UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KARSE and ARLENE SIMON, individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 12-12137-FDS**
ABIOMED, INC., MICHAEL R. MINOGUE, and ROBERT L. BOWEN,	)	
Defendants.	)	

MEMORANDUM AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

SAYLOR, J.

This is a putative class action involving alleged violations of the Securities Exchange Act of 1934. Karse and Arlene Simon brought suit on behalf of a class of similarly situated persons against Abiomed, Inc; its Chief Executive Officer, Michael R. Minogue; and its Chief Financial Officer, Robert L. Bowen. The City of Austin Police Retirement System and the Fire and Police Pension Association of Colorado have been selected as lead plaintiffs. Plaintiffs contend that they purchased the common stock of Abiomed from August 4, 2011, through October 31, 2012, at prices that were artificially inflated by the company's false and misleading statements.

The complaint in this case rests principally on the allegation that Abiomed, a manufacturer of medical devices, engaged in so-called "off-label" marketing. Specifically, plaintiffs allege that Abiomed engaged in a scheme to market the Impella 2.5, a percutaneous micro heart pump that provides circulatory support, for purposes that had not been approved by the United States Food and Drug Administration and made misleading statements about those

practices. This, according to plaintiffs, led to inflated revenues and inflated stock prices, which ultimately fell when the company was forced to change its marketing practices.

Defendants have filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). Notwithstanding the size of the complaint, which covers 228 paragraphs and 89 pages, the substantive allegations of securities fraud are relatively thin. While it appears that the complaint alleges sufficient facts to establish a claim of material misrepresentation, plaintiffs' claims that defendants acted with the requisite degree of scienter fail to clear the relatively high hurdle of the Private Securities Litigation Reform Act of 1995. Accordingly, and for the reasons set forth below, the motion to dismiss will be granted.

I. Background

Unless otherwise noted, all facts are stated as set forth in the amended complaint.

A. Factual Background

Abiomed, Inc., develops, manufactures, markets, and sells medical devices designed for circulatory support. (Compl. ¶ 24).[1] It is a small company of about 150 employees. It is incorporated in Delaware and maintains its principal place of business in Danvers, Massachusetts. (*Id.* ¶¶ 24, 36). Its stock is publicly traded on NASDAQ. As of January 31, 2012, 38.56 million shares of common stock were outstanding. (*Id.* ¶¶ 24, 207, 214).

Abiomed's main source of revenue is the Impella 2.5, a percutaneous micro heart pump with an integrated motor and sensors. (*Id.* ¶¶ 24, 32, 35). The Impella 2.5 is inserted into a patient's artery and assists the heart by pumping up to 2.5 liters of blood per minute. The complaint alleges that 85% of the company's revenues are derived from sales of Impella

[1] All citations are to the amended complaint.

products, and that "most" of that revenue came from sales of the Impella 2.5. (*Id.* ¶ 35).

The U.S. Food and Drug Administration regulates medical devices pursuant to the Food, Drug, and Cosmetics Act ("FDCA"). One manner of regulation is under section 510(k) of the FDCA, by which the agency "clears" devices that are substantially equivalent in safety and effectiveness to an existing lawfully marketed device to be used for the same intended purposes. (*Id.* ¶¶ 38, 41). Another manner is by granting an investigational device exemption ("IDE") to allow use of a device in a clinical study to collect safety and effectiveness data. (*Id.* ¶ 42).

The FDA imposes strict guidelines on the labeling and marketing of medical devices. (*Id.* ¶ 43). For example, a company may not market devices for uses for which they have not been approved, nor may it represent that an investigational device is safe or effective. (*Id.* ¶¶ 44, 50). The FDA does not, however, prohibit physicians or hospitals from "off-label" uses of a device. Companies may respond to physicians' unsolicited questions about "off-label" uses or requests for technical assistance. (*Id.* ¶ 51).

In June 2008, Abiomed obtained clearance for the Impella 2.5 under the 510(k) process. The clearance was for use in a patient up to six hours for "partial circulatory support using an extracorporeal bypass control unit" and "during procedures not requiring cardiopulmonary bypass." (*Id.* ¶ 54). It was also cleared to provide pressure measurements to determine intravascular pressure. (*Id.*). Under FDA regulations, Abiomed may not label, market, or promote the device for any other use. (*Id.* ¶ 55).

The principal competitor of the Impella 2.5 is the intra-aortic balloon pump ("IABP"). IABPs, which employ an older technology, are substantially less expensive and are used much more widely than the Impella devices. (*Id.* ¶ 57).

Abiomed received IDEs from the FDA for two clinical studies involving the Impella 2.5. First, in August 2007, it received an IDE for a clinical study to compare the Impella 2.5 to the IABP during high-risk percutaneous coronary interventions ("PCI," also known as angioplasty). (*Id.* ¶¶ 56, 58). The study, which was called the "Protect II" study, was intended, among other things, to measure major adverse events after the passage of 30 days. (*Id.* ¶ 58). On December 6, 2010, Abiomed announced that it was terminating the Protect II study on grounds of futility. (*Id.* ¶ 59). The company continued, however, to collect and analyze data, including 90-day results. (*Id.* ¶ 61). The study results, which found that the Impella 2.5 did not achieve superior outcomes after 30 days, were published in *Circulation* on September 4, 2012. (*Id.* ¶¶ 61-62). The study did, however, report "the results of a more promising secondary analysis suggesting a possible benefit for the device at 90 days," but noted that the "analysis of 90 day events remains exploratory." (*Id.* ¶ 62).

Second, in March 2008, Abiomed received an IDE for a study to compare the Impella 2.5 to the IABP in hemodynamically unstable patients undergoing a PCI due to an acute myocardial infarction ("AMI," also known as a heart attack). (*Id.* ¶ 56, 63). That study, which was called the "Recover II" study, was suspended in September 2009 and terminated for insufficient enrollment in September 2010. (*Id.* ¶ 64).

1. The Alleged Off-Label Marketing Scheme

Plaintiffs allege that during the Class Period—August 4, 2011, through October 31, 2012—Abiomed engaged in a "pervasive" scheme to promote off-label uses in violation of FDA rules. Plaintiffs allege, among other things, that Abiomed promoted off-label uses during PCI for patients who had an AMI; in place of heart transplantation; and in electrophysiology

procedures, which often last more than six hours. (*Id.* ¶¶ 79-82, 90). Plaintiffs also allege that Abiomed trained sales and clinical representatives concerning off-label marketing, including how to prompt physicians to ask about off-label uses, and the Protect II study. (*Id.* ¶¶ 83-86, 93).

2. The January 2010 Untitled Letter

On January 28, 2010, the FDA sent Abiomed an Untitled Letter concerning marketing of the Impella 2.5. (*Id.* ¶ 66).[2] The Untitled Letter raised two issues: (1) a magazine advertisement that made allegedly improper efficacy statements and comparisons to the IABP and showed use of the Impella 2.5 in high-risk PCI and AMI procedures, which are off-label uses, and (2) a press release stating that the Impella 2.5 was "safe" and "provides excellent support" during high-risk PCI procedures. (*Id.* ¶ 68; *see* Ward Decl., Ex. 3).[3]

Abiomed responded in writing on March 4, 2010, proposing changes to the challenged materials. (Compl. ¶ 69). The FDA responded on March 29, 2010, stating that Abiomed's proposed changes were inadequate and that further revisions were needed. (*Id.* ¶ 70; Ward Decl., Ex. 5). On April 7, 2010, the company again responded, stating that it had removed the cited materials from its website and that no other marketing materials claimed the Impella 2.5 was "safe" or "provides excellent support." (*Id.* ¶ 71). According to defendants, the FDA sent

[2] According to the FDA's Regulatory Procedures Manual, the agency issues an "Untitled Letter" to cite a violation that does not meet the threshold of a "Warning Letter" and does not include a warning that a company's failure to take prompt corrective steps could lead to an enforcement action. U.S. Food & Drug Admin., Regulatory Procedures Manual: Advisory Actions, 2004 WL 3363386, at *24 (2010). In contrast, the agency issues a Warning Letter for "violations of regulatory significance," that is, violations of FDA statutes or regulations. *Id.* at *1. However, a Warning Letter, and *a fortiori* an Untitled Letter, "does not commit FDA to taking enforcement action" and is not considered "final agency action." *Id.* at *2.

