UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re BOSTON SCIENTIFIC CORPORATION SECURITIES LITIGATION	Master File No.: No. 1:20-cv-12225-DPW CLASS ACTION AMENDED CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Page

I. PRELIMINARY STATEMENT 2

II. JURISDICTION & VENUE 10

III. THE PARTIES 11

A. Lead Plaintiff 11

B. Defendants 11

IV. BACKGROUND AND OVERVIEW OF DEFENDANTS' FRAUD 14

A. Boston Scientific's Structural Heart Business And The Promise Of 7 To 9% Organic Growth 14

B. Before The Start Of The Class Period, Transcatheter Aortic Valve Replacement Becomes The Standard Of Care And Boston Scientific Races To Catch Up To Competitors 16

C. Boston Scientific Seeks A Toehold In The Burgeoning TAVR Market With the Lotus Valve, Touted As A "Fully Repositionable Device" With Unmatched "Ease of Use" 19

D. Boston Scientific Issues Several Recalls Of The Lotus Due To The Malfunctioning Of Its Delivery System But Assures Investors It Had Remedied The Problem 23

E. Boston Scientific Continues to Reassure Investors About The Lotus Edge After Announcing Acquisition of "Complementary" Symetis TAVR Platform And The Company's Dual Valve Strategy 27

F. Boston Scientific Announces Another Lotus Delay, Again Pointing To Manufacturing "Validation Challenges" 28

G. Boston Scientific Resolves Long-Running TAVR Patent Litigation And Prepares Lotus Edge for Worldwide Commercial Launch 31

H. With The String Of Setbacks Purportedly Behind Them, At the Start of the Class Period, Defendants Commercially Launch The Lotus Edge And Tout Progress In Obtaining 150 Accounts 32

I. Unknown To Investors, Boston Scientific Never Fixed the Problems With The Device, Did Not Come Close To Opening 150 Accounts, And Embarked On A Reckless And Clinically Unsafe Product Launch 38

J. Prior to the Start of the Class Period, Boston Scientific Identified That The Market For Lotus Edge Was A Fraction Of What Defendants Publicly Claimed And Unsuitable For The Vast Majority Of TAVR Candidates 39

K. Rather than Offer "Ease of Use," The Executive Defendants Knew The Lotus Edge Was Incredibly Difficult to Use And Its Complexity Led To The Very Patient Outcomes the Device Was Supposed to Avoid 41

L. Boston Scientific Works To Develop A Replacement For The Lotus Edge Because The Device Was Difficult To Use And Unsuitable For The Vast Majority Of TAVR Patients 48

M. Defendants' Statements to Investors Were "Deceiving" Because, In Truth, Lotus Edge Sales Were "Struggling," There Was "No Organic Growth," and "No One Ordering the Product" 51

N. The Executive Defendants Convened An Emergency Meeting Of The Entire Lotus Edge Sales Force Over The Thanksgiving Weekend In 2019 Because The Launch Was In Crisis 54

O. The Lotus Edge Never Achieved Acceptable Manufacturing Yield Rates, A Viable Commercial Production State, Or Sustainable Profit Margins 55

P. After Receiving "No Re-Orders" In 2019, Boston Scientific Shuts Down A Key Lotus Edge Manufacturing Facility 57

Q. After Key Lotus Executives Depart The Company And Boston Scientific Secretly Concludes The Franchise Is Doomed, The Company Renegotiates Its Debt and Raises Over $2 Billion from Public Investors 58

R. After Boston Scientific Secretly Implements the Plan To Shutdown The Lotus Franchise, Defendant Mahoney Unloads $9 Million of His Personally Held Shares While Touting Lotus As An "Important Growth Driver" 64

S. Boston Scientific Raises Questions About The Lotus Edge By Revealing That Trial Enrollment Slowed But Falsely Claims That The Company Had "Opened More Than 150 Accounts In The U.S." 66

T. Defendants Stun Investors By Disclosing That Boston Scientific Was Recalling the Lotus Edge, Shutting Down the Business, And Abandoning the Two-Valve TAVR Strategy 71

V. POST-CLASS PERIOD EVENTS AND ADMISSIONS 75

A. Following The Lotus Recall, Defendants Are Unable To Answer Analysts' Repeated Questions About The Drastic About-Face For Lotus And Admit That Boston Scientific Never Achieved 150 Accounts 75

B. The SEC Initiates An Investigation Into Boston Scientific's Lotus Disclosures 78

VI. ADDITIONAL ALLEGATIONS OF SCIENTER 78

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS 91

A. Defendants Tout The Lotus Edge's "Ease of Use" While Concealing That Physicians Were Rejecting The Device Because It Was Extraordinarily Difficult To Use 91

B. Defendants Tell Investors They Are Conducting A Successful "Controlled" Launch To Ensure "Terrific" Patient Outcomes While Concealing That Egregiously Inadequate Training Led To Patient Injuries And Deaths 96

C. Defendants Continue To Tout The Launch's Success Even As the Company Missed Sales Targets, Had "Zero Orders," And Convened An Emergency Companywide Sales Meeting Because The Franchise Was In Crisis 106

D. Defendants Falsely Tout The Company's "Steady" Progress In Securing 150 Accounts In Order To Renegotiate Boston Scientific's Credit Agreements And Raise $2 Billion from Public Investors 112

E. Defendants Falsely Declare That Boston Scientific Had Secured 150 Accounts In the United States And That The Lotus Edge Continued To "Gain Momentum" 123

F. Defendants' False Statements About Boston Scientific's Financial Results 125

VIII. LOSS CAUSATION 126

IX. PRESUMPTION OF RELIANCE 128

X. THE STATUTORY SAFE HARBOR DOES NOT APPLY TO DEFENDANTS' FALSE AND MISLEADING STATEMENTS 129

XI. CLASS ACTION ALLEGATIONS 131

XII. COUNTS 133

XIII. PRAYER FOR RELIEF 135

Lead Plaintiff Union Asset Management Holding AG ("Union" or "Lead Plaintiff"), by its undersigned counsel, brings this action for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5, against Defendants Boston Scientific Corporation ("Boston Scientific" or "BSX"), Michael Mahoney ("Mahoney"), Shawn McCarthy ("McCarthy"), Ian Meredith ("Meredith"), Joseph Fitzgerald ("Fitzgerald"), Kevin Ballinger ("Ballinger") and Susan Vissers Lisa ("Lisa"). Lead Plaintiff brings these claims on behalf of a class of investors who purchased or otherwise acquired Boston Scientific common stock from February 6, 2019 through November 16, 2020, inclusive (the "Class Period") and were damaged thereby.

Lead Plaintiff alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff's information and belief as to allegations concerning matters other than themselves and their own acts are based upon the investigation of Lead Plaintiff and its counsel, including (1) review and analysis of documents filed publicly by Defendant Boston Scientific with the SEC; (2) Boston Scientific press releases and other public statements; (3) transcripts of Boston Scientific investor conference calls; (4) research reports by financial analysts and news reports concerning Boston Scientific; (5) other publicly available sources as described below; (6) consultations with relevant experts and consultants; and (7) communications with and review of documents from former employees of Boston Scientific and other sources. Lead Plaintiff's investigation into the factual allegations contained in this complaint is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations in this complaint after a

reasonable opportunity for discovery.

I. PRELIMINARY STATEMENT

1. This case arises from a series of material misrepresentations by the senior executives of Boston Scientific, about the device that represented the "biggest investment" the Company had made in recent years—the Lotus Edge—which they touted as the most promising revenue driver in the Company's most important and fastest-growing division.

2. The Lotus Edge is a device used to treat a form of heart disease called aortic stenosis, a chronic and progressive disease condition that can result in heart failure and death impacting over one in eight people over age 75. While aortic stenosis has been historically treated through artificial valve replacement accomplished through open heart surgery, over the past two decades, a procedure called transcatheter aortic valve replacement ("TAVR") has become the primary standard of care. Given the prevalence of the condition and the increasing uses of these procedures, the expected TAVR market was estimated to be approximately $8 billion at the start of the Class Period. In order to capitalize on this growing field, Boston Scientific would have to compete with two other manufacturers—Edwards Lifesciences and Medtronic—that manufactured two separate TAVR devices that held a dominant position in the TAVR market by the beginning of the Class Period.

3. To differentiate its device, Boston Scientific marketed the Lotus Edge as providing physicians with unique advantages over the devices sold by Edwards and Medtronic. Specifically, Boston Scientific touted the Lotus Edge as being the only "fully repositionable" TAVR device that provided surgeons with the ability to recapture and reposition the device during the TAVR procedure—a feature that was supposed to result in better patient outcomes by, among other things, enabling the surgeon to implant the valve only after the appropriate "seal" had been established. As Defendants told investors during the Class Period, the Lotus Edge purportedly offered

"physicians a unique ease of use feature," as it was "fully recapturable and 100% recapturable and deployable after deployment," and that "this precise predictable placement with Lotus…gives the physician total control."

4. Before its commercial launch at the beginning of the Class Period, the Lotus Edge and its predecessor, the "first generation" Lotus, faced a series of setbacks. Specifically, the Lotus device, which had had been approved for sale in Europe, was subject to three separate recalls needed to address what the Company claimed were "technical" issues that developed during the manufacturing process. By the start of the Class Period, however, Defendants reassured investors that the prior problems with the Lotus had been "fixed," and that the device was poised to be a "workhorse" valve capable of capturing 25% of the TAVR market.

5. To convince investors Lotus would deliver on this promise, Defendants publicly announced a target of securing 150 Lotus accounts—or about one-quarter of the total TAVR centers in the United States—within the first year of its approval by the FDA in April 2019. That milestone was a critical metric for investors who were focused on the performance of the device, its adoption by surgeons, and Boston Scientific's ability to compete with Medtronic and Edwards.

6. During virtually every investor conference call during the Class Period, Boston Scientific and its senior executives told investors the Lotus Edge was increasingly adopted by physicians. For example, Boston Scientific's senior executives told investors that the Company was "on track" to achieve this 150-account target, that the re-order rates by physicians were "strong," "very high," and growing, and that the product had been gaining momentum and had meaningfully contributed to the impressive 50% year-over-year revenue growth the Company reported in its Structural Heart division. In doing so, the Company also repeatedly underscored

that it had taken a "deliberate" and "controlled" approach to the launch in order to ensure "everything is proctored and trained" properly and safely to ensure the best patient outcomes.

7. Those representations and Lotus's success became all that more critical to investors as the pandemic began to impact device sales in the first quarter of 2020. While Boston Scientific initially reported a slowdown in Lotus sales purportedly triggered by the difficulties in conducting in-person physician training sessions, Boston Scientific's executives assured investors that the Company had successfully navigated the pandemic, and that Boston Scientific had in fact met and exceeded its goal to secure 150 U.S. Lotus accounts.

8. Contrary to Defendants' public statements, however, in reality, the Lotus launch was a disaster. As recounted by former Boston Scientific employees, the Company's statements about the Lotus launch were "deceiving" because, in truth, sales were struggling from the start. These former Boston Scientific sales representatives reported that the Company was missing sales targets by over 50% in 2019 and, after Lotus targets were cut by 25% every quarter, sales continued to come in 25% short of those reduced targets every quarter. Thus, former Boston Scientific employees reported that, rather than seeing "very high" and "strong" reorders, in truth, management "freaked out" because the reorders "just weren't coming in" and "there was just really no one ordering more product based on usage so there was no organic growth in the sales."

9. Moreover, rather than take a careful and "controlled" approach to ensure the best possible training, proctoring and patient outcomes, in truth, the launch was "clinically unsafe" because Boston Scientific clinical and sales staff were woefully ill-equipped to oversee Lotus Edge cases. As recounted by one former employee, clinical and sales staff for the Lotus Edge were only required to attend, at most, 25 Lotus Edge procedures before being certified to oversee Lotus Edge procedures on their own—whereas competitors Medtronic and Edwards required representatives

to handle twice to three times as many procedures (50 to 75) before being certified to oversee procedures involving their TAVR devices. Not only did a large percentage of the Lotus sales staff not have any prior TAVR experience whatsoever, the Lotus Edge was totally unlike Medtronic and Edwards' devices, which were simple and easy to use compared to the Lotus Edge—which was in reality the "most complicated device on the planet." As a result of this poor training and the complexity of the device, Lotus Edge procedures resulted in alarming numbers of adverse events—including scores of patient deaths and other life-threatening injuries—that the Executive Defendants closely tracked.

10. In fact, while Defendants were touting the purported "ease of use" of the Lotus Edge device, the Company was at the same time developing an alternative TAVR device to replace the Lotus Edge precisely because it was incredibly difficult to use. In fact, one former Boston Scientific engineer reported that the Company was scrambling to develop a replacement for the Lotus Edge during the Class Period because it took "three hands to operate"—when surgeons obviously only have two. As that engineer explained, the Lotus Edge was not developed using industry-standard human factor engineering, and Boston Scientific did not even have any user studies, task analyses or other records or data of the kind tracked and employed by other medical device companies (like Medtronic) for the Lotus Edge. At Boston Scientific, such records simply did not exist. This engineer, who previously worked in aviation, explained that Boston Scientific's development of the Lotus Edge reflected a disturbing disregard for basic human engineering practices that were similar to those that led to the Boeing 737 Max crashes.

11. Further, rather than "fix" the manufacturing issues that led to the prior recalls, as Defendants had represented, former Boston Scientific employees reported that the Company was never able to get the manufacturing process to an acceptable commercial production state. For

example, former Boston Scientific employees explained that, from 2016 to 2018, the manufacturing yields for a key component of the Lotus Edge delivery system were around 5 to 10%—meaning that only one of every 10 to 20 units was acceptable and passed specifications—while other components struggled to approach industry-standard yield rates. While medical device yield rates are generally around 85% by the time of commercial production, and a yield rate of 50% would be considerably "extraordinarily low" in the industry, the yield rates for the key components of the Lotus Edge delivery system never even approached 20%. As a result, the costs to manufacture the Lotus Edge resulted in margins that were unsustainable, and an extraordinary drag on the Company's financials.

12. By the end of 2019, as the complexities involved in operating the Lotus Edge's delivery system and its disadvantages to competitors sold by Medtronic and Edwards resulted in dismal sales results and poor patient outcomes, the Executive Defendants recognized the launch was in crisis. In fact, following several patient injuries and deaths and experiencing sales results that were less than half of the Company's internal targets, the Executive Defendants convened an emergency companywide meeting for the entire Lotus salesforce in Maple Grove, Minnesota over the Thanksgiving weekend in 2019. That meeting was attended by Defendant Ballinger, Defendant McCarthy and Defendant Meredith and the head of Lotus sales, Samuel Conaway, and focused on retraining the sales staff to help prevent the bad outcomes Lotus patients had been experiencing and to provide sales representatives with talking points on how to "sell" Lotus to physicians inclined to use competitor products.

13. Following this emergency meeting, and in light of dismal sales, a lack of re-orders, and the extraordinary expense involved in manufacturing the product, by no later than the first quarter of 2020, Boston Scientific senior management determined that the Lotus franchise was

doomed and determined to exit the business. However, at the same time, the Company was also facing a financial crisis. Over the prior two years, Boston Scientific had been one of the most acquisitive large cap medical device manufacturers, amassing over $10 billion in debt in the process, and its leverage ratios were approaching the default limits set forth in the debt covenants with the Company's lenders. At the same time, Boston Scientific recognized that the burgeoning COVID-19 pandemic would significantly hamper device sales for many of its other business lines. Indeed, in the first week of February, Boston Scientific estimated it would lose up to $40 million revenue from its business in China in the first quarter alone because of the pandemic—and knew even a slightest slowdown in revenues in the following two quarters would cause the Company to breach its loan covenants.

14. To avoid this outcome, Boston Scientific concealed the fact that the Lotus platform was failing and instead continued to misrepresent the product's performance. For example, in mid-March—about nine-tenths of the way through the first year after FDA approval—Defendant Mahoney told investors that Boson Scientific was "essentially on our planned goals on Lotus of 150 accounts open in the first year." Rather than disclose that the business was doomed, Boston Scientific concealed Lotus's dismal performance so that it could raise capital and renegotiate its debt covenants and avoid default. Specifically, in April and March 2020, Boston Scientific renegotiated its credit agreements, refinanced over $2 billion worth of debt and carried out an unprecedented secondary equity offering—raising over $2 billion from public investors, the largest equity raise the Company had conducted since its IPO.

15. Unknown to investors, however, by this time, Boston Scientific had already taken steps to terminate the Lotus franchise and, in fact, ordered that the Company's Lotus manufacturing facility in Penang, Malaysia be shut down. As recounted by one former

manufacturing engineer at the Penang facility, there were "zero orders" for the Lotus Edge throughout the second half of 2019 and 2020 and, because the facility was "getting zero orders," the plant was shut down by March 2020. As this former employee explained, the plant was shutdown because of Lotus—not as the result of the pandemic—and the shutdown occurred before other worldwide manufacturing shutdowns caused by COVID-19.

16. Knowing that publicly disclosing the Lotus franchise failure would trigger a sharp decline in the price of Boston Scientific shares, on August 25, 2020, Defendant Mahoney, Boston Scientific's CEO, entered into a Rule 10b5-1 trading plan that enabled him to sell over $9 million worth of stock before Boston Scientific would make that disclosure. That Rule 10b5-1 trading plan was highly unusual, unlike any other trading plan entered into by Defendant Mahoney or any other Boston Scientific executive before that time. Among other things, never before had a Rule 10b5-1 trading plan at Boston Scientific terminated so close in time to the date of adoption, involved such a large dollar volume so close to the date of plan adoption, and sold such a large dollar volume all at once.

17. After entering into this plan, Defendant Mahoney and other Boston Scientific senior executives made a series of representations to convey the false impression that the Lotus franchise was still thriving. For example, at the annual Transcatheter Cardiovascular Therapeutics ("TCT") conference on October 15, 2020, Defendant Fitzgerald told investors that "I'm proud to report that we have opened more than 150 accounts in the United States," that "I like what I see in terms of us being now in 150 accounts in United States" and that "we are expanding our footprint in the US, each month we're growing actual procedures per center, per month." And on the Company's third quarter earnings call two weeks later on October 28, 2020, Defendant Mahoney told investors

that "we're seeing strong results in the sites that are using Lotus in the U.S." and that the sites "are using it quite regularly."

18. Two business days after these positive statements, on Tuesday, November 3, 2020, Defendant Mahoney sold over $9 million of his personally held shares pursuant to the Rule 10b5-1 trading plan he entered into in August, and which was set to terminate at the end of that week.

19. Exactly 14 days after that trade, Boston Scientific stunned investors by disclosing that it was recalling the Lotus Edge and shutting down the franchise. Contrary to Defendant Mahoney and Defendant Fitzgerald's positives statements about the product just a few weeks earlier, Boston Scientific disclosed that the Company was abandoning Lotus because of "complexities associated with the product delivery system" and the "product development work required to reintroduce and enhance the delivery system to the market and reduce the training and case support necessary to scale clinical use and ensure competitiveness"—"complexities" and costs that had been concealed from investors throughout the Class Period.

