UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| In re BOSTON SCIENTIFIC CORPORATION SECURITIES LITIGATION | ) | CIVIL ACTION NO. 20-12225-DPW |

MEMORANDUM AND ORDER
December 20, 2022

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Before me is a motion [Dkt. No. 53] to dismiss a putative securities fraud class action against Boston Scientific Corporation ("Boston Scientific"). The motion to dismiss submissions were developed in accordance with the demanding protocols of the Private Securities Litigation Reform Act. The operative Amended Consolidated Complaint [Dkt. No. 44] ("the Complaint") presents a narrative alleging attempts to deceive investors regarding the success of the company's new medical device in an effort to prop up Boston Scientific stock prices, raise capital and support improper insider trading.

Boston Scientific and seven high-ranking executives are alleged to have perpetrated securities fraud on Boston Scientific investors by making a host of false and misleading statements about the commercial viability of Boston Scientific's Transcatheter Aortic Valve Replacement ("TAVR") device: the Lotus Edge. The overarching contention is that Boston Scientific executives hid technical failures and sluggish sales of the Lotus Edge from the public during the period February 6, 2019 to November 16, 2020. The Complaint alleges that by providing false reassurances that the device was safe, simple, and marketable, Defendants caused artificial inflation of Boston Scientific common stock, in violation of Section 10(b), 15 U.S.C. § 78j(b) and Rule 10b-5, 17 C.F.R. § 240.10b-5 (Count I) and in violation of Section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78t(a) (Count II).

Defendants have moved to dismiss the Complaint for failure to meet the heightened pleading requirements for securities fraud claims under FED. R. CIV. P. 9(b) and the Private Securities Litigation Reform Act. I consider primarily two questions, both of which must be answered in the affirmative if Plaintiff's case is to proceed: 1) whether any of the statements detailed in the Complaint are both misleading and actionable and, if so, 2) whether particularized facts alleged in the Complaint give rise to a strong inference of Defendants' scienter.

I will grant Defendants' Motion to Dismiss the Complaint as to Count I, except as to Defendant Mahoney — the Boston Scientific Chairman, President and Chief Executive Officer — and Boston Scientific, the corporation to which his scienter may be imputed — because Plaintiff successfully pleads scienter and material misrepresentations as to him. Meanwhile, I will deny Defendants' Motion to Dismiss Count II of the Complaint as to the Section 20(a) claims alleged against the Executive Defendants.

## I. BACKGROUND

### *A. The Parties*

**Defendant Boston Scientific** is a publicly traded manufacturer of medical devices. Headquartered in Massachusetts, Boston Scientific develops, manufactures, and markets a range of medical device platforms, including interventional cardiovascular technologies.

The Complaint names seven individual **Boston Scientific** executives as Defendants (collectively, the "Executive Defendants"):

- **Michael Mahoney**, the Chairman, President, and Chief Executive Officer;
- **Daniel Brennan**, the Executive Vice President and Chief Financial Officer;
- **Joseph Fitzgerald**, the Executive Vice President and President of Rhythm Management (through July 6, 2020), and thereafter Executive Vice President and President of Interventional Cardiology;
- **Shawn McCarthy**, the Vice President and General Manager of Structural Heart Valves (through 2020);
- **Kevin Ballinger**, the Executive Vice President and President of Interventional Cardiology (through July 3, 2020);
- **Ian Meredith**, the Executive Vice President and Global Chief Medical Officer; and
- **Susan Vissers Lisa**, the Vice President of Investor Relations.

**Union Asset Management Holding AG** is the **Lead Plaintiff**. Lead Plaintiff brings suit on behalf of a class of investors who purchased or acquired Boston Scientific common stock between February 6, 2019 and November 16, 2020 (the Class Period). Lead Plaintiff is the parent holding company of the Union Investment Group, an asset management firm based in Frankfurt-am-Main, Germany. Union Asset Management funds purchased common stock in Boston Scientific during the Class Period. I refer to Lead Plaintiff and the putative class it would represent as Plaintiff throughout the remainder of this Memorandum except when reciting the circumstances in which Union Asset Management became Lead Plaintiff.

***B. Factual Background***

This action arises from Boston Scientific's 2020 recall of its Lotus Edge device and its decision to retire the entire Lotus Valve Platform.

The Lotus Edge device is a transcatheter heart valve used to treat patients suffering from aortic stenosis.[1] Physicians historically treated aortic stenosis with surgical aortic valve replacement. A surgeon would perform open heart surgery to replace a faulty aortic valve with a new mechanical or biologic valve. Complaint, Dkt. No. 44 at ¶ 49. Surgical aortic valve replacement was attended by high risks and prolonged recovery times.

In 2002, however, surgeons began to see clinical success with a new method: transcatheter aortic valve replacement, or TAVR. TAVR surgery involved only a small incision to insert a catheter, as opposed to an open heart surgery. Using the catheter, a surgeon could then implant a new aortic valve prosthesis to replace the diseased aortic valve. TAVR patients recovered far faster and more easily than open-heart patients.

[1] Aortic stenosis is a chronic and progressive form of heart disease caused by narrowing of the aortic valve. Complaint, Dkt. No. 44 at ¶ 45. Narrowing in this pathway reduces blood flow from the heart's left ventricle to the aorta. Consequently, the aorta does not receive the blood necessary to pump through the body, while the left ventricle sees a dangerous build-up of blood and pressure. *Id.* at ¶ 47.

The new TAVR procedure took the medical community by storm. The global market for TAVR devices was projected to double in between 2018 and 2023. *Id.* at ¶ 51. With the increasing popularity of TAVR treatment came "immense competition among several of the top medical device manufacturers to develop TAVR valves." *Id.* at ¶ 52. Boston Scientific's competitors, Edwards [Lifesciences Corporation] and Medtronic [PLC], quickly developed their own TAVR devices and enjoyed "near total market domination." *Id.* Their devices utilized self-expanding or balloon expanding valves.[2]

In 2010, Boston Scientific sought to claim a share of the lucrative TAVR market by developing its own unique valve replacement device, the Lotus Valve Platform.[3] *Id.* at ¶ 53. Unlike other TAVR devices on the market, the Lotus valve was the first "fully repositionable device." *Id.* at ¶ 53. With the Lotus device, surgeons could position the valve, deploy it, and then recapture and reposition it after deployment, allowing optimal final placement of the valve. *Id.* at ¶ 55. The Lotus valve also included a seal that would fill in gaps between the implanted valve and the cardiac tissue, thereby preventing

[2] Using these devices, a surgeon would insert the new valve with the catheter, position it across the damaged aortic valve, and deploy the valve where it would expand and seal into place, pushing the remains of the diseased valve aside. *Id.* at ¶ 54.
[3] For purposes of the Complaint, the Lotus Valve Platform is presented as encompassing the first iteration of the Lotus device (Lotus), and the Lotus Edge device, the iteration of Lotus launched in the United States in 2019.

leakage.[4] Boston Scientific marketed the Lotus device as offering surgeons "superior ease of use" and "total control" over the replacement valve's positioning. *Id.* at ¶¶ 58-60.

Beginning with its announcement of the product in 2016, Boston Scientific maintained an optimistic view of the device's potential in the structural heart therapies market. On November 17, 2020, however, Boston Scientific initiated a voluntary recall of all Lotus Edge devices and announced its decision to terminate the entire Lotus Valve Platform.

1. The Early Lotus Valve Recalls and Delays

Boston Scientific's Lotus device first received regulatory approval in Europe in 2013 and began clinical trials in the United States shortly thereafter. *Id.* at ¶¶ 62-63 n.1. In its early years on the European market, the Lotus device was the subject of several recalls.[5] *Id.* at ¶ 63. In February of 2017, Boston Scientific recalled all Lotus devices based on reports

[4] The Lotus device was designed to prevent a specific adverse event associated with existing TAVR devices: paravalvular leakage. Paravalvular leakage occurred most frequently when a TAVR valve was not positioned properly to seal against cardiac tissue or because the TAVR valve is undersized. *Id.* at ¶ 56.

[5] Boston Scientific instituted a recall in November of 2014 due to malfunctions in the mechanical locking mechanism. *Id.* at ¶ 63. Boston Scientific then recalled 250 units of the device in August of 2016, including Lotus devices being used in United States clinical trials, this time due to breaks in the mechanism that released the valve from its delivery system. *Id.* at ¶ 64. In October of 2016, Boston Scientific recalled the second generation of the Lotus valve, Lotus Edge, when reports surfaced that the device could not be fully locked during the procedure. *Id.* at ¶ 64.

that a pin connecting the valve to the delivery system was faulty. *Id.* at ¶ 65.

Defendants reassured investors that each of these recalls resulted from an issue in the device's delivery and locking mechanism, "not a design flaw" of the valve itself. *Id.* at ¶¶ 67, 74. These issues, Boston Scientific maintains, could be dealt with through manufacturing adjustments and specification changes. *Id.* at ¶ 67. Nevertheless, in March of 2017 Boston Scientific took on a new TAVR valve platform, the Acurate TA, as a result of its acquisition of Swiss Manufacturer Symetis, which used the traditional self-expansion design of competitor TAVR devices, not the repositionable design of the Lotus. *Id.* at ¶ 71. Boston Scientific's Chairman, President and Chief Executive Officer, Executive Defendant Michael Mahoney, however, reassured investors that this new acquisition was not intended to replace the Lotus device. *Id.* at ¶¶ 72-73.

Throughout 2017, Boston Scientific faced a series of delays to the Lotus platform's return to the European market and to its approval by the United States Food and Drug Administration. Boston Scientific executives maintained, however, that the problem had been identified and resolved. *Id.* at ¶¶ 70, 74, 78. In the final months of 2018, Boston Scientific announced its plans for an early 2019 European relaunch of the Lotus Edge. Executives expected FDA approval for the Lotus device by the middle of 2019. *Id.* at ¶ 80.

2. Launch in the United States

On the first day of the Class Period, February 6, 2019, Mr. Mahoney announced plans for a "controlled launch" of the Lotus Edge in the United States to begin in the second quarter of 2019. *Id.* at ¶ 84. The FDA approved the Lotus Edge device for certain high-risk surgical patients on April 23, 2019 and Boston Scientific began its controlled launch. The full launch of the Lotus Edge, however, was not scheduled to begin until the fall of 2019. *Id.* at ¶ 96.

Mr. Mahoney told investors he expected that Lotus Edge would be a "workhorse valve" as well as a specialized tool for complex cases. *Id.* at ¶ 87. The United States launch strategy was to open "roughly 150 accounts within the first 12 months of launch" with at least 50 accounts to be opened by centers not involved in the Lotus Edge clinical trials. *Id.* at ¶¶ 92, 94.

3. The Launch as Reported by Boston Scientific

Boston Scientific executives are alleged to have told investors repeatedly that the Lotus launch was moving forward as planned throughout 2019 and into early 2020. *Id.* at ¶¶ 95-97, 260, 279-281, 287, 292, 296. One of the early priorities of the United States launch was ensuring a controlled, safe rollout of this unique TAVR device. Various Executive Defendants also represented that they were satisfied with the Lotus Edge's early success and Mr. Mahoney stated that he believed it was "doing very well in the market." *Id.* at ¶¶ 260, 280, 282, 302-303.

Analysts asked Boston Scientific executives repeatedly about their goal of opening roughly 150 accounts in the United States in the first year of the launch. Each time, they were told that the Lotus team was on pace to meet its goal.

At a virtual event on August 19, 2020, an analyst asked for a progress report as to the number of accounts opened in the United States. The question was referred to Boston Scientific's vice president of Investor Relations, Executive Defendant Susan Vissers Lisa, and her Director of Investor Relations, Lauren Tengler. Ms. Tengler, who is not named as an Executive Defendant, responded "we're on track pre-COVID and we hit 138 accounts." *Id.* at ¶¶ 99, 305.

On September 16, 2020 Mr. Mahoney told analysts that he expected that "Lotus will continue to be an important product for us. It's a significant market as you know, and even small share gains are significant for us. And so, Lotus will continue to be an important growth driver for us supported with our whole platform . . . ." *Id.* at ¶ 308. On October 15, 2020, Boston Scientific's executive vice president and president of Interventional Cardiology, Executive Defendant Joseph Fitzgerald, notified investors that Boston Scientific had reached its goal of opening over 150 Lotus accounts in the United States. *Id.* at ¶¶ 100, 313-314. The launch, he represented, was "gaining momentum" and the Lotus platform was

"growing actual procedures per center, per month" in the United States. *Id.* at ¶ 316.

On October 28, 2020 an analyst asked Mr. Mahoney whether it made sense for Boston Scientific to be developing two different TAVR platforms, the Lotus Edge and the more traditional self-expanding Acurate valve. Mr. Mahoney maintained that developing the Lotus Edge alongside the Acurate valve platform made strategic sense, because the company was "seeing strong results in the sites that are using Lotus in the U.S." despite the challenges they encountered opening new accounts. *Id.* at ¶ 319.

4. Boston Scientific Terminates the Lotus Valve Platform

On November 17, 2020, Boston Scientific issued a press release announcing a "global, voluntary recall of all unused inventory of the Lotus Edge Aortic Valve System due to complexities associated with the product delivery system." *Id.* at ¶ 181. With "the additional time and investment required to develop and reintroduce an enhanced delivery system," the company decided to "retire the entire [Lotus] product platform immediately." *Id.* Consequently, Boston Scientific would face "pre-tax GAAP charges of approximately $225 million to $300 million" of which 100 to 150 million would impact the company's adjusted results. *Id.*

During a conference call on the Lotus recall, Boston Scientific's Executive Vice President and Chief Financial Officer, Executive Defendant Daniel Brennan, stated that Lotus

was "overall a drag on the bottom line for the company." *Id.* at ¶ 183. Lotus sales, he said, accounted for only $60 million in revenue in 2019 and would only reach about $75 million in 2020. *Id.* Mr. Fitzgerald further explained Boston Scientific's reasons for retiring the Lotus platform at this stage:

> So we just rounded the corner right at around TCT [October 15, 2020] of a 1- year anniversary of launching in the U.S. . . . And we're – we have done a really good job of training and retraining around the complexities of the delivery system. But we came to the conclusion that to scale this, to go from sub-100 accounts today in the United States to hundreds of accounts, right, we really were going to struggle in replicating that deep technical, clinical support as we scale cases and go to 2, 3, 4, 5x without a design enhancement. So I think it was the proper thing for us to do to really be our own worst critics after the first full year of having [Lotus] Edge on the market and commercialized in the U.S. And it became very apparent that without a design enhancement, that our program wasn't scalable and that [Lotus] would ultimately remain as a niche device in a pretty expensive space to operate.

Dkt. No. 60-1 at 13.

By the end of the first year of the full United States launch, it had become clear, he said on November 18, 2020, that the Lotus Edge operated in a niche of the TAVR market, while Boston Scientific's Acurate platform would be a "super workhorse valve." Dkt. No. 64-1 at 6-7. According to Mr. Fitzgerald, it took a full year of "the U.S. experience" to decide to terminate Lotus. *Id.* at 6.

Following Boston Scientific's announcement on November 17, Boston Scientific common stock decreased in value by about $3.00

per share or approximately 8%, beginning the day at a price of $38.03 and ending at $35.03. Dkt. No. 44 at ¶ 324.

5. Failures of the Lotus Launch Revealed after the Class Period

Plaintiff alleges that it became clear to the Executive Defendants that Lotus Edge was not commercially viable at least six months before Boston Scientific announced its decision to terminate the program. Plaintiff presents accounts from nine confidential sources, each a former Boston Scientific employee ("FE"), in support of this claim.