[3] 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; or for documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). *See Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 86 (1st Cir. 2008).

an acknowledgment letter on April 20, 2010, stating that the "corrective actions" taken were "adequate." (Ward Decl., Ex. 7). Abiomed did not publicly disclose the correspondence until June 2011. (Compl. ¶ 72).

3. The June 2011 Warning Letter

On June 10, 2011, the FDA issued a Warning Letter concerning the Impella 2.5. (*Id.* ¶ 73). The Warning Letter stated that other Abiomed marketing materials improperly compared the Impella 2.5 to the IABP, promoted the device for off-label uses, or asserted unproven claims. (*Id.*; *see* Ward Decl., Ex. 8).

Specifically, the Warning Letter identified three items of concern: (1) a magazine advertisement that showed an image of a hand puncturing a red balloon with a pin and text stating "Old ideas about heart recovery" and "After 40 years, there is something other than the [IABP] for circulatory support in the Cath lab," together with comparative statements concerning mortality in AMI patients; (2) a presentation (according to defendants, made by a physician) at the 2010 Transcatheter Cardiovascular Therapeutics meeting that allegedly promoted the safety and efficacy of the Impella 2.5 in AMI procedures; and (3) the Abiomed slogan, "Recovering Hearts, Saving Lives," which the FDA stated "would require a randomized clinical study performed under an IDE specifically to evaluate whether the device could salvage heart tissue and muscle." (Compl. ¶¶ 73-75; Ward Decl., Ex. 8).

The 2011 FDA Warning Letter was published on the FDA website in June 2011. (Compl. ¶ 76). As reported in a June 28, 2011 article in the *Boston Business Journal*, an Abiomed spokeswoman stated in response to an inquiry that "[t]his letter addresses specific promotional items from 2010 . . . . We are working with the FDA to ensure all of our

promotional materials comply with the agency moving forward." (*Id.*).

As set forth below, the letter was addressed in a Form 10-Q on August 5, 2011.[4]

4. The August 4, 2011 Press Release and Conference Call

On August 4, 2011, Abiomed issued a press release that stated the following:

> Fiscal first quarter worldwide Impella revenue totaled $22.2 million, up 33% compared to revenue of $16.7 million during the same period of the prior year. U.S. Impella revenues of $20.5 million were up 31% from the prior year. Impella revenue from outside the U.S. totaled $1.7 million, up 70% from the prior year.

(*Id.* ¶ 105).

That same day, Minogue said the following on an analyst conference call:

> In regard to high-risk PCI, the PROTECT II study is the first-ever FDA study for high-risk PCI requiring hemodynamic support and first intra-aortic balloon pump FDA study overall. To summarize PROTECT II, the Impella patients were treated more aggressively and had significantly better outcomes at 90 days.

(*Id.* ¶ 107). On the call, Bowen added:

> [W]e expect the positive effects of the PROTECT II clinical story to materialize in the second half of fiscal year 2012 as the clinical community digest[s] the outcome and economic benefits.

(*Id.* ¶ 110).

In response to questioning about the 2011 FDA letter, Minogue said that the company was "working with" the FDA and that "[n]othing in the warning letter had anything to do with the patient safety or patient outcomes . . . ." (*Id.* ¶ 112). Abiomed did not address the impact of off-label marketing on revenue growth or any ongoing scrutiny by the FDA in the press release or during the call. (*Id.* ¶¶ 106, 108, 111).

[4] Defendants also contend that they sent a formal response letter on August 8, 2011, in which they addressed the FDA's concerns. (Def. Mem. at 7; Ward Decl., Ex. 11).

5. The August 2011 Form 10-Q

Abiomed's quarterly report, Form 10-Q, filed on August 5, 2011, stated the following:

> Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In June 2011, we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We have cooperated with the FDA in addressing its concerns and believe that we have resolved the matter without any penalties. Although we believe that this issue has been resolved, if similar matters come up in the future, we may not be able to resolve them without facing significant consequences.

(*Id.* ¶ 116). The Form 10-Q also stated as follows:

> In April 2011, we announced final results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 21% reduction in major adverse events compared to the IAB at 90 days per protocol.

(*Id.* ¶ 114). The Form 10-Q also reported Abiomed's revenue for the first quarter of 2012, but did not discuss the impact of off-label marketing on revenue. (*Id.* ¶¶ 118-19).[5]

The Form 10-Q stated that total revenue for the quarter grew, and that "[t]he increase in total revenue was primarily due to higher Impella orders due to greater demand in the U.S.," and that "[m]ost of our Impella revenue was from disposable product sales of Impella in the U.S., as we focus on increasing utilization of these products through continued sales force and physician training." (*Id.* ¶ 118).

6. The November 2011 Press Release, Conference Call, and Form 10-Q

Abiomed issued a press release on November 3, 2011, that reported its second-quarter

[5] Minogue and Bowen certified, as in every Form 10-Q or 10-K filed with the SEC, that the filing did not contain "any untrue statement of a material fact or omit to state a material fact," that "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company," and that the company maintained effective disclosure controls and procedures. (*Id.* ¶¶ 172-73).

2012 revenue. (*Id.* ¶ 120). In an analyst conference call that same day, Minogue and Bowen remarked on the revenue numbers and the company's strong growth. (*Id.* ¶¶ 121-22). Minogue also stated:

> On the warning letter, I believe we've resolved the issues and taken the feedback from the FDA and are working that into our operating mechanism.

(*Id.* ¶ 124).

In its November 2011 Form 10-Q, Abiomed stated as follows:

> In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary endpoint, which we view as likely to have resulted from how rotational athorectomy was used in the study. In April 2011, we announced the final results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 21% reduction in major adverse events compared to the intra aortic balloon at 90 days per protocol.

(*Id.* ¶ 126). The Form 10-Q included a paragraph identical to that in the August 2011 filing concerning the company's policy "to refrain from statements that could be considered off-label promotion" and its belief that issues with the FDA were resolved. (*Id.* ¶ 128). It also contained essentially identical statements concerning the reason for the increase in total revenue. (*Id.* ¶ 130).

7. <u>The February 2012 Press Release and Conference Call</u>

On February 3, 2012, Abiomed issued a press release reporting revenue and growth in the third quarter of 2012. (*Id.* ¶¶ 133, 135). In addition, the release stated that Protect II clinical analyses "demonstrated that patients undergoing extensive revascularization showed the most clinical benefit in the Impella arm to 90 days." (*Id.* ¶ 133).

In a conference call that same day, Minogue said the following:

In PROTECT II, the economic study revealed that the Impella patients had lower

> hospital charges at 90 days, driven by 47% reduction in repeat revascularization and 67% lower charges per readmission as compared to the intra-aortic balloon pump.

(*Id.* ¶ 137). Again, Minogue and Bowen commented about the revenue growth, but did not discuss off-label marketing or any FDA scrutiny. (*Id.* ¶ 141).

The February 7, 2012 episode of the CNBC television program *Mad Money* broadcast an interview with Minogue. During the interview, Minogue referred to positive results of the Protect II study, mentioned off-label uses, and compared the Impella 2.5 to the IABP. (*Id.* ¶¶ 81, 142; *see* Ward Decl., Ex. 12).

Abiomed's February 2012 Form 10-Q included a paragraph, identical to its earlier filings, concerning off-label promotion, cooperation with the FDA, and the company's belief that matters with the FDA had been resolved. (Compl. ¶ 144). It also contained identical statements concerning the reason for the increase in total revenue. (*Id.* ¶ 146).

8. The February 2012 FDA Meeting

On February 24, 2012, Minogue and other Abiomed executives met with the FDA to discuss Abiomed's marketing practices concerning the Protect II study and high-risk PCI. (*Id.* ¶ 98). According to the complaint, the "purpose of the meeting was to discuss the Protect II study and the FDA's concerns, including safety concerns, in regard to the claims Defendants were making in regard to that study." (*Id.*). Abiomed did not publicly disclose the February 24 meeting until a Form 8K was filed on May 22, 2012. (*Id.* ¶ 152).