20. Moreover, Defendant Fitzgerald admitted than rather than surpass the 150-account Lotus target, there were in fact just "sub-100" Lotus accounts in the United States, or a third less than Defendants told investors had been secured just weeks earlier. Defendants further disclosed that actual and estimated Lotus sales for 2019, 2020 and 2021 were almost half analysts' consensus estimates for the product—revealing that the product had performed far worse than investors had appreciated based on Defendants' misrepresentations. As Defendant Fitzgerald admitted the next day, Boston Scientific never secured the 150 accounts the Company had touted in October—but rather, after it "launched about 100 accounts in the U.S.," the Company determined to shut down the franchise because the business was unsustainable.

21. In response to these disclosures, Boston Scientific shares collapsed, falling nearly 10% on one of the highest single-day trading volumes for Boston Scientific shares in the past several years. Analysts were incredulous, and repeatedly asked what could have possibly changed from the time Defendants made their positive statements boasting of Lotus's success in mid-October to becoming a total failure by mid-November—a question Defendants could not answer.

22. On December 15, 2020, the Boston Regional Office of the SEC initiated an investigation into Boston Scientific's Lotus disclosures, submitting an information request for documents and information related to the statements at issue in this action and Boston Scientific's decision to recall and discontinue Lotus. On February 10, 2021, the SEC issued a second request for documents and information. The SEC's investigation remains pending.

23. Lead Plaintiff brings this action to recover the damages to Boston Scientific investors caused by Defendants' misconduct and to seek accountability for the violations of the securities laws alleged herein.

II. JURISDICTION & VENUE

24. The claims asserted in this complaint arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated under Section 10(b) by the SEC, 17 C.F.R. § 240.10b-5. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

25. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading statements, occurred in substantial part in this District. In addition, Boston Scientific's principal place of business is located in this District.

26. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchanges.

III. THE PARTIES

A. Lead Plaintiff

27. Lead Plaintiff Union is the parent holding company of the Union Investment Group. The Union Investment Group, based in Frankfurt-am-Main, Germany, was founded in 1956, and is one of Germany's leading asset managers for retail and institutional clients with more than €292 billion assets under management. As set forth in the certification filed herewith, Union's funds purchased Boston Scientific common stock during the Class Period and was damaged by Defendants' conduct as alleged herein.

B. Defendants

28. Defendant Boston Scientific is incorporated in Delaware, and the Company's principal executive offices are located at 300 Boston Scientific Way, Marlborough, Massachusetts 01752. Boston Scientific's common stock trades on the New York Stock Exchange under the symbol "BSX."

29. Defendant Mahoney served at all relevant times as the Company's Chairman, President, and Chief Executive Officer. As set forth below, Defendant Mahoney made representations alleged herein that were materially false and misleading and possessed material non-public information about the Lotus Edge which rendered his statements false and misleading at the time they were made.

30. Defendant Brennan served at all relevant times as the Company's executive vice president and chief financial officer, a position he has held since January 2014. Defendant

Brennan's began at Boston Scientific in December 1996 and has held various positions at the Company, including as vice president of finance and information technology for worldwide financial and strategic planning, investors relations, international finance and Cardiovascular. As set forth below, Defendant Brennan made representations alleged herein that were materially false and misleading. Defendant Brennan possessed material non-public information concerning the Lotus Edge which rendered his statements false and misleading at the time they were made.

31. Defendant Fitzgerald served as Boston Scientific's executive vice president and president, Rhythm Management beginning February 2014 and became Boston Scientific's executive vice president and president, Interventional Cardiology effective July 6, 2020. As set forth below, Defendant Fitzgerald made representations alleged herein that were materially false and misleading and possessed material non-public information concerning the Lotus Edge that rendered his statements false and misleading at the time they were made.

32. Defendant McCarthy served as Boston Scientific's Vice President and General Manager of Structural Heart Valves from July 2017 through January 2020. As set forth below, Defendant McCarthy made representations alleged herein that were materially false and misleading and possessed material non-public information concerning the Lotus Edge that rendered his statements false and misleading at the time they were made.

33. Defendant Ballinger served as the executive vice president and president, Interventional Cardiology, until he resigned on July 3, 2020. As set forth below, Defendant Ballinger made representations alleged herein that were materially false and misleading and possessed material non-public information concerning the Lotus Edge that rendered his statements false and misleading at the time they were made.

34. Defendant Meredith currently serves and served as Boston Scientific's executive vice president and global chief medical officer throughout the Class Period. In this role, he is responsible for leading clinical science and medical affairs across Boston Scientific and providing global leadership of the company's clinical trial strategy. As set forth below, Defendant Meredith made representations alleged herein that were materially false and misleading and possessed material non-public information concerning the Lotus Edge that rendered his statements false and misleading at the time they were made.

35. Defendant Lisa is vice president of Investors Relations at Boston Scientific and has served in that role since December 2013. As set forth below, Defendant Lisa made representations alleged herein that were materially false and misleading and possessed material non-public information concerning the Lotus Edge that rendered her statements false and misleading at the time they were made.

36. Because of their position and access to material non-public information available to them, Defendants Mahoney, Fitzgerald, Brennan, McCarthy, Ballinger, Meredith and Lisa knew, or recklessly disregarded, that material, adverse facts alleged herein had not been disclosed to, and were being concealed from, the public, and that the representations, which were being made, were materially false and misleading. Defendants Mahoney, Fitzgerald, Brennan, McCarthy, Ballinger, Meredith and Lisa because of their respective positions with Boston Scientific, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional and individual investors. Defendants Mahoney, Fitzgerald, Brennan, McCarthy, Ballinger, Meredith and Lisa were provided with copies of the Company's reports and press

releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected.

37. Defendants Mahoney, Fitzgerald, Brennan, McCarthy, Ballinger, Meredith and Lisa are referred to as the "Executive Defendants." Defendants Boston Scientific and the Executive Defendants are collectively referred to as "Defendants."

IV. BACKGROUND AND OVERVIEW OF DEFENDANTS' FRAUD

A. Boston Scientific's Structural Heart Business And The Promise Of 7 To 9% Organic Growth

38. Boston Scientific is one the largest manufacturer of medical devices in the world and describes itself in its filings with the SEC as a "medical technology leader" that has "advanced the practice of less-invasive medicine." During the Class Period, Boston Scientific conducted its business through six core businesses: Interventional Cardiology, Cardiac Rhythm Management, Endoscopy, Urology and Pelvic Health, Peripheral Interventions, Neuromodulation, and Electrophysiology.

39. By far, the most important unit was the Interventional Cardiology business responsible for the Lotus Edge. As reported in the Company's Annual Report for the fiscal year ended December 31, 2019, the Interventional Cardiology business was responsible 28% of the Company's revenues—almost twice the amount of revenues of the next largest business segment, Cardiac Rhythm Management—with the Structural Heart business responsible for the Lotus Edge expected to account to 40% of that total over the next several years.

40. Moreover, by the start of the Class Period, the Interventional Cardiology business—and the Structural Heart therapies that included the Lotus Edge—was by far the most important and fastest growing business at Boston Scientific. As Boston Scientific reported in its 2019 Form 10-K, "[s]tructural heart therapies are one of the fastest growing areas of the medical

technology," and the Lotus Edge in particular was touted by the Company as being a core growth driver for that business.

41. Analysts relied on these representations and modeled the impact of Lotus Edge sales as contributing up to $4 to the price of Boston Scientific shares at the beginning of the Class Period. For example, at the time the Company announced it would be submitting its pre-market approval application to the FDA on August 8, 2018, analysts from Morgan Stanley estimated that, at the time, Lotus Edge sales in 2019 and 2020 were worth about $1 to $2 to the stock price, and that, "in a bull case where Lotus returns to market and is well received, Lotus could add 100 bps+ to 2019 and 2020 growth rates, respectively, worth ~$4 to the stock."

42. Boston Scientific told investors during the Class Period that it had set an ambitious target to achieve 6 to 9% organic revenue growth per year, and to increase profit margins to drive double-digit earnings per share ("EPS") growth. As Defendant Mahoney told investors at the Company's biennial investor day on June 19, 2019, "in the next three years, we're providing organic guidance of plus 6% to 9%" with "our goal would be two years from now, at our Investor Day, that we've accelerated our organic growth profile in this three-year period versus 2017, 2018 and 2019, so which would be consistent with what we've done over the past few years." And at the same time, the Company would seek to "improve margins and deliver double-digit EPS growth," explaining that it was on pace to achieve a 50- to 100-basis-point margin improvement over these three years.

43. The success of the Lotus Edge was critical to achieving these ambitious targets, and Boston Scientific specifically identified that product as being a "growth accelerator" in a "high growth market," with a-greater-than 8% compounded annual growth rate. Boston Scientific noted that while the Company's Structural Heart division reported $475 million in sales in 2018, the

available market for heart valve procedures addressed by the Lotus Edge would reach approximately $8 billion in the next few years.

B. Before The Start Of The Class Period, Transcatheter Aortic Valve Replacement Becomes The Standard Of Care And Boston Scientific Races To Catch Up To Competitors

44. The Lotus Edge addresses a huge and growing patient need. For years, heart disease has been the leading cause of death in the United States, responsible for 655,000 Americans deaths per year and more than $320 billion in annual healthcare costs. According to Barbara Bowman, Ph.D., Director of the Center for Disease Control's Division for Heart Disease and Stroke Prevention, in the United States, "about one in three adults—approximately 86 million people—have at least one type of cardiovascular disease."

45. One of the most common forms of heart disease affecting the valves of the heart is aortic stenosis—a chronic and progressive disease that can result in heart failure and death. More than one in eight people over the age of 75 have moderate to severe aortic stenosis. Put simply, aortic stenosis is a narrowing of the aortic valve which allows blood to pass from the left ventricle to the aorta—the largest artery in the body.

46. The heart is separated into four chambers: the right atrium and left atrium and the right ventricle and left ventricle. The right atrium receives blood from the body and empties into the right ventricle, which in turn pumps blood to the lungs. The left atrium receives the oxygenated blood from the lungs, and empties into the left ventricle which then pumps the blood to the organs and muscles of the body. The aortic valve rests between the left ventricle and aorta, the large muscular artery that transmits all blood ejected by the left ventricle to the body. The heart's electrical conducting system ensures coordination between the chambers and valves and synchronizes their activity.

47. Aortic stenosis is the narrowing of the valve that lies between the left ventricle from the aorta, resulting in a progression reduction of blood flow to the aorta while pressure builds in the left ventricle. The symptoms of severe aortic stenosis include angina (chest pain), shortness of breath and fainting. Aortic stenosis predisposes patients to sudden death, heart failure, and atrial rhythm disorders. The mortality of inoperable patients with severe aortic stenosis is 50% at two years from diagnosis, a worse prognosis than many malignancies.

48. Aortic stenosis commonly develops during the aging process as calcium deposits or scarring damage the aortic valve in the seventh decade of life. The calcification makes the aortic valve rigid and narrows the orifice through which blood must travel to reach the body. In some patients, aortic stenosis is caused by a congenital heart defect called a bicuspid aortic valve. A bicuspid valve has only two leaflets as opposed to three. This structural difference results in accelerated wear and tear and typically a presentation for replacement one to two decades earlier than a tricuspid valve.

49. For many decades, the standard treatment for aortic stenosis was open heart surgery. Specifically, surgical aortic valve replacement ("SAVR") would be used to treat aortic stenosis—a procedure where an incision is made in the chest to access the heart and the diseased valve is removed and replaced with either a mechanical valve made from carbon or titanium or a biologic valve made from bovine (cow) or porcine (pig) pericardium (fibrous sack around the heart) tissues. SAVR necessitates an extensive post-operative recovery period, as open-chest surgery involves cutting the sternum (breast bone) and retracting surrounding muscles and tissues. Open heart surgery typically requires six months for a full recovery, although may take longer in elderly and frail patents. High risk patients for surgery, due to frailty, compromised organ function, or comorbidities pose a substantial risk of death, stroke, kidney dysfunction, prolonged

ventilator dependence and ICU stay, and remain a challenge even in the most sophisticated settings. For this group of patients, surgery is not often offered or accepted.

50. The high risk and prolonged recovery associated with SAVR procedures for a substantial portion of the population with aortic stenosis—or an estimated 30% to 40% of all such patients—created a significant need for a minimally invasive approach. Following years of research, a catheter-based approach called transcatheter aortic valve replacement ("TAVR") was developed. TAVR enabled doctors to replace a diseased aortic valve by implanting a new, biologic aortic valve prosthesis through a catheter inserted through a small incision in the skin was developed. Depending on the imaging assessment, the TAVR device is inserted preferentially through the femoral artery via an incision in the groin or, alternatively, through a small incision to access a large artery in the neck, or directly through the aorta. In all three of these approaches, a lengthy incision through bone and muscle and a spreading of the chest wall, as required in the SAVR procedure, is avoided. Most importantly, for all TAVR approaches, the heart lung bypass machine is not used and all procedures are performed on a beating heart.

51. The use of TAVR to treat aortic stenosis has grown remarkably since its early clinical success in 2002, with studies showing it has similar or better outcomes as compared with SAVR. Randomized clinical trials with systems from two manufacturers have demonstrated equivalent or better results with TAVR versus SAVR in high, medium, and low risk surgical patients. A July 20, 2017 article in Cardiology Magazine quoted a physician as noting that "[t]he evolution of TAVR over the past 15 years has been unprecedented. It has gone from a crazy idea to the standard of care for many patients suffering from aortic stenosis." It is estimated that globally TAVR procedures will exceed 300,000 per year by 2025. Immediately before the start

of the Class Period, in February of 2019, the global market for TAVR treatment was projected to double over the next five years, increasing from $4 billion in 2018 to $8 billion in 2023.

C. Boston Scientific Seeks A Toehold In The Burgeoning TAVR Market With the Lotus Valve, Touted As A "Fully Repositionable Device" With Unmatched "Ease of Use"

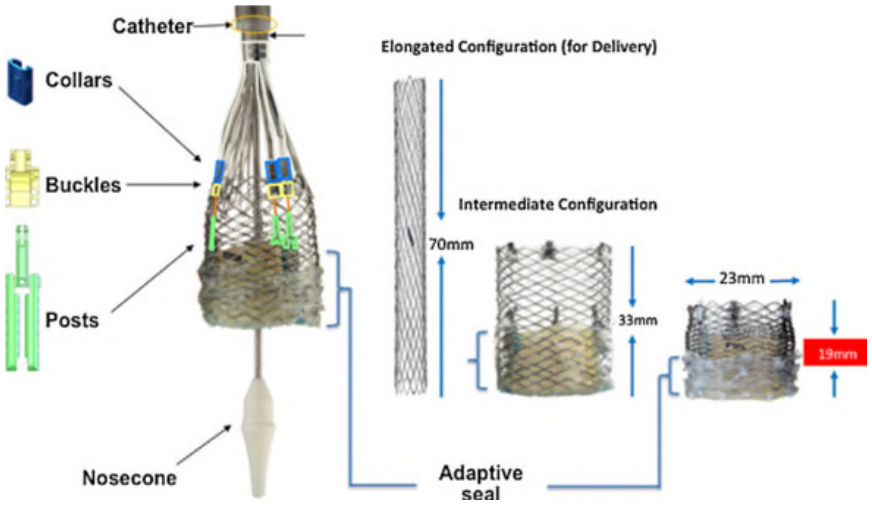
52. The increasing adoption of TAVR triggered immense competition among several of the top medical device manufacturers to develop TAVR valves—with two Boston Scientific competitors, Edwards and Medtronic, enjoying early success. Edwards was the first to receive FDA approval to market a TAVR device in 2011, and manufactures and sells a TAVR device called SAPIEN that utilizes a balloon-expandable mechanism for delivering the artificial valve into the patient. In 2009, Medtronic purchased CoreValve and its TAVR device of the same name, which utilizes a self-expanding mechanism for delivering the artificial valve into the patient, and obtained FDA approval to market the device in January 2014. In 2014, Edwards and Medtronic agreed to resolve years-long patent litigation involving their SAPIEN and CoreValve products—at which time were the only two FDA-approved TAVR devices in the United States and had near total market domination.

53. In November of 2010, Boston Scientific set out to gain a foothold in the burgeoning TAVR market by acquiring Sadra Medical Inc., a device maker that was developing an aortic valve replacement system called the Lotus Valve System, in a deal for about $450 million. Recognizing it was a late comer to a market dominated by two other devices, Boston Scientific sought to differentiate Lotus. To do so, Boston Scientific marketed the Lotus as the first "fully repositionable device" that afforded the physician precise control and "ease of use" when deploying the valve.

54. Edward's SAPIEN and Medtronic's CoreValve used balloon-expanding and self-expanding designs, respectively. Edward's SAPIEN valve is inserted through a sheath (tube),

usually placed into a large artery in the leg, using a delivery system—a tube with a balloon on the end. The Sapien valve is crimped on the delivery system balloon using a mechanical crimper, the Sapien valve and delivery system combination are then inserted through the sheath into the body. Once the valave mounted on delivery system assembly reaches and crosses the diseased valve, the balloon is inflated with fluid, expanding the new valve into place. In doing so, the Sapien valve pushes the leaflets of the diseased valve aside. The frame of the new valve uses the calcified diseased valve leaflets to anchor itself in place. The balloon will then be deflated and removed. Medtronic's CoreValve device, on the other hand, has a self-expanding nitinol frame is deployed by allowing the frame to expand while across a diseased valve using passive radial force pushing the diseased valve leaflets out of the way.

55. The Lotus Edge, by contrast, uses a novel mechanical expansion and retraction to position and anchor the valve. The Lotus Edge's design utilizes interdigitating posts (attached to the base of the valve) and buckles (attached to the top of the valve) to lock it in position. When the valve is expanded, the posts attach and lock into buckles keeping the valve securely locked in the expanded position. With mechanical expansion and retraction, the valve is designed to be fully recapturable after positioning, ensuring that final release only occurs when the valve is optimally placed within the native valve.



56. This ability to re-position the valve was designed to address one of the major adverse events associated with TAVR procedures—perivalvular or paravalvular leakage ("PVL"), which results in "paravalvular regurgitation" ("PVR"). PVL refers to blood flowing through the space between an implanted valve and cardiac tissue anchoring it resulting from a lack of an appropriate seal. PVR is a frequent complication of TAVR procedures, and occurs at a much higher rate than in conventional SAVR procedures where valves are sutured into place. TAVR valve anchoring and stability relies on friction with the surrounding tissues. Most commonly, PVL occurs because a TAVR valve is undersized, does not seal properly against the cardiac tissue due to excessive calcium deposition or malpositioning of the device.

57. By enabling physicians to mechanically expand and retract the valve, and thereby reposition or even completely remove the valve once fully deployed, the Lotus Edge was designed to ensure that a controlled final release only occurs when the valve is optimally positioned to eliminate PVL. Further, the Lotus Edge's polycarbonate-based urethane adaptive seal skirt was designed to reduce PVL by filling in irregular gaps between stent frame and the native anatomy. Last, the metal frame has to be maximally foreshortened for the locking mechanism to engage, and thus was intended to ensure optimal hemodynamics (or blood flow).