During the Lotus launch in the United States, FE 1[6] surveyed physicians on how many TAVR patients they expected to treat using the Lotus device. Physicians reported that the Lotus device was not appropriate for most patients, that the Lotus device would be used in about 5-6% of TAVR patients and that it would achieve at most, 5-10% market share. *Id.* at ¶ 104. FE 2[7] reported that that the Lotus Edge device saw higher risk than did its competitors, which hampered its sales. *Id.* at ¶ 106.

FE 3[8], a Therapy Consultant, described many challenges associated with Lotus Edge's delivery system. The complex

[6] FE 1 was a Principal Therapy Consultant in Boston Scientific's Structural Heart Division in New York and New Jersey from 2000-2021. *Id.* at ¶ 104.
[7] FE 2 was a Principal Clinical Field Manager in Boston Scientific's Structural Heart division from 2017 to 2021. *Id.* at ¶ 106.
[8] FE 3 was a Therapy Consultant in the Structural Heart Division in San Diego from 2017 to 2021. *Id.* at ¶ 108.

delivery system required extensive training to operate and involved many moving parts and steps to implant. *Id.* at ¶¶ 108-111. To FE 4[9], Lotus "was the most complicated device on the planet." *Id.* at ¶ 113. Lotus Edge's multi-step implantation process was far more difficult, according to human factor engineer FE 6[10] for example, than the two step process to implant competitors' valves. *Id.* at ¶ 124.

FE 3 also described specific malfunctions associated with the Lotus delivery system, including the "Twisted Post" phenomenon, wherein the rods in the delivery system prevented the valve from locking into position.[11] If the valve did not lock into place, surgeons could be forced to convert the patient to open heart surgery. *Id.* at ¶¶ 109, 128. According to FE 4, malfunctions like the Twisted Post were common, happening in "50% of all cases." *Id.* at ¶ 112. FE 4 also claimed the Lotus salesforce, clinical staff, and certified representatives lacked the experience with TAVR procedures generally and the Lotus Edge specifically to implement the Lotus launch responsibly. *Id.* at

[9] FE 4 was an Interventional Cardiology Territory Manager at Boston Scientific from 2016 to 2021. *Id.* at ¶ 112.
[10] FE 6 was a Principal Human Factors Engineer at Boston Scientific from 2019 to 2020. *Id.* at ¶ 122.
[11] FE 5, a salesperson and care coordinator for Boston Scientific's southern Germany region from 2017 to 2020, noted that the issues in the Lotus delivery system in 2019-2020 launch were similar to those that plagued the device in 2016 and 2017. *Id.* at ¶¶ 114, 135.

¶¶ 112-113. As a result, FE 4 characterized the launch as "clinically unsafe." *Id.* at ¶ 113.

FE 6 reported that by the end of 2019, knowledge of Lotus Edge's complexity and delivery-system failures "went all the way up" to the executive level.[12] *Id.* at ¶ 123. Boston Scientific reportedly shifted its objective from refining the Lotus platform to replacing it with another TAVR system as soon as possible. *Id.*

Senior Financial Analyst FE 7[13] revealed that the Lotus launch also had not produced the kind of revenue that Boston Scientific anticipated. In 2019, the Lotus Edge group failed to meet their forecasted revenues by half. *Id.* at ¶ 133. By 2020, it was clear to FE 7 that the Lotus Edge group was "consistently underperforming." *Id.* at ¶ 132. As of mid-2020, only twelve United States centers were implementing two or more Lotus devices per month. *Id.* at ¶ 131. Even with recalculated forecasts reduced by 25% every quarter, FE 7 reported that the Lotus Edge group's revenue was still 25% below where it should have been. *Id.* at ¶ 133. FE 1, too, noted the Lotus Edge's dwindling sales in 2020; of 120 sales representatives in the Structural Heart group in the United States, he estimated that

[12] As a basis for this view, FE 6 explained that the Lotus Edge chief engineer Dan Foster told FE 6 during their job interview that the Lotus Edge required "three hands to operate" and was difficult for the surgeons to deploy. *Id.* at ¶ 124.

[13] FE 7 was a Boston Scientific Senior Financial Analyst from January 2019 to August 2020. *Id.* at ¶ 132.

only about 15-20 hit their quotas, while the others missed often by 50% or more. *Id.* at ¶ 134.

Beyond these sales challenges, Financial Analyst FE 8 reported that the Lotus Edge was abnormally difficult to manufacture. The standard manufacturing yield rate for medical devices (i.e., the proportion of devices produced that were acceptable for commercial use) is about 85%. *Id.* at ¶ 141. One Lotus Edge plant in the United States saw manufacturing yield rates between 5-10% from 2016 to 2018, which only rose to about 20% in 2019. *Id.* Low yield rates presented challenges at other factories as well, according to FE 9, a Manufacturing Engineer at the Boston Scientific plant in Penang, Malaysia. *Id.* at ¶ 142. The poor yield so increased the cost of Lotus Edge production that the device sales had a gross margin of less than 30%, compared to the industry norms of around 90%. *Id.* at ¶ 144. Further, at the Penang plant, FE 9 reported that "zero orders" for the Lotus Edge came in between the end of 2019 and March of 2020. *Id.* at ¶ 273. Boston Scientific ultimately shut down the plant and terminated its employees in March of 2020. *See id.*; *see also id.* at ¶ 310.

The Complaint paints the Lotus platform as a slowly but plainly sinking ship whose demise was obscured by Executive Defendant disclosure misconduct. Plaintiff contends that the Executive Defendants hid the Lotus Edge's failures and delayed

disclosing their decision to terminate the Lotus platform to inflate Boston Scientific's stock value artificially.

6. Allegations of Executive Defendant False Statements

Plaintiff's lengthy Complaint appears to raise sixty-three of what it calls actionable false statements by the Executive Defendants during the Class Period. I have gathered these alleged misstatements by individual Executive Defendants said to be the declarants in a Chart attached as an Appendix to this Memorandum and Order.[14]

*a. Mr. Mahoney's Alleged Misstatements*

About half of the alleged misstatements are attributed to **Executive Defendant Michael Mahoney**, Boston Scientific's Chairman, President, and Chief Executive Officer. Mr. Mahoney is alleged to have misled investors throughout 2019 and 2020 by affirming the United States Lotus launch was "going extremely well" and was "on track" to reach the company's goal of opening roughly 150 accounts in the first year.[15] Mr. Mahoney touted the

[14] Defendants identified seventy-five alleged misstatements in Exhibit B [Dkt. No. 54-2] filed in support of their motion [Dkt. No. 53] to dismiss. Some of those misstatements are attributed to individuals not named as Defendants, appear to be the result of fractionated versions of the statements reported, or refer to company documents. The Appendix to this Memorandum and Order sets forth only alleged misstatements made by the named Executive Defendants.

[15] Mr. Mahoney stated that the launch was going well, there was a market demand for the product, and he remained confident in the Lotus platform on February 6, 2019, Dkt. No. 44 at ¶ 237, , April 24, 2019, *id.* at ¶ 241, May 29, 2019, *id.* at ¶ 243, July 24, 2019, *id.* at ¶¶ 245-246, January 14, 2020, *id.* at ¶ 277, February 5, 2020, *id.* at ¶ 279, March 11, 2020, *id.* at ¶ 296,

"very high" rates at which centers were using and reordering the device on four occasions.[16] Plaintiff also asserts that Mr. Mahoney's proclamations of the Lotus Edge's ease of use and his descriptions of the initial Lotus launch as "controlled" were materially misleading.[17] In the months before the Lotus recall, Mr. Mahoney allegedly misled investors as to the future prospects of the Lotus Edge as well. In July of 2020, he confirmed that the "gates [were] open[ing] up" for new Lotus accounts. *Id.* at ¶ 303. On September 16, 2020, Mr. Mahoney claimed that the Lotus platform was and "will continue to be an important growth driver" for Boston Scientific. *Id.* at ¶ 308. On October 28, 2020, about three weeks before announcing the end

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and July 29, 2020, *id.* ¶ 301. He represented that the launch was "on track" or "on pace" to achieve 150 accounts on July 24, 2019, *id.* at ¶ 246, October 23, 2019, *id.* at ¶¶ 260-261, February 5, 2020, *id.* at ¶ 279, and March 11, 2020, *id.* at ¶ 296.

[16] Mr. Mahoney told investors on September 5, 2019 that the Lotus team was seeing "very high" and "strong" reorder rates. *Id.* at ¶ 251. On July 29, 2020, he affirmed that the Lotus Edge "continues to see strong utilization within existing accounts," *id.* at ¶ 301, and then stated that "current centers are using the device quite consistently," *id.* at ¶ 302. He told investors again on September 16, 2020 that the "reorder rate for existing users is quite high." *Id.* at ¶ 308. On October 28, 2020, Mr. Mahoney stated that although opening new sites had proven challenging, "the sites that are using Lotus in the U.S. are using it quite regularly." *Id.* at ¶ 319.

[17] Mr. Mahoney described "[p]ositive physician feedback highlight[ing] the benefit of [the] complete control" afforded by the repositionable Lotus device on July 24, 2019. *Id.* ¶ 245, 246. He also, at various times, described the company's approach to the Lotus launch as a "deliberate" and "controlled" one and "focused on quality, strong patient outcomes, and proctoring." *Id.* ¶¶ 246, 253.

of the Lotus platform, Mr. Mahoney told investors "we're seeing strong results in the sites that are using Lotus in the U.S. . . . So we do believe that the two-valve strategy makes sense." *Id.* at ¶ 319.

*b. Mr. Ballinger's Alleged Misstatements*

Plaintiff relies upon four misstatements by Boston Scientific's executive vice president and president of Interventional Cardiology until his resignation on July 3, 2020, **Executive Defendant Kevin Ballinger**, as to the success of the Lotus launch and the Lotus Edge's ease of use. Boston Scientific engineers, Mr. Ballinger claimed, made "something that is very complex feel really simple" with the Lotus Edge. *Id.* at ¶ 226. Mr. Ballinger told investors in September of 2019 that the Lotus Edge was "not a complicated device" but one that "actually takes stress out of the [TAVR] procedure." *Id.* at ¶ 258. Like Mr. Mahoney, Ballinger described the Lotus rollout as "self-constrained" due to the "exceptional proctoring [and] training" the company hoped to provide for users. *Id.* at ¶ 256. Finally, Mr. Ballinger also stated, in September 2019, that Boston Scientific was "on track" for its goal of 150 accounts. *Id.* at ¶ 255.

*c. Ms. Lisa's Alleged Misstatements*

Boston Scientific's vice president of Investors Relations, **Executive Defendant Susan Vissers Lisa**, is said to have misled investors by repeatedly expressing satisfaction with the

progress of the Lotus launch. She also gave allegedly false descriptions of a "controlled" initial Lotus launch, *id.* at ¶ 253, and the Lotus team's focus on training and proctoring, *id.* at ¶¶ 267, 269. Plaintiff disputes Ms. Lisa's characterization of the Lotus Edge as a "big driver" for Boston Scientific and a product that was "gaining [market] share. . . from both the competitors in the U.S. market." *Id.* at ¶¶ 275, 286. Ms. Lisa, like Mr. Mahoney, stated throughout the Class Period that the Lotus launch was "on target" or "on track" to achieve 150 accounts. During a conference call with analysts on August 19, 2020, Ms. Lisa allowed her Director of Investor Relations, Lauren Tengler, to report without contradiction that "we hit 138 accounts" when, Plaintiff alleges, the company had only opened around 100 accounts. *Id.* at ¶ 99, 305.

*d. Mr. Fitzgerald's Alleged Misstatements*

Boston Scientific's executive vice president and president of Interventional Cardiology beginning in July 2020, **Executive Defendant Joseph Fitzgerald**, is alleged to have misled investors with his public statements in the weeks leading up to the Lotus recall. On September 28, 2020, Mr. Fitzgerald told investors that the Acurate neo2 TAVR device represented "the natural evolution of our complementary dual-valve TAVI toolkit," along with the Lotus Edge. *Id.* at ¶ 311. Plaintiff contends Boston Scientific planned to replace the defective Lotus Edge with the Acurate platform.

On October 15, 2020, Mr. Fitzgerald announced "we have opened more than 150 accounts in the U.S." *Id.* at ¶ 314. Mr. Fitzgerald reiterated that "I like what I see in terms of us being now in 150 accounts . . . I think our launches, I know our launch is gaining momentum." *Id.* at ¶ 316. He then described the launch as "a ground game where we are expanding our footprint in the US, each month we're growing actual procedures per center, per month." *Id.* at ¶ 316.

*e. Mr. Brennan's Alleged Misstatements*

Boston Scientific's executive vice president and chief financial officer, **Executive Defendant Daniel Brennan**, is alleged to have mischaracterized the Lotus launch as "very controlled" and paced according to the proctoring and training needs for a safe introduction of the Lotus Edge to the market.[18] Mr. Brennan predicted throughout the Class Period that the Lotus launch would grow and gain momentum. He also periodically affirmed that the launch was "on track for 150 centers."[19] *Id.* at ¶ 292.

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[18] Mr. Brennan referred to the launch as "controlled" in November 2019 and February and March of 2020. *Id.* at ¶¶ 271, 281, 292. He explained that the launch has been "more kind of slow and steady" with a "heavy emphasis on proctoring and making sure folks are 100% able and ready to use the valve." *Id.* at ¶ 292.

[19] On November 19, 2019, Mr. Brennan predicted "Lotus, as we continue to go at a controlled rollout pace and enter new accounts, will continue to grow." *Id.* at ¶ 271. On February 5, 2020, he predicted the launch "should gain momentum over time." *Id.* at ¶ 281. On March 3, 2020, Mr. Brennan maintained that the company's successes "should be built on the momentum that we have with the launches [including] Lotus." *Id.* at ¶ 291.

*f. Mr. McCarthy's Alleged Misstatements*

Boston Scientific's vice president and general manager of Structural Heart Valves from July 2017 through January 2020, **Executive Defendant Shawn McCarthy**, is said to have made two alleged misstatements. Both statements related to the function of the Lotus Edge. On June 26, 2019, Mr. McCarthy stated "we believe we're offering unmatched control and predictability" with the Lotus Edge. He also affirmed that "early indications... are very positive" and that "we'll want to make sure we're doing the exact work we will as a world-class organization to train physicians to use and reuse the technology" as the Lotus team pursued its goal of launching roughly 150 accounts in the first year. *Id.* at ¶ 244.

*g. Dr. Meredith's Alleged Misstatements*

Boston Scientific's executive vice president and global chief medical officer during the Class Period, **Executive Defendant Ian Meredith**, is said to have misled investors as to the success and pacing of the launch. On October 23, 2019, he claimed "the limited market release is going very well. It's on track and the plans haven't changed thus far.... But the rollout of Lotus Edge of course is a planned controlled release. And in the short term, it will be determined by training." *Id.* at ¶ 263.

7. Allegations of Executive Defendant Scienter

*a. Executive Defendant Knowledge throughout the Class Period*

Plaintiff alleges that Boston Scientific's leadership was "absolutely aware" of Lotus Edge's failing performance, even as they touted its success. *Id.* at ¶ 204. Plaintiff identifies the following as evidence that the Executive Defendants knew the Lotus launch was doomed throughout the Class Period.

- In November of 2019, Executive Defendants Meredith, Ballinger, and McCarthy convened an emergency meeting of the entire Lotus Edge salesforce over Thanksgiving weekend to discuss the poor patient outcomes and malfunctions associated with the Lotus valve. FE 1 and FE 2, who attended the meeting, reported that the group also discussed Lotus's lagging sales and failure to meet revenue targets. *Id.* at ¶¶ 137, 208.
- According to FE 8, the device's low manufacturing yield rate was a "hot topic," discussed at monthly engineering status updates with Boston Scientific's senior leadership, though FE 8 does not specify which Executive Defendants allegedly attended these monthly updates. *Id.* at ¶ 143.