9. The April 2012 Follow-Up Letter

On April 5, 2012, the FDA sent a Follow-Up Letter to Abiomed. The Follow-Up Letter detailed the corrective actions Abiomed had taken and stated that certain of the company's other

promotional materials marketed the Impella 2.5 in ways that allegedly did not comply with the FDCA. (Compl. ¶ 99; Ward Decl., Ex. 13). The Follow-Up Letter identified three additional items: (1) the "Patient Stories" portion of the Abiomed website, which described accounts of patient experiences with Impella 2.5, including one that involved the use of the device in an off-label procedure; (2) an "AbiomedImpella" YouTube channel that included videos of patient stories, including one that an off-label use; and (3) the February 7, 2012, interview with Mr. Minogue on the "Mad Money" program. (Ward Decl., Ex. 13).

Abiomed did not publicly disclose the April 5 Follow-Up Letter until its June 2012 10-K filing. (Compl. ¶¶ 98-99).

10. The May 2012 Press Release, Conference Call, and Form 8-K

On May 16, 2012, Abiomed issued a press release about its fourth-quarter 2012 and full-year financial results, and both Minogue and Bowen discussed the results on a conference call. (*Id.* ¶¶ 148-50). They did not remark upon the impact of off-label marketing or communications with the FDA. (*Id.* ¶ 151).

The FDA posted information about the February 24 meeting on its website. (*Id.* ¶ 152). As a result, on May 22, 2012, Abiomed filed a Form 8-K that addressed that meeting. The Form 8-K stated in part:

> Abiomed is filing this 8-K to clarify two meetings held between FDA and Abiomed on February 24, 2012.
>
> A morning meeting was held with the FDA reviewers to present the final results of the PROTECT II study as part of the process to close out the IDE (Investigational Device Exemption). Included in Abiomed's presentation at this meeting were the 30- and 90-day results.
>
> . . .

> Abiomed had also requested that some of the meeting time be utilized for an update to the Impella cVAD 510(k) submission. In this context, safety aspects of the technology have to be reviewed with the FDA as a standard part of the 510(k) process.
>
> In a separate afternoon meeting, which was disclosed on the FDA website and held at the request of Abiomed's CEO with Dr. Shuren and his team, the following specific topics were discussed: . . . Clinical Indications/Labeling . . . .

(*Id.*). The complaint alleges that the 8-K was misleading, because the purpose of the meeting had been to discuss improper marketing of the Impella 2.5 and the Protect II study and that the filing failed to mention that purpose. (*Id.* ¶ 153).

11. <u>The June 2012 Form 10-K</u>

In its June 2012 Annual Report, Form 10-K, Abiomed reported its revenues for the prior year. It again attributed growth "primarily" to "higher Impella revenue due to greater utilization in the U.S." (*Id.* ¶ 158). It also stated that "[m]ost of our Impella revenue was from disposable product sales of Impella 2.5 in the U.S., as we focus on controlled rollouts for new sites and increasing utilization of these products through continued investment in our sales force and physician training." (*Id*.). The 10-K also discussed the Protect II study:

> In November 2011, we announced additional analysis of the results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 22% relative reduction in major adverse events compared to the IAB at 90 days per protocol (p=0.023), a 52% relative reduction in repeat revascularization (p=0.024) and a 56% relative reduction in material adverse events post hospital discharge (p=0.002). Furthermore, additional data analysis of the clinical data from the Protect II trial revealed that more aggressive revascularization is beneficial for patients with coronary artery disease and reduced left ventricular function.

(*Id.* ¶ 156). The company also reported on its interactions with the FDA:

> Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In June 2011

> we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to the warning letter. However, in April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. We are cooperating with the FDA in addressing its concerns. While we hope to be able to resolve this matter without incurring penalties, we may not be able to resolve it, or any similar matters that may come up in the future without facing significant consequences. Such matters could result in reduced demand for our products and would have a material adverse effect on our operations and prospects.

(*Id.* ¶ 154).

12. The August 2012 Press Release, Conference Call, and Form 10-Q

Abiomed released its first-quarter 2013 financial results on August 2, 2012. That day, it issued a press release and held a conference call in which it reported revenue growth and attributed the growth to Impella sales. (*Id.* ¶¶ 160-63). Minogue cited the Protect II study results in the conference call. (*Id.* ¶ 165).

The August 2012 Form 10-Q filing announced first-quarter revenues. The 10-Q contained statements identical to the most recent 10-K concerning the sources of revenue growth. (*Id.* ¶ 167). The 10-Q did not include the paragraph stating that Abiomed's policy was to refrain from off-label promotion or that it believed that it had resolved the FDA's concerns. (*Id.* ¶ 169).

13. Abiomed's Recall of Marketing Materials

Abiomed and the FDA participated in a further meeting on August 7, 2012, at which the FDA stated that the company was still using marketing brochures that had been cited in the June 2011 Warning Letter. (Ward. Decl., Ex. 16). Beginning the next day, the company recalled all of its marketing materials. (*Id.*). It also conducted an internal audit of its promotional materials.

(*Id.*; Compl. ¶¶ 14, 100, 154, 177). It later reissued marketing materials that did not discuss Protect II or cardiac power output. (*Id.* ¶ 100). The recall of its marketing materials was not disclosed until November 2012, as set forth below.

14. The November 2012 Investigation

On October 26, 2012, Abiomed was informed that the U.S. Attorney's Office for the District of Columbia was conducting an investigation into the company's marketing and labeling of the Impella 2.5. (*Id.* ¶ 175). On October 31, 2012, it received an administrative subpoena relating to the investigation. On November 1, 2012, Abiomed issued a press release that disclosed the investigation and the subpoena. The company announced that it was "responding to the subpoena and intend[ed] to cooperate fully." It also issued a Form 8-K stating essentially the same. (*Id.* ¶¶ 175-77; Def. Mem. at 45 n.62).

On the same day, Minogue stated on a conference call that Abiomed "has taken extensive actions to correct [its] noted compliance issues identified in our annual report," that it had conducted "an internal compliance audit of [its] marketing materials," and that it had "recertified the field team and management on [its] Impella labels." (Compl. ¶ 177; Ward Decl., Ex. 17).[6]

That day, Abiomed's stock price dropped from the October 31 closing price of $19.82 per share to close at $13.61 on November 1, a drop of 31%. (*Id.* ¶ 178).

15. The February 2013 Close-Out Letter

On February 19, 2013, the FDA issued a Close-Out Letter, stating that the FDA had completed its evaluation of the Company's "corrective actions in response to our [2011]

[6] In the same press conference, Minogue stated that the FDA had "audited" Abiomed "at our headquarters this summer," and that "there was no observations of quality issues related to our operations." (Compl. ¶ 177). Plaintiffs interpret that statement to mean that the FDA audited Abiomed's "marketing." (*Id.*).

Warning Letter" and that the Company had "addressed the violations" in this letter. FDA Close-Out Letter to Abiomed, Inc. (Feb. 19, 2013).[7] The FDA terminated its investigation without assessing any penalty or sanction.

16. Confidential Witnesses

The complaint alleges that plaintiffs have received information from seven confidential witnesses, all of whom are former employees. (Compl. ¶ 29). According to the complaint,

- CW1 was a clinical representative from March 2011 until April 2012;
- CW2 was a senior quality compliance and validation engineer from April 2008 to March 2011;
- CW3 was an account manager from September 2008 to March 2011;
- CW4 was a clinical representative from August 2007 to September 2010;
- CW5 was a clinical representative from February 2012 to February 2013;
- CW6 was a territory manager or sales representative from October 2008 to February 2011; and
- CW7 was a director of clinical operations from February 2009 to November 2011.

(*Id.*).[8]

The complaint includes some generalized allegations from confidential witnesses about the attitudes of management, or what they presume management must have known. (*See*, *e.g.*, *id.* ¶ 77). But it also includes some more specific claims about the Protect II study and the

[7] *See* Abiomed, Inc., SEC Current Report (Form 8-K) (Feb. 20, 2013) (disclosing Close-Out Letter), *available at* http://www.sec.gov/Archives/edgar/data/815094/000119312513067205/d490174d8k.htm.

[8] As defendants note, four of the confidential witnesses had left the company by the start of the class period (August 4, 2011).

alleged marketing of off-label uses. For example, paragraph 84 alleges in part:

> Former employees relayed that a major focus in the sales and clinical marketing initiative was Abiomed's misleading claims regarding Protect II and comparisons of the Impella 2.5 to the IABP. Both CW1 and CW5, former Abiomed clinical representatives, described how sales and clinical representatives were provided with "talking points" about Protect II and how to discuss the superiority of the Impella 2.5 over the IABP, including as to adverse events and cost-effectiveness. CW5 relayed that a lot of the marketing and training materials the Company gave the representatives in connection with their visits with customers related to Protect II, including a "Protect II slide deck" to use with customers.

