficial AEs posed a risk of misleading investors that was known to defendants (or so obvious that they must have known), such that they therefore acted intentionally or recklessly by not disclosing them. *See Mississippi Pub. Emps. Ret. Sys. II*,

649 F.3d at 20. Defendants' knowledge must be analyzed at the time that they made the allegedly misleading disclosures, not in hindsight of the patient death. *See Biogen*, 537 F.3d at 48 ("Defendants cannot have committed fraud if they did not know *at the time* that the failure to provide additional information was misleading.").

1. News and Scientific Articles

The scientific articles and other allegations concerning defendants' knowledge, all of which plaintiffs interpret with the benefit of hindsight, fall considerably short of supporting a strong inference of scienter.

The complaint's scienter allegations under an intent-to-defraud theory are barely plausible, and certainly not sufficient to raise a strong inference. Indeed, it would have been somewhat strange for defendants to alert investors to two serious AEs while, in the very same disclosures, intentionally hiding two superficial AEs. Moreover, the complaint contains no admissions, internal documents or e-mails, or discussions witnessed by confidential sources that would indicate or would even suggest that Hughes or any other Zafgen employee chose not to disclose the superficial AEs with an intent to defraud investors.

The allegations under a recklessness theory, while more plausible, do not raise a cogent and compelling inference of scienter. Based principally on news and scientific articles, most of which do not even mention Beloranib, the complaint alleges that defendants "knew—or were reckless in not knowing—that there was a significant risk of thrombotic [AEs] in future clinical trials." (Compl. ¶ 36). For a number of reasons, those allegations fall well short of demonstrating that defendants knew that they risked misleading investors by not disclosing the two superficial AEs, or that the risk was so obvious that they must have known that it existed.

As an initial matter, plaintiffs have not cited any case where publicly available articles

exploring a *potential* connection between a drug and certain adverse events established a strong inference of scienter on the part of individual defendants, none of whom are alleged to have discussed or even read the articles. Moreover, even assuming that plaintiffs' subjective, after-the-fact interpretation of the articles is accurate, which is doubtful at least to some extent, the articles fall short in several other ways.[18]

Principally, the articles do not establish that (1) defendants knew that they risked misleading investors by not disclosing the superficial AEs or (2) knew of that risk at the time of the disclosures—that is, before the Phase III patient death. Nor are they sufficient to demonstrate a risk so obvious that defendants must have known of its existence. According to the complaint, the articles "documented the elevated thrombotic risk that angiogenesis inhibitors such as Beloranib pose." (Compl. ¶ 40). However, the allegations are insufficient to form a strong inference that Beloranib caused thrombotic events, much less that *defendants knew* about such a connection *at the time of the disclosures* (or even that such a connection is known today). Indeed, two of the articles cited in the complaint discuss anti-angiogenics only generally, (*id.* ¶¶ 39, 41), and three discuss drugs other than Beloranib. (*Id.* ¶¶ 40, 42, 44). The complaint does not allege that any Zafgen employees read or discussed the articles. Furthermore, the complaint does not allege that anyone advised defendants to disclose the superficial AEs in light of the articles, that defendants rejected or ignored that advice, or even that there was an internal debate concerning disclosure. In addition, there are no allegations that anyone—an employee, third-

[18] For an example of plaintiffs' selective interpretation of the articles, the complaint cites an article written by Hughes and others concerning anti-angiogenics like Beloranib as evidence of his knowledge concerning a link between such drugs and thrombotic events. (Compl. ¶¶ 37-38). However, that article appears to suggest that significantly lower doses of Beloranib in obesity studies, such as the 2.4 mg prescribed in the ZAF-201 trial, reduced the risk of potential side effects that occurred in cancer studies with higher dosage levels, such as 50 mg. (Def. Reply Ex. A at 1785-87; Ex. B at 85).

party clinical investigator, or patient—thought that the undisclosed AEs were more serious than their "superficial" label indicated.