- The Executive Defendants are alleged to have known that the Lotus Edge was associated with disproportionately high rates[20] of adverse medical events because Boston Scientific was legally required to track these adverse events and report them to the FDA. *Id.* at ¶¶ 117-118. Executive Defendants Ballinger, Meredith and McCarthy reportedly discussed these adverse events regularly in companywide training sessions. *Id.* at ¶ 117.
- FE 7 reported that Boston Scientific's leaders often discussed "how to turn [Lotus] around" in 2019 and then in 2020. Defendant Mahoney, in particular, "constantly" asked the divisional controller about the progress of Lotus sales. *Id.* at ¶ 136. According to FE 1, Boston Scientific began to authorize bulk-order discounting for Lotus sales after low order rates for the Lotus Edge caused many units to "never be[] used and just expir[e] on the shelf." *Id.* at ¶ 147. FE 9 alleged that Boston Scientific then shut down the Penang plant in March of 2020 after it received "zero orders" from the end of 2019 to 2020. *Id.* at ¶ 146.

[20] Between May 2019 and November 2020, Lotus Edge accounted for 12% of all TAVR adverse events reported, though it was used in only 2% of TAVR procedures. *Id.* at ¶ 118.

- The Lotus group's underperformance was reflected in the monthly and quarterly revenues routinely uploaded to Boston Scientific's company-wide dashboard. *Id.* at ¶¶ 134, 204. As alleged, all Executive Defendants had access to this dashboard. *Id.* at ¶ 134.

*b. Boston Scientific's Need to Raise Funds to Keep Up with Its Debts*

Plaintiff alleges Boston Scientific's need to raise capital and renegotiate its debts in 2020 was Defendants' motive to delay announcement of the Lotus recall until November 17, 2020. *Id.* at ¶¶ 155-156, 214. Following the first quarter of 2020, Boston Scientific allegedly was in danger of breaching its loan covenants unless it could renegotiate its debts and raise capital.[21] *Id.* at ¶ 152. On May 21, 2020, the Company held its largest ever secondary public equity offering, raising over two billion dollars, at a common stock price of $34.25 per share. *Id.* at ¶ 156 & n.3. Around this same time, Boston Scientific

[21] According to the Complaint, Boston Scientific's covenants at the end of 2019 required the company to maintain a debt leverage ratio of total debt to consolidated EBITDA of 3.75, except if the company undertook a "Qualified Acquisition." *Id.* at ¶ 151. In the case of a Qualified Acquisition, Boston Scientific's leverage ratio maximum was 4.75, subject to quarterly "step-down[s]." *Id.* Boston Scientific made a "Qualified Acquisition" in 2019 and ended the year with a debt leverage ratio of 4.75. The Complaint alleges that, in 2020, even if the company used its available cash to reduce its debts, by the fourth quarter its leverage ratio would amount to 4.05, exceeding the 3.75 margin. *Id.* at ¶ 153.

was able to renegotiate over four billion dollars of its debt. *Id.* at ¶ 155.

According to Plaintiff, the failure of one of Boston Scientific's most significant investments could have caused share prices to plummet and made investors doubt the security of Boston Scientific's structural heart portfolio. *Id.* at ¶¶ 155-156. Boston Scientific would then have struggled to raise capital and renegotiate its debts. *Id.* at ¶ 155. Plaintiff asserts that Defendants decided in April of 2020 to delay announcing the retirement of the Lotus platform to prevent investors from losing faith in the TAVR portfolio until after Boston Scientific raised capital and renegotiated its debts.

*c. Executive Defendant Conduct throughout the Class Period*

At the end of 2019 and in 2020, several Executive Defendants made decisions for their own professional and financial futures that, according to Plaintiff, show their complicity in a plot to deceive investors.

Two leaders of the Lotus team resigned during the United States launch. Executive Defendant Shawn McCarthy, the General Manager of the Structural Heart Valves division, left his role at the end of 2019. *Id.* at ¶ 149. Executive Defendant Kevin Ballinger also resigned his post as the executive vice president and global president of Interventional Cardiology and left the Company in June of 2020. *Id.* In addition, a Lotus Edge sales

leader and area vice president for the Structural Heart division in the United States, Richard Maher, resigned in February of 2020 and the head of Lotus sales in Europe, Sandrine Maset, was removed from her post and transferred to a different department in May of 2019. *Id.*

The Complaint alleges improper insider trading by Executive Defendants Ballinger, Brennan, Fitzgerald, and Mahoney. Messrs. Ballinger, Brennan, and Fitzgerald received significantly greater proceeds overall from their sales during the Class Period than from their sales from the preceding one-year-and-nine-month period.[22] *Id.* at ¶ 224. Mr. Ballinger and Mr. Fitzgerald sold most of their shares based on trading plans adopted during the Class Period or otherwise outside of any Rule 10b5-1 plan.[23]

Mr. Mahoney set up a Rule 10b5-1 trading plan on August 25, 2020 for 259,207 shares of his own Boston Scientific stock, then

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[22] Plaintiff presents Executive Defendant insider sales records from the twenty-one-month period before the Class Period, April 28, 2017 to February 5, 2019 as a Control Period, to which they compare the Executive Defendant Class Period sales. *Id.* at ¶¶ 217, 223.

[23] According to the Complaint, Mr. Ballinger sold over 200,000 of his shares in excess of eight million dollars; only 11% of his shares were sold pursuant to a pre-Class Period trading plan. *Id.* at ¶ 223. Two of his major sales were in August and September of 2020, after he left Boston Scientific. *Id.* at ¶ 224. Mr. Fitzgerald sold over 250,000 of his shares for a total in excess of ten million dollars; 16% of these shares were sold pursuant to a pre-Class Period trading plan. *Id.* at ¶ 223. Mr. Brennan made over seven million dollars selling over 170,000 of his shares; 88% of these shares were sold pursuant to a pre-Class Period trading plan. *Id.*

worth about ten million dollars. *Id.* at ¶ 161. Mr. Mahoney's plan was designed to expire on November 6, 2020. *Id.* at ¶ 180. Mr. Mahoney's 10b5-1 plan covered a shorter period than all of his publicly available previous plans, which covered three-to-twelve-month periods. In fact, this plan covered the shortest period of any Boston Scientific executive since 2017. *Id.* at ¶ 162. Mr. Mahoney's August 10b5-1 plan also differed from his previous plans in that it sold all 259,207 shares at once, instead of in a series of sales over time. *Id.* at ¶ 220.

According to public records presented by Defendants [Dkt. No. 55-2 at 11], Mr. Mahoney's plan had a price trigger of $35.00 per share with an earliest sale date of October 29, 2020, the day after his third-quarter earnings call with investors.[24] The price of Boston Scientific shares rose to $35.06 on November 3 and Mr. Mahoney sold all 259,207 of his shares for about nine million dollars.[25] *Id.* at ¶¶ 218, 219. Two weeks later, on

[24] I consider Mr. Mahoney's plan documents as records integral to the Complaint. *Shaw* v. *Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996), *abrogated in part by* 15 U.S.C. § 78u-4(b). Though Plaintiff in its opposition brief characterizes Defendants' inclusion of these plan documents in their Motion to Dismiss as "improper" [Dkt. No. 61 at 43], Plaintiff does not appear to dispute the authenticity or accuracy of their contents.

[25] This was the first day after the plan's earliest sale date of October 28 when Boston Scientific shares reached the minimum price trigger of $35.00 dollars. [Dkt. No. 55-2 at 11]

November 17, Mr. Mahoney announced Boston Scientific's decision to terminate the Lotus platform.[26] *Id.* at ¶ 181.

***C. Development of Challenged Amended Complaint by Plaintiff***

On December 16, 2020, plaintiff Mariano Errichiello filed the original complaint in the instant action, on behalf of himself and similarly situated investors. Plaintiff Errichiello sought class certification pursuant to FED. R. CIV. P. 23(a). [Dkt. No. 1] On February 2, 2021, Union Asset Management Holding AG moved to be appointed Lead Plaintiff pursuant to Section 21D(a)(3)(B) of the Exchange Act, 15 U.S.C. § 78u-4(a)(3(B). [Dkt. No. 16] I consolidated *Errichiello* v. *Boston Scientific Corporation*, No. 1:20-cv-12225-DPW (D. Mass.) and *Jevons* v. *Boston Scientific Corporation*, No. 1:21-cv-10033-DPW (D. Mass.) pursuant to FED. R. CIV. P. 42(a), and appointed Union Asset Management Holding AG as the Lead Plaintiff for the putative class on March 30, 2021. [Dkt. No. 31]

Lead Plaintiff in due course filed the Amended, Consolidated Class Complaint now under consideration.

**II. STANDARD OF REVIEW**

To survive a motion to dismiss, a complaint must contain plausible factual allegations sufficient to "raise a right to

[26] I note that although Boston Scientific share prices did drop about 8% following the announcement that the Lotus would be recalled and terminated, the shares had approximately the same value at the close of trading on November 17, $35.03, as they had on November 3 when Mr. Mahoney traded his shares, $35.06. *Id.* at ¶¶ 219,324.

relief above the speculative level." *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 555 (2007). The plaintiff must allege specific facts supporting each element of their cause of action; conclusory assertions of the defendant's liability will not suffice. *Id.*

I accept as true all well-pleaded factual allegations in the Complaint and draw all reasonable inferences in Plaintiff's favor – though, as explained *infra* Part III, Plaintiff faces a higher standard as to inferences of scienter. *Tellabs, Inc.* v. *Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321, 324 (2007). "In deciding a motion to dismiss a securities action, [I] may [also] properly consider the relevant entirety of a document integral to or explicitly relied upon in the complaint . . . ." *Shaw* v. *Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996) (citing *Watterson* v. *Page*, 987 F.2d 1, 3–4 (1st Cir. 1993)),*abrogated in part by* 15 U.S.C. § 78u-4(b)(2). Here, although they were not appended to the Complaint, I consider the transcripts of Defendants' earnings calls, conference talks, question and answer sessions, and other public statements referenced in the Complaint.[27]

[27] No dispute as to the accuracy and authenticity of these transcripts and other public statements has been raised before me.

## III. COUNT I - VIOLATION OF SECTION 10(b) AND RULE 10b-5

### *A. Applicable Legal Standard*

Plaintiff raises in Count I a claim under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.[28] To allege a right to relief under Section 10(b), a plaintiff must adequately plead:

> (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation.

*Constr. Indus. & Laborers Joint Pension Tr.* v. *Carbonite, Inc.*, 22 F.4th 1, 6 (1st Cir. 2021) (quoting *In re Biogen Inc. Sec. Litig.*, 857 F.3d 34, 41 (1st Cir. 2017)).

Beyond the general requirements of an adequately pled complaint, the plaintiff in a securities fraud case must meet the heightened pleading requirements of FED. R. CIV. P. 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). 15 U.S.C. § 78u-4(b) (describing pleading requirements in private

[28] The U.S. Securities and Exchange Commission ("SEC") investigated whether Boston Scientific violated the federal securities laws with respect to its actions surrounding the discontinuation of Lotus Edge. Dkt. No. 72. That investigation concluded on January 3, 2022, with the SEC not recommending an enforcement action against Boston Scientific. Dkt. No. 72-1. That the SEC decided not to take an enforcement action is not material to my disposition on the motion to dismiss now before me. The SEC's letter explains that it "must in no way be construed as indicating that [Boston Scientific] has been exonerated or that no action may ultimately result from the staff's investigation." Dkt. No. 72-1 (quoting Procedures Relating to the Commencement of Enforcement Proceedings and Termination of Staff Investigations, Securities Exchange Act of 1933, Release No. 5310 (Sept. 27, 1972)).

actions alleging securities fraud); *see Isham* v. *Perini Corp.*, 665 F. Supp. 2d 28, 33 (D. Mass. 2009). All allegations of fraud must be stated "with particularity." FED. R. CIV. P. 9(b). The PSLRA requires the plaintiff to "specify each [defendant] statement alleged to have been misleading" and explain "the reason or reasons why the statement is misleading." *In re Biogen Inc. Sec. Litig.*, 857 F.3d at 41 (quoting 15 U.S.C. § 78u-4(b)(1)).

Under the PSLRA, a plaintiff is obligated to allege specific facts giving rise to a strong inference of the defendants' scienter, defined as either "intentional or willful conduct designed to deceive or defraud investors by controlling or artificially affecting the price of securities" or a "high degree of recklessness." *Id.* (internal quotations and citations omitted).

***B. Material Misstatements and Omissions***

To avoid dismissal, a plaintiff must identify at least one material misrepresentation or omission during the Class Period. *See Aldridge* v. *A.T. Cross Corp.*, 284 F.3d 72, 78, 82 (1st Cir. 2002).

Not every arguably false or misleading statement by a corporate executive is actionable under the PSLRA. *Shaw*, 82 F.3d at 1217; *Fire & Police Pension Ass'n of Colo.* v. *Abiomed, Inc.*, 778 F.3d 228, 242 (1st Cir. 2015). A defendant's forward-looking, predictive statement will not be found actionable if it

falls within the PSLRA's Safe Harbor provision, 15 U.S.C. § 78u-5(c)(1), as a statement that "(1) includes a disclaimer regarding risks and the possibility that results will differ from projections; (2) is immaterial; or (3) the executives of the company had no actual knowledge . . . was false or misleading." *In re Smith & Wesson Holding Corp. Sec. Litig.*, 604 F. Supp. 2d 332, 340 (D. Mass. 2009).

A plaintiff must also show that a defendant's misstatements were material, such that there is "a substantial likelihood that a reasonable investor would have viewed [the statement] as significantly alter[ing] the total mix of information made available" on the market. *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 240 (internal quotations and citations omitted). Statements constituting mere puffery, or vague corporate optimism on the current success of a product or its prospects, for example, are not material and do not prove a basis for a securities fraud action. *Metzler Asset Mgmt. GmbH* v. *Kingsley*, 305 F. Supp. 3d 181, 209 (D. Mass. 2018), *aff'd*, 928 F.3d 151 (1st Cir. 2019). Statements "clearly constituting the opinions of the speaker" are equally immaterial, *Shaw*, 82 F.3d at 1217, because a reasonable investor would not consider these statements important in assessing the market. *Id.* To sort actionable misrepresentations from non-actionable puffery or optimism, I consider "(1) whether [each] statement is so vague, so general, or so loosely optimistic that a reasonable investor

would find it unimportant to the total mix of information and (2) whether the statement was also considered unimportant to the total mix of information by the market as a whole." *In re Biogen Inc. Sec. Litig.*, 193 F. Supp. 3d 5, 41 (D. Mass. 2016) (internal quotations and citation omitted), *aff'd*, 857 F.3d 34 (1st Cir. 2017).

Here, I can discern four broad categories of what Plaintiff characterizes as material misrepresentations: (1) false reports as to the accounts opened and orders received during the Lotus Edge launch in the United States; (2) mischaracterizations of the Lotus Edge device as a simple, user-friendly device competitive with existing TAVR devices; (3) omissions and misstatements as to the safety of the Lotus Edge device and its launch; and (4) Executive Defendant failures to disclose their mid-2020 decision to terminate the Lotus Edge project and reporting misleading reports regarding the future of the Lotus Valve Platform.

1. Statements Regarding Lotus Edge Accounts and Orders

Plaintiff contends that a number of Executive Defendant progress reports on the success of the United States Lotus launch constitute fraud. I find that the vast majority of these misstatements are not material representations upon which the reasonable investor would rely.