(*Id.* ¶ 84). Paragraphs 85 through 96 of the complaint set forth other allegations from confidential witnesses concerning efforts to make unsupported claims of efficiency or to promote off-label use. (*See, e.g.*, *id.* ¶ 93 (CW1 alleges, among other things, that "sales 'reps were instructed to steer physicians to use the device off-label'" and that "sales representatives were trained to review cases with doctors during sales calls because if a sales representative had the opportunity to review cases with doctors, they could often influence doctors to ask about off-label use.")).

17. Trading by Insiders

According to the complaint, between January 28, 2010, when the FDA sent the Untitled Letter, and October 31, 2012, the end of the class period, defendants Minogue and Bowen, as well as other insiders, sold unusual quantities of Abiomed stock.

From January 28, 2010, to October 31, 2012, Minogue sold 586,149 shares—48% of his total holdings—for $9,636,124 in gross proceeds. In the 33 months prior to January 2010, he had sold 27,987 shares for $484,650. Between January 2010 and May 2011, while the FDA was investigating Abiomed's marketing practices, Minogue sold 525,491 shares for $8,208,551, and from May 2012 to June 2012, while "the FDA increased its scrutiny of Abiomed's marketing

which [led] to" the FDA audit and Abiomed "itself was conducting an internal audit," he sold 60,658 shares for $1,427,573. (Compl. ¶¶ 188-91).

During the same period, Bowen sold 57,919 shares for $1,302,878 in gross proceeds. Most of these trades occurred when the price per share was near its high and during the FDA and internal audits. Prior to January 2010, he made no stock sales. (*Id.* ¶¶ 192-95). Bowen joined Abiomed in December 2008.[9]

Defendants note that of Minogue's sales, six of the 23 cited by plaintiffs occurred during the class period. Those six sales amounted to 60,658 shares for $1,203,613 net proceeds. Three were options exercises and three were sales of restricted shares upon vesting, which is a tax realization event. All sales were made pursuant to 10b5-1 plans entered into on November 14, 2011, or August 9, 2011, amended on February 29, 2012. Overall, Minogue increased his holdings by 9.2% during the class period. (Def. Mem. at 38-40).

Of Bowen's sales, six of the seven cited by plaintiffs occurred during the class period. The seven sales reaped $1,064,525.50 in net proceeds, were made pursuant to 10b5-1 plans, and decreased his holdings by 6.52%. Bowen made three of the sales to cover taxes due to vesting in

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[9] Michael Howley, VP of Global Sales and Marketing, sold 31,378 shares for $624,177 in gross proceeds. He sold more than half of those shares during the class period, and he made no sales prior to January 2010. Howley joined Abiomed in March 2009. (Compl. ¶ 197).

Andrew Greenfield, VP of Healthcare Solutions, sold 78,172 shares for $1,367,996 in gross proceeds. He sold more than half of those shares during the class period, and sold 5,634 shares for $73,219 in the prior 33-month period. (*Id.* ¶ 198).

David N. Weber, Chief Operating Officer, sold 59,167 for $1,209,844 in gross proceeds. He sold the majority of the shares during the class period. He had sold 4,900 shares for $87,269 in the prior 33 months. (*Id.* ¶ 199).

William Bolt, SVP of Global Product Operations, sold 130,024 shares for $2,426,491 in gross proceeds. He sold the majority of those shares during the class period, and in the 33 months prior, he had sold 24,900 shares for $478,869. (*Id.* ¶ 200).

late May and early June 2012. (Def. Mem. at 40-42).

18. Plaintiffs' Purchases of Shares

The Fire and Police Pension Association of Colorado ("FPPA") purchased 25,035 shares of Abiomed stock on February 2, 2012; 601 shares on February 3; 6,284 shares on February 24; 6,248 shares on February 27; 8,268 shares on March 19; and 12,122 shares on October 16, for a total of 58,558 shares, at prices ranging between $19.40 and $22.45 per share. (Dkt. No. 13-1, Ex. A). The City of Austin Police Retirement System ("CAPRS") purchased 30,400 shares of Abiomed stock on October 1, 2012; 700 shares on October 25; 1,200 shares on October 26; and 800 shares on October 3, for prices ranging between $18.58 and $21.20 per share. (Dkt. No. 13-1, Ex. B). Neither lead plaintiff held any shares as of August 4, 2011, the beginning of the class period. (Dkt. No. 13-1, Exs. A, B). Both sold all of their holdings on November 1, 2012. (Dkt. No. 13-1, Exs. C, D).[10]

Neither lead plaintiff alleges a realized loss as a result of selling Abiomed shares after the conclusion of the class period. Instead, they allege only that they purchased shares at inflated prices during the class period.

B. Procedural Background

On November 16, 2012, Arlene and Karse Simon filed a complaint on behalf of all purchasers of Abiomed common stock between August 5, 2011, and October 31, 2012. On February 14, 2013, the Court appointed CAPRS and FPPA as lead plaintiffs. The lead plaintiffs filed an amended complaint on May 20, 2013. The amended complaint contends that Abiomed, Minogue, and Bowen violated Section 10(b) of the Securities Exchange Act of 1934 and

[10] On September 28, 2012, Karse and Arlene Simon sold five put options of Abiomed stock that matured in December 2012 at $20 per share. (Dkt. No. 1, Ex. A).

Securities and Exchange Commission Rule 10b-5; and that Minogue and Bowen violated Section 20A of the 1934 Act.

Defendants have moved to dismiss the complaint for failure to state a claim upon which relief can be granted, contending that plaintiffs have failed adequately to allege material misrepresentation, scienter, loss causation, and control-person liability.

II. Legal Standard

On a motion to dismiss a claim pursuant to Section 10(b) and Rule 10b-5, courts must, as with any such motion, accept plaintiff's 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. When a plaintiff alleges misrepresentation or omission of a material fact, the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737, 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). 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 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.

In evaluating the adequacy of a complaint, a court "cannot hold plaintiff to a standard that would effectively require them, pre-discovery, to plead evidence." *Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 90 (1st Cir. 2008) (*quoting Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996)). Courts should look at the

complaint "as a whole" and weigh "competing inferences" in a "comparative evaluation" of plaintiff's allegations and alternative inferences from those allegations. *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 59 (1st Cir. 2008); *see also Tellabs*, 551 U.S. at 314. If "there are equally strong inferences for and against scienter," then the tie goes to the plaintiff. *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008) (*quoting ACA Fin.*, 512 F.3d at 59).

III. Analysis

A. 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 this section, the SEC 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. Section 10(b) requires proof of six elements: "(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." *Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 649 F.3d 5, 20 (1st Cir. 2011)

(*quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 756 (1st Cir. 2011)).

B. Allegations of Material Misrepresentations

Information is material "if a reasonable investor would have viewed it as 'having significantly altered the total mix of information made available.'" *Boston Scientific Corp.*, 523 F.3d at 85 (*quoting Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988)). A statement that is merely false or incomplete, but not material, cannot give rise to a securities violation. *Basic*, 485 U.S. at 238. Nor is a company required to disclose all material information—only those facts that it has a specific duty to disclose. *See* 17 C.F.R. § 240.10b–5 (requiring that, when a company speaks, it disclose facts that would be "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading"); *see also Gross v. Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1996) (holding that a duty to disclose may arise if a company "previously made a statement of material fact that is either false, inaccurate, incomplete, or misleading in light of the undisclosed information").

The central allegation of the complaint is that defendants engaged in "widespread off-label marketing of the Impella 2.5 and ignored and misrepresented citations from the FDA regarding such practices." (Compl. ¶ 22). More particularly, the complaint alleges a combination of false statements and omissions, which may be summarized as follows:

1. defendants failed to disclose that Abiomed engaged in a "pervasive" and "widespread" scheme of off-label marketing, and falsely stated that the company's policy was to "refrain from statements that could be considered off-label promotion of our products";

2. defendants failed to disclose that the company's revenue growth was the "result of"

improper off-label marketing, and falsely stated that the company's revenue growth was primarily due to "greater utilization" of the Impella 2.5 in the United States;

3. defendants made false statements concerning the FDA investigation of its off-label marketing practices;

4. defendants made false statements concerning the Protect II study, including statements promoting off-label marketing; and

5. defendants made false statements certifying its internal controls.