58. The Company marketed the Lotus valve as providing these advantages over SAPIEN and CoreValve—and, in doing so, specifically represented that the device offered doctors superior "ease of use" as compared to these competitor products. For example, Defendant Mahoney repeatedly touted the "ease of use" afforded by the Lotus, which "offers physicians a unique ease of use feature, it is fully recapturable and 100% recapturable and deployable after deployment," and that "this precise predictable placement with Lotus … gives the physician total control," as distinct advantage in numerous investor conferences and other public presentations.

59. For example, when Defendant Mahoney was asked directly about how the Lotus Edge compared to the market leader, Edwards' SAPIEN, at a September 12, 2017 investor conference, he responded by highlighting the Lotus Edge's supposedly "superior ease of use" profile as one of the advantages that would help the device capture 20% of the TAVR market:

> We do think Lotus is better [than Sapien]. We think the mechanical properties and the way you can position the Lotus valve is very unique. It's very unique for complex patients and oftentimes as you build a lot of trust with cardiologist, we can help them out with their most complex cases. So we think the mechanical ease of use properties are differentiated. The PVL rates are best in class and the pacemaker rate continues to come down with Lotus Edge. So, we think we've got at least on par offering and I think superior ease of use characteristics of it.

60. Similarly, Defendant Lisa told investors at a June 7, 2016 Jeffries Healthcare Conference that Lotus's "ease of use, which I think maybe gets underestimated sometimes" and the "best-in-class parvalvular leak rates and then the ease of use" were the primary advantages that would enable the device to compete with Edwards and Medtronic. As Defendant Lisa told investors, "it has been a nice growth story for us really driven by the outcomes and as well as the ease of use."

61. Further, Boston Scientific's Annual Reports filed on Form 10-K during the Class period specifically identified the "ease of use" of its products as one of primary qualities on which

its products competed with those manufactured by rivals like Medtronic—a fact that demonstrated Boston Scientific itself deemed this information material to an understanding of the Company's business. 17 C.F.R. § 229.101. Analysts incorporated Defendants' representations concerning the Lotus Edge's purported "ease of use" when valuing the Company's stock, with Leerink analysts noting, for example, that Lotus Edge has a "more simple implantation procedure" and that the "valve will be very easy to use with a more flexible shaft, and a simplified procedure."

D. Boston Scientific Issues Several Recalls Of The Lotus Due To The Malfunctioning Of Its Delivery System But Assures Investors It Had Remedied The Problem

62. Despite Boston Scientific's touting of the Lotus and the Lotus Edge as affording doctors an ease-of-use and an unparalleled degree of control by being the first fully repositionable and re-deployable TAVR on the market, a series of recalls of the device in Europe before its commercial launch in the United States alerted Boston Scientific's management to serious flaws. These events also put Defendants on notice that a failure of the Lotus platform would trigger a significant decline in the Company's stock price.

63. The Lotus recalls began shortly after the Company had achieved regulatory approval for the device in Europe and had initiated clinical studies to support FDA approval in the United States.[1] On September 23, 2014, the Company announced that it initiated a REPRISE III IDE clinical trial in the United States to evaluate the efficacy of the Lotus against its competitor, Medtronic's CoreValve TAVR system—which was head-to-head randomized TAVR trial designed to support U.S. regulatory approval. Less than a year later, Boston Scientific initiated a recall of 278 units in Europe on November 19, 2014 due to the valve becoming "unlocked during

[1] After acquiring the Lotus in 2010, Boston Scientific began conducting clinical trials to seek regulatory approval for the device in Europe and the U.S. Boston Scientific announced CE Mark approval for the device at the annual Transcatheter Cardiovascular Therapeutics ("TCT") conference in San Francisco, California on October 28, 2013.

release from the delivery system." According to a notice posted on the FDA's website, when this occurs "it may be necessary to convert the patient to open heart surgery"—the very high-risk procedure the Lotus was designed to avoid.

64. Again, several years later, on August 2, 2016, the Company recalled several manufactured lots of the Lotus due to breaks occurring in the mechanism that released the valve from the delivery system. In total, 250 units were recalled, including investigational devices being used in the U.S.-based REPRISE III clinical trial, which had been fully enrolled and ongoing since the fourth quarter of 2015. Again, the field safety notice issued by the Company to initiate the recall noted that the component of the delivery system that was breaking was the "release mandrel." Next, on October 31, 2016, the Company announced a third voluntary recall, this time for its second-generation device the Lotus Edge due to reports that the device could not be fully locked during the procedure.

65. On February 23, 2017, Boston Scientific disclosed another set-back with Lotus—this time due to reports of a malfunctioning pin involved in the delivery system. As the Company reported in a Form 8-K filing, Boston Scientific had initiated a voluntary removal of all Lotus devices (including the Lotus Edge with Depth Guard) from global commercial and clinical sites following reports that a pin connecting the valve to the delivery system was releasing prematurely, and that the problem was caused by "excess tension in the pin mechanism introduced during the manufacturing process." According to the Company, a patient in Germany died after a doctor tried to implant the device. When the valve could not be separated from the catheter used to implant it, the Lotus valve was removed, and the doctors attempted to implant a second device. The patient then suffered an arterial tear, called an aortic dissection, that led to the death.

66. Evidencing that the Lotus Edge's regulatory and commercial success was material to investors, this announcement of the voluntary removal initially triggered a sharp decline in Boston Scientific stock—with shares falling nearly 10% in response to the news early on February 23, the largest single-day decline since August 2015.

67. After each of these recall announcements, Defendants spoke to analysts and investors to reassure investors the Company was making the necessary changes to remedy the problem and that it would not pose a risk to the viability of the Lotus platform. Specifically, Defendants told investors the problems with the Lotus platform had to do with malfunctioning of the delivery system, rather than a problem with the design of the TAVR valve itself, and that minor changes to the manufacturing process and specifications of the device would fix the problem. For example, at the J.P. Morgan Health Care Conference on January 10, 2017, speaking about the October 31, 2016 recall of the Lotus Edge, Defendant Mahoney assured investors that the Company had found a "fix" for the problems with the Lotus Edge stating "I'm pleased to say that we have identified both the issue and the solution to fix this. The solution is a combination of minor process and specification changes." Again in the conference, when asked by an analyst how the Company was able to resolve the issue so quickly, Defendant Mahoney explained that the engineering team "simply diagnosed the issue in the delivery system and the locking mechanism" and assured that "the team provided a fix for it, to the quality controls." Likewise, in response to the analyst's question, Defendant Meredith—who had been the principal investigator in the initial Lotus clinical trials—explained that the problem was that "the pin mechanism that uncouples the valve from the delivery system . . . was releasing early" and that "[i]t's just related to some excess tension in the system." Defendant Meredith further assured investors that "[i]t is not a design flaw.

And so, it was a simple matter of altering the specification and tolerances to the manufacturing, and the problem has been solved."

68. Likewise, with respect to the February 23, 2017 recall announcement, Defendant Brennan assured investors at an RBC investor conference that day that the Company had found a solution to the problems in the Lotus platform's delivery system by implementing changes to the manufacturing of the device, telling investors "It's similar to what we saw in November last year, when we halted our limited market evaluation in Europe, and the solution that we've identified and announced we believe does address that across the entire Lotus Valve platform. Its adjustments to the specifications and processes that we believe will address that across the entire platform." Defendant Brennan further assured "we are still 100% committed to being a leader in the structural heart space, have faith in the Lotus platform, its long-term prospects and what it can do and the unique benefits that it brings to physicians and patients."

69. Based on Defendants' assurances that the Company was working diligently to implement manufacturing and quality control changes to the address the Lotus Edge's malfunctioning delivery system, investors praised Defendants for their cautious approach, believing the Company would not launch the Lotus Edge until these issues were resolved.

70. For example, after the February 23, 2017 recall announcement, analysts from Cowen and Company noted that "the six-month setback is similar to the timeframe BSX just completed in resolving the Lotus Edge problem (importantly it was a manufacturing issue not a design flaw)…. Although a six-month pause is not optimal, the recent Lotus Edge experience serves as a nice precedent that a successful remedy is highly likely." Similarly, Guggenheim analysts cited the recall and fix to the problems with the device in November 2016, and suggested "that the fix may be similar as well, namely modifications to the manufacturing process rather than

tweaks to the design of the valve itself." Evercore ISI analysts took comfort in the fact that the issue was "similar to that seen with Lotus Edge (issue first identified in Nov 2016; Solution has been found) – which should provide confidence to longer term holders that is a solvable issue and BSX is taking a very conservative approach (as suggested by timeline delay) in getting this right."

E. Boston Scientific Continues to Reassure Investors About The Lotus Edge After Announcing Acquisition of "Complementary" Symetis TAVR Platform And The Company's Dual Valve Strategy

71. Boston Scientific executives continued to reassure investors about the Lotus platform after it announced the acquisition of Symetis, a Swiss manufacturer of structural heart products in March 2017—news that immediately raised concerns about the Company's confidence in the Lotus Edge. With the Symetis acquisition, Boston Scientific acquired an entirely new TAVR valve platform: the Acurate TA ("Acurate")—a self-expandable, transapical valve that had previously obtained a CE Mark of approval in Europe. The Company also took over the second generation Acurate valve, called the Acurate Neo ("Acurate Neo"), which was also a self-expandable valve that is inserted into the patient transfemorally, *i.e.*, through the femoral artery.

72. In the conference call announcing the Symetis acquisition on March 30, 2017, Defendant Mahoney stressed that Boston Scientific's Lotus valve and Symetis's Acurate platform were "highly complementary" of each other and stated that the "combined Lotus plus Acurate portfolio addresses a broader range of patient pathologies and anatomies as well as physician preferences," and sought to preempt the concerns that the acquisition signaled a lack of confidence in the success of the struggling Lotus franchise.

73. Defendant Mahoney emphatically rejected that concern, and told investors that Boston Scientific "absolutely" would have acquired Symetis regardless of any issues concerning Lotus. For example, Defendant Mahoney "absolutely" rejected the notion that the Acurate platform was intended to replace Lotus, stating that "I think the Symetis people are probably rolling

their eyes hearing this because we've been talking to this company for a couple of years now," and reiterated "we're very confident the manufacturing enhancements and the fixes that we've discussed [to Lotus]. . . and we're really pleased with the progress of our manufacturing teams."

74. In response to a question from a UBS analyst, Defendant Ballinger specifically reassured investors concerning the Lotus Edge by addressing the recalls in detail. Specifically, Defendant Ballinger made clear that the problem with the delivery system—the "early pin release" which necessitated the recall of the Lotus Edge in October 2016—was the "same single issue" that triggered the recall of the entire Lotus platform on February 23, 2017. Defendant Ballinger reiterated that the solution is "a combination of relatively minor process and specification changes along with a final inspection step that we think will be very robust" and that the "root cause is well understood by our teams in Ireland," and the problem was being resolved. As Defendant Ballinger explained, the Company was "in implementation mode in terms of revalidations and such," and that "as we said before, a combination of a relatively minor process and then specification changes, along with a final inspection step that we think will be very robust. So same issue. And it's the same singular issue that we've talked about previously."

F. Boston Scientific Announces Another Lotus Delay, Again Pointing To Manufacturing "Validation Challenges"

75. In what would become the fourth setback for the Lotus platform, after the close of trading on November 28, 2017, the Company announced a delay in both returning the Lotus platform to the European market and in seeking premarket approval from the FDA. Specifically, the Company told investors that the "company now expects to provide an update on the status of the Lotus Edge Valve during its fourth quarter 2017 earnings conference call on February 1, 2018, as it continues to focus on manufacturing and regulatory milestones."

76. In a conference call with analysts convened the next day specifically to address the delay, Defendant Mahoney framed the delay as being caused by unforeseen difficulties encountered during the manufacturing process, explaining "while completing the product testing required for our regulatory submissions, we did encounter some unexpected validation challenges, which will require additional attention from our internal teams." Defendant Mahoney told investors that the Company "moved as quickly as possible to inform investors and physicians that we'll not be able to meet our previously communicated timelines." Significantly, Defendant Mahoney also reassured investors that the recent changes would not impact the product's margins, explaining that Boston Scientific did not "expect any change to our adjusted operating margin goal of 28% by 2020" as a result of the changes to that would be required with the most recent round of Lotus modifications.

77. Defendants again provided strong reassurances to investors to assuage their concerns about the future of the device and specifically whether the most recently disclosed delay suggested problems with the device's design. Defendant Ballinger provided a detailed response, reporting that the issues were related to the "final qualifications and verifications," and were not related to any core valve design, stating that "unfortunately, as that final testing was completed and analyzed, we saw elements of the system performance that frankly didn't meet our expectations and honestly surprised us a bit towards the end."

78. Defendant Ballinger reassured investors that eliminating the Lotus program was not a possibility that investors should be concerned about, expressing confidence in the "dual valve strategy" as the "right strategy" and that the technical manufacturing issues at the heart of the delay had been addressed. Specifically, in response to an analyst's question, Defendant Ballinger affirmed that "excess tension in the pin mechanism," which was the cause of the October 2016 and

February 2017 recalls of the Lotus platform, "is still the root cause on this round of delay." As Defendant Ballinger noted, "we do understand that and we did resolve that early pin release. So that issue has been resolved. . . . So we're not seeing early pin release issues, but it's still part of that mechanism and that's where we've got more work to do." Defendant Ballinger further reassured investors that Boston Scientific was in close contact with regulators in the U.S. and Europe and that the recent delays were internally driven, not prompted by regulators. According to Defendant Ballinger, Boston Scientific's interaction with the FDA and other regulators has been "very, very positive," that the "FDA has been very, very constructive," and that "everything we're dealing with now is it's really on us, it's our internal – these are internally driven kind of design verification questions. And nothing that we're dealing with now has anything to do with any kind of regulatory guidance or concerns." Rather, these issues were just "typical stuff for med device."

79. Analysts credited Defendants' representations, and concluded that the Lotus platform was simply in need of tweaks to the manufacturing process. For example, in a December 1, 2017 report, BMO Capital Markets analysts noted that:

> We had the opportunity to catch up with Boston Scientific management where questions, not surprisingly, initially focused on its Lotus valve . . . . In essence, we do not believe that the Lotus program is dead and that this is a 'when' and not 'if' analysis. . . . In thinking about this, if the delay is not related to clinical data, valve design, or an FDA-related issue, but is one in which stringent internal manufacturing expectations are not being consistently met, this is likely solvable (in our memory, there is not a MedTech product that was left by the wayside because of manufacturing issues, clinical data issues yes – manufacturing issues no).

80. When the Company disclosed on August 8, 2018 that it would be submitting the final technical module for premarket approval to the FDA and anticipated commercially re-launching the Lotus platform in Europe in the first quarter of 2019 and commercially launching Lotus Edge in the U.S. market in mid-2019, analysts uniformly viewed the development positively.

For example, Evercore ISI analysts noted that the announcement eliminated "the last overhang on BSX shares in our mind, and today's announcement is clearly a positive (lays to rest any lingering doubts)." Morgan Stanley analysts noted the reintroduction of Lotus removed a key overhang and estimated the product could add $4 to the stock in a "bull case where Lotus returns to market and is well received." Guggenheim analysts said the announcement eliminated "significant uncertainty about the Lotus' fate" that had been "baked into the stock," reporting that "[o]ur model calls for Lotus to add $400-500M to BSX's top line by 2021, which combined with a strong outlook for the base business, makes BSX one of the best fundamental stories in [large cap] MedTech."

G. Boston Scientific Resolves Long-Running TAVR Patent Litigation And Prepares Lotus Edge for Worldwide Commercial Launch

81. Immediately before the Class Period, Defendants announced three pieces of purportedly positive news that inflated Boston Scientific's stock price. First, the Company disclosed it had raised Boston Scientific's annual guidance in an investor call on September 13, 2018—raising operational guidance to 7 to 10% for fiscal year 2019 to 2020, up from 6 to 9% for fiscal year 2018 to 2020, with Defendant Mahoney highlighting Lotus as "one of our big opportunities."

82. Second, the Company provided a definitive timeline for the Lotus launch at the Transcatheter Cardiovascular Therapeutics ("TCT") conference held on September 24, 2018, stating that a European launch for Lotus Edge was expected in the first quarter of 2019 and a commercial launch in the United States for mid-2019.

83. Third, on January 15, 2019, Boston Scientific and Edwards jointly announced their agreement to resolve all outstanding patent disputes around the world—and to not litigate any further patent disputes—concerning their respective portfolios of TAVR devices, including the Lotus Edge.

H. With The String Of Setbacks Purportedly Behind Them, At the Start of the Class Period, Defendants Commercially Launch The Lotus Edge And Tout Progress to Obtaining 150 Accounts

84. On February 6, 2019, Boston Scientific announced 2018 fourth quarter and year-end results and an update on the Lotus launch timeline, reporting that the Company expected U.S. approval by early in the second quarter with a limited European release in March. Addressing the Lotus commercial launch on the call, Defendant Mahoney explained that, "we want to ensure we deliver exceedingly well, to get out of the gate strong, to build up a strong reputation for the product in the U.S." by pursuing a "smartly planned" "controlled launch" focused on "delivering excellent outcomes, building greater confidence with the physician community"—an approach that the Company had already been pursuing, and which had purportedly resulted in "increased utilization rates each quarter." Analysts reacted positively to the news and understood the Lotus Edge would provide an immediate and material contribution to the Company's revenues, with Piper Jaffray analysts noting after the fourth quarter earnings call in a report that day that:

> Without question in our minds, the commentary on the Structural Heart business from management was the biggest takeaway from the call. Specifically, management anticipates this segment to generate $700-$725M of revenue this year compared to just over $475M in '18. We were surprised there were not more questions about this, but we suspect the relaunch of Lotus in Europe in March and domestically early in Q2 (a couple months ahead of expectations) accounts for close to half of this~$235M YOY increase.

85. The initiation of the commercial launch for Lotus was a substantial driver of the Company's share price performance. Indeed, from the disclosure of the Lotus Edge FDA submission through the announcement of Boston Scientific's fourth quarter results, Boston Scientific stock climbed nearly 15%, closing at $38.77 per share on February 6, 2019.

86. Then, after the close of the market on April 23, 2019, Boston Scientific issued a press release announcing that the FDA had approved the Lotus Edge for patients "with severe aortic stenosis who are considered at high risk for surgical valve replacement via open heart

surgery." The Company touted the Lotus Edge as providing "physicians a high level of control over the delivery and deployment of the device and offers surgical-like PVL results to help ensure the best patient outcomes."

87. On the first quarter 2019 earnings call held the next day, Defendant Mahoney announced the Company would "begin a controlled U.S. launch immediately" and noted that the Company "also began a controlled commercial launch of Lotus Edge in Europe late in the first quarter." Defendant Mahoney further told analysts "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."