The complaint's allegations as to the articles essentially plead fraud by hindsight under a "should-have-known" theory. However, as the First Circuit has noted, "a statement cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it." *Biogen*, 537 F.3d at 45; *see also id.* at 48 ("[D]efendants cannot have committed fraud if they did not know *at the time* that the failure to provide additional information was misleading."); *accord ACA Fin.*, 512 F.3d at 62. And even in hindsight, the questionable materiality of the omissions and defendants' disclosure of two *more serious* AEs make the risk of misleading investors far from obvious.[19]

In sum, the complaint's allegations contain no direct evidence of defendants' knowledge, and plaintiffs' subjective, selective, and post-hoc interpretation of scientific articles after the patient death is, at best, weak circumstantial evidence of scienter. The First Circuit has found complaints containing far stronger allegations insufficient under the PSLRA's robust scienter standard. *See, e.g.*, *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 245 (affirming dismissal of complaint even though seven confidential witnesses alleged that the company knew revenues were inflated by off-label marketing); *Waters Corp.*, 632 F.3d at 760 (affirming dismissal of complaint even though plaintiffs had reason to be "suspicious" of defendant's decision not to make certain disclosures); *Biogen*, 537 F.3d at 52-53 (affirming dismissal of complaint despite allegations from six confidential witnesses concerning company's knowledge of a connection

[19] To the extent that plaintiffs contend that the mere occurrence of AEs is sufficient to plead scienter, that argument has been rejected by the First Circuit. "The receipt of an adverse report does not in and of itself show a causal relationship between a drug and the illness mentioned in the report." *Biogen*, 537 F.3d at 53 (alterations and internal quotation marks omitted).

between its drug candidate and particular adverse events). The complaint does not demonstrate that "defendants knew or should have known that their failure to disclose [the superficial AEs] presented a danger of misleading buyers or sellers." *Waters Corp.*, 632 F.3d at 758 (alteration omitted). Accordingly, the complaint's allegations concerning defendants' knowledge of a link between Beloranib and thrombotic events are insufficient to raise a strong or compelling inference that defendants chose not to disclose the superficial AEs with intent to defraud or recklessness.

2. Motive

The motive allegations add little, if anything, to the complaint's relatively weak inference of scienter. The complaint alleges that defendants were motivated to inflate Zafgen's stock price by misleading investors about the number of thrombotic AEs in clinical trials. However, some of the allegations make little sense in the factual context of Zafgen's purported fraud, and they are otherwise too generic to support a strong inference of scienter. "'[C]atch-all allegations' which merely assert motive and opportunity, without something more, fail to satisfy the PSLRA." *In re Cabletron Sys.*, 311 F.3d at 39 (quoting *Greebel*, 194 F.3d at 197). Instead, motive allegations must state "more than the usual concern by executives to improve financial results." *Id.*

The complaint alleges that Zafgen's "performance-based cash bonuses" and "option awards" created an incentive for executives to inflate the company's stock price. (Compl. ¶¶ 34-35). In their memorandum, plaintiffs also contend that defendants had a "strong motive" to commit securities fraud because "Zafgen is a one-drug company" and defendants "kn[ew] they would rise or fall based solely on Beloranib's future." (Pl. Mem. 16). Of course, the same incentives to increase a company's earnings and stock price exist for almost every executive at

every company, especially small healthcare or technology companies. Accordingly, in the First Circuit, "[w]hen financial incentives to exaggerate earnings go *far beyond the usual arrangements of compensation* based on the company's earnings, they may be considered among other facts to show scienter." *Aldridge*, 284 F.3d at 83 (emphasis added); *see also In re Atl. Power Corp. Sec. Litig.*, 98 F. Supp. 3d 119, 133 (D. Mass. 2015) ("That the executives may have gained some compensation is not enough, since stock-based compensation is a common feature of pay packages.").[20]

Furthermore, the insider-trading allegations do not alter the conclusion that the complaint as a whole fails to raise a strong inference of scienter. "Depending on context, allegations of insider trading may offer some support for inferences of scienter." *Waters Corp.*, 632 F.3d at 760. "The vitality of the inference to be drawn depends on the facts, and can range from marginal to strong." *Id.* (quoting *Greebel*, 194 F.3d at 197-98). "For stock sales by corporate officials to bolster an inference of scienter, the trading must be, '[a]t a minimum, . . . unusual, well beyond the normal patterns of trading by those defendants.'" *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 245 (quoting *Waters Corp.*, 632 F.3d at 761); *accord Greebel*, 194 F.3d at 206-07 (sales must be "out of the ordinary or suspicious"); *see also Lenartz v. American Superconductor Corp.*, 879 F. Supp. 2d 167, 186 (D. Mass. 2012) (noting that plaintiffs "bear[] the burden of showing that insider sales were in fact unusual or suspicious in timing or amount").