The allegations in the complaint thus depend almost entirely on the contention that defendants did, in fact, engage in improper off-label marketing. That contention, in turn, is actionable under Rule 10b-5 only if it affected the price of the stock. The Court will address those two issues first, and then turn to the specific claims of misrepresentation alleged by plaintiffs.

1. Whether the Complaint Sufficiently Alleges the Existence of an Off-Label Marketing Scheme

The allegations of the amended complaint concerning off-label marketing rest on three basic elements: (1) the concerns raised by the FDA in its letters and meetings with Abiomed; (2) the allegations made by various confidential witnesses; and (3) the fact that the company took corrective actions in 2012.

First, the FDA raised a series of issues as to statements that the FDA believed promoted use of the Impella 2.5 for off-label procedures. It did so in the January 2010 Untitled Letter, the June 2011 Warning Letter, the February 2012 meeting, the April 2012 Follow-Up Letter, and various correspondence and discussions in between. After each letter or meeting, Abiomed appears to have responded and taken corrective action. However, the FDA continued to identify

new or ongoing problems; by August 2012, an FDA representative questioned whether "Abiomed was approaching the problem in a systemic enough way." (Ward Decl., Ex. 15 at 5).

Second, plaintiffs rely on a series of confidential witnesses. According to CW1, after Abiomed received the Untitled Letter, sales and clinic staff were not instructed to change their marketing practices. Although they were told about the FDA's concerns during a national meeting attended by Minogue and Bowen, members of the management team characterized the ad in question as "just a balloon." (Compl. ¶ 77). According to CW1 and CW5, representatives were provided Protect II talking points, instructed how to discuss the superiority of the Impella 2.5 over the IABP, and given materials that claimed that the Impella 2.5 was safe for high-risk PCI. (Compl. ¶¶ 84-87). According to CW7, there was an initiative to promote the Impella 2.5 in electrophysiology procedures, which usually last more than six hours, and that the initiative included hosting dinners for doctors and sponsoring presentations. (Compl. ¶ 90).[11] Abiomed trained representatives to help doctors identify patients, including those with high-risk PCI, with whom to use the Impella 2.5; to look for patients themselves and tell doctors to use the Impella 2.5; and to have conversations with doctors in such a way as to prompt questions about off-label uses. (Compl. ¶¶ 92-95). According to CW3, he had a conversation (the complaint does not allege when) with the Vice President of Global Sales and Marketing, who reported to Minogue, in which he said that the marketing materials were "inaccurate and can't be distributed." CW3 also did not believe that management intended to resolve the problem. (Compl. ¶ 89).

Third, by August 2012, because sufficient issues remained unresolved, the company had to conduct an internal compliance audit and recertify its "field team and management" on the

[11] According to the complaint, CW7 was a former Director of Clinical Operations, who reported to Mike Howley, who reported directly to Minogue. (Compl. ¶ 87).

labeling of Impella products. (Ward Decl., Ex. 17).

Defendants counter with multiple arguments. First, defendants contend that the confidential witnesses were not in a position to render credible testimony as to the existence of a company-wide scheme during the relevant period. Only three of the seven worked at Abiomed during the class period, and none of those three were employed for the entirety of the class period. Also, none were in management positions or claim to have had direct contact with management. Defendants further describe their assertions as "vague" and "conclusory." (Def. Mem. at 26). Second, according to defendants, the FDA took issue with only a "handful" of promotional materials. (Def. Mem. at 27). Defendants therefore assert that there was no "pervasive scheme" to engage in off-label marketing, but rather a series of minor issues as to specific materials that were eventually corrected to the FDA's satisfaction. Third, the FDA closed its investigation into Abiomed in February 2013 without imposing any sanctions.

Defendants' arguments are not without some force. Nonetheless, viewing the allegations as a whole, the complaint provides sufficiently detailed and plausible allegations under the circumstances to sustain a claim that the company engaged in off-label marketing practices. *See Chamberlain v. Reddy Ice Holdings, Inc.*, 757 F. Supp. 2d 683, 690 (E.D. Mich. 2010) (finding plaintiff plausibly demonstrated underlying antitrust violation for court to accept it as true); *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1018 (C.D. Cal. 2008) (finding plaintiff sufficiently alleged evidence of off-label marketing); *In re Unumprovident Corp. Sec. Litig.*, 396 F. Supp. 2d 858, 885-86 (E.D. Tenn. 2005) (finding plaintiff adequately alleged unethical and possibly illegal practices at defendant company).

The allegations of the confidential witnesses merit separate comment. When evaluating

such claims, the court must consider "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) (quotation and citation omitted). None of the seven confidential witnesses cited in the complaint were in senior management positions, and they appear to have had relatively little ongoing contact with senior management. However, most were clinical representatives, sales representatives, or otherwise in a position to know about the off-label marketing practices and training. Those who were not at the company during the class period were nonetheless there around the time that it received the Untitled Letter, and therefore plausibly have knowledge about off-label marketing practices at the time. A witness need not have been at the company for entire, or indeed any, of an asserted class period to have probative information. The information of the confidential witnesses, which is partly corroborated by other sources, provide sufficiently detailed and plausible allegations to support the claim of the existence of an off-label marketing policy, at least at some level in the company, during the relevant time.

In summary, and taken as a whole, the complaint plausibly alleges that the company had a policy or practice, during the class period, of marketing the Impella 2.5 for off-label uses. That said, this case is not about whether or not defendants violated the FDCA or FDA regulations. It concerns alleged violations of securities law, and that is where the Court will direct its focus. *See Amgen*, 544 F. Supp. 2d at 1033 ("The issue before the Court is not whether the FDA improperly approved [defendant's] products as safe and effective, but rather whether Defendants

violated securities laws by improperly marketing [the products] for off-label uses.").

2. Whether the Alleged Off-Label Marketing Scheme Affected the Stock Price

The next question is whether the existence of the alleged policy or practice—the promotion of off-label uses—had a material affect on the company's revenues, and thus the stock price. Again, the question is not whether defendants violated the FDA, but whether they committed a fraud in connection with the sale of securities.

As plaintiffs note, at least four other courts have denied motions to dismiss in cases involving claims of securities fraud arising out of improper off-label marketing practices. *See In re Gilead Sciences Securities Litigation*, 536 F.3d 1049 (9th Cir. 2008); *Amgen*, 544 F. Supp. 2d at 1034; *Halford v. Atricure, Inc.*, 2010 WL 8973625 (S.D. Ohio Mar. 29, 2010); *Minneapolis Firefighters' Relief Ass'n v. Medtronic Inc.*, 2010 U.S. Dist. LEXIS 10029 (D. Minn. Feb. 3, 2010). In two of those cases, the impact of off-label sales on revenues was both explicitly alleged and significant. *See Gilead*, 536 F.3d at 1051 (75% to 95% of company's sales resulted from off-label marketing efforts; stock price dropped 12% after corrective disclosure); *Minneapolis Firefighters*, 2010 U.S. Dist. LEXIS 10029 at * 7 (more than 85% of products sales involved off-label use, and the product itself generated $800 million in sales, or 6% of the company's total revenue). The *Amgen* court concluded that it was sufficient for purposes of causation to show that the stock price dropped 9.1% after disclosure of the improper marketing practices. 544 F. Supp. 2d at 1034.[12]

[12] The *Halford* court did not specifically address the question whether the policy led to a growth in sales (although it concluded that a drop in stock price of 40% following the announcement of a Department of Justice investigation into the company's marketing practices, was sufficient to show loss causation). *See Halford*, 2010 WL 8973625 at *18.