88. The Company also issued guidance for its structural heart division for the year 2019 of $700 million to $725 million, indicating that the Lotus Edge would be a significant contributor to the Company's results. Indeed, Defendant Mahoney told investors that Lotus Edge was part of the Company's "combined strength" of products "that position us well to deliver on our guidance for $700 million to $725 million in structural heart revenue in 2019."

89. Analysts reacted favorably to news of the Lotus launch and incorporated Lotus Edge sales into their valuations of the Company's shares. For example, analysts at Piper Jaffray noted in an April 24, 2019 report that:

> [T]he Structural Heart business is the key to the story right now with Lotus Edge receiving FDA approval last night. Management continues to anticipate Structural Heart will deliver $700-$725M in revenue this year, a strong y/y profile compared to ~$475M in '18. We would assume the outlook accounts for around half of this $235M y/y increase for Lotus Edge, which could prove highly conservative at the end of the day depending on the cadence of the launch this year.

90. Similarly, Raymond James noted that the Lotus launch was one of two "key factors impacting growth in 2019," while Cowen analysts reported they "heard increasingly frequent commentary that BSX has a potential 'game-changer' in its hands."

91. Thereafter and throughout the Class Period, Boston Scientific executives repeatedly assured investors that the Lotus Edge commercial launch had been carefully and thoughtfully planned, had been a resounding success, that physicians were rapidly adopting the technology, "re-ordering" the product in droves, and that the Company had been "on track" and "on plan" in meeting the target of establishing Lotus Edge accounts at 150 centers in the United States a year from the date of FDA approval—i.e., by April 2020.

92. For example, at the Company's 2019 Investor Day on June 26, 2019, Defendant McCarthy—the General Manager for Structural Heart Valves—explained the Company's controlled launch strategy was "to launch in roughly 150 accounts within the first 12 months of launch and then soon after we'll start to increase the rate of new customers," and would rapidly expand that 150-account base following the initial "controlled launch" period. As Defendant McCarthy told investors on that call, "we've got a great distribution; large, medium, small and whether it's academic or otherwise, it represents the market in our early days of launch, and it's going extremely well." Defendant Mahoney also highlighted the Company's new facility in Malaysia, which was "ramping up right now with Lotus valve," and noting that the launch had "gained good early momentum."

93. While the Company stated its focus would be on centers involved in its REPRISE III clinical trial, McCarthy clarified in response to analyst questions that in order to reach 150 centers within the first 12 months, the Company would need to penetrate the accounts at centers that were distinct from those Boston Scientific used for its TAVR clinical trials. For example, an analyst for Credit Suisse referenced Defendants' stated intention to launch the Lotus Edge in 150 centers within the first 12 months of the launch and asked "how many U.S. centers do you think you'll have running clinical studies for TAVR with various trials for various devices?"

94. Boston Scientific executives clarified that the 150-center total, or about one-quarter of the total TAVR centers in the United States, would include at least 50 centers with doctors who were not involved in any Boston Scientific TAVR clinical trials—and thus achieving the 150-center target would strongly indicate growing and widespread physician adoption. Specifically, Defendant McCarthy clarified that there were approximately 70 distinct centers involved in the two pending Lotus and Acurate TAVR device trials, and that "of the 40 to 50 centers that are in each of those studies, as mentioned previously, we expect from a Lotus – U.S. Lotus launch to be in roughly at about 150 accounts in the first 12 months, so the balance obviously being outside of those 50." In other words, in order to reach the target of opening in 150 centers within the first year, the Lotus Edge would have to be purchased by a substantial number of centers other than those that were involved in the Company's TAVR clinical trials.

95. Thereafter, and throughout the Class Period, Defendants told investors the Company was on track to reach its target of opening accounts in 150 centers in the first 12 months of the launch, and highlighted "very high reorder rates" for the product, "strong reorder" numbers, and said the "reorder rate for existing users is quite high." For example, on the Company's second quarter earnings call on July 24, 2019, Defendant Mahoney told investors the Company was "really pleased" with Lotus and "we're essentially delivering per our commitment. The 150 accounts that we expect to open, we're on track to deliver that." Similarly, on September 5, 2019, Defendant Mahoney told investors that the Lotus "results have been very strong," that "We're seeing very high reorder rates of Lotus, and the launch really is going as planned as adjusted in 2019" and "we're seeing strong reorder rates with it."

96. As Boston Scientific had previewed, the Company also announced a "full launch" of the product in the fall of 2019—following the initial "controlled launch" immediately after

approval—and represented that the "full launch" had accelerated sales. Specifically, at TCT on September 27, 2019, Defendant Ballinger told investors the Company was "on track to open 150 accounts" and by that time, the "ramp has now accelerated":

> Just on the Lotus launch, so what I would say is the ramp has now accelerated and the mode that we predicted in terms of the – so opening the number of accounts per month that we predicted at full launch. And so we purposely, over the course of the summer, were more in a self-constrained, limited market evaluation mode. And we started loosening that obviously in the July and August timeframe with a stronger ramp and now September.

97. Boston Scientific executives also claimed that, not only was the Company "on track" to reach 150 accounts in the first year, but that new Lotus sales were materially contributing to revenues. For example, Defendant Lisa told investors at a December 5, 2019 investor conference that the fact that revenue increases for interventional cardiology, and the fact that the Company was reaffirming guidance for its Structural Heart division, showed Lotus had been a material revenue driver:

> And I'd say, we're really pleased with how the Lotus launch is going. And we're not giving specifics in terms of dollars or accounts. And we 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. But I think one point of evidence is we grew mid-teens in interventional cardiology in Q3, which was a clear acceleration. And back to Structural Heart, we're comfortable with the high end of our guidance range.

98. And even after the onset of the COVID-19 pandemic in the first quarter of 2020 raised concerns about the launch given COVID-19's impact on medical procedures generally, Boston Scientific told investors that it had in fact achieved the Company's 150 account target. Specifically, despite an initial slow-down in March 2020, the Company purportedly experienced strong sales and account openings in June and July 2020, with Defendant Mahoney reporting that "we are starting to see the gates open up a bit more in terms of new account openings with Lotus," and reaffirmed that "the reorder rate for existing users is quite high."

99. Boston Scientific continued to tout the Company's purported progress toward the 150-account target after the initial COVID-related slow-down. For example, at a Virtual Fireside Chat with Credit Suisse on August 19, 2020, the analyst hosting the event asked Defendant Brennan, Defendant Lisa, and Tengler about the Company's progress in opening 150 accounts, asking, "have we crossed that threshold at this point?" Defendant Brennan, Defendant and Tengler reassured investors that the launch was "going well" and the Company was opening new Lotus accounts despite the initial COVID-related slowdown. Specifically, Defendant Brennan told the analysts that new TAVR centers without a preexisting relationship with Boston Scientific TAVR products were adopting the device, including because Boston Scientific had implemented a number of measures in response to the remote environment necessitated by COVID-19 travel restrictions, including by using the "good digital tools that we have – we had developed and we are continuing to develop around proctoring." Defendant Brennan further explained that "were doing it at an appropriate pace, albeit probably slower than and – in a pre-COVID world. But again, we're not willing to compromise the safety and the outcomes for the patients to try and outpace a particular number. So, that is probably slower than pre-COVID but – going well for us overall." The Credit Suisse analyst then asked:

> Miksic: Can I ask ...
>
> Brennan: Yes. Sure. Go ahead.
>
> Miksic: ... then before you hop in to the neo2 is you had set a target to get to all the sort of U.S. pivotal study centers for the LOTUS in your rollout. Have we – have we crossed that threshold at this point?
>
> Brennan: Yes. We had said that we get to 150 U.S. accounts one year post launch. I'll defer to Lauren and Susie as to what the latest public comment would be on that.

Tengler: Yes. 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. We have a very thoughtful and methodical approach.

Miksic: OK. So, you're off of that 130 and that – is that – does that – covers, in other words, to your point about training, that covers folks who had some familiarity with valves? Who are into new – (went into) new centers (that are) seeing it for the first time?

Brennan: Right.

Miksic: Got it. OK.

100. Then, at the TCT conference on October 15, 2020, Defendant Fitzgerald declared victory on the 150-center target, telling investors "Now turning to Lotus Edge, I'm proud to report that we have opened more than 150 accounts in the United States." Defendant Fitzgerald explained in response to an analyst question that while COVID had impacted the launch, "I like what I see in terms of us being now in 150 accounts in United States" and that "we are expanding our footprint in the U.S., each month we're growing actual procedures per center, per month."

I. Unknown To Investors, Boston Scientific Never Fixed the Problems With The Device Did Not Come Close To Opening 150 Accounts, And Embarked On A Reckless And Clinically Unsafe Product Launch

101. While Defendants touted the success of the launch of the Lotus Edge, claimed that the Company had opened over 150 accounts in the United States, and that re-order rates for Lotus Edge were "strong," "very high," and increasing, in reality, Boston Scientific never fixed the problems with the device and did not come close to reaching the Company's publicly announced 150-account target.

102. As set forth below, numerous former Boston Scientific employees detail how, even after winning FDA approval, the Lotus Edge had fatal design flaws that frequently caused the valve to become unable to lock in place or become stuck during the implantation procedure, requiring the patient to undergo open heart surgery—the very (dangerous) procedure that high-risk

patients had sought to avoid by using the Lotus Edge. And rather than experience "strong" reorder rates with the Company "growing actual procedures per center, per month," in truth, Boston Scientific continually missed its own internal sales targets for the Lotus Edge with little to no centers re-ordering the product. Indeed, as Boston Scientific admitted after the Class Period, Boston Scientific never opened 150 accounts, the true number of accounts was actually one-third less than Defendants had represented. In fact, Defendants concluded by no later than the first quarter of 2020 that the Lotus franchise was unsalvageable.

J. Prior to the Start of the Class Period, Boston Scientific Identified That The Market For Lotus Edge Was A Fraction Of What Defendants Publicly Claimed And Unsuitable For The Vast Majority Of TAVR Candidates

103. Even prior to the start of the Class Period, Defendants recognized that the Lotus Edge would never become the "workhorse" valve they claimed and, according to their own customers, would only be used in a small fraction of TAVR procedures. The small potential market for the Lotus Edge was documented in surveys conducted by Boston Scientific confirming that, at best, the Lotus Edge would be used in 10% of all TAVR procedures.

104. For example, Former Employee ("FE") 1, a 20-year veteran at Boston Scientific who worked as a Principal Therapy Consultant in the Structural Heart division from 2000 to January of 2021 in the New York/New Jersey area described how, in 2017 and early 2018, the Structural Heart Vice President of Sales and Marketing, Michael Lang, oversaw a survey of Boston Scientific's customers to find out what the Company could expect in terms of the number of patients that would use the Lotus device. FE 1 was tasked with carrying out that survey for the centers FE 1 covered and, according to the feedback FE 1 received, the Lotus Edge would be applicable in 5-6% of patients. Moreover, based on conversations with Boston Scientific Structural Heart colleagues around the country, the consensus from TAVR centers was that the Lotus Edge could achieve at most a 5-10% market share.

105. That finding—that Lotus Edge would only be used in 5-10% of all TAVR procedures—was documented in internal company records, purportedly used to assess the market for Lotus Edge, but disregarded by senior management. As FE 1 recounted, "in 2018 we all go into the training [for the Lotus] and were all surprised. The VP of marketing is saying we're expected to go out and get 25% market share. I've been in the business for a long time and so I said to him, 'You've got to be out of your mind.'" According to FE 1, Boston Scientific senior management was, at best, "willfully blind to the reality" of the market potential for Lotus. In truth, "Maybe there were three or four doctors [across the country] that said they'll use the Lotus every day. So, they listened to those three and not the other 300 that said they'll use it a handful of times a year." FE 1 confirmed that the 5-10% market share was consistent across the U.S. sales staff surveys: "We were all getting the same numbers from our people" demonstrating that the potential TAVR market was between 5-10% of cases.

106. One substantial impediment for the Lotus was the device's comparatively high pacemaker rate as compared to Edwards' and Medtronic's TAVR devices. According to FE 2, a Principal Clinical Field Manager in Boston Scientific's Structural Heart division from January 2017 through January 2021, the relatively high pacing rate for the Lotus was a substantial barrier to sales—as the higher pacemaker incidence clearly increased the risk for patient outcomes (including the risks involved in introducing another device into the procedure, the increased risks of infection, and longer recovery times and hospital stays). Moreover, according to FE 2, even the centers that used the Lotus Edge were getting higher pacemaker rates than reported in the literature. FE 2 noted that "a lot" of Boston Scientific sales representatives "still had centers that were still getting pace rates in the high teens to 20% range, which is higher than our competitors that were in single digits or low teens."

K. Rather than Offer "Ease of Use," The Executive Defendants Knew The Lotus Edge Was Incredibly Difficult to Use And Its Complexity Led To The Very Patient Outcomes the Device Was Supposed to Avoid

107. While Defendants were representing that the Lotus Edge was being rapidly adopted by hospitals and TAVR centers and well received by physicians during the Class Period, Defendants concealed that the Lotus Edge still suffered from the fatal design flaws that caused the delivery system to malfunction before the Class Period, and which had repeatedly previously delayed FDA approval.

108. For example, FE 3, a Therapy Consultant at Boston Scientific in the Structural Heart Division, in San Diego responsible for the launch of the Lotus Edge, market development, and customer education and training, described several flaws of the Lotus Edge's delivery system that were not remedied prior the Lotus commercial launch, contributed to the poor adoption by surgeons, and led the Company to pull the product. Specifically, FE 3, who worked at Boston Scientific in February 2017 (just as the Company announced the global recall of the Lotus Valve) through January 2021, explained that the complexity of the delivery system—and the fact that there were numerous moving parts that had to work and perform together in a challenging anatomical environment—could cause the valve to malfunction. And in certain cases, in order to address the malfunction, surgeons would convert to open-heart surgery—the very risk that the TAVR device was intended to avoid.

109. FE 3 explained that this malfunction—termed internally by Boston Scientific personnel as "Twisted Post"—occurred when the three push-pull rods utilized in the Lotus delivery system prevented the Lotus valve from locking into position properly because it would be impeded by friction due to heavy calcium or other issues in the patient's anatomical valve. As FE 3 explained, "The complexity is there are too many moving parts. It's kind of like a high school track: one on the inside has the shorter route and the outside has a longer route." If all three-push

pull rods are not coaxial, one of the rods will have a longer distance to travel, and the user will have trouble locking the valve.

110. The Twisted Post phenomenon was well known within the Company and, in fact, FE 3 confirmed that Boston Scientific had an "absolute laser focus" on the Twisted Post problem and "constantly" trained consultants on how to identify this issue and where in the anatomy it was most likely to happen. FE 3 recounted that almost every weekly training call in the last six months of FE 3's tenure at Boston Scientific addressed Twisted Post. FE 3 explained that the Company's senior management focused on the Twisted Post issue in weekly training sessions conducted by Chris Frawley, and also in quarterly sales meetings attended by Defendants Meredith, Kevin Ballinger and Shawn McCarthy. According to FE 3, Defendant Meredith was involved in working with sales representatives and addressing the Twisted Post problems in training sessions.

111. FE 3 also confirmed that a related phenomenon—termed Floppy Post—had led to the prior global Lotus recall in 2017. FE 3 was hired in February 2017 at the same time Lotus was recalled in order to fix the pins that keep the valve's post attached to the delivery system until the posts latch into the buckles. FE 3 explained that the Lotus Edge has three locking mechanisms, and if two locked but one did not, it caused the valve to work improperly, necessitating removal and replacement. FE 3 explained further that Floppy Post can occur when the pins in the locking mechanism are pulled out of the post prematurely, or a pin is pulled out because it did not lock into place, causing a post to be free instead of locked into the flow portion of the valve. FE 3 explained that while Floppy Post could be remedied by recapturing and redeploying the valve, Twisted Post cannot be remedied and was "the main problem" with the Lotus platform. According to FE 3, a Twisted Post meant means that when the post and buckle do not lock together, it is stuck

bad enough that the patient will have to undergo open heart surgery—which was an outcome FE 3 said happened after the April 2019 launch.

112. FE 4, an Interventional Cardiology Territory Manager at Boston Scientific responsible for Lotus sales from January 2016 to January 2021, reported that while Boston Scientific sales force training guides claimed Twisted Post was a "rare event," in fact, the opposite was true. In reality, it was "not a rare event, it happened 50% of all cases." FE 4 highlighted that, not only were serious incidents like Twisted Post extraordinarily common, but the Lotus Edge sales staff was woefully underprepared to address them. As FE 4 explained, a major failing of the Lotus Edge launch was a lack of training and experience of the salesforce with TAVR procedures. FE 4 explained that the industry standard—and the requirement for both Medtronic and Edwards for their TAVR devices—was for a sales representative to participate in 50 to 75 TAVR procedures before being "certified" to oversee procedures as a sale representative. But at Boston Scientific for Lotus Edge, sales representatives would be certified after participating in, at most, 25 Lotus Edge procedures, and often certified with far fewer. As FE 4 recounted, sales training for Boston Scientific's Watchman device—which is a "super easy" device in comparison—required representatives to participate in about 75 to 100 procedures prior to certification.

113. Further compounding the problems associated with a lack of training, a substantial number of Lotus Edge representatives had no prior TAVR experience whatsoever—a particularly problematic feature of the launch given that, as FE 4 described, the Lotus Edge "was the most complicated device on the planet" involving an inherently complicated TAVR procedure. The Lotus Edge clinical support staff at Boston Scientific was so ill-equipped that, as late as mid-summer 2020—more than a year after the launch—Boston Scientific only had 21 (out of 85) representatives and clinicians that could support all levels of sites/implanters in the country for the

Lotus Edge. Moreover, many of these 21 purportedly "fully qualified" representatives were "certified" by Boston Scientific to oversee Lotus Edge cases on their own after participating in only five or so Lotus Edge procedures. As FE 4 explained, while Boston Scientific would accelerate the certification of those representatives by taking into account prior experience with other TAVR devices, like Sapien and CoreValve, the Lotus Edge was entirely unlike those devices and that prior experience did not equip those representatives from handling Lotus Edge procedures on their own. In short, the lack of training and expertise provided to support Lotus Edge—one of the most "complicated devices on the planet"—rendered the launch "clinically unsafe."