The insider-trading allegations here are relatively weak, because the trades are fairly unsuspicious in both timing and amount. The sales, which began in September 2015, occurred more than a year after Zafgen disclosed the results of the ZAF-201 trial in April 2014. It is

[20] Plaintiffs do not contend that Hughes's compensation was abnormally high, based on options and bonuses, compared to other executives. According to the complaint, he earned more than 70 percent of his 2014 total compensation in salary. (Compl. ¶ 33). While that percentage was higher in 2013, all of the alleged misrepresentations occurred in 2014 and 2015.

implausible that defendants intended to inflate Zafgen's share price by not disclosing two superficial AEs, while simultaneously disclosing two more serious AES, and then waited more than a year to reap the profit of that supposed deception. Furthermore, the timing of the sales in relation to the patient death is unsuspicious. During the October 16 conference call, which occurred almost a month after the final insider sale on September 18, Hughes stated that Zafgen disclosed the patient death to the FDA approximately two weeks earlier, and "well within" the one week requirement from the death to the FDA disclosure. Thus, even liberally construed, the complaint's allegations support an inference that the patient death occurred at least a week after the final insider sale. Notably, the complaint does not allege otherwise, and plaintiffs do not strongly contest the issue. Moreover, the insider sales occurred well before Zafgen unblinded the study to learn that the patient was taking Beloranib, and also before the FDA hold.[21] In short, the timing of the trades in relation to the patient death is not particularly suspicious.[22]

In addition to their unsuspicious timing, the amount of the sales does not create a strong inference of scienter. While the complaint alleges "[a]fter all of his transactions in September 2015, Dr. Hughes owned just 11,320 shares of Zafgen," (Compl. ¶ 78), plaintiffs acknowledge that the Court must also consider the number of vested options owned by Hughes. *See Waters*

[21] In addition, it is relevant that Zafgen's share price increased by almost thirty percent during the first half of September 2015, peaking at the time of the insider sales. (*See* Def. Ex. L); *see Local No. 8 IBEW Ret. Plan v. Vertex Pharms. Inc.*, 140 F. Supp. 3d 120, 136 (D. Mass. 2015) ("[T]here is nothing unusual, or necessarily suspicious, about insider sales during periods of rapid stock price increases" because "[i]t is commonplace for executives at publicly-traded companies to hold low-basis stock in the company or stock options with relatively low strike prices.").

[22] Plaintiffs acknowledge that the executives sold shares pursuant to Rule 10b-5 trading plans, which would ordinarily undercut an inference of scienter. (Compl. ¶ 78) ("Hughes's reports to the SEC regarding these transactions claimed that the trades were made pursuant to a Rule 10b-5 trading plan but did not identify the date on which the trading plan was adopted."). Plaintiffs urge the Court to draw a negative inference against defendants because the trading plans were adopted during the class period. However, the Court notes that plaintiffs extended the class period all the way back to Zafgen's IPO date, the earliest that such a plan could have been effectively adopted. In any event, for the reasons discussed above, the Court "need not address the parties' arguments concerning defendants' Rule 10b-5 trading plans because plaintiffs' arguments concerning the purported insider trading fail even without considering those plans." *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 246 n.14.

Corp., 632 F.3d at 760-61 ("In calculating the percent holdings sold, however, it is appropriate to consider not only the shares of stock that [defendants] held prior to their sales, but also the shares that they could have sold through the exercise of options, which plaintiff did not do."). Taking into account his vested options, Hughes retained at least 93 percent of his Zafgen holdings, and every other insider specified in the complaint retained at least 85 percent. Those amounts are not out of the ordinary under the circumstances. *See Biogen*, 537 F.3d at 42 (affirming dismissal of complaint where three defendants sold "virtually all" of their shares, not pursuant to Rule 10b-5 plans, because the timing was not suspicious); *In re Cabletron Sys.*, 311 F.3d at 27 (concluding that allegations permitted strong inference of scienter, in part, because three defendants sold approximately one-third of their holdings, and two defendants sold more than 90 percent of theirs).

3. Opposing Inference

In summary, the complaint's allegations, as a whole, do not support an inference of scienter that is strong, cogent, or compelling. Moreover, the Court "must weigh 'not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged.'" *Biogen*, 537 F.3d at 45 (quoting *Tellabs*, 551 U.S. at 314). Defendants' proposed non-fraudulent inference is that after the patient death, Zafgen focused on a potential connection between Beloranib and thrombotic episodes. As a part of that focus, the company decided to reassess and disclose all thrombotic AEs in Beloranib's completed and ongoing trials. (*See* Compl. ¶ 49; Def. Ex. I at 5). There are several factors that support that non-fraudulent inference and further weaken the inference of scienter.