Executive Defendant pronouncements that the launch was going well, that Boston Scientific was "on track" to meet the

goal of roughly 150 accounts, that the launch was "gaining momentum" and that Boston Scientific was seeing "strong" sales and order rates, are all statements of immaterial corporate puffery. Dkt. No. 44 at ¶¶ 260, 265, 267, 274-275, 279-280, 286-287, 291-292, 296, 303, 305, 309, 313, 316, 319. "Analysts and arbitrageurs rely on facts in determining the value of a security, not mere expressions of optimism from company spokesmen." *Suna* v. *Bailey Corp.*, 107 F.3d 64, 72 (1st Cir. 1997) (internal quotations omitted) (quoting *Raab* v. *Gen. Physics Corp.*, 4 F.3d 286, 290 (4th Cir. 1993)). None of these rosy assessments, devoid as they are of detail, would have been confused for factual representations important to the market. *See In re Wayfair, Inc. Sec. Litig.*, 471 F. Supp. 3d 332, 339 (D. Mass. 2020) (executives' reports that they were "delighted" with the progress and that the market-share would grow were not actionable); *In re iRobot Corp. Sec. Litig.*, 527 F. Supp. 3d 124, 138 (D. Mass. 2021) (statements related to market momentum or reports of traction are not actionable). To the extent that these statements were demonstrably false at all, they were vague proclamations of progress to which a reasonable investor would assign little weight. *See Hensley v. Imprivata, Inc.*, 260 F. Supp. 3d 101, 124 (D. Mass. 2017) (citing *Shaw*, 82 F.3d at 1217-18).

Opinions offered by Executive Defendants, for example, that the Lotus team was "really pleased" by the pace of the launch, that Lotus was "doing very well on the market," that the device was being used and ordered "quite consistently," and that results were "encouraging," are equally immaterial. Dkt. No. 44 at ¶¶ 260, 267, 274, 286, 292, 301, 302. These opinions regarding the current state of the Lotus launch and its future prospects are not the factual representations that would be considered in the total mix of information in the market. *In re iRobot Corp. Sec. Litig.*, 527 F. Supp. 3d at 138 (citing *In re Boston Sci. Corp. Sec. Litig.*, No. 1:10-cv-10593-DPW, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011), *aff'd*, 686 F.3d 21 (1st Cir. 2012)).

Finally, Plaintiff contends that several forward-looking statements, such as the predictions that Lotus "will continue to grow" in new accounts and sales were "expect[ed] to get back to our regular cadence" in the second half of 2020, are actionable. Dkt. No. 44 ¶¶ 271, 301. Those predictions fall under the PSLRA's Safe Harbor provision and do not give rise to liability.

Not all of Executive Defendant alleged misstatements may be disposed of as non-actionable puffery, opinions, or predictions, however. Four representations from Ms. Lisa, Mr. Mahoney, and Mr. Fitzgerald require more careful analysis.

- On August 19, 2020, Ms. Lisa allowed her Director of Investor Relations to report without contradiction that "we hit 138 accounts" in the Lotus Launch.[29] *Id.* at ¶¶

[29] Plaintiff alleges "Boston Scientific" reported the 138-account tally on August 19, 2020. Yet the Complaint attributes the statement "we hit 138 accounts" to Director of Investor Relations Lauren Tengler, who is not named as a Defendant in the Complaint. Dkt. No. 44 at ¶ 99, 305-306.

The only possible Defendant to whom this statement might be attributed is Ms. Lisa, the vice president of Investor Relations, because Plaintiff presents no facts to suggest that Ms. Tengler's scienter may be imputed to Boston Scientific itself. Ms. Lisa 1) presumably supervised Ms. Tengler, 2) was on the conference call with Ms. Tengler when she made this statement, and 3) permitted Ms. Tengler to respond to an analyst's request for account tallies that had been directed to both Ms. Lisa and Ms. Tengler. Though I need not resolve the issue in this case, I note that whether Ms. Lisa can be said to have "ma[d]e" this alleged false statement within the meaning of Section 10(b) is not a question to which First Circuit case law provides a clear answer.

Section 10(b) imposes liability on "any person, [that] directly or indirectly, . . . make[s] any untrue statement of a material fact or [omits] a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 15 U.S.C. § 78j(b), as refined in 17 C.F.R. § 240.10b-5(b).

In *Janus Capital Group, Inc.* v. *First Derivative Traders*, 564 U.S. 135, 145 (2011), the Supreme Court considered whether Janus Capital Management LLC could be held liable for statements made in its wholly owned subsidiary's prospectuses, which allegedly were misleading. *Id.* at 137–142. Holding that Janus Capital Management could *not* be held liable, the Supreme Court explained that the "maker" of a false statement is "the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." *Id.* at 142; *see also id.* at 148. Accordingly, only the wholly owned subsidiary could be held liable because Janus Capital Management did not have "the statutory obligation to file prospectuses with the SEC." *Id.* at 146–147.

Since *Janus*, courts have disagreed as to whether Section 10(b) contemplates liability for the corporate executive who knowingly permits third parties to make false statements in her presence but does not author such statements herself. For example, the Seventh Circuit explained there is "no statute or rule" that

99, 305.

- On September 16, 2020, Mr. Mahoney told analysts that "**Lotus remains a key growth driver for us**. And we're not

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imposes a "duty to correct" misstatements made by others, and "if there were one, *Janus Capital* itself would have come out the other way." *Fulton Cnty. Emps. Ret. Sys.* v. *MGIC Inv. Corp.*, 675 F.3d 1047, 1051–52 (7th Cir. 2012). Other courts apply *Janus* similarly. *See Oaktree Principal Fund V, LP* v. *Warburg Pincus LLC*, No. CV 15-8574 PSG (MRWx), 2017 WL 3187688, at *8 (C.D. Cal. Jan. 17, 2017) ("[S]peakers are only liable for failing to correct their own omissions."); *Ho* v. *Duoyuan Glob. Water, Inc.*, 887 F. Supp. 2d 547, 572 n.13 (S.D.N.Y. 2012). In contrast, at least one court post-*Janus* has explained that "a high ranking company official cannot sit quietly at a conference with analysts, knowing that another official is making false statements and hope to escape liability for those statements." *Ga. Firefighters' Pension Fund* v. *Anadarko Petroleum Corp.*, 514 F. Supp. 3d 942, 956 (S.D. Tex. 2021) (quoting *Barrie* v. *Intervoice-Brite, Inc.*, 397 F.3d 249, 262 (5th Cir. 2005)).

The First Circuit has not weighed in on this issue post-*Janus*, though courts have acknowledged its earlier decision in *SEC* v. *Tambone*, 597 F.3d 436, 442–43 (1st Cir. 2010) (en banc) as "consistent with *Janus*." *See, e.g.*, *SEC* v. *City of Victorville*, No. ED CV13-00776 JAK (DTBx), 2017 WL 11679413, at *60 (C.D. Cal. June 2, 2017). In *Tambone*, the Court of Appeals explained that "[r]eading 'make' to include the use of a false statement by one other than the maker" would stretch liability under Rule 10b-5(b) too far. *Tambone*, 597 F.3d at 446. Even in *Tambone*, however, the First Circuit left open the possibility that Rule 10b-5(b) liability may attach where "defendants have expressly or impliedly adopted the [mis]statements, placed their imprimatur on the [mis]statements, or have otherwise entangled themselves with the analysts to a significant degree." *Id.* at 449 (quoting *In re Cabletron Sys., Inc.*, 311 F.3d 11, 37–38 (1st Cir. 2002)).

I need not decide the question of whether Ms. Tengler's alleged false statement or misleading omission could be said to have been "made" by Ms. Lisa. For the purposes of this Memorandum only I will refer to the statement as one made by Ms. Lisa. However, as further explained *infra* Part III.C.2, I hold that even if Ms. Lisa is legally responsible for failing to correct the inaccurate 138-account tally, Plaintiff has not made a sufficient showing of Ms. Lisa's scienter to support its claims.

going to give share [] estimates, but we're continuing to invest along those lines. We're starting to do more account openings, **the reorder rate for existing users is quite high**, and we're slowly beginning to penetrate some new accounts . . . ." *Id.* at ¶ 308 (emphasis added).

- On October 15, 2020, Mr. Fitzgerald told analysts "**we have opened more than 150 accounts** in the [United States]." He then announced that the Lotus Edge launch was "expanding our footprint in the [United States]" and that "**each month we're growing actual procedures per center, per month.**" *Id.* at ¶¶ 314, 316 (emphasis added).
- On October 28, 2020, when Mr. Mahoney was asked whether it made strategic sense for Boston Scientific to develop two different TAVR platforms — the Lotus platform and the Acurate platform — he responded "**we do believe that the two-valve strategy makes sense**" despite the continued challenges of opening new Lotus accounts in the United States. *Id.* ¶ 319 (emphasis added).

In contrast to most statements discussed above these are, at least arguably, factual representations. I turn to whether Plaintiff has stated with particularity that they are both false and material. *See Greebel* v. *FTP Software, Inc.*, 194 F.3d 185, 193–194 (1st Cir. 1999).

*a. Statements Tallying the Lotus Edge Accounts and Expressions of Satisfaction with the Launch*

Plaintiff pleads adequately that Ms. Lisa and Mr. Fitzgerald misstated the number of Lotus accounts opened in the United States as of August 19, 2020 (138 accounts) and October 15, 2020 (over 150 accounts) and that the misstatements were material. As alleged, the day after Boston Scientific announced its decision to terminate the Lotus platform, Mr. Fitzgerald announced that Lotus Edge had only launched "about 100 accounts in the U.S." Dkt. No. 44 at ¶ 194. Making all reasonable inferences in Plaintiff's favor, I find Mr. Fitzgerald's November report of 100 accounts, accompanied by Boston Scientific's decision to terminate the Lotus platform, support the conclusion that Ms. Lisa and Mr. Fitzgerald presented inaccurate tallies of Lotus Edge accounts.[30]

Account reports by Ms. Lisa and Mr. Fitzgerald's are also material. Ms. Lisa and Ms. Fitzgerald both represented that the Lotus Edge launch was hitting concrete milestones when, according to the allegations in the Complaint, it was not.

[30] Defendants read Mr. Fitzgerald's November tally of about 100 open Lotus accounts as including only then-active accounts and contend there may have been more accounts open when Ms. Lisa and Mr. Fitzgerald gave their earlier tallies. I, however, read the allegations in the light most favorable to Plaintiff and find that Plaintiff has pleaded falsity with sufficient particularity. However, I do recognize that Mr. Fitzgerald's November 18 statement could be read to a narrower class of accounts than the class of accounts described by Ms. Lisa and Mr. Fitzgerald in their August and October tallies in my analysis of scienter, *infra* Part III.C.2.

These are not the subjective, vague statements of corporate optimism that reasonable investors would disregard. Rather they should be considered at this stage as factual representations relevant to potential investment decisions. *In re Cytyc Corp.*, No. 1:02-cv-12399-NMG, 2005 WL 3801468, at *20 (D. Mass. Mar. 2, 2005) ("The more specific, definite or concrete the outward statement is . . . the greater the likelihood the statement is material and not mere puffery.").

*b. Growing Use of Lotus Edge and Reorder Rates*

Mr. Fitzgerald's statement that "each month we're growing actual procedures per center, per month," Dkt. No. 44 at ¶¶ 100, 316, is not materially misleading. Plaintiff claims that Mr. Fitzgerald's statement was false because by mid-2020 "only 12 Lotus Edge accounts in the country used more than 2 devices per month, and only nine of those centers used more than 2.5 per month." *Id.* at ¶ 204. Mr. Fitzgerald's statement and the rates of use alleged are not mutually exclusive. Plaintiff does not allege that the *average number* of monthly procedures performed per center was not increasing, month after month, or that there were few centers using more than two per month. *Cf. Coyne* v. *Metabolix, Inc.*, 943 F. Supp. 2d 259, 268-69 (D. Mass. 2013) (plaintiffs failed to plead falsity when the defendant's statements and the facts pleaded in the complaint were not necessarily mutually exclusive). Consequently, Mr. Fitzgerald's statement is not actionable.

Plaintiff claims that Mr. Mahoney further misled investors by claiming that "the reorder rate for existing [Lotus Edge] users is quite high," Dkt. No. 44 at ¶ 308, when "only 12 Lotus Edge accounts in the country used more than 2 devices per month." *Id.* at ¶ 204. With the Lotus device used so rarely, Plaintiff claims, Defendants could not have been seeing "very high" reorder rates. *Id.* at ¶ 203. Again, Plaintiff has not explained with particularity why Mr. Mahoney's statement was misleading. *See Shaw*, 82 F.3d at 1217.

First, Plaintiff has not alleged that the rate at which a center *orders* Lotus devices is the same as the rate at which it *uses* the device; centers may order more devices than they use monthly or be unable to predict the number of devices needed each month.

Second, Plaintiff has not pleaded that an order rate of one to two Lotus devices per month *is not* a high reorder rate to Mr. Mahoney. I cannot conclude that Mr. Mahoney's statement was false under these circumstances. *See Fitzer* v. *Sec. Dynamics Techs., Inc.*, 119 F. Supp. 2d 12, 26-27 (D. Mass. 2000).

Even if it were false, Mr. Mahoney's statement is too vague to be one upon which investors would rely. Mr. Mahoney made no representation as to the actual rate at which centers that purchased one Lotus device returned for future orders. He did not claim that the device was used at a certain rate across the existing accounts. He stated only that the frequency of reorder

was "high" in his view. This alone does not constitute a fraudulent statement. *See id.* at 26 (representation of "continued market demand" for a company's product is too vague to be material as defendants did not specify "a particular market demand, a market share figure, or represent that the market demand is static, shrinking, or growing").

2. Simplicity and Ease of Use of Lotus Edge

Defendant statements in marketing the Lotus Edge as a device offering "superior ease of use" were, Plaintiff alleges, materially false and misleading. *See* Dkt. No. 44 at ¶¶ 226, 229, 233-235, 269. In reality, Lotus Edge was a complicated instrument that Plaintiff alleges required three hands and thirty-five steps to implant. *Id.* at ¶ 124. Defendants contend that any statements of their hopes for the Lotus Edge's simplicity and ease of use were statements of opinion and corporate optimism.

Defendant comments regarding the Lotus Edge's ease of use and marketability are not actionable misstatements. The statements to which Plaintiff directs my attention are vague statements of corporate puffery and overly optimistic opinion. To the extent Plaintiff raises any material statements by Defendants, its claims are of fraud by hindsight and must fail. *City of Dearborn Heights Act 345 Police & Fire Ret. Sys.* v. *Waters Corp.*, 632 F.3d 751, 759 (1st Cir. 2011).

*a. Ease of Use Statements*

Defendants' rosy assessments of the Lotus Edge product as "a simpler device to use" or "a superb choice for operators early in their TAVR experience" were not objective assessments that could deceive investors. Dkt. No. 44 at ¶¶ 231-232. Plaintiff does not claim, for example, that Defendants made false statements as to the number of steps it took to implement the Lotus Edge, the mechanics by which it operated, or the limits of its use in TAVR procedures. A reasonable investor would not rely on Defendants' vague praise of their own product's potential market-advantages. *See Wang Yan v. ReWalk Robotics Ltd.*, 330 F. Supp. 3d 555, 571 (D. Mass. 2018) (references to medical device as a "breakthrough product" and to "compelling" clinical data found to be "unquestionably subjective, optimistic statements that a reasonable investor would not consider material"), *aff'd sub nom. Yan* v. *ReWalk Robotics Ltd.*, 973 F.3d 22 (1st Cir. 2020).