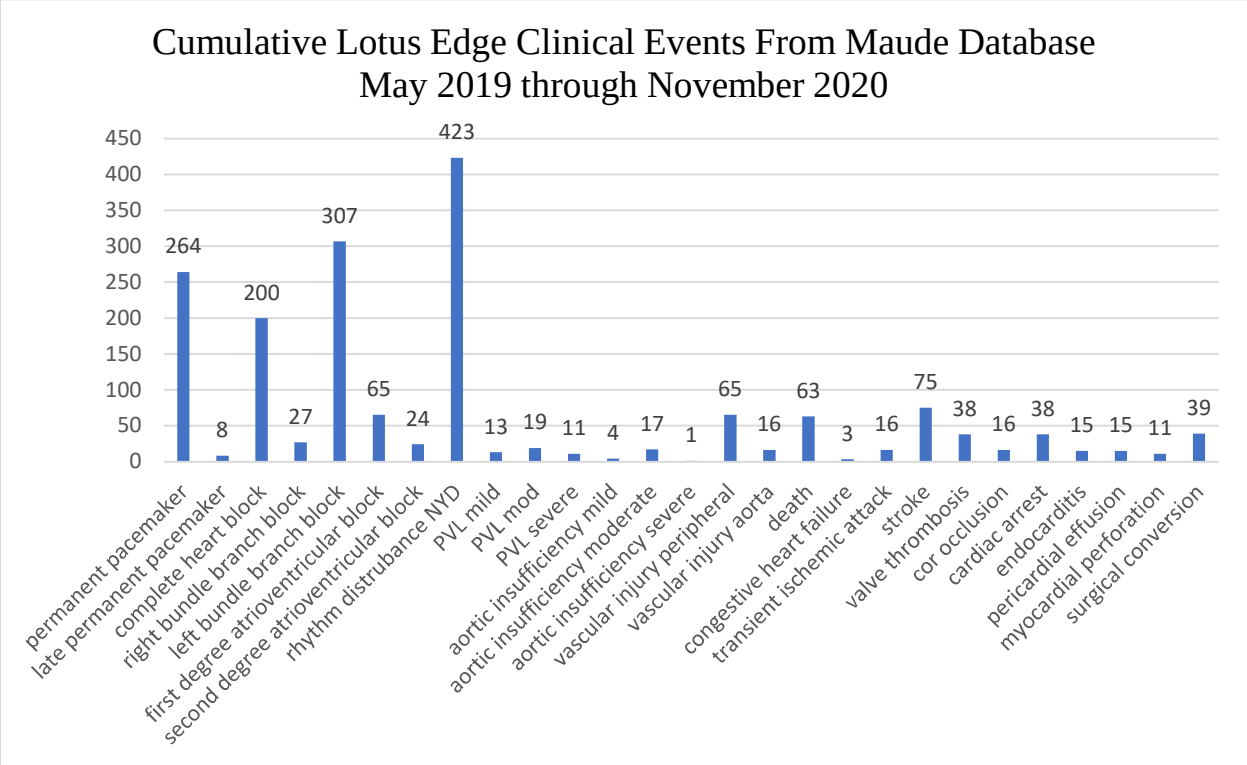
114. Similarly, FE 5, a salesperson for Boston Scientific in the Southern Germany region from 2017 until October 2020, confirmed that the problems in 2019 and 2020 with the Lotus's delivery system were similar to the issues that had led to the 2017 recall. FE 5 knew about the problems in the United States because employees were required to write a complaint about every issue experienced, and according to FE 5, the complaints were regularly discussed at firm-wide conference calls conducted by Chris Frawley, the product engineer in charge of Lotus Edge.

115. In fact, Boston Scientific regularly submitted to the FDA adverse event reports concerning the Lotus Edge that revealed problems with the device were causing an alarming incidence of deaths, serious injuries, and complications from the device's delivery system malfunctioning. Under FDA regulations, "device user facilities"—essentially, hospitals and other health care centers—are required to report to both the FDA and the manufacturer whenever a device is believed to have caused or contributed to a patient's death. 21 C.F.R. § 803.30(a)(1). User facilities are also required to report to the manufacturer when a serious injury occurs that may reasonably be attributed to a device. 21 C.F.R. § 803.30(a)(2).

116. In turn, when the manufacturer receives information about an adverse event involving its device—whether from a user facility or through a complaint from any other source—it is required to conduct its own investigation and report to the FDA if the incident involved either (1) a death or serious injury to a patient attributable to the device or (2) a malfunction of the device that could cause a death or serious injury if it were to recur in the same or a similar product. 21 C.F.R. § 830.50. Further, Boston Scientific was specifically required to monitor and track adverse events associated with the Lotus Edge in connection with its approval by the FDA. The adverse event reports that are sent to the FDA are compiled in the agency's Manufacturer and User Facility Device Experience ("MAUDE") database, which is used to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. *See* 21 C.F.R. Pt. 803.

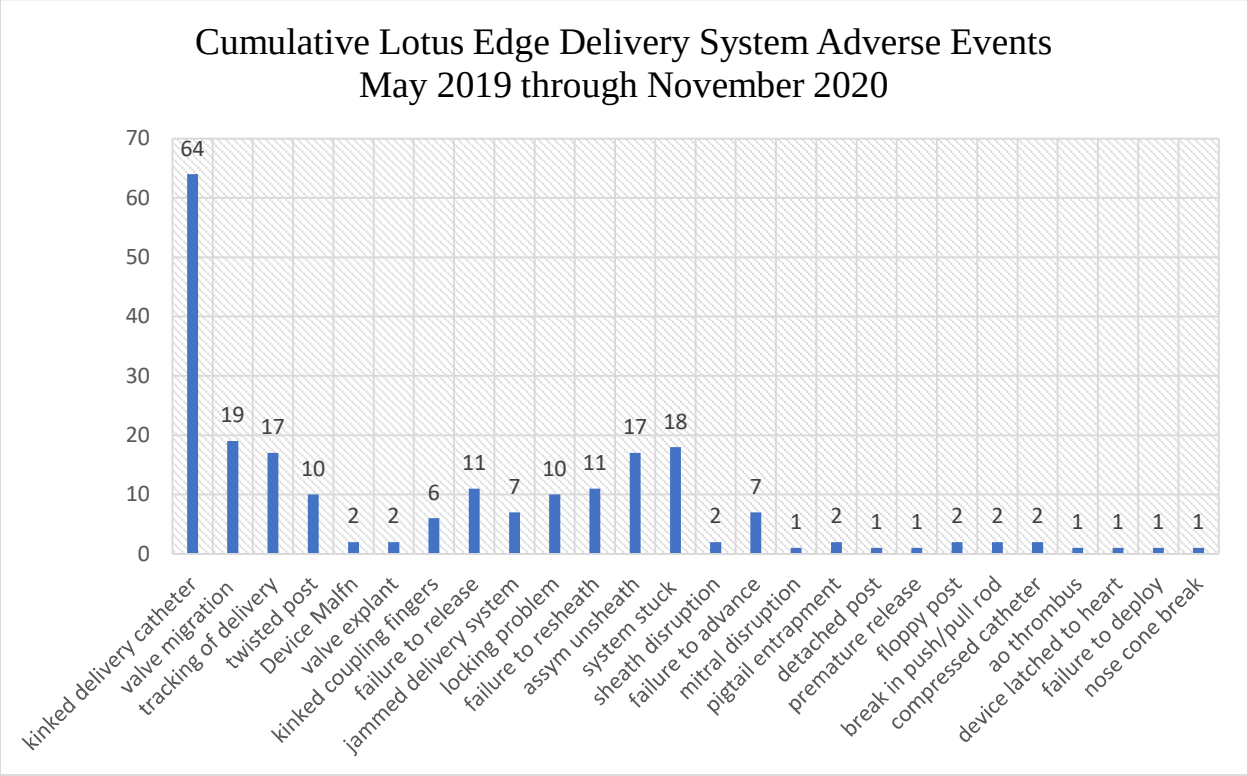
117. As the manufacturer of the Lotus Edge, Boston Scientific was required by federal law to monitor, investigate and report adverse events to the FDA, and the Executive Defendants in fact closely tracked the adverse events associated with the Lotus Edge. As recounted by numerous former Boston Scientific employees, the Company held nationwide weekly sales training sessions during the Class Period addressing Lotus Edge adverse events, as well as other companywide training sessions attended by Defendant Ballinger, Defendant Meredith and Defendant McCarthy at which adverse events were discussed. And, as Defendant Ballinger himself told investors before the Class Period specifically regarding the Company's interactions with the FDA concerning Lotus, "the FDA dialogue…has been frequent, it's been constructive. I've made that point before. That's been very, very positive in terms of just the ongoing dialogue and understanding and back and forth between Boston Scientific and those agencies."

118. As the Executive Defendants knew well, during the Class Period, the number of adverse events for Lotus Edge far outpaced the numbers of adverse events reported for Lotus's competitors, Edwards' SAPIEN and Medtronic's CoreValve. In fact, while the Lotus Edge accounted for only 2% of all TAVR procedures, it accounted for approximately 12% of adverse events reported for the three devices from May 2019 through November 2020 based on an analysis of MAUDE report. Moreover, those adverse events included 63 deaths, 91 incidents of stroke or transient ischemic attack, and hundreds of other life-threatening events (such as heart attacks, atrioventricular and complete heart block requiring permanent pacemakers, and other cardiac conduction abnormalities, such as right and left bundle branch block), as shown below:



119. Importantly, these adverse events occurred on a consistent basis throughout the Class Period, with the number of adverse events averaging around 50 per month, and steadily increased throughout 2020, with 67, 79, and 64 events reported for the months of September, October, and November, respectively.

120. Moreover, between May 2019 and November 2020, 222 MDRs were submitted to the FDA indicating an adverse event occurred due to a problem with the Lotus Edge's delivery system—including dozens of serious life-threatening events that demonstrated the severity of the risk and danger posed by this aspect of the device:



121. These adverse events, and others like those described in the MAUDE database, were used as exemplars in internal Boston Scientific sales and clinical training presentations as presenting serious, life-threatening risks. To take one example, internal Boston Scientific training manuals warned that "**Kinked** catheters ***MUST*** be ***removed***," that "a kinked catheter needs to be replaced as the mechanisms in the delivery system will no longer work appropriately," and that "kinked catheters are potentially dangerous and can lead to significant complications if the kinked system is not removed." In another example, internal Boston Scientific training slides instructed that upon identifying "asymmetric unsheathing"—which can occur due to anatomical

circumstances not allowing the inflow portion of the valve to fully open—to "perform a partial resheath and re-deploy to resolve." The training guides warned that a "full resheath" may be required if the valve is initially placed too high, which could impair coronaries or lead to suboptimal valve anchoring (i.e., the valve would not be placed securely)—and that a "full resheath" could only be performed once because that would damage the valve leaflets. In that instance, the operator would have to take that valve out, and the implantation process would have to start over with a new valve.

L. Boston Scientific Works To Develop A Replacement For The Lotus Edge Because The Device Was Difficult To Use And Unsuitable For The Vast Majority Of TAVR Patients

122. At the same time Defendants were touting the success of the Lotus Edge's launch and its adoption by physicians based on its purported "ease of use," the Company was developing a new TAVR device that would replace the Lotus Edge precisely because the Lotus Edge was difficult to use. FE 6, a Principal Human Factors Engineer at Boston Scientific from February 2019 to April 2020, was hired to work on developing a new deployment system for a next generation TAVR valve that was intended to replace the Lotus Edge, and said that Boston Scientific misrepresented the issues with Lotus.

123. FE 6 explained that the Company's idea was to release the Lotus Edge, after FDA approval, but release a next generation TAVR system to replace it as soon as possible. As FE 6 recounted, this was because Boston Scientific senior management knew that the Lotus Edge was hard for physicians to use—an issue that was known and "went all the way up" to the senior-most levels of the Company—but the Company needed to have a TAVR valve in order to "keep their share" of the market.

124. FE 6 explained that the complexity and difficulty in operating the Lotus Edge delivery mechanism was a critical problem and an intense focus by the Company during the Class

Period. In fact, when interviewing for the job at Boston Scientific in July 2018, FE 6 was told by the Lotus Edge chief engineer who hired FE 6, Dan Foster, that the Lotus required three hands to operate due to its complexity. FE 6 confirmed that the knowledge that the Lotus was hard to use "went all the way up" in the Company and that the next generation TAVR initiative was a big priority and that Boston Scientific was "throwing" money at it because they knew Lotus was "an issue." According to FE 6, Boston Scientific's senior leadership knew that the Lotus had safety issues because it was hard to deploy and difficult to use by surgeons. FE 6 also said the Company knew physicians were not adopting it because it was hard to operate. As FE 6 explained, "you need three hands to operate it, and doctors have two." FE 6 stated that physicians did not want to use the Lotus Edge; it was too difficult to use and required extensive training to learn how to use. According to FE 6, the Company was desperately seeking to replace the Lotus Edge during the Class Period because it had a "such crappy design," and physicians would rather use Medtronic's or Edwards' TAVR products because their devices required two steps "rather than 35."

125. As a human factor engineer, FE 6 was responsible for addressing the device from the perspective of the user by addressing and augmenting systems to reduce human error and enhance performance. FE 6 confirmed that Boston Scientific did not perform this work when it initially developed the Lotus—a fact that was evident to FE 6 because, when FE 6 asked to see prior user studies, task analyses, and data on the product of the kind he was used to reviewing when working on devices at FE 6's former employer (Medtronic), they did not exist at Boston Scientific. Typically, feedback and information from product users is abundant after a product like Lotus is released into the market—and that was FE 6's experience at Medtronic—but the lack of feedback and information at Boston Scientific with regard to physicians' experience with Lotus was a "big problem." For example, while Medtronic compiled yearly system engineering reports

summarizing everything that went wrong with a product, Boston Scientific's information was scattered, hard to retrieve and near impossible to use. For example, FE 6 explained that while Boston Scientific maintained a database for product complaints as required by the FDA, this database was "near impossible" to sift through, had to be read line-by-line, and did not identify human engineering issues—even though the database should have been a key source of information concerning human engineering issues.

126. According to FE 6, Boston Scientific's priority on "selling" Lotus interfered with its engineers' ability to make it a useable and safe device from a human factor engineering standpoint. FE 6 explained that performing effective human factor engineering requires interacting with and interviewing the actual users of the product—physicians—and that was not an option at Boston Scientific. Boston Scientific did not want FE 6 or other engineers interacting with doctors because Boston Scientific management was worried engineers might say something "wrong" to the doctors—even though a human factor engineer's job is to interact with the users of the product to understand how mistakes are made and prevent them from happening.

127. At Boston Scientific, however, FE 6 said that trying to interact with physicians was a "dead end." In fact, FE 6, who used to work in aviation, said Boston Scientific's approach to the Lotus Edge shared disturbing similarities with the disregard for human factor engineering that led to the Boeing 737 MAX crashes. While FE 6's job was to figure out the problems with the delivery system that led to the prior recalls, those issues were not going to be solved because the human factor engineering group did not have access to information about what the problems actually were. According to FE 6: "It was not going to get solved and that's why I left…no one took it seriously."

128. Like FE 3, FE 6 explained that the problems with the Lotus Edge delivery system in numerous cases required the physician to abandon transcatheter implantation and resort to open

heart surgery. FE 6 explained the mechanism of the delivery system was "easy to mess up," and the valve was difficult to successfully implant. First, Lotus is "packed" in the valve and folded up like origami and must be opened like a flower once the artificial valve reaches the native aortic valve. Once there, the artificial valve has to be pushed out the end of the catheter using one knob, while another knob opens the petals of the flower, i.e., the valve. And once the Lotus is opened, it is moved inside the heart using another wheel on the delivery system handle that moves it backwards or forwards. When the physician opens the Lotus from its packed origami position, the physician must always be monitoring and shifting the valve at the same time because if the Lotus is overextended, it can break or be placed in the wrong position. FE 6 stated that "it's easy to mess it up, and the ramification of that is open heart surgery."

129. While working at the Company, FE 6 repeatedly raised concerns that the Company needed to perform adequate human factor engineering on the customer-end while developing the Lotus Edge replacement—but that this was not done. FE 6 brought this concern up with his direct reports and program managers, but was told to work within the system and how they did things at Boston Scientific. Ultimately, FE 6 explained, Boston Scientific "didn't want to deal with me and booted me. I was [previously] in aviation and it's life or death things, and they weren't doing these things."

M. Defendants' Statements to Investors Were "Deceiving" Because, In Truth, Lotus Edge Sales Were "Struggling," There Was "No Organic Growth," And "No One Ordering the Product"

130. As a result of the difficulty for physicians to properly use the product and the extensive training doing so required, the Lotus launch never got off the ground. Indeed, contrary to Defendants' claims during the Class Period that the Company was "seeing very high reorder rates of Lotus," that "the reorder rate for existing users is quite high," that "we're growing actual procedures per center, per month," in reality, physicians did not embrace the Lotus Edge—and the

few centers that initially purchased the device did not re-order it. The poor reception of the Lotus Edge caused the Company to continually miss internal sales and revenue targets that the Executive Defendants closely tracked, and the actual sales figures they reviewed demonstrated that the Lotus Edge was severely underperforming.

131. In fact, rather than experience "strong" reorder rates of the supposedly 150 accounts that Boston Scientific opened during the Class Period, in truth, internal nonpublic Company documents confirmed that by mid-2020, "to date, only 12 accounts are implanting 2 / month or more (9 at a rate of 2.5+)"—demonstrating that a mere nine accounts were responsible for the supposed "strong" reorders of Lotus Edge.

132. Indeed, former Boston Scientific employees who had access to the Company's internal sales figures confirmed that, throughout the Class Period, Lotus sales were far below targets and that Defendants' claims that the Lotus Edge launch was going "extremely well" were not true. For example, FE 7, a Senior Financial Analyst at Boston Scientific from January 2019 to August 2020 who worked on the operating expenses team and was responsible for projecting sales commissions for the North American sales staff said that the Lotus Edge was "consistently underperforming."

133. According to FE 7, who reviewed internal non-public Lotus Edge revenues and worked closely with the financial team that forecasted product revenues, Lotus Edge "came in at less than half of what they expected for 2019." And then, after the 2019 sales experience was taken into account and incorporated into the 2020 forecasts, "it still really underperformed." The team that handled Lotus Edge's financials was "constantly not meeting expectations from a revenue standpoint," it was well known that "they were really missing their targets," and the revenue performance never changed throughout FE 7's tenure at Boston Scientific. According to

FE 7, the Lotus Edge group came into 2020 "50% short" and "they were chopping the forecast every quarter by about 25% during the quarterly forecast recalculations. Even then they were still missing every quarter by 25%." FE 7 said that Defendants' claims to the contrary—that the Lotus Edge launch was "going extremely well" and that there was "continued uptake"—were "deceiving" because, in reality, sales were "struggling" throughout the Class Period.

134. As FE 1 recounted, while the Company's revenue targets for the Lotus Edge were aggressive, but the sales "just weren't coming in." FE 1 explained that for 2020, of the 120 sales representatives in Structural Heart across the U.S., only 15 to 20 sales representatives were hitting their quota, and the remaining 100 sales representatives were missing and "missing big," typically by 50% or more. According to FE 1, "[o]ur target for 2020 was $220 million. We ended the year at $40 million in sales." FE 1 knew this because he would see reports and slides with the monthly and quarterly results from across the U.S., and FE 1 also had access to a dashboard that showed these numbers. The Executive Defendants had access to these dashboards, and Defendants McCarthy, Ballinger, and Meredith would discuss them at quarterly company-wide sales meetings, and it was clear throughout 2019 and 2020 that sales were coming in far below targets. As FE 1 explained, "There was just really no one ordering more product based on usage so there was no organic growth in the sales."