As an initial matter, the marginal materiality of the superficial AEs, especially at the time that Zafgen chose not to disclose them, weakens the inference that defendants either intentionally

or recklessly misled investors. As the First Circuit has noted, materiality and scienter are linked:

> We do address the strength of the materiality of the statements because "[t]he question of whether a plaintiff has ple[aded] facts supporting a strong inference of scienter has an obvious connection to the question of the extent to which the omitted information is material." *Waters Corp.*, 632 F.3d at 757. "If it is questionable whether a fact is material or its materiality is marginal, that tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact." *Id.*
>
> The materiality of the impugned omission here—[defendant's] failure to state that some of the increased revenues were due to off-label marketing—is marginal at best. Plaintiffs' contention that the omission would have mattered to a reasonable investor depends on a long chain of inferences, most of which are not sufficiently substantiated by the allegations in the complaint.

Fire & Police Pension Ass'n of Colo., 778 F.3d at 242. The Supreme Court has explained that AEs occurring in drug trials are not necessarily material, much less AEs that are deemed superficial by third-party investigators.

> Adverse event reports are daily events in the pharmaceutical industry; in 2009, the FDA entered nearly 500,000 such reports into its reporting system. The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event. The question remains whether a *reasonable* investor would have viewed the nondisclosed information as having *significantly* altered the total mix of information made available. For the reasons just stated, the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy that standard. Something more is needed, but that something more is not limited to statistical significance and can come from the source, content, and context of the reports. This contextual inquiry may reveal in some cases that reasonable investors would have viewed reports of adverse events as material even though the reports did not provide statistically significant evidence of a causal link.

Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 43-44 (2011) (citations and internal quotation marks omitted); *see also Biogen*, 537 F.3d at 50 (noting that an adverse event "does not in and of itself show a causal relationship between a drug and the illness mentioned in the report" because "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill").

It is doubtful, under the circumstances, that a reasonable investor would have viewed the superficial AEs as significantly altering the total mix of information. That conclusion is especially warranted here because the total mix of information available to investors already included (1) the two *serious* AEs in the ZAF-201 trial and (2) the independent investigators' conclusion that none of the AEs were related to Beloranib. (Compl. ¶¶ 49, 53). The superficial AEs became material, if at all, only *after* the patient death. In short, the marginal materiality of the two superficial AEs weakens any inference of scienter and instead supports the non-fraudulent inference.

Furthermore, defendants' other disclosures during the class period support the inference that they simply did not believe that the superficial AEs were sufficiently meaningful to warrant disclosure at the time. Zafgen warned investors that it may not disclose all serious AEs (much less superficial AEs) until the final FDA approval process, and that previously unreported AEs could negatively affect the company.

> [Serious] AEs that are not characterized by clinical investigators as possibly related to Beloranib or [serious] AEs that occur in small numbers *may not be disclosed to the public until such time the various documents submitted to the FDA as part of the approval process are made public*.
>
> Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positives results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things . . . safety or efficacy observations made in clinical trials, *including previously unreported adverse events*.

(*Id.* ¶¶ 44-45, 51) (emphasis added). The First Circuit has noted that "attempts to provide investors with warnings of risks generally weaken the inference of scienter." *Waters Corp.*, 632 F.3d at 760 (quoting *Ezra Charitable Trust*, 466 F.3d at 8); *accord Genzyme Corp.*, 754 F.3d at

42-43 (noting that a corporation's informative disclosures "undercut any inference of fraudulent intent on the part of defendants").

In addition, there is no dispute that Zafgen promptly disclosed the two serious AEs from the ZAF-201 trial, the one serious AE from the ZAF-203 trial, and the patient death from the ZAF-311 trial. (Compl. ¶ 49; Def. Ex. I at 5). Thus, the fundamental theory of plaintiffs' case—that defendants misled investors by fraudulently failing to disclose the superficial AEs when they had already disclosed the serious AEs promptly and transparently—is unpersuasive. It is also notable that Hughes and the other company insiders, who the complaint alleges engaged in "heavy selling," retained the overwhelming majority of their Zafgen holdings. (Compl. ¶ 77).