Even were Defendants' ease of use statements more than vague puffery, Plaintiff has pleaded nothing more than fraud by hindsight. Plaintiff essentially claims that investors were promised a simple and easy-to-implement design but ended up with a device that required "three hands to operate." Dkt. No. 44 at ¶¶ 233-234. However, Plaintiff cannot "simply contrast a defendant's past optimism with less favorable actual results, and then contend[] that the difference must be attributable to

fraud." *Shaw*, 82 F.3d at 1223 (alteration in original) (citation omitted). There are no facts in the Complaint suggesting that the Defendants' expressed their goal to build a user-friendly yet repositionable device in bad faith. Here, the Complaint makes out "general allegations that defendants knew earlier what later turned out badly" which are not sufficient to sustain a claim for securities fraud. *Ezra Charitable Tr.* v. *Tyco Int'l, Ltd.*, 466 F.3d 1, 6 (1st Cir. 2006) (internal quotations and citation omitted).

*b. Failure to Disclose the Complexity of Device and Delivery Malfunctions*

Plaintiff also contends that various descriptions by Defendants regarding the Lotus device omit essential information about the complexity of the device and its malfunctions. I disagree.

As an initial matter, "[a] defendant does not have a duty to cast the descriptions of its business in the most negative light." *Coyne*, 943 F. Supp. 2d at 269. A defendant is liable for omissions in statements comparing its product's merits (i.e. its simplicity and safety) to those of competitors only if his statements are "so incomplete as to mislead" reasonable investors. *Backman* v. *Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc) (citation omitted).

Here, Plaintiff relies primarily on the accounts of confidential sources that Defendants failed to disclose the Lotus valve's known design flaws:

- Sales representatives in charge of overseeing Lotus procedures described the Lotus Edge as "the most complicated device on the planet," Dkt. No. 44 at ¶ 231, and the complexity of the Lotus device and delivery system posed significant medical and sales challenges, *id.* at ¶ 232.
- The Lotus device's complexity required "extensive training that Boston Scientific failed to provide." *Id.* at ¶ 235.
- Malfunctions in the delivery system resulted in "an alarming rate of adverse events, including patient deaths and injuries, that far outpaced those of its two primary competitor devices." New iterations of the device did not resolve these issues. *Id.* at ¶¶ 235-236.

Plaintiff presents accounts from confidential sources FE 3, 4, and 6, describing the Lotus device as overly complex and prone to specific malfunctions in the delivery system. Weighing these source accounts based on "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, [and] the reliability of the sources," I conclude Plaintiff has not

properly alleged a material omission. *In re Cabletron Sys., Inc.*, 311 F.3d 11, 29-30 (1st Cir. 2002). Plaintiff's confidential sources make conclusory statements about the complexity of the Lotus device and the training challenges it posed. They do not, however, explain with sufficient particularity the factual basis for their conclusions.[31] *See* Dkt. No. 44 at ¶¶ 234-235.

It also does not appear that Defendants withheld information from investors that would have been new and material. "A plaintiff fails to plead an actionable § 10(b) claim predicated on the concealment of information if that information was, in fact, disclosed." *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 (D. Mass. 2009). Here, investors and analysts were well-acquainted with the challenges posed by the Lotus delivery system. When Defendants announced the decision to end the Lotus platform, one analyst noted "the delivery issues have been front and center for years." Dkt. No. 44 at ¶ 194. Defendants discussed the complexities of the Lotus device's delivery system with

[31] None of Plaintiff's confidential sources report, for example, that the Lotus valve's design or mechanical function differed from Defendants' descriptions to the public. None suggested that Defendants concealed records of adverse patient events or instances of device malfunction from the public. The sources opined on the incredible complexity of the device and physicians' difficulty using it but Plaintiff has not supported these accounts with any internal reports or accounts from physicians who used the device.

investors as early as 2016 and 2017 during the first Lotus recalls. *Id.* at ¶¶ 65, 67-68, 78. Moreover, Boston Scientific made records of each instance of the Lotus device malfunction, including malfunctions that occurred within the delivery system, and reported them to the FDA. These reports were made available through the FDA's public Manufacturing and User Facility Device Experience database. *Id.* at ¶ 116. I cannot conclude that Defendants misled, let alone intended to defraud, investors as to the safety and design of the Lotus device.[32]

I also reject Plaintiff's contention that Mr. Fitzgerald admitted on November 18, 2020 that Defendants knew as of April 2020 that the Lotus valve design posed too many clinical support challenges to be commercially viable. As further discussed *infra* Part.III.B.4.a., Mr. Fitzgerald's full November 18 statement states the view that the company determined that the Lotus valve was not commercially viable in the fall of 2020, not that it was perceived as such in April of 2020. Boston

[32] I observe that Defendants do not assert a truth on the market defense, as Plaintiff suggests in its opposition brief. *See* Dkt. No. 61 at 40. "The truth on the market defense is used to rebut a plaintiff's presumption of reliance on the market by arguing that even if fraudulent statements were made, truthful information later entered the market." *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 155 n.75 (D. Mass. 2009). Here, Defendants point to their public disclosures as evidence that they had no intent to mislead investors or conceal safety data regarding the Lotus Edge. *See id.* ("Defendants have not raised a truth on the market defense, but instead argue that 'Plaintiffs have failed to plead facts to show that there were any misstatements or scienter in the first place.'" (citation omitted)).

Scientific weighed the high manufacturing costs of the device, the resources needed to train representatives to use it safely, and the niche position the device occupied in the TAVR market just before the Lotus platform was terminated. With these allegations, I see no basis to support the contention that Defendants failed to timely disclose material information to investors.

3. Misstatements and Omissions as to the Safety of the Lotus Edge Launch

Plaintiff argues Defendants misled investors by proclaiming that the Lotus launch was a safe and controlled one, when it was actually conducted in a manner that was "clinically unsafe." Dkt. No. 44 at ¶ 248. Further, Plaintiff alleges that Defendants should have disclosed the fact that Defendants' "[e]gregiously [i]nadequate [t]raining [l]ed [t]o [p]atient [i]njuries [a]nd [d]eath." *See id.* at 96. I find no actionable misrepresentations or omissions.

Several of the misrepresentations alleged in this category occurred *before* the Class Period and, as such, I need not consider them as bases for a securities fraud claim. *Shaw*, 82 F.3d at 1217 n.31 ("We limit our analysis of the. . .plaintiffs' claims of affirmative misrepresentation to the statements allegedly made by defendants within the Class Period."); *see also In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 643 (S.D.N.Y. 2007) ("Although pre-class-period statements can be

relevant for showing whether defendants had knowledge that their later statements were false, those statements cannot themselves give rise to liability." (internal citations omitted)). So far as appears, Plaintiff's remaining allegations, that Defendants did not require sufficient training for its sales and clinical representatives and that Defendants did not provide the level of clinical support necessary, are thinly veiled criticisms of the way that Boston Scientific conducted its product launch, not particularized claims that Defendants' deceived investors.

The Complaint does not adequately support Plaintiff's contention that Defendants withheld information about the safety of the Lotus launch and jeopardized patient safety. As discussed *supra* Part III.B.2.b, information regarding the safety of the Lotus Edge and its launch in the United States was made publicly available to investors.[33] Plaintiff has not clearly articulated which of Defendants' duties, if any, would obligate them to disclose further information regarding the Lotus's design and function. Plaintiff has not, for example, alleged that Defendants failed to meet their obligations under 21 C.F.R. §§ 803.50 and 803.52 to disclose safety information or adverse device events to the FDA. At most they allege that puffing by certain Executive Defendants suggesting that the Lotus launch

[33] In fact, Plaintiff presents exactly this publicly available data in the Complaint to demonstrate the number of adverse events associated with the Lotus Edge Delivery System throughout the Class Period. *Id.* at ¶¶ 118, 120.

would be a controlled one focused on strong patient outcomes was misleading because, in the conclusory opinion of one of the Plaintiff's confidential sources, the launch was clinically unsafe. The Complaint fails to allege satisfactorily that Defendants withheld material information from investors based on these allegations.

4. Misleading Reports of the Success of the Lotus Platform and its Role in the TAVR Portfolio

*a. Disclosure of the Lotus Recall and Termination*

Plaintiff claims Defendants decided to terminate the Lotus platform in April of 2020 but delayed announcing this decision to inflate the value of Boston Scientific stock during a financially challenging period for the company. Plaintiff bases this allegation on carefully excerpted phrases from Executive Defendant Joseph Fitzgerald's November 18, 2020 explanation of when Boston Scientific decided to terminate the Lotus platform: according to the Complaint Mr. Fitzgerald allegedly "admitted" that Boston Scientific senior management made the decision by "no later than April 2020" when he said "[i]t took us about 12 months after full launch to evaluate [Lotus]." *Id.* at ¶¶ 194-195. The "full launch," according to Plaintiff, began when the device gained FDA approval on April 23, 2019, meaning Boston Scientific leaders fully evaluated Lotus around or before April of 2020. *Id.* at ¶ 195.

Plaintiff's interpretation of Mr. Fitzgerald's words is strained and contorted. The Complaint makes clear that April 23, 2019 marked the beginning of a *controlled* launch of the Lotus Edge. The *full launch* began in the fall of 2019. *Id.* at ¶ 96. Mr. Fitzgerald apparently shared this understanding. Asked on November 18, 2020 why it "took so long" to end the Lotus platform, Mr. Fitzgerald responded:

> So really, when you think about it, with getting approval in April and then going into our limited market release a few months later and **then really full launch this time last year, right? So we've had essentially 12 months.** And oh, by the way, COVID is right in the middle of those 12 months. **But we needed to get the U.S. experience to determine what's going to be the rightful place in the universe for the LOTUS valve.** And the decision we came to after thousands of implants, we launched about 100 accounts in the U.S., was that LOTUS was going to remain a niche. . . And it took launching in a country like the U.S. for us to figure that out because of the past of what we purposefully did in Europe. **So I think, you look at it, and I think I would characterize it as it took us about 12 months after full launch to fully evaluate LOTUS, to fully understand ACURATE neo2.**

Dkt. No. 64-1 at 6 (emphasis added). Mr. Fitzgerald made clear that he was stating that Boston Scientific leaders decided to terminate the Lotus platform in the fall of 2020, within weeks of later disclosing that decision to investors. I therefore find no adequate basis for a securities fraud claim on the ground that the Defendants delayed disclosure of the Lotus shutdown.

*b. The Future of Lotus as a Growth Driver and Strategic Investment*

Plaintiff identifies Executive Defendant Michael Mahoney's September 16 statement[34] and October 28 statement[35] to investors affirming that the Lotus platform remained an important growth driver and strategic investment. Given their temporal proximity to Defendants' decision to terminate the Lotus platform

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[34] On September 16, 2020 Mr. Mahoney made the following statement at the Morgan Stanley Health Conference, in response to an analyst question:

> I think, you know, certainly Lotus will continue to be an important product for us. It's a significant market as you know, and even small share gains are significant for us. And so, Lotus will continue to be an important growth driver for us supported with our whole platform with ACURATE neo2. So, overall, Lotus remains a key growth driver for us. And we're not going to give share estimates, but we're continuing to invest along those lines. We're starting to do more account openings, the reorder rate for existing users is quite high, and we're slowly beginning to penetrate some new accounts with some new training.

Dkt. No. 44 at ¶ 307–08.

[35] On October 28, 2020 during Boston Scientific's third quarter earnings call, Mr. Mahoney allegedly "highlighted [Boston Scientific's] 'continued U.S. and Japan rollout of Lotus Edge and U.S. intermediate risk trial enrollment'" and emphasized the "'distinct benefits' of the Lotus Edge." *Id.* at ¶ 318. Mr. Mahoney also made the following statement, in response to an analyst's question:

> And we've obviously had the two-valve strategy, and we're seeing strong results in the sites that are using Lotus in the U.S. Opening new sites has been a challenging exercise for us given the pandemic, but the sites that are using Lotus in the U.S. are using it quite regularly. So we do believe that the two-valve strategy makes sense and we're excited about the Acurate neo2 launch in Europe.

*Id.* at ¶ 319.

altogether, these statements are adequately alleged to have misled the reasonable investor.

The First Circuit, in *Construction Industry and Laborers Joint Pension Trust* v. *Carbonite, Inc.*, 22 F.4th 1 (1st Cir. 2021) (*"Carbonite"*), and my colleague Judge Young, in *In re Allaire Corporation Securities Litigation*, 224 F. Supp. 2d 319 (D. Mass. 2002), addressed similar representations and found them actionable. I find their reasoning persuasive.

In *In re Allaire Corporation Securities Litigation*, 224 F. Supp. 2d 319, 331-332 (D. Mass. 2002) the defendant president of the company stated in an interview that the company's latest software product was "fueling growth" when the product was known —by "customers, distributors, sales personnel, and technical personnel"— to be defunct. *Id.* at 331. Judge Young concluded that the defendant's "precise statement" that a specific product is driving profit growth for the company is actionable when the statement "could not have been believed by its maker — at least not without recklessness on his part." *Id.* at 331-332.

The statements in *Carbonite* were similar, though some were "presented in the form of a statement of belief." 22 F.4th at 7. Despite the at-issue product allegedly never working, the defendant CFO stated that the company "put something out that **we think** is just completely competitive and just a super strong product" and the defendant CEO stated that the product "improves our performance" and "makes us really competitive." *Id.*

(emphasis in original). Although defendants argued, *inter alia*, that the statements were opinions, the First Circuit explained that the use of certain phrases, such as "I think" or "I believe," to characterize a statement "does not preclude the possibility that the statement as a whole may still mislead as to some fact." *Id.* (internal citation omitted) (citing *Omnicare, Inc.* v. *Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 193 (2015)). Statements of opinion "may convey three facts: that the speaker has such a belief; that the belief fairly aligns with the facts known to the speaker; and . . . that the speaker has made the type of inquiry that a reasonable investor would expect given the circumstances." *Id.*

Guided by the reasoning of *Carbonite* and *In re Allaire Corp. Sec. Litig.*, I find Mr. Mahoney's statements are adequately alleged to have been materially misleading when viewed in the light most favorable to Plaintiff. According to Mr. Fitzgerald's November 18 account of the decision to retire the Lotus platform, discussed above, Defendants were in the process of critically evaluating the Lotus platform in the fall of 2020. When Mr. Mahoney made these representations that Lotus was driving growth and a dual-valve strategy made sense for the company, Boston Scientific's leadership had either already decided the Lotus platform was unsalvageable or was on the cusp of doing so in a matter of weeks. Under these circumstances, the representations that the Lotus platform was still driving

growth and its continuation made sense from an investment standpoint are adequately alleged to constitute specific misrepresentations that the Lotus Edge was and would remain viable. *See In re Cytyc Corp.*, No. Civ.A. 02-12399-NMG, 2005 WL 3801468, at *20 (more concrete representations are more likely to be misleading). Unlike the less concrete claims discussed in Part III.B.1, these statements could have been material to investors.

To the extent Defendants argue that these statements are nonactionable opinions, I disagree. Here, Mr. Mahoney's statements "could be reasonably construed in context as a statement of fact," such that "it would be false as compared to the [C]omplaint's contention that" leadership at Boston Scientific was deciding to pull the plug on the Lotus platform. *Carbonite*, 22 F.4th at 7. Moreover, as the First Circuit explained, framing a statement as a "belief" is not dispositive of whether it is an opinion and nonactionable. *Id.* Here, Mr. Mahoney's statement could have "plausibly conveyed" that he "actually believed" the Lotus platform "will continue to be an important product," that his opinion was "fairly align[ed] with" the information he possessed at the time, and that this "opinion was based on the type of reasonable inquiry that an investor in context would expect to have been made." *Carbonite*, 22 F.4th at 7.