135. Similarly, FE 5, a sales representative and care coordinator in Boston Scientific's southern Germany region from 2017 through October 2020 who was responsible for selling Lotus Edge, confirmed the disastrous sales rates throughout 2019 and 2020. FE 5 explained that the high cost of the device, as well as the fact that the LOTUS Edge required extensive training and presented a steep learning curve for surgeons who had not used it before, severely hampered sales. According to FE 5, in Germany, insurance reimbursement limits—combined with relatively high

price of Lotus Edge compared to Medtronic and Edwards' devices—provided little financial incentive for doctors to use it. And because the device required extensive training and was only appropriate for a small number of high-risk patients, sales in Germany collapsed in 2019 and 2020.

136. The continual underperformance of the Lotus Edge was not lost on Boston Scientific's leadership. FE 7 stated that the "C-Suite" was "absolutely aware" of the poor sales performance for Lotus Edge. According to FE 7, "a lot of time was spent discussing Lotus with all the leadership [throughout 2019 and 2020] about how to turn it around," and that divisional controller "was constantly being asked questions" by Defendant Mahoney about Lotus sales—a fact that FE 7 learned from Mike Lang, the Vice President of Global Structural Heart Valves Marketing.

N. The Executive Defendants Convened An Emergency Meeting Of The Entire Lotus Edge Sales Force Over The Thanksgiving Weekend In 2019 Because The Launch Was In Crisis

137. Because of the poor Lotus sales results and, following several patient injuries and deaths, the Executive Defendants convened an emergency companywide meeting of the entire Lotus Edge sales force over the Thanksgiving weekend in 2019. As reported by numerous former Boston Scientific employees, including FE 2 and FE 1, this meeting, held on the Saturday and Sunday following Thanksgiving in November 2019 (November 30 and December 1) at the Company's offices in Maple Grove, Minnesota, was attended by Defendant Meredith, Defendant Ballinger, and Defendant McCarthy, as well as the head of Structural Heart sales, Samuel Conaway, to provide additional instruction to representatives after a series of bad patient outcomes that the Company had blamed on poor sales representative training. At the meeting, sales representatives were provided additional retraining and addressed cases in which the Lotus Edge had been improperly placed, and discussed how to handle instances of floppy post and twisted post. The companywide salesforce meeting also addressed the poor sales results for Lotus, how

the Company was well behind targets, and provided talking points for sales representatives to get physicians comfortable using the Lotus Edge given its higher risk indication, higher pacemaker rate numbers, and other difficulties physicians expressed about the device as compared to Medtronic and Edwards' TAVR devices.[2]

O. The Lotus Edge Never Achieved Acceptable Manufacturing Yield Rates, A Viable Commercial Production State, Or Sustainable Profit Margins

138. At the same time Boston Scientific was experiencing abysmal sales and reorder rates for the Lotus Edge, the Lotus Edge was beset by manufacturing challenges that made the Lotus Edge margins unsustainable. While Defendants made repeated assurances to investors about the manufacturing tweaks it purportedly made to address the problems with the Lotus that had led to the prior recalls—describing those changes as "a combination of minor process and specification changes" and "relatively minor process and specification changes along with a final inspection step"—in reality, the device's manufacturing problems were never fixed.

139. In truth, the manufacturing challenges posed by the Lotus Edge were extraordinary, resulted in yield rates that were unacceptable and far below industry-standard commercial production rates, and like nothing the Boston Scientific employees responsible for manufacturing the Lotus Edge had ever encountered.

140. For example, FE 8, a Financial Analyst at Boston Scientific's Maple Grove plant from April 2016 until July 2019, recounted that, throughout FE 8's tenure at the Company, there were technical challenges with the Lotus Edge's delivery system that Boston Scientific was constantly trying to fix. According to FE 8, the Maple Grove plant struggled to manufacture the extruded tube that held all of the control cables for the Lotus Edge's delivery system. Specifically,

[2] A similar emergency retraining meeting for clinical support staff in Europe led by Chris Frawley was held in Paris around this same time.

one end of the delivery system has the handle and controls that the physician is using while the actual TAVR valve inserted inside the patient is on the other. Connecting these two end points is a long, extruded tube that houses all the cables that send the handle's commands to the TAVR device and its releasing component and communicate information back to the user.

141. But according to FE 8, the difficulties in manufacturing this extruded component were so incredibly challenging, and the yields were so low, that the Company was "struggling to get it to a commercial production state." Specifically, FE 8 said that prior to the Class Period, from 2016 to the end of 2018, the manufacturing yields for the extruded tube were a mere 5-10%, meaning that for every 10 to 20 units the Maple Grove plant produced, only one was acceptable and moved forward into the final assembly of the Lotus device. FE 8 said that by the time FE 8 left the Company in the middle of 2019, the yield rate for this unit had only risen to just around 20%. By contrast, industry standard baseline yield rates for medical devices at the time of commercial production are generally 85%—including the yield rates for other devices that FE 8 had worked on at Boston Scientific and while previously employed by another large medical device company—and are expected to improve after that time; even a 50% yield rate is "extraordinarily low."

142. Similarly, FE 9, a Manufacturing Engineer at Boston Scientific's manufacturing facility in Penang, Malaysia, reported that another component of the Lotus Edge—the bovine tissue component of the valve—also had a very low yield rate. Specifically, FE 9 said the bovine component manufactured in the Penang facility had a "very high-risk scrap rate" and that the engineers in Penang "were never able to solve the issues completely." FE 9 reported that the yield rate for this component was approximately 70% at best, "maybe lower"—meaning that about one-third of the component did not meet specifications and had to be scrapped. FE 9 reported that

throughout her time at Boston Scientific from 2018 through March 2020, the scrap rate for this component never improved.

143. These manufacturing problems were closely tracked by Boston Scientific's senior management and discussed at monthly meetings. For example, FE 8 stated that the extraordinarily low yield rates were a major concern of the Company and a "hot topic" discussed with the plant's senior leadership, and documented in PowerPoints and excel charts and shared at engineering status updates every month as part of regular engineering status updates.

144. Numerous other former Boston Scientific employees confirmed the impact of the poor yield rates for the key components for the Lotus Edge on the product's gross margins. For example, FE 3 confirmed that the Cost of Goods Sold ("COGS") of the Lotus Edge was always extraordinarily high and outside industry norms, where gross margins are around 90%. According to FE 3, the Lotus Edge cost around $20,000 to manufacture. At the same time, Edwards and Medtronic were selling their devices for much lower prices, and hospitals and clinical practices were in turn demanding that Boston Scientific meet or beat those lower prices. FE 3 said that, as a result, the price of the Lotus Edge declined during the Class Period to approximately $28,000—leaving the device with a less than 30% margin.

P. After Receiving "No Re-Orders" In 2019, Boston Scientific Shuts Down A Key Lotus Edge Manufacturing Facility

145. Following numerous adverse events and deaths the Company blamed on a lack of sales representative training, an emergency company-wide sales meeting in Minnesota, and reviewing abysmal sales figures for 2019—which amounted to half the Company's internal targets—Boston Scientific decided to shut down certain manufacturing operations for the Lotus Edge.

146. Specifically, FE 9, a Manufacturing Engineer at Boston Scientific's facility in Penang, Malaysia from early 2018 until March 2020, recounted that there were "zero orders" for the Lotus Edge through the end of 2019 and first quarter of 2020. Indeed, contrary to Defendant Mahoney's statement to investors in June 2019 that the Penang facility was "ramping up right now with Lotus valve" after it had "gained good early momentum," FE 9 reported that the facility was "getting zero orders" for Lotus at the end of 2019, that little to no work was being done, and that the plant was shut down in March 2020. FE 9 confirmed that the fact that there were "zero orders" for Lotus, and that no manufacturing work was being performed on the device in Penang, was something that occurred before the major worldwide slowdowns resulting from COVID-19. This shutdown is also significant in light of the fact that the device has a nine-month expiration date, meaning that a shutdown in the first quarter 2020 would mean there would be no usable product in the fourth quarter of 2020, and that any product that had been manufactured in June 2019 when the Penang facility was purportedly "ramping up" would be expired by March 2020.

147. As recounted by FE 1, even though Boston Scientific was desperately pushing sales by providing discounts for TAVR centers to purchase Lotus in bulk at the end of 2019, most of those units "ended up never being used and just expiring on the shelf." Thus, according to FE 1, Boston Scientific pursued the bulk-discount strategy to "put the revenue in 2019 and worry about 2020 when it comes around," which left TAVR centers without any usable Lotus inventory—meaning that Boston Scientific shut down production in Penang when there would have been little to no unexpired inventory for Boston Scientific to sell.

Q. After Key Lotus Executives Depart The Company And Boston Scientific Secretly Concludes The Franchise Is Doomed, The Company Renegotiates Its Debt and Raises Over $2 Billion from Public Investors

148. By the end of 2019, after the dismal sales results confirmed that Lotus Edge sales would never penetrate the 20% of the market Defendants claimed, and that the product's disastrous

margins would never improve, it was clear the franchise was doomed. Indeed, reading the writing on the wall, the key executives responsible for the Lotus Edge headed for the exits at the end of 2019—evidencing their knowledge that there was no hope for the product.

149. For example, Defendant McCarthy, the General Manager of Structural Heart Valves, who had served as the leader of the Lotus franchise and the product's spokesperson at the Company's biannual investor day just months before, resigned to take on another role at a different company later that year. Similarly, the head of Lotus sales and Structural Heart in Europe for the past five years—Sandrine Maset—was transitioned over to a new department (Urology and Pelvic Health) in May 2019, just one month after Lotus was approved in the United States. One of the primary Lotus Edge sales leaders in the United States, Area Vice Presidents for Structural Heart, Richard Maher—who had formally worked in TAVR sales at Edwards and recruited a number of sales representatives from Edwards to Boston Scientific to develop the Lotus sales team—left the Company in February 2020. And Defendant Ballinger, the executive vice president and global president, Interventional Cardiology who announced the FDA's approval of Lotus Edge, took a job at a venture capital firm in June 2020. As FE 4, an Interventional Cardiology Territory Manager at Boston Scientific responsible for Lotus sales during her tenure at the Company from January 2016 to January 2021 said that senior executives in charge of Lotus kept leaving the Company because they knew "the shit would hit the fan," as Lotus was clearly not a viable option and its use resulted in complaints and deaths. As FE 4 reported, there were serious problems with Lotus Edge that were not being publicly disclosed including concerning patient safety and sales, and that "people left the Company and did not want to be affiliated or associated. The writing was on the wall."

150. Rather than disclose the truth about Lotus, the Company continued to tout the product's purported success. Boston Scientific and the Executive Defendants were highly motivated to do so because, by the end of 2019, the Company's finances were in a precarious condition, which only intensified with the onset of the pandemic. Specifically, after a string of acquisitions in 2018 (nine acquisitions totaling approximately $6 billion) and 2019, Boston Scientific was increasingly at risk of breaching its loan covenants with its lenders.

151. At of the end of 2019, Boston Scientific's debt covenants required Boston Scientific to maintain a debt leverage ratio of total debt to consolidated EBITDA of 3.75 times, except in the case of a "Qualified Acquisition." In that case, the leverage ratio maximum was 4.75, subject to a step-down for each successive quarter. Boston Scientific's purchase of British oncology device-maker BTG had increased Boston Scientific's total debt balance 150%, from approximately $7 billion to over $10 billion, from December 31, 2018 to December 31, 2019. While the BTG acquisition was a "Qualified Acquisition" that increased Boston Scientific's maximum leverage ratio to 4.75 at the end of 2019—the Company's debt covenants required Boston Scientific to reduce that ratio in each successive quarter to 4.50 times, 4.25 times, 4 times, and 3.75 times by year-end 2020.

152. However, in 2020, Boston Scientific almost triggered its leverage ratio. Indeed, immediately prior to renegotiation of its agreements with its lenders, total debt for the quarter ended March 30, 2020 was $10.336 billion and Consolidated EBITDA for the quarter (as defined by the lender agreements) was approximately $615 million. Assuming that the Company repeated its first quarter performance in the next three quarters and reported Consolidated EBITDA of $615 million in each successive quarter—a highly dubious proposition given that, by that time, the pandemic had significantly slowed other parts of Boston Scientific's business—the Company

would have breached its loan covenants by at least the fourth quarter of 2020, if not earlier. Specifically, under the scenario in which the Company (improbably) repeated its first quarter 2020 earnings performance in subsequent quarters but did not pay down or refinance its debt, Boston Scientific would have a leverage ratio of 4.2 in the fourth quarter of 2020—placing the Company in default and exceeding its maximum leverage ratio of 3.75 by a wide margin.

153. In fact, even if the Company had used all available cash on hand as of March 31, 2020 ($370 million) to pay down its debt (rather than renegotiate or issue equity), repeating first quarter performance in the following three quarters would result in a fourth-quarter 2020 leverage ratio of 4.05—again, well above the permitted 3.75 margin. In other words, assuming the Company could repeat its first-quarter performance in the second and third quarters of 2020, Boston Scientific would still exceed its leverage ratios by year-end, and would be in default. But as pandemic set in, Boston Scientific's senior management expected the Company's performance to be far worse than it was in first quarter.

154. Indeed, by the time of the first quarter earnings call on April 20, 2020, Boston Scientific was predicting revenue performance to be far worse in the second and third quarters—with Company revenues being cut in half compared to the prior-year quarters. As Defendant Brennan explained on the earnings call that day, even despite drastic cost-cutting measures taken by the Company in response to the pandemic, "given the relatively high fixed-cost nature of our business, we would expect a high decremental margin rate on lost revenue, including a sharp decline in adjusted operating margin in Q2 versus Q1, improving sequentially into Q3, and then Q4, where our goal is to return to revenue growth and ultimately more normalized margins, although certainly uncertain at this time."

155. Given the Company's dire financial condition in the first half of 2020, Defendants were highly motivated to keep the LOTUS failure a secret. Indeed, over that time, Boston Scientific renegotiated over $4 billion of its debt to avoid triggering the Company's debt leverage ratios. Boston Scientific would hardly have been able to successfully re-negotiate those loan terms had it truthfully disclosed that it was shutting down the LOTUS franchise—the business Defendant Mahoney had described as the Company's single biggest investment over the past several years.

156. Keeping the Lotus failure a secret not only enabled the Company to successfully renegotiate its debt terms, but also to raise over $2 billion from public investors. Specifically, after secretly shutting down its Malaysian Lotus manufacturing facility and terminating its employees, on May 21, 2020, Boston Scientific conducted the largest secondary public equity offering in the Company's history in which it generated approximately $2 billion in proceeds. Defendants were highly motivated to keep Boston Scientific's stock price as high as possible when conducting this unprecedented capital raise—indeed, Boston Scientific could not have raised this capital, and certainly not on the terms it did, if had it timely disclosed the failure of the Lotus franchise.[3]

157. The Executive Defendants' publicly stated they were very focused on the Company's debt ratios and the need to raise capital. For example, at an investor conference on May 27, 2020—the same day the offerings closed—an analyst questioned Defendant Mahoney about the timing and need for the capital raise. In response, Defendant Mahoney told investors that the substantial capital raise was "one we didn't take lightly. We spent a lot of time thinking about it."

[3] Specifically, Boston Scientific sold 25,550,000 shares of its common stock at a price of $34.25 per share and 8,750,000 shares of 5.50% Mandatory Convertible Preferred Stock, Series A, generating proceeds of approximately $2 billion.

158. Moreover, when another analyst suggested the capital raise indicated possible concerns about the success of the Lotus launch, Defendant Mahoney flatly rejected those concerns. Specifically, at the September 16, 2020 Morgan Stanley Health Conference, an analyst asked whether the capital raise w motivated by a belief that the Company's current pipeline of products could not achieve Boston Scientific's 6% to 9% organic growth target, and whether it indicated the Company had doubts about the LOTUS franchise:

> I've got this thesis that I don't think you agree with, but I'm going to throw it out there anyway. This dynamic that Lotus was supposed to be a much bigger product in my mind [than] maybe it's turned out to be and my concern was that Lotus may have resulted in kind of a gap in the portfolio and like I said, we've talked about this, I'm not sure you'll agree. But any concerns that Lotus could have been a $400 million, $500 million, $600 million product, $700 million product and it's not and that has sort of forced the company to sort of shift things around or it created a void in the LRP [long range plan] that has to be filled with M&A?

159. In response, Defendant Mahoney rejected that notion and assured investors the Lotus Edge would be an important "growth driver" and that the Company was seeing a "high" "reorder rate for existing users":

> No. 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.

160. Unknown to investors, however, at the time Defendant Mahoney made these statements on September 16, 2020, Boston Scientific had shut down its Penang facility because there were "zero orders" for Lotus, had already concluded it would shut down the business because of the extraordinary costs of manufacturing and selling the product, and had experienced dismal sales results from the start of the launch.

R. After Boston Scientific Secretly Implements the Plan To Shutdown The Lotus Franchise, Defendant Mahoney Unloads $9 Million Of His Personally Held Shares While Touting Lotus As An "Important Growth Driver"

161. Prior to publicly disclosing the shutdown of the LOTUS franchise—but after Boston Scientific senior management concluded it would do so—Defendant Mahoney entered a highly unique Rule 10b5-1 trading plan so that he could sell $9 million worth of stock. Specifically, on August 25, 2020, just one week after Boston Scientific falsely reported that the Company had opened 138 accounts and was continually and increasingly opening new accounts—when in truth, the Company never opened 100 accounts and already determined to shut down the business—Defendant Mahoney entered into a Rule 10b5-1 trading plan covering the sale of up to 259,207 shares of Boston Scientific stock worth approximately $10 million at the date of adoption. This trading plan was highly unusual and provides strong support for Defendant Mahoney's scienter.

162. First, this Rule 10b5-1 plan was designed to expire in exactly 50 business days from adoption—the shortest-lived Rule 10b5-1 plan ever adopted by Defendant Mahoney or any Boston Scientific executive based on publicly available records. Every single previous Rule 10b5-1 plan adopted by Defendant Mahoney covered a period of three to 12 months—and indeed, every other plan adopted by a Boston Scientific executive since 2017 (the earliest date for which data is publicly available) covered such a period.

163. Second, when Defendant Mahoney executed his trades under this plan, the shares were sold at prices below the share price over the preceding week—suggesting that the sales under the plan were triggered by a date threshold, as opposed to a price threshold. Such a timing trigger—instead of a price trigger—reflects a desire for short-term execution, and enabled Defendant Mahoney to time the disclosure of the Lotus Edge announcement such that the trades would be executed before the negative news was disclosed. Conversely, a plan that executed

pursuant to a limit order in which shares would be sold only after Boston Scientific shares reached a certain price (as is typical for Rule 10b5-1 plans) risked not executing at all before disclosure of the Lotus Edge recall.

164. Third, the shares executed under the plan were sold all at once—and thus it operated as a "single trade plan" that academics have identified as a red flag indicating insider trading or Rule 10b5-1 abuse. This was a first for Defendant Mahoney. Here, the sales under every prior Rule 10b5-1 plan adopted by Defendant Mahoney had been sold over the course of three or more months—not on a single day, as was the case here.