The complaint here does not contain the types of specific allegations found to be sufficient in *Gilead* or *Minneapolis Firefighters*. Plaintiffs here do not allege a specific percentage of revenue or dollar amount attributable to off-label marketing. Indeed, the complaint does not allege any direct evidence of the actual impact of any off-label marketing practices on the revenues of the company. Plaintiffs do not, for example, claim to have insider information, whether in the form of documents or confidential witness testimony, as to the amount of off-label sales, or the effect of its marketing practices on those sales. Instead, plaintiffs assert a claim based on circumstantial evidence. Plaintiffs are of course permitted to do so, but something more than raw speculation is required.[13]

Stripped of its conclusory adjectives, the complaint here in essence alleges the following: (1) Abiomed engaged in off-label marketing of the Impella 2.5; (2) the Impella 2.5 was its most important product (the Impella lines combined were 85% of revenues, although there is no allegation as to the Impella 2.5 specifically); and (3) when the company revealed the existence of the U.S. Attorney's Office investigation, and that it had corrected its marketing materials, (a) its stock price dropped 31% in one day and (b) it "maintained its Impella revenue guidance at approximately 30% for the fiscal year, despite 45% growth throughout the first have of the year, implying a marked slowdown during the second half of the year." (Am. Compl. ¶ 176). This, plaintiff contends, demonstrates that a material portion of the revenues of Abiomed were

[13] It is by no means conclusive that an off-label marketing policy would lead to a material increase in sales. The target audience, presumably, is composed of medical professionals (for example, those who perform open heart surgery); surely such sophisticated professionals, purchasing such a sophisticated product, are unusually well-informed purchasers. Moreover, and in any event, those professionals may legally purchase and use the product for off-label purposes, and the company may legally respond to their inquiries and provide technical support. The issue, therefore, is not the quantity of sales for off-label purposes, but the quantity of off-label sales resulting from improper marketing.

due—perhaps more precisely, *must* have been due—to its improper marketing practices.

Defendants note that if plaintiffs' theory is correct, logically one would expect that the revenues of the company would have declined after the change in marketing practices. In fact, Impella sales were $20.4 million in fiscal year 2011, $28.7 in fiscal year 2012, and $33.4 million in fiscal year 2013. The company's revenues therefore continued to increase after the marketing practices stopped. Defendants also point to an annual sales cycle that makes it inappropriate to extrapolate an annual figure directly from a quarterly figure. (Def. Reply Mem. at 5 n.7). Finally, defendants argue that the complaint fails to allege that the drop in Abiomed's stock price on November 1, 2012, was not due to other market forces. For example, the November 1 press release also revealed that the FDA was holding a meeting at which it might decide (and later did decide) to impose more rigorous approval processes on the Impella. (Def. Mem. at 45). Plaintiffs counter that the growth of revenue declined after the practice stopped, and in any event that defendants are raising factual matters well outside the complaint that are not appropriate for consideration on a motion to dismiss.

Again, defendants' arguments are far from frivolous, and plaintiffs' case is far from overwhelming. Nonetheless, the complaint makes plausible allegations of (1) a persistent practice of improper off-label marketing (2) of the major product (3) of a small company, coupled with (4) evidence of potentially significant financial consequences when the practice stopped. While the complaint is relatively low on specifics and relies heavily on inferences, that is a sufficient basis on which to draw the inference that the practice had a material effect on the stock price. That aspect of the claim is thus pleaded with sufficient particularity to clear the bar of the PSLRA and survive a motion to dismiss.

3. Whether the Complaint Alleges Actionable Misrepresentations

The next set of questions concern whether, in light of the company's alleged off-label marketing practices, the complaint properly alleges misleading statements or omissions within the meaning of Rule 10b-5.

a. Alleged Failure to Disclose and False Statements Concerning Off-Label Marketing

In multiple annual and quarterly reports, defendants stated that it was company policy to refrain from off-label marketing. (Compl. ¶¶ 116, 128, 144, 154). Plaintiffs contend that those were materially false statements because Abiomed did, in fact, have a policy to engage in off-label marketing.[14]

"[T]he federal securities laws do not create an affirmative duty on the part of a company to disclose the details of its business practices, opine as to their legality, or make predictions as to the likelihood and/or impact of potential litigation surrounding those practices." *In re Unumprovident Corp. Sec. Litig.*, 396 F. Supp. 2d at 886. However, if a company chooses to speak, those laws require that it do so in a manner that does not leave a false or misleading impression. *Id.* at 885. Moreover, "[w]hile the mere specter of possible but uncertain regulatory enforcement does not impose a duty to disclose, knowledge of the illegality of the allegedly unlawful conduct does." *Chamberlain*, 757 F. Supp. 2d at 708.

[14] Plaintiffs further contend that defendants had an affirmative duty to disclose the fact that it was engaged in off-label marketing whether or not it made any statements on the topic. A company is not, of course, required to accuse itself of wrongdoing. *See id.* at 25-26; *see also Greenstone v. Cambex Corp.*, 777 F. Supp. 88, 91 (D. Mass. 1991) *aff'd*, 975 F.2d 22 (1st Cir. 1992). But neither is illegality a "justification for withholding information that the corporation is otherwise obligated to disclose." *In re Par Pharm., Inc. Sec. Litig.*, 733 F. Supp. 668, 675 (S.D.N.Y. 1990). Because the company did in fact make statements concerning its policy, the Court does not reach the question here.

Here, plaintiffs have made plausible allegations that Abiomed had an actual policy or practice of off-label marketing, while its public statements were that its policy was to refrain from such marketing. Under the circumstances, that is sufficient to make out a claim for misrepresentation. *See Gilead*, 536 F.3d at 1051 ("The company and its Officers emphasized to the public that they carefully complied with federal and state regulations, when in fact they knew that they were acting unlawfully by aggressively marketing [the pharmaceutical] for off-label uses."); *Amgen*, 544 F. Supp. 2d at 1034 ("Defendants repeatedly represented in their SEC filings that Amgen marketed its products for their approved indications, while at the same time promoted unapproved uses . . . .") (internal quotation and citation omitted).

Defendants note that they did not merely attest to a policy of refraining from off-label promotion, but qualified the assertion, noting that "the FDA or another regulatory agency could disagree." (*See, e.g.*, Compl. ¶ 116). Under some circumstances, that might suffice to defeat a claim of material misrepresentation. Here, however, the complaint alleges that the company persisted in improper practices even after it received multiple cautions or warnings from the FDA. The qualification of the statement is therefore not enough, under the circumstances, to require dismissal of the claim. *See In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d at 1021, 1033-34 (finding false and misleading a statement that the company "only promotes" its products on-label when the company in fact pursued a "sophisticated and multifaceted scheme" of off-label marketing).

b. Alleged Failure to Disclose and False Statements Concerning Source of Revenue Growth

In each annual and quarterly filing with the SEC, and in quarterly conference calls, defendants reported revenues and growth for the relevant time period. Accurate reporting of

past results, without more, is not a violation of securities laws. *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 59-61 (D. Mass. 1998); *Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 250-51 (D. Mass. 2001).

However, in several instances, defendants attributed revenue growth to a particular primary source, such as "greater utilization in the U.S." of the Impella line of products. (*See, e.g.*, Compl. ¶¶ 118). If a company provides false explanations for revenue growth, those statements may be materially misleading. *See City of Roseville Employees' Retirement Sys. v. Horizon Lines, Inc.*, 713 F. Supp. 2d 378, 389 (D. Del. 2010) ("A statement regarding financial performance, even when accurate, is still misleading under the securities laws if the speaker attribut[es] the performance to the wrong source." (internal quotation and citation omitted)). As noted, while the actual impact of off-label marketing on defendants' revenue growth is unknown, plaintiffs have plausibly contended that it was material. *See Gilead*, 536 F.3d at 1052 (statement that company's success was "driven primarily by strong sales growth" misleading where "off-label marketing was driving prescription volume"). That is sufficient, under the circumstances, to support a claim for misrepresentation as to those statements.

c. Alleged False Statements Concerning FDA Inquiries

During the class period, defendants disclosed various communications with the FDA. *See Gallagher v. Abbott Labs.*, 269 F.3d 806, 809 (7th Cir. 2001) (explaining that the SEC requires periodic, not continuous, disclosures, on prescribed filing dates); *see also In re Genzyme Corp.*, 2012 WL 1076124, at *10, 12 (D. Mass. Mar. 30, 2012) (noting the prompt disclosure of adverse FDA letters in subsequent filings). Plaintiffs contend that those disclosures were false and misleading because defendants created the impression that the FDA's inquiry had been

closed, when in fact it had not.