5. Conclusion

Nearly all of the misrepresentations alleged by Plaintiff amount to nonactionable corporate puffery, opinions, and predictions. Two sets of statements detailed in the Complaint, however, are actionable: 1) The inaccurate tallies of the number of accounts opened in the Lotus launch by Ms. Lisa and Mr. Fitzgerald on August 19 and October 15, 2020, respectively; and 2) Mr. Mahoney's September and October statements that the Lotus platform was a key growth driver and a viable investment. I turn now to whether Plaintiff has met its burden of pleading the Defendants' scienter with respect to these statements.

***C. Scienter***

Under Section 10(b)'s scienter element, Plaintiff must plead particularized facts that raise a "strong inference" that Defendants made their actionable misstatements and omissions with "either conscious intent to defraud or 'a high degree of recklessness.'" *ACA Fin. Guar. Corp.* v. *Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (quoting *Aldridge*, 284 F.3d at 82); 15 U.S.C. § 78u-4(b)(2)(A). "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." *N.J. Carpenters Pension & Annuity Funds* v. *Biogen IDEC Inc.*, 537 F.3d 35, 45 (1st Cir. 2008). Recklessness in the Section 10(b) context involves "not merely simple, or even

inexcusable, negligence, but an extreme departure from the standards of ordinary care, and . . . presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Mehta* v. *Ocular Therapeutix, Inc.*, 955 F.3d 194, 206 (1st Cir. 2020)(quoting *Brennan* v. *Zafgen, Inc.*, 853 F.3d 606, 613 (1st Cir. 2017)).

Under the PSLRA, the pleading standard for scienter is a "rigorous" one, *ACA Fin. Guar. Corp.*, 512 F.3d at 58, in its requirement of a "strong inference" of scienter, *Tellabs, Inc.*, 551 U.S. at 314 (quoting 15 U.S.C. § 78u-4(b)(2)). Alleged facts said to evidence a defendants' scienter "need not be irrefutable" but, taken together, they must raise "at least as compelling [an inference] as any opposing inference one could draw from the facts alleged." *Tellabs, Inc.*, 551 U.S. at 323-324. The "classic evidence" of scienter are facts showing that the defendant knew their public statements to be inaccurate or recklessly disregarded the risk that they would be. *Aldridge*, 284 F.3d at 83.

To plead a corporate defendant's knowledge of or disregard for the misleading nature of statements successfully, a plaintiff must do more than describe a declarant's high-ranking position at the company. *Coyne*, 943 F. Supp. 2d at 272 ("[S]cienter allegations based solely on a defendant's high-ranking position in the company are not sufficient."). A

defendant's motive and opportunity to deceive investors, without more, also may not suffice to establish the defendant's knowledge. "[C]lear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so" are often necessary to meet the PSLRA's scienter requirement. *In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012).

Finally, "the importance of a particular item to a defendant can support an inference that the defendant is paying close attention to that item," but that inference can only aid a plaintiff "in establishing scienter if that close attention would have revealed an incongruity so glaring as to make the need for further inquiry obvious." *Local No. 8 IBEW Retirement Plan & Tr.* v. *Vertex Pharms., Inc.*, 838 F.3d 76, 82 (1st Cir. 2016) (internal citations and quotations omitted); *see also Carbonite*, 22 F.4th at 9–10.

Guided by these principles, I consider whether Plaintiff here has raised a strong inference that the misrepresentations were made with the required scienter. I first address Plaintiff's generalized allegations of scienter, which I do not find sufficient. Then, because I have found actionable only statements by Ms. Lisa, Mr. Fitzgerald, and Mr. Mahoney, I will focus my analysis on those Executive Defendants. *See N.J.*

*Carpenters Pension & Annuity Funds*, 537 F.3d at 44 ("The PSLRA requires that the plaintiffs' complaint, '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.'" (quoting 15 U.S.C. § 78u-4(b)(2))).

1. Plaintiff's General Scienter Allegations

Plaintiff makes generalized allegations of scienter on the basis of the following evidence: (1) accounts from confidential sources, which Plaintiff alleges bear upon corporate executives' knowledge; (2) insider trading activity by four Executive Defendants; (3) resignations by two Executive Defendants involved with the Lotus platform; and (4) inferences concerning Boston Scientific's motive to hide the Lotus platform's failure in order to raise capital and renegotiate its debts. *See* Dkt. 44 at ¶¶ 201–224. As I explain, these allegations are not sufficient to raise a "strong inference" of scienter, either individually or collectively, as to Defendants.

*a. Confidential Source Accounts*

Plaintiff contends that its nine confidential sources provide accounts of Defendants' knowledge required to infer scienter. I disagree. These former employees accounts are largely devoid of the facts necessary to raise a strong inference of scienter, including "particular times, dates, places, or other details of the alleged fraudulent activity." *Orton* v. *Parametric Tech.*

*Corp.*, 344 F. Supp. 2d 290, 306 (D. Mass. 2004) (quoting *Gross* v. *Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1996)); *see id.* at 307-308("spotty and vague" accounts from unnamed former employees will not establish scienter). "The absence of [such] key details 'is indicative of the excessive generality of [Plaintiff's] allegations'" of scienter. *Sousa* v. *Sonus Networks, Inc.*, 261 F. Supp. 3d 112, 120 (D. Mass. 2017) (quoting *Greebel*, 194 F.3d at 204).

First, the sources upon which Plaintiff relies most heavily in the Complaint provide only their own opinions as to what the senior leadership knew about the Lotus launch. These include FE 7 with his oft quoted opinion that Executive Defendants were "absolutely aware" that Lotus sales were sluggish and FE 6's claim that knowledge of the Lotus valve's design issues "went all the way up." These accounts do not provide the details at the core of scienter: "what [each] defendant[] had knowledge of and when." *In re Boston Tech., Inc. Sec. Litig.*, 8 F.Supp.2d 43, 57 (D. Mass. 1998). Such conclusory opinions from confidential sources, unsupported by detail or explanation, do not establish scienter. *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 245.

I also do not find an adequate basis for scienter in conclusory assertions by former employees that specific obstacles to the Lotus launch's success were "constantly" discussed at meetings with senior leadership. "[A]llegations

that the defendants attended unspecified meetings where" the Lotus platform's challenges were "discussed constantly . . . fall[] well below the threshold for adequately pleading scienter." *Coyne*, 943 F. Supp. 2d at 273 (internal quotation omitted).

Those former employees who did recount meetings attended by the named Executive Defendants still have not recounted facts that suggest fraud or a high degree of recklessness. FE 1 and FE 2's account of the Thanksgiving 2019 Lotus salesforce meeting, for example, allows me to infer only that certain Executive Defendants were aware of early adverse events associated with the Lotus valve and lagging Lotus sales in November of 2019. According to the Complaint, Defendants were still committed to making the Lotus platform a success at this stage; this Thanksgiving meeting was "focused on retraining the sales staff to help prevent the bad outcomes [for] Lotus patients" and teaching sales representatives to sell physicians better on the Lotus valve. Dkt. No. 44. at ¶ 12.

Allegations that various employees at Boston Scientific believed the Lotus platform was beset by fatal flaws is also not compelling; there is no evidence that any of the Executive Defendants shared the views of these nameless former employees. In the 140-page Complaint, Plaintiff has not provided a single contemporaneous statement *from any of the Executive Defendants* to demonstrate their fraudulent intent. *Cf. Crowell* v. *Ionics*,

*Inc.*, 343 F.Supp.2d 1, 5-6, 17-18 (D. Mass. 2004)(suggesting that an allegation that a specific defendant said "I want to go on the record stating it's not proper accounting—but it's nice to make money" during a specific meeting supported a strong inference of fraudulent intent).

*b. Insider Trading Activity*

Plaintiff's insider trading allegations are equally lacking as a basis for scienter. To be sure, insider trading "may offer some support" for an inference of securities fraud, *Fire & Police Pension Ass'n of Colo.*, 778 F.3d at 245-246 (quotations and citation omitted), but only when the trade is so unusual that it goes "well beyond the normal patterns of trading" for a given defendant, *Greebel*, 194 F.3d at 198.

Mr. Mahoney's November 3, 2020 sale was not so unusual or suspicious as to be probative of his scienter. First, this trade was made according to a 10b5-1 trading plan. Use of a prescheduled 10b5-1 plan "negates an inference of scienter." *Leavitt* v. *Alnylam Pharms., Inc.*, 451 F. Supp. 3d 176, 188 (D. Mass. 2020). Mr. Mahoney's plan specified that the earliest date he could sell was October 29, 2020 and the plan was scheduled to terminate on November 6, 2020. The plan-provided shares could only be sold at a price equal to or higher than $35.00 per share. Dkt. No. 55-2 at 11. November 3, the date of the sale, was the first day in the sale period during which Boston Scientific stock reached a value of over $35.00 per

share. The structure of this 10b5-1 plan, even if shorter in duration than Defendants' prior plans, is not so unusual as to raise suspicion.

Plaintiff nevertheless characterizes the timing and quantity of the sales as highly suspicious. On its face, the timing of the sales, does not evince fraudulent intent. It also cannot be said that Mr. Mahoney sold his shares at the height of their value; in fact, Mr. Mahoney's shares had nearly the same value on November 3 as they did on November 17, after it was announced that the Lotus platform had been terminated.[36] Further, Plaintiff has not alleged sufficient information about Mr. Mahoney's trading practices to suggest that the timing, amount, and price of his sales were otherwise highly suspicious. *Leavitt*, 451 F. Supp. 3d at 187–188 ("The plaintiff bears the burden of showing that insider sales were suspicious and must provide a complete picture of the defendant's trading, both before and after the class period."). These facts do not lead me to infer that Mr. Mahoney's acted with fraudulent intent.

As for Defendants Ballinger, Fitzgerald, and Brennan, Plaintiff has not shown that their trading during the Class Period was so unusual or suspicious as to raise an inference of scienter. Plaintiff contends that because these Defendants

[36] Boston Scientific common stock was valued at $35.06 per share on November 3. *Id.* at ¶ 219. It was valued at $35.03 following the Lotus recall on November 17. *Id.* at ¶ 324.

reaped greater proceeds during the Class Period than the control period, their trading warrants suspicion. Those circumstances may warrant some degree of suspicion, but that, however, is not enough. As Defendants point out, Mr. Fitzgerald and Mr. Brennan made their trades through Rule 10b5-1 plans. Mr. Fitzgerald increased his holdings in Boston Scientific over the Class Period, undermining Plaintiff's theory that his advanced knowledge of Lotus's doom led him to sell off his shares before their value declined. Mr. Ballinger made his large sales immediately after leaving his position at Boston Scientific, not an unusual decision as the First Circuit has noted in the past. *Greebel*, 194 F.3d at 206 ("It is not unusual for individuals leaving a company . . . to sell shares.").

*c. The Resignations of Mr. McCarthy and Mr. Ballinger*

Plaintiff has not alleged particularized facts regarding the reason for and timing of either Mr. McCarthy's or Mr. Ballinger's resignation to support a strong inference of scienter. So far as appears, these resignations were not the result of any investigation of fraud or recklessness on the part of these defendants. *Cf. Collier* v. *ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 65, 76 (D. Mass. 2014) (SEC investigation into the company's accounting practices led to an internal audit that "culminated in the resignation" of two key executives and contributed to a strong inference of scienter).

Even if these Executives Defendants resigned to distance themselves from the challenges and disappointments of the Lotus launch, that circumstance does not raise a strong inference that Executive Defendants knew that the Lotus platform was not commercially viable. None of the confidential sources recount statements or reports from Executive Defendants McCarthy or Ballinger that express such knowledge. Their resignations also do not allow me to infer that the Defendants intentionally or recklessly deceived investors.

*d. Boston Scientific's Need to Raise Capital and Renegotiate Its Debts*

Plaintiff contends that Defendants' capital-raise on May 21, 2020 and its efforts to renegotiate its debts in April of 2020 provided a compelling motive to lie to investors, from which I should infer scienter. I reject this contention. The First Circuit has "set a high bar" for a plaintiff seeking to rely upon an inference of scienter based on a defendant's public equity offering during the Class Period. *Kader* v. *Sarepta Therapeutics, Inc.*, 887 F.3d 48, 60 (1st Cir. 2018). The generic claim that Defendants had a motive to inflate stock values before conducting public equity offering, without some other indication of fraud, is not sufficient. *See id.*

Moreover, it must be noted that none of the *actionable* misstatements alleged in the Amended Complaint predate the Defendants' capital-raise and debt renegotiation. Ms. Lisa and

Mr. Fitzgerald offered their allegedly inaccurate account tallies in August and October of 2020 and Mr. Mahoney made his alleged misstatements in September and October. Defendants had already secured their two billion dollars in capital and renegotiated four billion dollars of debt by May 21, 2020. Even if Defendants were motivated to inflate Boston Scientific stock values in advance of the capital raise in this setting, the Defendants would not have been so motivated *after* they successfully raised the desired capital and avoided default on their debts. I can draw no strong inference of scienter on this basis.

*e. Conclusion*

None of Plaintiff's general allegations of scienter, either individually or considered together, give rise to an inference that is "at least as compelling as any opposing inference of nonfraudulent intent". *Tellabs, Inc.*, 551 U.S. at 314. I now turn to whether allegations of misrepresentation, specific to Ms. Lisa, Mr. Fitzgerald, and Mr. Mahoney, can meet the "rigorous" inference standard for scienter. *ACA Fin. Guar. Corp.*, 512 F.3d at 58.

2. Scienter of Ms. Lisa and Mr. Fitzgerald

Ms. Lisa and Mr. Fitzgerald may have given investors *inaccurate* tallies of Lotus accounts but that does not raise a strong inference that they provided *fraudulent* tallies. The Complaint provides no particularized facts upon which to

conclude that Ms. Lisa or Mr. Fitzgerald were aware of the true account tallies but inflated the numbers to reassure investors. That they were executives involved in the Lotus Launch and had access to the company sales dashboard, without more, does not establish that these Defendants intentionally lied to investors. *See In re Wayfair, Inc. Sec. Litig.*, 471 F. Supp. 3d at 344-345.

Although Plaintiff may suggest *an* inference, it is certainly not "strong" nor is it "at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc.*, 551 U.S. at 314. There are multiple explanations for the discrepancy between counts offered by Ms. Lisa and Mr. Fitzgerald, and the statement by Mr. Fitzgerald that the launch only reached 100 accounts. Ms. Lisa and Mr. Fitzgerald could have been operating with inaccurate or outdated information when they made those initial tallies. They could have been referring to a broader category of accounts than just those opened in the United States during the launch. Some of the accounts open in August and October of 2020 may have closed by November 18, when Mr. Fitzgerald noted there were only 100 accounts opened. In the absence of any allegations that Executive Defendants Lisa and Fitzgerald had access to reports and data reflecting only 100 open accounts, I cannot find the high degree of recklessness required to support scienter. Accordingly, Plaintiff has not pleaded scienter as to Ms. Lisa and Mr. Fitzgerald at the time of these statements.

3. Scienter of Mr. Mahoney

As I have already indicated, I do not find Plaintiff's allegations related to Mr. Mahoney's insider trading activity adequate to show scienter. However, Mr. Mahoney's actionable statements are undeniably similar to those held to show scienter in *Carbonite* and raise an inference of scienter on that basis. *Compare* Dkt. No. 44 at ¶¶ 308 ("Lotus will continue to be an important growth driver for us. . . ."); 319 ("[W]e do believe that the two-valve strategy makes sense. . . ."), *with Carbonite*, 22 F.4th at 7, 11 ("[W]e have put something out that we think is just completely competitive and just a super strong product." (alteration in original) (emphasis removed)).