165. Fourth, the "effective cooling off" period for the plan—i.e., the time between adoption and when trades were executed—was less than 60 days, another red flag academics have warned indicates Rule 10b5-1 plan abuse.

166. Fifth, the timing of the sales under the plan appears non-random in light of the fact that they were executed three days prior to the scheduled expiry of the plan and *exactly* 14 days prior to the announcement of the Lotus shut-down.

167. In sum, of all of the Rule 10b5-1 trading plans disclosed by Boston Scientific for its named executive officers since 2017 (the earliest date such data is publicly available), never before had such a plan been adopted that was (1) designed to terminate so close to plan adoption, (2) sold such large dollar amount so close to plan adoption, and (3) sold such a large dollar amount all at once. This Rule 10b5-1 plan was a total outlier, unlike any plan that Defendant Mahoney or any other Boston Scientific executive had ever adopted, and has numerous characteristics that academics have identified as "red flags" of Rule 10b5-1 plan abuse.

168. Indeed, the unique and highly unusual characteristics of this 10b5-1 trading plan enabled Defendant Mahoney to sell over $9 million worth of his personally held stock exactly two

weeks before Boston Scientific disclosed the Lotus shut-down, and is highly probative of fraudulent intent. Defendant Mahoney was acutely aware that disclosure of bad news about Lotus would cause Boston Scientific stock to decline—as the Company's stock price had declined significantly in other prior instances before the Class Period when the Company had disclosed negative news about Lotus. And delaying disclosure of the Lotus shut-down until after his pre-planned November 2020 sales benefitted Defendant Mahoney enormously; had the shut-down been disclosed just two weeks earlier—for example, on the Company's October 28, 2020 third quarter earnings call—Defendant Mahoney's proceeds would have been slashed significantly.

S. Boston Scientific Raises Questions About The Lotus Edge By Revealing That Trial Enrollment Slowed But Falsely Claims That The Company Had "Opened More Than 150 Accounts In The U.S."

169. On October 15, 2020, at the Transcatheter Cardiovascular Therapeutics Conference, Boston Scientific showcased the purported success of the Lotus Edge platform. In prepared remarks, Defendant Fitzgerald—who had recently taken over for Defendant Ballinger as the head of Interventional Cardiology at Boston Scientific—said he was "really excited" about the success the Company had in the "LOTUS Edge launch in the U.S. and Japan and getting neo2 launched … despite the challenges with COVID around the globe." With respect to LOTUS Edge's launch, Fitzgerald declared that the Company had exceeded its publicly reported sales goals, and that the product was gaining momentum:

> Now turning to LOTUS Edge, I'm proud to report that we have opened more than 150 accounts in the United States. We are just starting to wrap up our limited market release in Japan with LOTUS Edge. And we, I think, are – and I think I know we are accelerating our momentum in our REPRISE IV medium risk indication trial, which like all of our other IDEs and clinical studies did take a bit of a hit there in Q2 and the early parts of Q3.

170. During the call, a Morgan Stanley analyst directly asked about where Boston Scientific was "in terms of the LOTUS Edge's rollout globally and thoughts about expectations

for share gains over the next few months." Rather than disclose the truth—that Boston Scientific had concluded earlier that year to shut down the business, that its Penang facility had not been manufacturing Lotus for months, and that there were "zero reorders" for the product—Defendant Fitzgerald told investors that Lotus was "growing actual procedures per center, per month" and that the launch was "gaining momentum." Specifically, Fitzgerald responded:

> [L]et's start with U.S. We – I consider that we just annualized our launch COVID sat right in the middle of that first 12 months of launch. But 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. We've got an improved version of iSLEEVE that will hit the US for an LMR [limited market release] in November.
>
> So we think that will have sort of an improvement in the ease of use in the overall implant experience. As well we continue to iterate the LOTUS Edge implant technique from learnings all over the globe. And I really like what I see Sam Conaway's team doing there. So we're going to continue this. This is now a ground game where we are expanding our footprint in the U.S., each month we're growing actual procedures per center, per month.
>
> And I probably don't want to give a point estimate, but we are going to continue to improve our ground game and then add on things like improved iSLEEVE and continue to make every implant and every next case better than the last case. And then the only other comment I'll make is we're very early in the Japan launch. That's been a very targeted LMR with a few sites in Japan that has just wrapped up. And now we are starting to plan for our market expansion in Japan.

171. Further, a presentation provided in connection with meeting stated that, for the Lotus Edge, there was "continued account expansion with over 250 accounts opened globally"—conveying to investors that there was an additional 100 accounts outside of the United States at the time of Defendants' statements.

172. Despite these positive statements about the Lotus Edge momentum and improving sales, Boston Scientific also disclosed a significant setback for the device. Specifically, Defendants disclosed that the Company expected a delay for FDA approval of the Lotus Edge for use in intermediate risk patients in 2024—or three years later than previously expected—which

Boston Scientific blamed on slow enrollment in the clinical trial assessing the device for that indication on COVID-19. As Defendant Fitzgerald disclosed at the conference, both the timeline for the FDA approval for an intermediate risk indication for Lotus Edge, as well as for the Accurate neo2, would be pushed out to 2024.

173. However, even when disclosing this negative news about the Lotus Edge timeline, Defendant Fitzgerald was adamant that future growth for Lotus Edge was a question of "when" not "if." For example, when an analyst asked for clarification about the timeline for the Lotus Edge and Acurate Neo2 intermediate risk approvals, Defendants Fitzgerald responded, "[T]hey're both 2024… it's a good question. I mean, this is an area I've really focused on. I'm kind of a stickler for putting realistic plans and then hitting those plans." In other words, Defendant Fitzgerald was assuring investors that even while the timeline had been pushed back, it was only because this timeline would be "hit"—a milestone Defendant Fitzgerald said he was confident about because he "really like[d] what I see Sam Conaway's team doing" and the fact that Boston Scientific was "expanding our footprint in the U.S., each month we're growing actual procedures per cent, per month."

174. Analysts reacted to the disclosure in assessing their valuations of Boston Scientific stock, but were reassured by Defendants' explanations that the trial enrollment difficulties were due to COVID—not some underlying problems with the device. For example, analysts at Cowen said that "Regarding the delays in the U.S. timelines for neo2 and Lotus Edge in intermediate risk to 2024, both are unfortunate but have explainable causes," and that for Lotus, "enrollment in Reprise IV has been hurt by COVID-19 and by general slowness in enrolling TAVR studies when several commercial options are available (so-called TAVR trial 'fatigue')." Similarly, Credit Suisse called the Lotus Edge delay "disappointing but manageable," estimating that, together with

the delay in the Neo2 timeline, the Lotus Edge intermediate risk delay had about a $1 impact per share based on current valuations. And analysts at Morgan Stanley questioned whether the COVID-19 pandemic was the full reason for the slow enrollment in the clinical trial, stating while "[i]t's reasonable to assume a 6-9 month impact from COVID-19 . . . there are clearly other factors at play. Simply, Lotus is feeling the effects of delayed, third to market status and the inability of Boston to enroll this study reflects the niche position of the valve in the commercial market."

175. But the analysts were reassured that, with Lotus, "BSX continues to gain share and expand to new centers, reaching over 150 accounts in the U.S. and over 250 globally" and noted Defendants' reassuring statements that the Company "continues enrolling patients in the U.S. REPRISE IV clinical trial to expand the indication to intermediate-risk patients." Boston Scientific shares declined in response to the news about the Lotus Edge, with Boston Scientific shares falling $1.12, from a close of $40.12 per share on October 14, 2020 to $39.00 per share on October 15, 2020, on heavy trading volume.

176. Investors were further reassured that the Lotus approval delay was manageable and otherwise a non-event two weeks later, when Boston Scientific held its third quarter earnings call. During that call, Boston Scientific addressed the Lotus Edge delay head-on in prepared remarks and in direct response to analyst questions, and highlighting growing TAVR sales:

> TAVR sales grew both year-over-year and sequentially as we continue to focus on the EU launch of ACURATE neo2 and US IDE enrollment as well as continued US and Japan rollout of LOTUS Edge and US intermediate risk trial enrollment.
>
> We're also pleased with the consistent progress of our cerebral embolic protection device, SENTINEL, which grew over 20% in the third quarter. As disclosed at our TCT webcast earlier this month, we now expect US approval for ACURATE neo2 in 2024 as well as LOTUS Edge indication expansion into intermediate risk in 2024.
>
> Our next-generation ACURATE neo2 is launching in Europe and now offers low PVL rates, best-in-class pacemaker rates, and great hemodynamics. LOTUS Edge

> offers predictable control with a platform that may be fully recaptured and repositioned at any time. We believe both valves offer distinct benefits, while SENTINEL has uniquely demonstrated a reduction in stroke rates during TAVR procedures in both as IDE and numerous large registries.

177. Further, in response to questions from Wells Fargo analyst Larry Beigelsen about the validity of the "two-valve" TAVR strategy—seeking to commercialize both Lotus and Acurate Neo2—Defendant Mahoney reassured investors of the Company's "strong results" for Lotus:

> Biegelsen: Good morning, guys. Thanks for taking the question. Just a follow-up on TAVR, actually, a couple TAVR questions, and I'll just leave it at that. Mike, at a high level, does it still make sense from an ROI perspective to develop two TAVR platforms?
>
> ****
>
> Mahoney: On the first question on our product portfolio, we're always looking at across our portfolio where investment spend makes the most sense, given the market opportunities. 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.

178. Analysts credited Defendants' representations, and reacted positively to the reassuring statements about Lotus. For example, analysts at Canaccord wrote that day that they felt "comfortable with BSX's overall long-term positioning" even as COVID cases had continued to accelerate, and highlighted the performance of the Structural Heart division, stating that the Company "continues to see encouraging results in existing sites that use LOTUS Edge but continues to struggle opening new sites given dynamics of the pandemic" and that the Company "continues to target indication expansion into intermediate risk by 2024." Analysts from Credit Suisse were similarly reassured, noting the Company's statements during the third quarter earnings call had mollified their concerns about the Lotus intermediate risk delay, stating "while the stock

had been under pressure since the company's announcement to push out the timeline for two of its TAVR clinical programs at TCT, we expect Q3 results, management's renewed commitment to its Q4 growth aspiration and robust product pipeline position BSX as an attractive name heading into 2021."

179. As investors and analysts digested the Company's representations, and analysts published reports on October 29, 2020 reaffirming their buy ratings for Boston Scientific, the stock closed up to close at $34.27 per share that Friday, October 30, 2020.

180. The following Tuesday, November 3, 2020, Defendant Mahoney sold over $9 million of his personally held shares pursuant to the Rule 10b5-1 plan he had adopted exactly 70 days earlier—and which was set to expire at the end of that week, on November 6, 2020.

T. Defendants Stun Investors By Disclosing That Boston Scientific Was Recalling the Lotus Edge, Shutting Down the Business, And Abandoning the Two-Valve TAVR Strategy

181. On November 17, 2020, before the market opened, Defendants stunned investors by disclosing that Boston Scientific had "initiated a global, voluntary recall of all unused inventory of the Lotus Edge Aortic Valve System due to complexities associated with the product delivery system." The release stated that, "[g]iven the additional time and investment required to develop and reintroduce an enhanced delivery system, the company has chosen to retire the entire LOTUS product platform immediately." Boston Scientific disclosed the Company faced "pre-tax GAAP charges of approximately $225 million to $300 million due to inventory, fixed asset, intangible asst and certain other exit charges" and noted that "$100 million to $150 million of these charges will impact the company's adjusted results."

182. That morning, Defendants held a special conference call related to their decision to recall the Lotus and terminate the platform, which Defendants had just two weeks earlier touted as one of the Company's brightest prospects. Defendants Mahoney, Fitzgerald, Brennan, Lisa, and

Meredith participated in the call. In a prepared statement on the call, Defendant Mahoney said, "The Lotus Chapter has been a difficult one for the company." Defendant Mahoney stated that Boston Scientific arrived at the decision to recall and discontinue Lotus "[a]fter much analysis and careful consideration," claiming that "we can better serve our patients by prioritizing and focusing our financial and employee resources on [a] one-valve platform, the Acurate neo2 system." Mahoney claimed the discontinuation of the Lotus platform "gives us the ability for greater commercial, clinical and development emphasis upon the other aspects of the IC [Interventional Cardiology] portfolio."

183. Defendant Brennan also disclosed on the call that Lotus "was overall a drag on the bottom line for the company," and for the first time revealed that in 2019, Lotus sales accounted for only $60 million in revenue, that 2020 sales were only on track for $75 million, and that the Company had estimated approximately $125 million in sales for 2021—amounts that were nearly half of what analysts had been estimating based on the Company's Class Period statements. Defendants also revealed that, with Lotus out of the picture, the Company would no longer achieve the 6-9% revenue growth that had been the Company's publicly touted growth profile.

184. During the question-and-answer session of the call, analysts reacted to news of the Lotus cancellation with shock and confusion. For example, an analyst from Morgan Stanley asked Defendant Mahoney why the Lotus decision should not make the market second guess whether "there's not other issues in the core portfolios" of Boston Scientific, since "when the company made a decision to have a two-valve platform, a lot of investors questioned [that]." Similarly, a SVB Leerink analyst asked whether the surprising disclosure about the Lotus franchise would permanently injure the Boston Scientific brand, questioning how Boston Scientific would prevent the recall from "frustrating customers across the brand and the product portfolio and interventional

cardiology."

185. Then, expressing confusion, a Guggenheim analyst asked Defendants to "clarify whether this decision was driven primarily by manufacturing challenges and your ability to make the delivery system, or was it pushback from customers who found it too complex to deploy?" He then added, "[I]s this in any way related to the pin release problem, which drove the issues back in 2017?" In stark contrast to his statements to investors just a month earlier that Boston Scientific was "expanding our footprint in the U.S., each month we're growing actual procedures per center, per month," Defendant Fitzgerald identified a laundry list of problems concealed from investors during the Class Period, including "the manufacturing challenges, the clinical support challenges, the repeatability, the scalability, the overall COGS profile, all of those" had led Boston Scientific to pull the product from the market and shut down the business.

186. Incredulous, the Guggenheim analyst directly asked what could have possibly changed over the course of a single month for Lotus to have been one of the Company's most promising Structural Heart products to a total loss, asking, "We've spoken a couple times in the last month [including at TCT]. Was there some event that occurred that caused you guys to make this decision now?"

187. Defendant Fitzgerald responded by admitting that—contrary to Boston Scientific's representation just a month earlier that it had landed 150 U.S. accounts—Boston Scientific had in fact never reached that milestone and that, in truth, the Company was still at "sub-100 accounts." Specifically, Defendant Fitzgerald admitted that "we came to the conclusion that to scale this – to go from sub-100 accounts today in the United States to hundreds of accounts [] we really were going to struggle … without a design enhancement."

188. Investor and analyst reaction was immediate and severe, with analysts pointing out

that Boston Scientific's disclosure was flatly inconsistent with the Company's repeated prior representations touting the success of Lotus—including the comments the Company had made about the product just weeks before. For example, BTIG analysts published a report noting that the Lotus recall "Adds Insult to Injury for Investors," slashed its price target by nearly 20% (from $48 to $41), and pointed out that "this decision comes just a month after BSX expressed confidence in its dual-valve TAVR strategy at the [TCT] meeting on the heels of disappointing SCOPE II data at that meeting." BTIG continued, "We believe this news adds to recent investor frustration on product timeline slippage and increases skepticism about BSX's ability to execute consistently" and "think investors will remain wary of new products, particularly in TAVR, for a while." Similarly, SVB Leerink published a report and "acknowledge[d] that this [Lotus news] – now in a series of what we'd characterize as mishaps… is likely frustrating for investors."

189. In addition, Raymond James published a report that noted that, "BSX will trade lower today on this morning's disclosure … The discontinuation of Lotus is a credibility ding to management, which will weigh on the stock." Likewise, in a report titled "Lotus Retirement Clipping Growth," UBS analysts said that the "Lotus cancellation is another setback for BSX, which has had its share of struggles over the past two years," while cautioning that "BSX has become more of a show-me story where the delivery of better numbers will be needed to get valuation credit."

190. In connection with the Lotus shutdown, the Company also disclosed the mass layoffs it had been planning for months. For example, the *Minneapolis/St. Paul Business Journal* reported that, in connection with recalling and discontinuing the Lotus Edge platform, Boston Scientific would lay off 106 employees associated with its Maple Grove facility.

191. Also on November 17, 2020, *Mass Device* published an article about Defendants'

disclosure recalling and discontinuing the Lotus Edge platform titled, "Boston Scientific throws in the towel on Lotus TAVR," noting that "Boston Scientific's move locks the company out of the competitive U.S. TAVR market for another two to three years, setting the company back after it was expected that Lotus Edge would be a 'major growth engine.'" Similarly, characterizing Boston Scientific's announcement as a "surprise," *MedTechDive* noted that "Boston Scientific had spoken about prospects for the Lotus product as recently as its investor presentation at TCT and its third-quarter earnings call, both last month."

192. As a result of the disclosure recalling Lotus and discontinuing the platform, Boston Scientific's stock price declined by $3.00 per share, or approximately 8%, from a price of $38.03 on November 16, 2020, to close at $35.03 per share on November 17, 2020 on the second-largest single-day trading volume in almost five years.

V. POST-CLASS PERIOD EVENTS AND ADMISSIONS

193. Events subsequent to Boston Scientific's November 17, 2020 disclosure have provided further confirmation that the Executive Defendants knew the truth about the Lotus Edge during the Class Period and deliberately misled investors.

A. Following The Lotus Recall, Defendants Are Unable To Answer Analysts' Repeated Questions About The Drastic About-Face For Lotus And Admit That Boston Scientific Never Achieved 150 Accounts

194. On November 18, 2020, at the Stifel Healthcare Conference, the hosting analyst asked Defendant Fitzgerald about the Company's announcement the prior day recalling and discontinuing the Lotus, asking, "I apologize for asking you. It's sort of a rude question, but what the heck took so long? I mean, the delivery issues have been front and center for years… What took so long to make the decision to focus elsewhere?" Fitzgerald responded, "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, a really important niche for a subset of patients, and that's the

physician feedback we can get into later." Fitzgerald then added, "It took us about 12 months after full launch to evaluate LOTUS."

195. These admissions confirm Defendants' Class Period statements were knowingly false. First, Defendant Fitzgerald confirmed that Boston Scientific had only sold to 100 accounts—two-thirds of the 150 accounts touted during the Class Period. Further, Defendant Fitzgerald did not offer any facts suggesting something changed for Boston Scientific from the October 15, 2020 conference in which Defendants boasted of Lotus's growth prospects to the about-face to abandon the platform on November 17. To the contrary, Defendant Fitzgerald admitted that Boston Scientific had all the information it needed to determine that LOTUS was a failure by no later than April 2020—the year anniversary of its commercial launch in the United States—and the month before Boston Scientific raised over $2 billion in equity from public investors without disclosing the truth about Lotus.