The mere fact that the FDA was critical of the company is not enough to sustain a claim of securities fraud. Not "every critical comment by a regulatory agency—even about matters as important as good manufacturing practices—has to be seen as material for securities law reporting purposes, especially in an industry like [biotechnology], where there is constant and close supervision by the FDA." *In re Genzyme Corp.*, 2012 WL 1076124, at *10. Mere warning letters, which are "informal and advisory" and do not "commit the FDA to taking enforcement action," may not be material in all circumstances. *Id.* Reasonable investors would likely be aware of the complexities and uncertainties of federal agency oversight. *See id.* at *10-11; *see also In re SeaChange*, 2004 WL 240317, at *9 ("While the information may have been, in some predictive sense, incomplete, I find that, given the well understood vagaries of litigation, it was not so incomplete as to mislead investors.").

The context in which defendants made the allegedly misleading statements is critical. Most of the alleged misrepresentations outlined in the complaint were made in response to the FDA Warning Letter. (*See* Compl. ¶¶ 116, 128, 144). In its quarterly filings in August and November 2011 and February 2012, the company stated:

> In June 2011, we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We have cooperated with the FDA in addressing its concerns and *believe* that we have resolved the matter *without any penalties*. Although *we believe* that this issue has been resolved, if similar matters come up in the future, we may not be able to resolve them without facing significant consequences.

(*Id.*) (emphasis added).

It is true—plaintiff does not argue otherwise—that the matters identified in the FDA

Warning Letter were resolved without any penalties. Management's statement of belief, in that respect, was accurate.[15] Furthermore, the company did not assert that all issues concerning off-label marketing had been definitively resolved; instead, it stated that the company "believed" that the "matter" (that is, the issues raised in the Warning Letter) had been resolved. It also noted that similar matters may come up in the future. *See In re SeaChange Int'l, Inc.*, 2004 WL 240317 at *8 (finding statements about pending patent infringement litigation, where defendant was ultimately found liable, were not materially misleading because they did not promise a specific outcome). And the correspondence with the FDA supports the assertion that defendants were engaged with the agency, and therefore the statement regarding cooperation was not materially false. *Cf. In re Boston Scientific Corp. Sec. Litig.*, 2011 WL 4381889, at *10 (D. Mass. Sept. 19, 2011) *aff'd*, 686 F.3d 21 (1st Cir. 2012) (finding statement that company was cooperating with federal agency not misleading).

Plaintiffs nonetheless contend that the statement should be read to suggest that the company was providing assurances that *all* matters with the FDA involving off-label marketing had been resolved. But that is not what the statement says; it states that the Warning Letter "matter" (that is, the complaints addressed in that letter) had been resolved. More plausibly, the statement could be deemed misleading because it fails to apprise the reader that further problems with the FDA were likely, in light of the fact that company's corrective measures were inadequate, or that the company continued its off-label marketing practices. To that extent, the statement is arguably misleading.

[15] Although the FDA did not issue a close-out letter until February 2013, it appears that the company withdrew or modified the specific marketing materials that were the subject of the Warning Letter well before that point.

Plaintiffs further contend that the disclosure in the May 2012 8-K filing was misleading because it did not reveal the true purpose of the February 2012 meetings between Abiomed and the FDA, which was to discuss the Protect II study and off-label marketing. In fact, the 8-K does appear to disclose those facts. The listed topics for the meetings, among other things, were "the final results of the Protect II study" and "Clinical Indications/Labeling." (*See* Compl. ¶ 152). Because defendants made an accurate disclosure to investors within a reasonable time period, those statements are not materially false.

Finally, plaintiffs contend that defendants minimized the threat of enforcement action when it disclosed the FDA's April 2012 letter. The June 2012 10-K, in which defendants made that disclosure, states that Abiomed received the letter, that it was cooperating with the FDA, and that "which we hope to be able to resolve this matter without facing significant penalties, we may not be able to resolve it . . . without facing significant consequences." (Compl. ¶ 154). That statement does not appear to minimize the FDA inquiry and accurately reflects the letter's contents. (*See* Ward Decl., Ex. 13). Accordingly, that statement likewise is not materially false.

d. Alleged False Statements Concerning the Protect II Study

On various occasions, defendants publicly referred to the Protect II study. (*See* Compl. ¶¶ 107, 109, 126, 133, 137, 142, 158, 165). Most often, they quoted results of the study. On one occasion, Bowen stated that he expected the study's "positive effects . . . to materialize in the second half of fiscal year 2012." (Compl. ¶ 110). Plaintiffs acknowledge that defendants did disclose that the study was terminated for reasons of futility, but assert that they failed to disclose that the FDA had safety concerns about the study or that the company was misrepresenting the results as part of the promotion of off-label marketing.

The reporting of factual data cannot, standing alone, support a claim of fraud. Moreover, while defendants may have emphasized favorable data, the complaint states that defendants released the final results of the study in April 2011. Investors therefore had access to the full information and defendants' statements would not be misleading on that ground. It would be unreasonable to require that defendants reiterate all related, material information about a subject every time they touched upon it, if that information had already been released to the public. Defendants also did disclose that they discussed "safety" with the FDA during the February 2012 meeting. (Compl. ¶ 152). If the FDA had additional safety concerns, the complaint fails to detail what, specifically, those were. As for Bowen's statement, it is akin to a nebulous wish that previous courts have found not actionable. *See Gross*, 93 F.3d at 995 (finding "vague and loosely optimistic statements . . . nonactionable as a matter of law").

To the extent that defendants made statements concerning the Protect II study in order to promote off-label marketing, the statements may be actionable for the reasons outlined above. But to the extent defendants simply gave accurate information about the study, it cannot form the basis of a claim of misrepresentation.

e. Alleged False Statements Concerning Internal Controls

In each filing with the SEC, defendants asserted that they established and maintained adequate internal controls to ensure compliance with Exchange Act Rules 13a-15(e) and 15d-15(e). (Compl. ¶¶ 172-73). Plaintiffs' explanation as to how these statements are misleading is threadbare, but seemingly rests on a hindsight deduction that because off-label marketing occurred, there must have been a failure of internal controls, for which defendants are responsible.

These SEC-mandated statements do not relate to a company's general compliance with the law. The regulations in question define "internal controls" to mean procedures to ensure accurate and timely accounting and reporting of a company's finances. 17 C.F.R. § 240.13a–15(e); 17 C.F.R. § 240.15d-15(e). The complaint does not allege that defendants violated generally accepted accounting principles, or otherwise engaged in accounting or financial irregularities; its allegations focus on off-label marketing. To a reasonable investor, who would be familiar with this certification, defendants' statements would not be misleading.

Accordingly, and in summary, the complaint includes sufficient allegations of material misrepresentations to survive a motion to dismiss.

C. Allegations of Scienter

To be actionable, a statement must not be merely material and misleading; it also must have been made with the requisite scienter—either a conscious intent to defraud or a high degree of recklessness. *ACA Fin.*, 512 F.3d at 58; *see also Boston Scientific Corp.*, 649 F.3d at 20 ("Scienter is an intention to deceive, manipulate, or defraud." (internal quotation omitted)). The pleaded facts must give rise to a "strong inference" that the defendant had actual knowledge that the representation or omission was misleading. 15 U.S.C. §§ 78u-4(b)(2)(A), (f)(10)(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.

Complaints satisfying the pleading standard for scienter "often" include "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 Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012). Contemporaneous insider trading may provide additional evidentiary support. *Biogen IDEC*, 537 F.3d at 55.

Plaintiffs here have not alleged the existence of a high-level corporate whistleblower, or any other direct evidence of statements of knowledge or intent. Although the complaint identifies seven confidential witnesses, none allege that they were present at any meetings at which critical statements or admissions were made by senior management. Nor have plaintiffs alleged the existence of internal records showing the requisite knowledge or intent by any insider. Instead, plaintiffs assert an entirely circumstantial case, essentially alleging that senior management must have known about the off-label marketing, the effect of the practice on revenues, and therefore the effect of it on the stock price. In substance, the claim of scienter is based on the following chain of reasoning: (1) the Impella 2.5 was the most important product sold by the company; (2) the practice of off-label marketing is illegal; (3) the company engaged in off-label marketing of the Impella 2.5; (4) the company is relatively small, and therefore senior management must have been aware of the company's off-label marketing practices; and (5) at the least, once the FDA raised concerns with management about off-label marketing, management was actually aware of the marketing practice and its illegality.