In *Carbonite*, the First Circuit held that defendants had the requisite scienter based on "two specific plugs from top management" despite the product "never once [doing] what it [was] supposed to do," and allegations in the complaint that did not "leave open the possibility that . . . management was somehow in the dark about [its] true status." 22 F.4th at 9, 10. On those facts, there was a "strong inference" that the executive defendants "either inquired about [the product] before deciding to promote it to investors or were reckless in failing to do so." *Id.* at 10. The Court of Appeals contrasted the facts in *Carbonite*, where it was allegedly widely known within the company that the product was defective, with *Vertex Pharmaceuticals, Inc.*, 838 F.3d at 82–83, where the product

received inaccurate positive testing results, but the complaint did not allege that anyone at the company (including experts) "noticed or suspected" that the results as reported were wrong. There were no allegations in *Vertex Pharmaceuticals, Inc.* showing the results were "so obviously suspect" as to warrant a "strong inference that the defendants were reckless in failing to consult the raw data themselves for verification." 838 F.3d at 83.

Plaintiff's allegations fall somewhere in between those at issue respectively in *Carbonite* and *Vertex Pharmaceuticals, Inc.*, but I find that they are sufficient to raise the required strong inference of scienter. Unlike in *Carbonite*, where the product *never* worked, there was a market for Lotus, albeit modest. Dkt. No. 44. at ¶ 105. Similarly, Plaintiff's allegations related to management's awareness of Lotus' shortcomings are not as strong as those in *Carbonite*. However, I am cognizant of my duty "not to scrutinize each [scienter] allegation in isolation but to assess all the allegations holistically." *Tellabs, Inc.*, 551 U.S. at 326. I must ask whether there is an inference of scienter "[w]hen the allegations are accepted as true and taken collectively." *Id.* Taken together, and in light of *Carbonite*, Plaintiff's pleadings sufficiently allege an inference of scienter. *See ACA Fin. Gur. Corp.*, 512 F.3d at 59 ("[W]here there are equally strong

inferences for and against scienter, *Tellabs* now awards the draw to plaintiff." (citing *Tellabs, Inc.*, 551 U.S. at 324)).

Mr. Mahoney, the CEO of Boston Scientific, on two occasions in fall 2020 — shortly before directing discontinuance of the Lotus platform — made specific statements touting Lotus and the two-valve strategy. Dkt. No. 44 at ¶¶ 308, 319. As I discussed *supra* Part III.B.4., Mr. Fitzgerald's November 18, 2020 explanation of the termination of the Lotus platform reasonably construed indicates that the decision was made in fall 2020. Plaintiff does not plead specifically that Mr. Mahoney was party to the decision to terminate the Lotus platform; however, Mr. Mahoney announced the decision to discontinue Lotus, stating that the decision was made "[a]fter much analysis and careful consideration." *Id.* at ¶ 182 (alteration in original). It is not unreasonable to infer that Mr. Mahoney was privy to, or at least aware of, discussions surrounding Lotus during this time period, given his September and October statements plugging the product and his position as CEO of Boston Scientific.

Moreover, the Complaint alleges that the Lotus' limited market share "was documented in internal company records." *Id.* at ¶¶ 104, 105. Accordingly, "nothing in the alleged facts renders less than sufficiently compelling the conclusion that [Mr. Mahoney] would have known of the product's status had [he] inquired." *Carbonite*, 22 F.4th at 10. In light of the preceding, "the [C]omplaint, alleges facts raising a strong

inference that [Mr. Mahoney] either inquired about [Lotus] before deciding to promote it to investors or [was] reckless in failing to do so." *Carbonite*, 22 F.4th at 10.

As the Court of Appeals explained in *Carbonite*, "the relevant point here is not that [Lotus] was the only or the most 'outsized' [Boston Scientific] product." *Id.* at 9. The point is that when a chief executive, like Mr. Mahoney, makes specific remarks on the role of a product in a company's portfolio, there is a "very strong inference" that such an executive "would have paid at least some attention to the product's status." *Id.* I find that, on the facts as pleaded in the Complaint, the inference applies. In summary, Plaintiff has pleaded scienter as to Mr. Mahoney.

Defendants do not dispute the other elements of Plaintiff's Section 10(b) claim, namely reliance, economic loss, and loss causation, however, in the interest of completeness and in anticipation of further proceedings, I will briefly address reliance, economic loss, and loss causation.[37]

***D. Reliance***

Plaintiff invokes the fraud on the market rebuttable presumption under *Basic, Inc.* v. *Levinson*, 485 U.S. 224 (1988)

[37] As to "connection with the purchase or sale of a security," Plaintiff pleaded [Certification Pursuant to the Federal Securities Laws, Dkt. No. 45] many purchases and sales of Boston Scientific stock throughout the class period.

to prove reliance.[38] Dkt. No. 44 at ¶¶ 329–330. I find that Plaintiff has sufficiently pleaded this element.

As the Supreme Court has explained, "[t]he 'traditional (and most direct) way' for a plaintiff to prove reliance is to show that he was aware of a defendant's misrepresentation and engaged in a transaction based on that misrepresentation." *Goldman Sachs Grp., Inc.* v. *Ark. Teacher Ret. Sys.*, 141 S. Ct. 1951, 1958 (2021) (quoting *Halliburton Co.* v. *Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014)). Under *Basic*, however, a plaintiff may prove reliance "by invoking a [rebuttable] presumption that the price of stock traded in an efficient market reflects all public, material information—including material misstatements." *Halliburton Co.*, 573 U.S. at 263. The "fraud-on-the-market theory undergirding" *Basic* is that "an investor presumptively relies on a misrepresentation so long as it was reflected in the market price at the time of his transaction." *SEC* v. *Sargent*, 589 F. Supp. 3d 173, 198 (D. Mass. 2022) (quoting *Erica P. John Fund* v. *Halliburton Co.*, 563 U.S. 804, 813 (2011)).

The rebuttable presumption "has particular significance in securities-fraud class actions." *Amgen, Inc.* v. *Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 462 (2013). It "allows plaintiffs to

[38] Plaintiff also alleges that the presumption in *Affiliated Ute Citizens of Utah* v. *United States*, 406 U.S. 128 (1972) applies. *See* Dkt. No. 44 at ¶ 331. I need not address those allegations because I have not found any alleged omissions actionable.

establish the necessary element of reliance through common proof." *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 25 (1st Cir. 2008). In an efficient market, "the theory goes," prices take into account all public information, "so that an investor who buys or sells stock in reliance on the integrity of the market price is in fact buying or selling stock in reliance on the material misrepresentations." *Id.* At this stage, Defendants do not dispute Plaintiff's assertion that the presumption in *Basic* applies.

***E. Economic Loss and Loss Causation***

To plead loss causation, Plaintiff must have "adequately alleged a causal connection between the [D]efendants' material misrepresentations and the drop in [Boston Scientific's] share price." *Mass. Ret. Sys.* v. *CVS Caremark Corp.*, 716 F.3d 229, 237 (1st Cir. 2013). Said another way, "the stock market must have reacted to the subsequent disclosure of the misconduct and not to a 'tangle of [other] factors.'" *Bricklayers & Towel Trades Int'l Pension Fund* v. *Credit Suisse Sec. (USA) LLC*, 752 F.3d 82, 86 (1st Cir. 2014) (alteration in original) (quoting *Dura Pharms., Inc.* v. *Broudo*, 544 U.S. 336, 343 (2005)). Plaintiffs typically allege[39] loss causation by

[39] It is up for debate whether the Rule 9(b) pleading standard applies to loss causation. *See Coyne*, 943 F. Supp. 2d at 273–74 (describing Circuit split regarding proper pleading standard for loss causation). In *Coyne* I applied the Rule 9(b) standard, and

> (1) identifying a 'corrective disclosure' (a release of information that reveals to the market the pertinent truth that was previously concealed or obscured by the company's fraud); (2) showing that the stock price dropped soon after the corrective disclosure; and (3) eliminating other possible explanations for this price drop, so that the factfinder can infer that it is more probable than not that it was the corrective disclosure . . . that caused at least a 'substantial' amount of the price drop.

*Mass. Ret. Sys.*, 716 F.3d at 237–38 (quoting *FindWhat Inv. Grp.* v. *FindWhat.com*, 658 F.3d 1282, 1311–12 (11th Cir. 2011)). A corrective disclosure "must *connect* the current, present, negative information to the earlier false or misleading statement." *Coyne*, 943 F. Supp. 2d at 273 (internal citations omitted). Accordingly, "[i]f [p]laintiff's loss resulted from the disclosure of negative information other than a prior false or misleading statement by the Defendants, then she cannot show that Defendants' conduct caused her injury and she has not pled an adequate claim for securities fraud." *Id.*

Here, Plaintiff's allegations fall into the "inflation-disclosure-deflation cycle," whereby "loss causation may be established, provided the disclosure is sufficiently connected to the misstatement or omission." *Miller Inv. Tr.* v. *Morgan Stanley & Co., LLC*, 308 F. Supp. 3d 411, 445 (D. Mass. 2018).

1. The Alleged Corrective Disclosures

Plaintiff alleges two corrective disclosure events: (1) the

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I proceed in the same manner here. *Id.* at 274; *see also Miller Inv. Tr.* v. *Morgan Stanley & Co., LLC*, 308 F. Supp. 3d 411, 445 (D. Mass. 2018).

October 15, 2020 statement that Lotus Edge would not receive an intermediate risk indication from the FDA until 2024, delaying the expansion of Lotus Edge's market from high risk patients to intermediate risk patients, *see* Dkt. No. 44 at ¶¶ 86, 172, and (2) the November 17, 2020 Lotus Edge recall announcement, *id.* at ¶ 324.

As a threshold matter, Plaintiff has alleged economic loss. *See id.* at ¶ 324 (summarizing declines in share price following each corrective disclosure). However, Plaintiff has only demonstrated a causal connection between the loss and the actionable misstatements as to the November 17, 2020 corrective disclosure.

Mr. Mahoney's statements on September 16 and October 28, 2020 are the only actionable statements made with scienter. Those statements emphasize Lotus' role as "an important growth driver," and the benefits of the two-valve strategy. *See id.* at ¶¶ 307, 308, 319. The first alleged corrective disclosure, on October 15, 2020, relates to the timeline for Lotus' intermediate risk indication, not whether Lotus will be a "growth driver" or whether the two-valve strategy "makes sense." Although the corrective disclosure "need not be a mirror-image" or "direct admission that a previous statement is untrue," it "must relate *to the same subject matter* as the alleged misrepresentation." *Mass. Ret. Sys.*, 716 F.3d at 240 (emphasis added) (internal citations and quotations omitted). The alleged

corrective disclosure on October 15, 2020 relates to the intermediate risk indication for Lotus, not the future of Lotus within Boston Scientific's TAVR portfolio, which is the subject matter of the actionable misstatements. Accordingly, Plaintiff cannot plead loss causation on this ground.

In contrast, the November 17, 2020 recall announcement is related to the same subject matter as the actionable misstatements. When Defendants announced Lotus' recall on November 17, 2020, Mr. Mahoney explained that "[Boston Scientific] [could] better serve [its] patients by prioritizing and focusing our financial and employee resources on [a] one-valve platform," Dkt. No. 44 at ¶ 182, clearly indicating that the two-valve strategy did *not* "make[] sense" and Lotus would *not* drive growth, *id.* at ¶¶ 308, 319. The recall announcement at least "partially disclosed what the alleged misrepresentations had concealed from the market." *Omanoff* v. *Patrizio & Zhao LLC*, No. 14-723, 2015 WL 1472566, at *6 (D.N.J. Mar. 31, 2015) (quoting *In re Bradley Pharms., Inc. Sec. Litig.*, 421 F. Supp. 2d 822, 829 (D.N.J. 2006)).

2. Additional Loss Causation Considerations

Plaintiff has adequately pleaded that "the stock price dropped soon after the corrective disclosure" on November 17, 2020. *Mass. Ret. Sys.*, 716 F.3d at 237 (citation omitted); *see* Dkt. No. 44 at ¶¶ 192, 324. Plaintiffs have also, as alleged, "eliminat[ed] other possible explanations for this price drop."

*Mass. Ret. Sys.*, 716 F.3d at 238 (citation omitted). In the Complaint, Plaintiff described in detail the questions analysts asked following the announcement on November 17, 2020, as well as articles[40] published after the announcement, which all centered on the decision to terminate the Lotus platform. *See* Dkt. No. 44 at ¶¶ 182–191. As alleged, "[I] can infer that it is more probable than not that it was the corrective disclosure. . . that caused at least a 'substantial' amount of the price drop." *Mass. Ret. Sys.*, 716 F.3d at 238 (citation omitted).

3. Conclusion

Plaintiff's allegations adequately pleaded loss causation and economic loss, though only as to the alleged corrective disclosure on November 17, 2020 based on the alleged misstatements in the Complaint that I have found actionable.

***F. Whether Boston Scientific May Be Held Liable***

Having determined that Executive Defendant Mahoney, the Chairman, President, and Chief Executive Officer of Boston Scientific, has violated Section 10(b), I now turn to whether Boston Scientific may be held liable also. I look to the

[40] Plaintiff, for example, points to one article, allegedly published in *Mass Device* on November 17, 2020, that described the disclosure and recall, noting that the decision "set[] the company back after it **was expected that Lotus Edge would be a 'major growth engine.'**" Dkt. No. 44 at ¶ 191 (emphasis added). This language clearly mirrors Mr. Mahoney's actionable statements.

principles of agency when considering whether Mr. Mahoney's actions and scienter can be imputed to Boston Scientific. *See In re ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d 471, 475 (9th Cir. 2015); *cf. SEC* v. *Tropikgadget FZE*, 146 F. Supp. 3d 270, 280 (D. Mass. 2015) (explaining in the context of a civil enforcement action under Section 10(b) that "[a]lthough a corporate entity is not capable of intent, the knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation, and the scienter of executives can be imputed to corporate entities for purposes of claims arising under the federal securities laws" (internal citations and quotations omitted)).

Mr. Mahoney "was hardly a random corporate bureaucrat or mid-level manager. He was [Boston Scientific's] . . . CEO" and he made material misrepresentations with the requisite scienter. *In re ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d at 479; *see also Makor Issues & Rts., LTD.* v. *Tellabs Inc.*, 513 F.3d 702, 708 (7th Cir. 2008) ("A corporation is liable for statements by employees who have apparent authority to make them.") (citing *In re Atl. Fin. Mgmt., Inc.*, 784 F.2d 29, 31-32 (1st Cir. 1986)). Under these circumstances, Plaintiff has adequately pleaded that Boston Scientific, acting through Executive Defendant Mahoney, violated Section 10(b).[41]

[41] To plead a Section 10(b) claim against a corporate entity, Plaintiff must show "that the pleaded facts . . . create a

***G. Summary***

Plaintiff has alleged a Section 10(b) violation as to Mr. Mahoney and Boston Scientific, though only on the limited basis of Mr. Mahoney's misrepresentations regarding Lotus' status as a "growth driver" and the two-valve strategy's role for Boston Scientific.

## IV. COUNT II - VIOLATION OF SECTION 20(a)

Because Plaintiff successfully pleaded a Section 10(b) violation, I now turn to Plaintiff's second claim, which alleges a violation of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) by the Executive Defendants as "controlling person[s]." *See Mehta*, 955 F.3d at 211 (explaining that a Section 20(a) claim is "derivative" of the Section 10(b) claim).

Section 20(a) "establishes liability for any person who 'directly or indirectly[ ] controls any person liable' for a violation of securities laws." *Miss. Pub. Emps.' Ret. Sys.* v. *Boston Sci. Corp.*, 523 F.3d 75, 93 (1st Cir. 2008) (alteration in original) (quoting 15 U.S.C. § 78t(a)). To plead a violation

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strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." *Teamsters Local 445 Freight Div. Pension Fund* v. *Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008). The Second Circuit has explained that "the most straightforward way to raise such an inference for a corporate defendant will be to plead it for an individual defendant." *Id.* Because the pleaded allegations support a Section 10(b) claim against Mr. Mahoney, an Executive Defendant whose scienter could be imputed to Boston Scientific, Plaintiff has sufficiently alleged that Boston Scientific may also be held liable.

of Section 20(a), Plaintiff must show "(i) an underlying violation of the same chapter of the securities laws by the controlled entity . . . and (ii) control of the primary violator by the defendant." *In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 194 (1st Cir. 2005).