4. Conclusion

In sum, "[t]hese are not the actions of a company bent on deceiving investors . . . ." *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 243. Considered as a whole, the complaint presents allegations of scienter that are fairly weak, and the resulting inference is certainly not "cogent and compelling." *Tellabs*, 551 U.S. at 324; *see also ACA Fin.*, 512 F.3d at 59 (noting that scienter "should be evaluated with reference to the complaint as a whole rather than to piecemeal allegations"). Even after drawing all reasonable inferences on behalf of plaintiffs, the complaint falls short of alleging a strong inference of intentional or reckless conduct, as required by the heightened pleading standard of the PSLRA. Accordingly, Count One will be dismissed for failure to state a claim.[23]

D. Count Two: Section 20(a) Liability

Count Two asserts a claim against Hughes under Section 20(a) of the Exchange Act, which imposes joint and several liability on persons in control of entities that violate securities

[23] Because the complaint fails to satisfy the PSLRA's pleading standard for scienter, the Court need not address defendants' arguments concerning loss causation and duty to disclose.

laws. 15 U.S.C. § 78t(a). However, violations of Section 20(a) depend on an underlying violation of the Exchange Act. *Id.*; *see Waters Corp.*, 632 F.3d at 762 ("Because the plaintiff's Section 20(a) claim was derivative of the Rule 10b-5 claim, it was properly dismissed as well."); *ACA Fin.*, 512 F.3d at 67-68. Because the complaint fails to state a claim for an underlying violation of the Exchange Act, Count Two will be dismissed.

E. Leave to Amend

Plaintiffs have not formally requested leave to amend the complaint. Instead, on the final page of their opposition to defendants' motion to dismiss, they state that "[i]n the event the Court is inclined to grant defendants' motion to dismiss, plaintiffs respectfully request leave to amend the complaint." (Pl. Mem. 30). Plaintiffs do not indicate that they have discovered, or even could discover, new evidence to suggest that amendment would not be futile, nor do they state that their investigation is ongoing.

As the First Circuit succinctly stated in denying a request for leave to amend in another securities-fraud class action:

> On a hopeless quest, plaintiffs argue we should remand to allow them to amend the complaint. No proper request was made to the district court, only a mention in a footnote in their opposition to dismissal.
>
> In any event, it is far too late; plaintiffs were put on notice of the deficiencies in the complaint by the motion to dismiss. If they had something relevant to add, they should have moved to add it then. And even now there is no suggestion that amendment would be anything other than futile. *We wish to discourage this practice of seeking leave to amend after the case has been dismissed.*

Fire & Police Pension Ass'n of Colo., 778 F.3d at 247 (emphasis added) (citations omitted); *see also ACA Fin.*, 512 F.3d at 57 (rejecting plaintiffs' argument that district court erred in denying leave to amend because "[p]laintiffs took no action to add new allegations" in response to defendants' motion to dismiss "even though they knew what they would add if they amended,"

and noting that allowing such a practice would "lead to delays, inefficiencies, and wasted work"); *but see Genzyme Corp.*, 754 F.3d at 47 ("We pause to note our discomfort with the district court's choice to dismiss the complaint with prejudice. The district court granted relief in the form petitioned for by defendants, and it is certainly within the bounds of the district court's discretion to dismiss with prejudice. However, as we have done in the past, we again make clear that the PSLRA has not modified the liberal amendment policy of Rule 15(a).").

Under the circumstances, dismissal with prejudice is appropriate. The original complaint in this case was filed on October 21, 2015, and the Court appointed lead plaintiffs in January 2016, providing plaintiffs with an additional 45 days from that date to file an amended complaint. Accordingly, plaintiffs had approximately four additional months between the filing of the initial complaint and the amended complaint to investigate their claims thoroughly—an investigation that should have been completed, at least predominantly, before filing the *original* complaint. Moreover, plaintiffs had the opportunity to request leave to amend the complaint after defendants filed their motion to dismiss, as well as after the motion hearing. The Court is aware of no other area of law where plaintiffs can fully litigate a motion to dismiss with prejudice, without moving for leave to amend, and then request leave to amend "in the event" that the Court decides the complaint fails to state a claim. Such a practice, which the First Circuit seeks to "discourage," is inefficient, unfair to defendants, and burdensome to the Court.

Accordingly, the Court will not grant plaintiffs' informal request for leave to amend after ruling on defendants' motion to dismiss.

V. Conclusion

For the foregoing reasons, defendants' motion to dismiss is GRANTED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
Dated: August 9, 2016 United States District Judge