Again, plaintiffs are entitled to allege (and try to prove) a circumstantial case. Nonetheless, the inference of scienter must be "cogent and compelling." *Tellabs*, 551 U.S. at 324. To try to bridge that gap, plaintiffs place considerable emphasis on the allegations concerning the illegality of the marketing practices and insider stock sales during the relevant

period.

Allegations that a defendant engaged in "deliberate illegal behavior" can, under some circumstances, create a strong inference of scienter. *Novak v. Kasaks*, 216 F.3d 300, 308, 311 (2d Cir. 2000); *see Chamberlain*, 757 F. Supp. 2d at 690 (allegations of antitrust violations); *In re Par Pharm.*, 733 F. Supp. at 679 (allegations of bribery); *In re Unumprovident Corporation Securities Litigation*, 396 F. Supp. 2d at 885 (allegations of "company-wide policy pursuant to which disability claims were approved or denied based not upon merit, but instead according to pre-determined financial objectives").[16] Certainly off-label marketing is illegal. However, inferring intent merely from the existence of the practice, even in a small company, is problematic.

Companies routinely make mistakes, even significant ones, particularly in highly regulated industries. While of course a trained person would be expected to know the difference between improper off-label marketing and proper marketing, an untrained person might not. Improper off-label marketing practices may thus be the result of deliberate actions, or they may be the product of corporate mismanagement or negligence. Sales and marketing personnel, particularly individuals operating independently in the field, may require substantial training and close supervision; negligence on the part of senior management in training and supervising such personnel may lead to serious problems, particularly in highly regulated fields such as pharmaceuticals or medical devices. Furthermore, without careful controls, marketing materials may be created, or remain in circulation, without the knowledge of senior management. Here, it

[16] After noting that the practices may constitute only "poor business judgment" or "mere mismanagement," the *Unumprovident* court nonetheless found that a strong inference of scienter could be drawn from plaintiff's "detailed allegations of an intentional scheme to manipulate claim reserves and income by denying legitimate disability claims." *Id.* at 895.

is equally reasonable to infer that senior management was merely negligent, inattentive, or even incompetent, rather than engaged in deliberate acts of securities fraud. While evidence of admissions or similar expressions of intent would create the required strong inference, plaintiffs have alleged no such evidence here.

"If there is reason to be concerned about material omissions or misrepresentations, the presence of insider trading can be used, in combination with the other evidence, to establish scienter." *Biogen IDEC Inc.*, 537 F.3d at 55. Plaintiff bears the burden of demonstrating that sales by insiders were "unusual or suspicious in amount or timing." *Lirette v. Shiva Corp.*, 27 F. Supp. 2d 268, 283 (D. Mass. 1998). Often, that burden may be carried by comparing insiders' sales during the class period to their sales during an equal period prior to the class period, or showing that insiders sold large percentages of their holdings. Defendants, in turn, may offer in rebuttal the existence of Rule 10b5-1 trading plans or alternative explanations for their sales.

The complaint alleges that Minogue sold 586,149 shares (48% of his holdings) for proceeds of $9,636,124 during the 33-month period between the first FDA letter on January 28, 2010, and the end of the class period on October 31, 2012. (Compl. ¶ 189). During that same period, Bowen sold 57,919 shares for proceeds of $1,302,878. (*Id.* ¶ 193). In contrast, in the prior 33-month period, Minogue had sold 27,987 shares for proceeds of $484,650, and Bowen had sold no shares. (*Id.* ¶¶ 190, 194).

Defendants first contend that the appropriate frame of reference is the class period itself, not the entire period of the alleged off-label marketing. Courts in fact have generally looked to the class period itself when considering the issue of scienter. *See, e.g.*, *Auto. Indus. Pension Trust Fund v. Textron Inc.*, 682 F.3d 34, 40 (1st Cir. 2012) (stating that stock sales cannot "add

much to the inference of scienter without something (*e.g.*, points of comparison from outside the class period) to show that these sales were unusual"); *Mississippi Pub. Employees' Ret. Sys.*, 523 F.3d at 92; *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 163-64 (D. Mass. 2009). It is during those months that the stock price was (allegedly) artificially inflated, and insiders would have had the capacity and incentive to reap improper profits.

Defendants further contend that the inquiry must also take into account purchases made during the relevant period. Here, Minogue purchased shares during the class period—although the exact dates, prices, and number of shares are not in the record—so that his total shares of Abiomed stock actually increased from 1,124,391 to 1,227,733, an increase of 9.2%.[17]

Finally, defendants contend that there are legitimate explanations for the stock sales. All sales during both the class period and the longer 33-month period were made pursuant to Rule 10b5-1 trading plans, some (although not all) of which were entered into prior to the class period.[18] Nearly every trade prior to the class period was made pursuant to a Rule 10b5-1 plan executed in November 2009, even before the 33-month period began. Three of Minogue's sales during the class period, and three of Bowen's, involved the exercise of options; in the remaining sales, the shares had vested and defendants sold shares in order to cover taxes. Moreover, Bowen joined Abiomed in December 2008, which provides a plausible reason as to why he did not sell any shares prior to December 2009. Defendants further assert that the sales were not

[17] Defendants further contend that net proceeds (that is, the net of sales proceeds over the options exercise price), not gross proceeds (sales proceeds only), is the relevant measure. During the class period, Minogue made six sales totaling 60,658 shares for $1,203,613 in net proceeds. (Ward Decl. Ex. 1). During the same period, Bowen made six sales totaling 54,271 shares for $1,064,525 in net proceeds. While net proceeds is undoubtedly a more accurate measure than gross proceeds, in this context, the distinction is not controlling, in light of the large amount of net proceeds involved.

[18] Minogue executed five Rule 10b5-1 plans between November 17, 2008, and August 8, 2011, covering sales from December 22, 2008 to June 16, 2014. (Ward Decl. Exs. 19-24).

temporally close to any disclosures of adverse information, which other courts have found probative of scienter. *See First Marblehead*, 639 F. Supp. 2d at 164. In short, defendants contend that most of Minogue's sales of stock occurred prior to the class period, and that his holdings during the class period itself actually increased; that Bowen's sales were a small percentage of his ownership; and that all the sales were pursuant to Rule 10b5-1 trading plans.[19]

Considered as a whole, the complaint presents allegations of scienter that are plausible—indeed, reasonable—but not "cogent and compelling." *Tellabs*, 551 U.S. at 324. Again, plaintiffs have no direct evidence of scienter, and their circumstantial case is not compelling. The insiders' stock sales provide at best equivocal support of the proposition that defendants intended to defraud investors. Accordingly, under the heightened pleading standard of the PSLRA, the complaint does not state a claim.[20]

D. Section 20(a)

Section 20(a) of the Exchange Act imposes joint and several liability on persons in control of entities that violate securities laws. 15 U.S.C. § 78t. Section 20A of the Exchange Act provides that an insider who trades stock "while in possession of material, nonpublic information" is liable to any person who traded contemporaneously with the insider. 15 U.S.C. § 78t–1(a). However, violations of Section 20(a) and 20A each depend on an underlying violation

[19] Plaintiffs add that, during the 33-month period, other Abiomed executives sold stock. Michael Howley (VP of Global Sales and Marketing) sold 31,378 shares for $624,177 in gross proceeds; Andrew Greenfield (VP of Healthcare Solutions) sold 78,172 shares for $1,367,996; David Weber (COO) sold 59,167 shares for $1,209,844; and William Bolt (SVP of Global Product Operations) sold 130,024 shares for $2,426,491. According to plaintiffs, those insiders would have knowledge of off-label marketing and their sales are unusual compared to prior periods. Without greater detail about sales within the class period, net proceeds, and the exact responsibilities of the insiders, a clear inference of scienter cannot be drawn from that information alone. But those trades do add something to the mix.

[20] The Court does not reach the issue of loss causation.

of the Exchange Act. 15 U.S.C. § 78t–1(a); *Waters*, 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. Guar. Corp.*, 512 F.3d at 67-68; *Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 257 (D. Mass. 2001) ("To state a claim for insider trading, the plaintiffs must have adequately alleged a violation of the Exchange Act."). Because no underlying securities violation exists here, the second count of the complaint will be dismissed.

IV. Conclusion

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

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: April 10, 2014