In *Aldridge* v. *A.T. Cross Corp.*, 284 F.3d 72 (1st Cir. 2002), the First Circuit explained that the Circuits are split as to whether a plaintiff must also allege that "defendants are in a meaningful sense culpable participants in the fraud in question." *Id.* at 84–85. That question remains unsettled in the First Circuit. *See Dahhan* v. *OvaScience, Inc.*, No. 1:17-cv-10511-IT, 2021 WL 2186466, at *6 n.5 (D. Mass. May 28, 2021). In the absence of direct guidance from the First Circuit my colleague, Judge Tauro, required "culpable participation" to survive a Rule 12(b)(6) motion to dismiss. *See id.*; *see also Akamai Techs., Inc.* v. *Deutsche Bank AG*, 764 F. Supp. 2d 263, 266 (D. Mass. 2011); *Special Situations Fund III, L.P.* v. *Am. Dental Partners, Inc.*, 775 F. Supp. 2d 227, 246-247 (D. Mass. 2011).

Here, "Defendants have challenged only the first element [of Section 20(a)]: an underlying violation of the securities laws by the controlled entity." *Special Situations Fund III, L.P.*, 775 F. Supp. 2d at 247. Defendants' sole contention is that Plaintiff's purported failure to plead a Section 10(b) claim successfully precludes Section 20(a) liability. *See* Dkt.

No. 54 at 17. But I have found to the contrary that Plaintiff has pleaded violations of Section 10(b) by Mr. Mahoney and Boston Scientific. *See supra* Parts III.C.3. and F. Accordingly, I need not determine whether any of the other Executive Defendants were culpable participants because that question is not before me. Cognizant of the First Circuit's direction that "[c]ontrol is a question of fact that will not ordinarily be resolved summarily at the pleading stage" because it "raises a number of complexities that should not be resolved on such an underdeveloped record," *In re Cabletron Sys., Inc.*, 311 F.3d at 41 (internal citations and quotations omitted), and the parties' limited argument on the Section 20(a) claim, I will DENY Defendants' motion to dismiss [Dkt. No. 53] as to Count II of the Complaint.

## V. CONCLUSION

For the reasons set forth above, I GRANT in part and DENY in part Defendants' Motion [Dkt. No. 53] to Dismiss; specifically, I GRANT Defendants' Motion to Dismiss as to Count I, except as alleged against Mr. Mahoney and Boston Scientific because Plaintiff has alleged misrepresentations involving a strong inference of fraudulent scienter as to those Defendants and I DENY Defendants' Motion to Dismiss as to Count II, the Section 20(a) claim against the Executive Defendants.

In light of this disposition of the motion to dismiss, this case now moves to the stage of factual development in anticipation of class certification and summary judgment practice. In order to frame the next stage of this litigation, the parties shall meet and confer with a view toward presenting a proposed schedule for such proceedings. The parties shall file their proposed schedule — jointly, if possible; separately, if deemed necessary to preserve perceived concerns for a resolution that can only be provided by court intervention — on or before noon on January 20, 2023. The parties shall appear in person in Courtroom 1 on Monday, January 23, 2023 at 2:30 p.m. for a scheduling conference to establish the schedule for the next stage of these proceedings.

***/s/ Douglas P. Woodlock***
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

**APPENDIX A**[42]

**ALLEGED EXECUTIVE DEFENDANT MISSTATEMENTS**

**Mr. Mahoney**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 1. "We believe there will be adequate demand for Lotus in the marketplace . . .So we think the market's there." | 2/6/19 | ¶237 |
| 2. "[The Launch] will be smartly planned, delivering excellent outcomes . . . ." | 2/6/19 | ¶238 |
| 3. "We believe Lotus Edge is a differentiated valve that will be sought after by physicians and operators, both as a workhorse valve as well as a valve that can be counted on to provide superior outcomes in complex cases . . . ." | 4/24/2019 | ¶240 |
| 4. "I think in the U.S., we're very confident in the capabilities of the Lotus valve. . . . [S]o you'll see Lotus priced at competitive rates with the market in the U.S." | 4/24/19 | ¶241 |
| 5. The Lotus launch "is going well." | 5/29/19 | ¶243 |
| 6. "The Lotus Edge controlled launch is going extremely well. Positive physician feedback highlights the benefit of complete control and drama free TAVR." | 7/24/19 | ¶245 |

[42] Defendants identified seventy-five alleged misstatements in Exhibit B [Dkt. No. 54-2] filed in support of their motion [Dkt. No. 53] to dismiss. Some of those misstatements are attributed to individuals not named as Defendants, appear to be the result of fractionated versions of the statements reported, or refer to company documents. This Appendix to this Memorandum and Order sets forth only alleged misstatements made by the named Executive Defendants.

| Statement Excerpt | Date | Cite |
|---|---|---|
| 7. "We are on pace to open the 150 accounts in the first 12 months that we cited in Investor Day. . . .[W]e're very confident that our launch approach will position both Lotus Edge and our entire structural heart portfolio for long term leadership in this substantial market." | 7/24/19 | ¶245 |
| 8. "You'll see greater acceleration of Lotus Edge, which we're very pleased with the initial results, over the second quarter." | 7/24/19 | ¶246 |
| 9. "On Lotus, really pleased. We're essentially delivering per our commitment. The 150 accounts that we expect to open, we're on track to deliver that." | 7/24/19 | ¶246 |
| 10. "I would say doctors are pleasantly surprised by the unique features that it delivers.. . . It's delivering on its promise. | 7/24/19 | ¶246 |
| 11. "[W]e're really focused on quality, strong patient outcomes, and proctoring." | 7/24/19 | ¶246 |
| 12. "And we're in this for the long run with two valves. And [we're] going to deliver as planned our financial commitment and the rollout of Lotus." | 7/24/19 | ¶246 |
| 13. "[Lotus] is going very well ....We're seeing very high reorder rates of LOTUS, and the launch really is going as planned as adjusted in 2019.... So, we're seeing strong reorder rates with it." | 9/5/19 | ¶251 |
| 14. Boston Scientific was conducting a "deliberate" and "controlled" launch of the Lotus Edge. | 9/5/19 | ¶253 |
| 15. "The [Lotus] Edge launch is going extremely well and we're building momentum in both the US and Europe....We remain on pace to open 150 accounts in our first 12 months in the US." | 10/23/19 | ¶260 |

| Statement Excerpt | Date | Cite |
|---|---|---|
| 16. "[T]he outcomes with [Lotus] have been very favorable.... And we're really on track with our opening the 150 accounts really per our plan." | 10/23/19 | ¶261 |
| 17. [Form 10-Q for 3rd quarter 2019, which Mr. Mahoney certified] "[Y]ear-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies, including . . . Lotus Edge." | 11/5/19 | ¶265 |
| 18. "[I]n TAVR, we're very pleased with the Lotus Edge launch and growth." | 1/14/20 | ¶277 |
| 19. "[W]e continue to be pleased with the launch and progress of Lotus Edge and remain on track to open 150 accounts in the first 12 months post-approval...." | 2/5/20 | ¶279 |
| 20. "Lotus is doing very well in the market. It's kind of on plan for 150 accounts." | 2/5/2020 | ¶280 |
| 21. [Form 10-K for 4th quarter certified by Mr. Mahoney] "This year-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies...." | 2/25/20 | ¶284 |
| 22. "[W]e're essentially on our planned goals on Lotus of 150 accounts open in the first year." | 3/11/20 | ¶296 |
| 23. "Lots of focus on training in the U.S.... [M]any doctors are enjoying the benefit of Lotus, and we continue to get kind of smarter and better as we proctor new physicians in the U.S." | 3/11/20 | ¶296 |
| 24. "[Post-COVID] we do look forward to the recovery in procedure volumes." | 4/29/20 | ¶299 |

| Statement Excerpt | Date | Cite |
|---|---|---|
| 25. "Lotus Edge continues to see strong utilization within existing accounts .... [W]e expect to get back to our regular cadence of account openings in the U.S. and continue our launch in Japan in second half of 2020." | 7/29/20 | ¶301 |
| 26. "[T]he current centers are using the device quite consistently." | 7/29/20 | ¶302 |
| 27. "[W]e are starting to see the gates open up a bit more in terms of new account openings with Lotus...." | 7/29/20 | ¶303 |
| 28. "[C]ertainly Lotus will continue to be an important product for us .... And so, Lotus will continue to be an important growth driver for us supported with our whole platform with Acurate neo2. ... So, overall, Lotus remains a key growth driver for us. And we're not going to give share [] estimates, but we're continuing to invest along those lines." | 9/16/20 | ¶308 |
| 29. "We're starting to do more account openings, the reorder rate for existing users is quite high, and we're slowly beginning to penetrate some new accounts with some new training. So, Lotus is important for us, but we have other tailwinds to support the company." | 9/16/20 | ¶308 |
| 30. "We're very confident in the performance of the [Lotus] device, the infrastructure that we have around it." | 9/16/20 | ¶309 |
| 31. [Q3 earnings call question regarding whether dual valve strategy "make[s] sense"] "[W]e're seeing strong results in the sites that are using Lotus in the U.S....So we do believe that the two-valve strategy makes sense...." | 10/28/20 | ¶319 |

**Mr. Ballinger**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 32. "The engineers have done a really good job making something that is very complex feel really simple for the end-users." | 2019 | ¶226 |
| 33. "[T]he early stages of the launch is now going very, very well.... [And is] on track to open 150 accounts." | 9/27/19 | ¶255 |
| 34. "And so we purposely, over the course of the summer, were more in a self-constrained, limited market evaluation mode.... We've launched about the number of accounts that we think is appropriate to ensure that we do exceptional proctoring, training...." | 9/27/19 | ¶256 |
| 35. "[Lotus] is not a complicated device and it actually takes stress out of the procedure." | 9/27/19 | ¶258 |

**Ms. Lisa**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 36. "[Y]ou are seeing kind of out of the gate site[s] trying [Lotus] in their most complex patients.... So back to ensuring terrific outcomes, that's another reason for the controlled launch. And then over time, it is a workhorse valve making sure that that's the role that it takes over." | 9/5/19 | ¶253 |
| 37. "[W]e're really pleased with how the launch is going. We've talked extensively about it being a limited market release. It's training of centers because it's a new method of deployment." | 11/12/19 | ¶267 |
| 38. "We are on target to get to 150 centers we talked about opening in the US by Q1 of 2020." | 11/12/19 | ¶267 |

| Statement Excerpt | Date | Cite |
|---|---|---|
| 39. "We have talked about a limited market release, taking our time to get to 150 accounts in the first year of launch to make sure that everything is proctored and trained because it's a different – it's not harder." | 11/14/19 | ¶269 |
| 40. "[W]e are really encouraged by the initial uptake.... We think that physicians understandably were skeptical....And we've seen them I think being really pleased with the results...." | 12/4/19 | ¶274 |
| 41. "We're pleased with that pace of opening accounts because the order rates we[']re see[ing], and then most importantly with the outcomes and the clinical aspects to how the valve is performing." | 12/4/19 | ¶274 |
| 42. "Lotus Edge launching in the US and Europe this year is a big driver." | 12/5/19 | ¶275 |
| 43. "[W]e're really pleased with how the Lotus launch is going. .... [W]e said we're on track to launch into 150 accounts in the US, one year in, so that'd take us to the end of Q1 of 2020....So, pleased with how Lotus is going." | 12/5/19 | ¶275 |
| 44. "I think that we're really excited about Lotus Edge and how it's going and the opportunity in front of it. And with respect to where we're gaining share, we are seeing conversion from both the competitors in the U.S. market." | 2/27/20 [date corrected] | ¶286 |
| 45. "So we're on track we said to hit 150 centers opened in the first year...." | 2/27/20 [date corrected] | ¶287 |
| 46. [An analyst's question was directed to Ms. Lisa and her Director of Investor Relations, Lauren Tengler. Ms. Tengler answered.] "So, we're on track pre-COVID and we hit 138 accounts. And so, you can expect our work to be similar in the next 12 months." | 8/19/20 | ¶305 |

**Mr. Fitzgerald**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 47. "Combined with the Lotus Edge . . . the Acurate neo2 valve represents the natural evolution of our complementary dual-valve TAVI toolkit." | 9/28/20 | ¶311 |
| 48. "[I'm] really excited about [Boston Scientific's] ability [to] continu[e] our Lotus Edge launch in the U.S. and Japan and getting neo2 launched...." | 10/15/20 | ¶313 |
| 49. "I'm proud to announce that we have opened more than 150 accounts in the U.S." | 10/15/20 | ¶314 |
| 50. "I like what I see in terms of us being now in 150 accounts in United States. I think our launches, I know our launch is gaining momentum." | 10/15/20 | ¶316 |
| 51. "This is now a ground game where we are expanding our footprint in the US, each month we're growing actual procedures per center, per month." | 10/15/20 | ¶316 |

**Mr. Brennan**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 52. [Form 10-Q for 3rd quarter 2019, which Mr. Brennan certified] "[Y]ear-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies, including . . . Lotus Edge." | 11/5/19 | ¶265 |
| 53. "[B]oth valves [Lotus and Acurate] can operate in workhorse valve territory .... It's playing out well in Europe and we're excited to bring it to the U.S." | 11/19/19 | ¶271 |
| 54. "[W]e would expect that Lotus, as we continue to go at a controlled rollout pace and enter new accounts, will continue to grow." | 11/19/19 | ¶271 |
| 55. "[A]s you look at the Lotus launch, that's obviously a very controlled rollout that we've had and that should gain momentum over time." | 2/5/20 | ¶281 |

| Statement Excerpt | Date | Cite |
|---|---|---|
| 56. [Form 10-K for 4th quarter certified by Mr. Brennan] "This year-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies...." | 2/25/20 | ¶284 |
| 57. "[O]ur successes should be built on the momentum that we have with the launches [including] Lotus in the U.S., Lotus in Europe." | 3/3/20 | ¶291 |
| 58. "[Q]ualitatively, we're on track for the 150 centers by the end of Q1. And the whole tenet of that launch is then to make sure that it is controlled, with great outcomes for physicians and patients. That's all going well." | 3/3/20 | ¶292 |
| 59. "It's been more kind of slow and steady as you go through it, right. There's a heavy emphasis on proctoring and making sure that folks are 100% able and ready to use the valve." | 3/3/20 | ¶292 |
| 60. "So this is all about making sure that everybody is proctored, ready to go. And I think the slow and steady wins the race, you'll see that continue to go." | 3/3/20 | ¶293 |

**Mr. McCarthy**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 61. "[W]e believe we're offering unmatched control and predictability. It's designed to give physicians what they want on the table acutely, but also give patients what they need over time, the chronic long-term solutions." | 6/26/19 | ¶244 |
| 62. "So, of course, we'll want to make sure we're doing the exact work we will as a world-class organization to train physicians to use and reuse the technology. So, our focus will be to launch in roughly 150 accounts within the first 12 months of launch ... Early indications I would suggest are very positive." | 6/26/19 | ¶244 |

**Dr. Meredith**

| Statement Excerpt | Date | Cite |
|---|---|---|
| 63. "So, the limited market release is going very well. It's on track and the plans haven't changed thus far.... But the rollout of Lotus Edge of course is a planned controlled release. And in the short term, it will be determined by training." | 10/23/19 | ¶263 |