196. Similarly, on December 1, 2020, Defendant Mahoney presented at the Evercore ISI HealthCONx Conference, where an Evercore ICI analyst pressed him on the about-face Boston Scientific took with respect to LOTUS a few weeks earlier. The analyst zeroed in on the abrupt change of tone from Boston Scientific between TCT in October 2020 and the November 17, 2020 recall and discontinuation of LOTUS, noting that TCT "was a pretty bullish conference overall for you guys… LOTUS rollout being on plan, but yet a month later, I think the timing of the announcement of pulling LOTUS from the market caught people by surprise." Kumar asked bluntly, "did anything happen between that month for you guys to come down to this conclusion to pull LOTUS off the market []?"

197. In response, Defendant Mahoney refused to specify any timeline concerning the decision—and did not identify a single event between the short time span from the October 15

TCT conference, or the third quarter earnings call on October 29, to the November 17 Lotus recall that would have triggered the change-of-heart. As Defendant Mahoney explained:

> Yeah. So I would say overall that TCT was successful. I'm talking about LOTUS with the expansion of WATCHMAN, ELUVIA's additional reimbursement, we got RANGER approval and a lot of good tailwinds. And we had some tough TAVR news at that conference with the delay – with the SCOPE II results as we launch in a year or two in Europe with the SCOPE II results, and then 30 days later the announcement on LOTUS.
>
> And what you should expect from us and from any company and we're clearly disappointed by the news, but is to make the smart, difficult choices in our portfolio to maximize shareholder value as well as to drive great clinical outcomes for our physicians. And that's a difficult decision. But we wanted to be very objective about our current position with LOTUS and more importantly what we saw as the future of the next two or three years.
>
> And essentially, what we decided after doing a lot of work with our customer base and internally, essentially the cost to invest to further advance the LOTUS device in terms of its delivery system and a time line to do that to make it more of a workhorse valve just wasn't feasible versus other strategic options that we have in the company. And so the financial impact to do that, because currently it's used more in a niche way and physicians, many physicians really enjoyed it and saw a lot of value in it, but to make it a workhorse valve where you could drive greater share position, the time and cost and investment to do that versus other options we have in the company just didn't make sense. So it's a difficult decision to make but I'm actually proud of our team to do that and to kind of own up to it and make that decision rather than kind of kick it down the road any further.

198. Instead of pointing to any catalyst in between the October 15 TCT conference and the November 17 recall, Defendant Mahoney's statement that Boston Scientific had done "a lot of work" before pulling the Lotus from the market—and disclosing that remarkable about-face in an investor conference call held for that specific purpose—indicates the decision had been made long ago. Indeed, the Lotus shut-down involved scores of decisions and approvals at the highest levels of the Company including, among others, in human resources (which had to approve the WARN notices that were drafted and sent before November 17), senior operations personnel (which had been working with Lotus suppliers and others at the manufacturing plants in Penang, Maple Grove, and Galway to reallocate resources and exit over 100 personnel), the regulatory and medical

personnel that developed the recall plans and communications for FDA approval, and the financial, accounting, and investor relations managers that calculated the impact of the shut-down and developed the November 17 communications, to name a few.

199. Later in the discussion, the analyst asked Mahoney about the enrollment in trials for Boston Scientific TAVR devices now that LOTUS was no longer on the market. Mahoney admitted the two-valve strategy had been a failure—but again, without identifying any new facts that would explain Defendants' dramatic about-face in November 2020, explaining only that "We realized it wasn't making the progress that we needed. And so we've essentially down-selected on to one platform which will give us greater focus and clinical focus in R&D, [and] focus on cost improvement of manufacturing."

B. The SEC Initiates An Investigation Into Boston Scientific's Lotus Disclosures

200. In a Form 10-K filed with the SEC on February 23, 2021, Boston Scientific revealed to investors that the Boston Regional Office of the SEC had been conducting an investigation into the Company's decision to shut down Lotus. As revealed in the filing, the SEC sent its original notice on December 15, 2020, which included a request for documents and information related to the decision to recall and discontinue Lotus and, on February 10, 2021, the SEC issued a second request for documents and information.

VI. ADDITIONAL ALLEGATIONS OF SCIENTER

201. Numerous facts including those detailed above, considered collectively, demonstrate that Defendants knew they were misrepresenting the Lotus Edge or, at minimum, acted recklessly.

202. First, the development and commercial launch of the Lotus platform was one of the largest investments in the Company's history, and Defendants spoke about it on every conference call with investors and repeatedly emphasized its importance during the Class Period. For

example, on May 29, 2019, Defendant Mahoney told investors "[t]his has been the biggest investment of the company for a number of years now" and that "we think, that is dollar-wise, likely our biggest incremental growth driver over the next three years and really excited about finally bringing that to market." As a result, the Executive Defendants were intently focused on the launch of Lotus Edge before and throughout the Class Period, and were intimately familiar with its actual performance and sales at the time they made their misstatements.

203. Second, the Company's own internal records accurately reflected the true sales performance and re-order rates of the Lotus Edge, which was a critical and closely tracked internal metric that Defendants repeatedly assured investors they followed. For instance, during virtually every conference call during the Class Period, the Executive Defendants reported on the Company's publicly-announced plan to open 150 U.S. accounts within the first year of the product's launch, reported on the progress in reaching that goal, and claimed to know in detail about the actual re-order rates for the Lotus Edge, describing them as "strong," "very high," and "growing"—and purported to know the actual performance of the Lotus Edge because, as Defendant Mahoney stated, "we have spent a lot of time in Lotus cases and we're spending a lot of time in that area."

204. In fact, the Executive Defendants' statements suggesting they closely tracked the Lotus Edge's sales performance were confirmed by numerous former Boston Scientific employees who reported that the Executive Defendants in fact closely tracked this information, and it was available to the Executive Defendants in Boston Scientific's own books and records and sales dashboard information that was available to them. Those internal documents showed that rather than exhibit "strong" reorder rates, 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. Further, as FE 7

reported, the Executive Defendants were "absolutely aware" of the Lotus's poor performance because, among other things, a lot time was spent discussing Lotus with all of Boston Scientific's leadership, who were focused on how to turn the franchise around. Further, as FE 7 reported, the Executive Defendants knew that Lotus Edge sales had repeatedly failed to meet internal sales quotas management had set, which "came in at less than half of what they expected for 2019" and were 50% short of targets in 2020 even after sales quotas were drastically reduced. Indeed, Defendant Mahoney knew that Lotus was missing sales targets every quarter by at least 25% even after management reduced quotas by another 25% because he was "constantly" asking questions of the Company's divisional controller about that very fact. In addition, Defendants Mahoney, Meredith, McCarthy, and Ballinger discussed the performance of the Lotus Edge with internal Lotus Edge sales staff on monthly sales meetings during which the sales force would raise challenges they were experiencing in the field. Given that the Executive Defendants admitted that they possessed this data and purported to review it, there is a strong inference that they knew what the Lotus Edge actual sales were at the time they made their material misrepresentations.

205. Third, Defendants repeatedly assured investors that the Company was "on track" to open 150 accounts with the Lotus Edge within the first year of the launch and falsely assured investors the Company in fact reached this milestone. In repeatedly making these representations to investors, Defendants held themselves out as knowledgeable regarding how many accounts the Company had actually opened. For example, at the TCT conference on October 15, 2020, Defendant Fitzgerald told investors "I like what I see in terms of us being now in 150 accounts in United States." That the Executive Defendants repeatedly assured investors the Company was on track to and did achieve the 150 U.S. account milestone, and represented that they checked the account opening pace against their earlier predictions, is clear evidence that Defendants were

aware of the actual number of account openings throughout the Class Period. The fact that Boston Scientific admitted that it never opened 150 U.S. accounts and was in truth "sub-100 accounts" at the time Lotus Edge was abandoned provides powerful evidence that Defendants knowingly misled investors by falsely representing that the Company was on track to open and had opened 150 Lotus Edge accounts.

206. Fourth, during the Class Period, the Executive Defendants took numerous actions in response to the poor performance of the Lotus that were not disclosed to investors—including convening an emergency companywide Lotus salesforce meeting over the Thanksgiving weekend in 2019 because sales were so far below targets and patients had suffered injuries and deaths in Lotus procedures. That companywide meeting, which was attended by Defendants Ballinger, McCarthy and Meredith, demonstrated that rather than "going very, very well" and "on track to open 150 accounts," the Lotus launch was in fact in crisis. Indeed, as FE 9 reported, the Company shut down its production facility in Penang, Malaysia because it was "getting zero orders" by the end of 2019. The fact that the Company shut down the Penang facility in the middle of the Class Period because it was receiving "zero orders," and after the Executive Defendants convened an emergency companywide meeting to address the Lotus crisis in November 2019, provides strong evidence that the Executive Defendants knew their statements touting the "strong," "very high" and "quite high" re-order rates were false when made.

207. Fifth, the Executive Defendants had a close and personal connection to the Lotus Edge and professed to know about the actual performance of the product, repeatedly spoke knowledgably about it in detail on conference calls with investors, and personally oversaw the issues that led to the recall. For example, Defendant Meredith was the principal investigator on one of the initial Lotus clinical trials and said he personally participated in or witnessed dozens of

Lotus TAVR procedures, and Defendant Mahoney and Defendant Meredith repeatedly touted that they had personally participated in Lotus TAVR procedures. For example, at the World Medical Innovation Forum on May 3, 2017, Defendant Mahoney explained that in one procedure he witnessed, the Lotus Edge re-positioning ability enabled the cardiologist to switch the size of valve implanted mid-procedure: "So I've been in cases where an interventional cardiologist has deployed a 25-millimeter valve, fully deployed, and decided that there was too much paravalvular leak and upsized it to a 27, and actually redeployed the valve and put another one in."

208. Defendants Meredith, McCarthy, and Ballinger participated in quarterly companywide sales meetings concerning Lotus during which the problems that sales representatives were encountering during patient cases were discussed. Defendants spoke to investors about the Lotus platform in detail over many years both before and during the Class Period and conveyed an intimate knowledge of the product and its delivery system on conference calls with investors when addressing the numerous recalls and delays prior to the FDA's approval of Lotus Edge. Defendants Ballinger, Meredith, and McCarthy convened and personally attended an emergency Thanksgiving 2019 meeting in Minnesota with the entire Lotus sales force to address patient injuries and deaths caused by poor valve deployments and, at quarterly company-wide sales meetings, discussed the fact that sales results for Lotus throughout 2019 and 2020 were no more than half the Company's internal targets. That Defendants had a long-standing involvement with the Lotus platform and took an active role managing the Lotus's commercial launch during the Class Period strongly supports an inference of scienter.

209. Further evidencing their knowledge that the Lotus Edge was severely underperforming, Defendants Ballinger and McCarthy, the President of Interventional Cardiology and General Manager of Structural Heart Valves, respectively, who were some of the senior-most

executives at Boston Scientific responsible for the launch and commercial rollout of the Lotus platform, resigned unexpectedly in the middle of the Class Period, just after the emergency meeting of the Lotus sales force over Thanksgiving 2019 and as the Company was shutting down the Lotus manufacturing facility in Penang because it was getting "zero orders" for Lotus. The resignations of Defendants Ballinger and McCarthy strongly support the inference of scienter.

210. Sixth, immediately following the 2017 recall of the Lotus Edge, the Company acquired Symetis and its Acurate Neo device specifically because of doubts over the Lotus franchise—but publicly and repeatedly dismissed investors' concerns about those doubts. Specifically, in the face of repeated analyst questioning as to whether the Symetis acquisition suggested a loss of confidence in Lotus, Defendant Mahoney told investors "you shouldn't read anything into that," that "the Symetis people are probably rolling their eyes hearing this," and that for Boston Scientific, "doubling-down with these two TAVR platforms is the winning formula for what will be a very strong market for years to come."

211. In truth, during the Class Period, the Company was racing to develop a replacement for the Lotus Edge and "throwing money" at the effort because of the difficulties with the device's delivery mechanism and the fact that it was difficult for physicians to use. As FE 6 explained, the Company was planning to release a next generation TAVR system to replace the Lotus Edge it as soon as possible and that the Company's senior management knew that the Lotus Edge was hard for physicians to use. Further evidencing that Defendants knew about the problems with Lotus, the Company unexpectedly announced the discontinuance of the Lotus Edge a mere month after the Company announced on October 15, 2020 that the timeline for the FDA approval for an intermediate risk indication for Lotus Edge, as well as for the Acurate neo2, would be pushed out to 2024 from the previously expected 2021 timeframe. That Defendants repeatedly denied that the

Symetis acquisition was due to the poor performance of the Lotus, spent a considerable amount of resources during the Class Period to develop a replacement for the Lotus, and announced the discontinuance of the Lotus platform so shortly after disclosing a delay for regulatory approval, is compelling evidence that Defendants knowingly misled investors regarding the commercial success of the Lotus's launch during the Class Period.

212. Seventh, the fact that the size and scope of the Lotus business shut-down was a substantial undertaking that required months of advance planning and approval by senior management supports scienter. For example, in connection with the Lotus Edge recall, the Company shut down its Penang facility in March 2020—and laid off 232 workers in its Maple Grove, Minnesota and Menlo Park, California facilities and 30 workers in Galway, Ireland—actions that required forethought and extensive planning. The Company was also required by FDA regulations to develop a device recall plan—including, among other things, developing the recall strategy, recall communications, and press release—all of which had to be prepared by Boston Scientific's medical and regulatory personnel and then reviewed by the FDA prior to the initiation of the recall. *See* 21 C.F.R. § 7.46. And prior to announcing the recall, the Company's financial, accounting and investor relations personnel had to calculate the impact on the Company's business and financial results and prepare the disclosures concerning the business shut-down. These extensive, senior-level actions and decisions further support that Defendants knew the truth about Lotus's poor performance during the Class Period.

213. Eighth, Defendants were highly motivated to delay announcing the discontinuance of the Lotus platform in the face of a dire need to raise capital to pay down its debt—which had increased almost 150% from year-end 2018 to year-end 2019. Indeed, by the start of 2020, the

Company was at risk of breaching its leverage ratios with its lenders, a risk that intensified with the onset of the pandemic.

214. The need to address the Company's debt profile and shore up liquidity provided a powerful motive to delay disclosing the failure of the Lotus franchise—which was at the time the Company's largest investment. Moreover, setting the Lotus franchise aside, Boston Scientific was in serious danger of violating its loan covenants during 2020, and likely would have done so had it not renegotiated the terms of its credit facilities.

215. Indeed, starting in April 2020, Boston Scientific undertook a series of financial transactions in which it renegotiated its lending agreements, entered into a new loan facility, raised $1.7 billion in debt, and conducted offerings to raise over $2 billion in equity from public investors—the single largest secondary public equity offering the Company had ever conducted. Those transactions would not have been possible had Defendants disclosed the truth about Lotus—as Boston Scientific's lenders would not have extended further credit to Boston Scientific on the terms they did had the Company revealed its largest investment and a core source of future growth was in fact a failure, and that Boston Scientific would be required to record $182 million in charges. Moreover, Boston Scientific's public equity offerings would have been on far worse terms for the Company, and raised far less capital—if they could have been conducted at all—had Boston Scientific shares not been inflated by Defendants' false and misleading statements.

216. Ninth, as Boston Scientific revealed after the end of the Class Period, the Lotus closure resulted in approximately $182 million in restructuring charges, which translates into a $0.13 "hit" to GAAP EPS in the quarter the charge was incurred. Disclosing and incurring that charge in earlier quarters—as opposed to the fourth quarter 2020, when Defendants belatedly reported the business shut-down—would have made the refinancing and capital raises discussed

above extraordinarily difficult if not impossible. Moreover, Defendants were particularly motivated to delay incurring the EPS hit throughout 2020 as the pandemic heightened investor concern about the Company's financial condition, and recording the charge earlier would have had a dramatic impact on the Company's reported EPS. Specifically, had Boston Scientific disclosed the shut-down in the first quarter of 2020, Boston Scientific's reported profit would have swung to a loss, while recording the charge in either the second or third quarters would have approximately doubled the reported quarterly EPS loss in those periods. In fact, the only quarter in which Boston Scientific could have recorded the Lotus shut-down charge and still have showed a profit was in the fourth quarter of 2020, when the Company actually disclosed the news—providing additional powerful evidence that Defendants were motivated to and in fact gamed the timing of the disclosure of the shut-down.

217. Tenth, Defendants' insider trades were highly unusual and departed from their historical trading patterns. During the Class Period, the Executive Defendants sold far more Boston Scientific shares than they did during the one year and nine-month period that preceded the Class Period (the "Control Period"). Specifically, during the Class Period, four Executive Defendants adopted 10b5-1 plans covering over $42 million in equity, and $27 million during the Control Period—meaning they were expecting or anticipating to sell over 50% more equity during the Class Period than during the prior Control Period. Moreover, of the total $42 million in sales established under the Rule 10b5-1 plans, those plans only sold less than half that amount, approximately $20.4 million in equity, suggesting that considerable equity was covered under these plans with trading prices above prevailing market prices—which also provided an incentive to inflate the price of the Company's shares so as to trigger additional planned stock sales. Indeed, delaying the Lotus shut-down until the fourth-quarter of 2020 allowed Boston Scientific to avoid

disclosing a $0.13 EPS hit, which given the importance of this metric to analysts and investors, would otherwise have had a dramatic negative impact on Boston Scientific's share price, and thus the ability for the Defendants to sell shares under their plans.

218. Eleventh, the fact that Defendants sold millions of dollars' worth of Boston Scientific stock after the Company concluded that the Lotus was a failure and would be shut down, but before that failure and associated shutdowns were made public, supports an inference of scienter. On November 3, 2020, just two weeks after Boston Scientific had touted that it had obtained its 150 U.S. account goal at the October 15 TCT conference and just three days after Defendant Mahoney personally reassured investors about the "strong results" the Company was seeing with Lotus, Defendant Mahoney sold over $9 million worth of stock in a single trade. That trade also occurred exactly 14 days prior to the November 17, 2020 revelation that the Company never achieved 150 account openings with the Lotus Edge and that the device was being globally recalled, and conducted under a Rule 10b5-1 trading plan that was unlike any other Rule 10b5-1 trading plan that Defendant Mahoney or any other Boston Scientific executive had ever entered into.

219. Defendant Mahoney's Rule 10b5-1 trading plan is highly unusual and exhibits characteristics of Rule 10b5-1 trading plans that academics have identified as strong "red flags" for abuse and indicative of fraudulent intent. To start, because the sale occurred at $35.06 per share, which was below the closing prices of Boston Scientific stock over the week prior to the sale, the sale appears to have been triggered by a date threshold as opposed to a limit order, *i.e.*, an instruction to sell once the stock appreciates to a certain price. The fact that the sales under the plan appear to have used a timing—as opposed to price—trigger evidences that Defendant Mahoney adopted the plan with the goal of unloading the stock by a certain date.

220. Further, unlike every other Rule 10b5-1 plan Defendant Mahoney or any other Boston Scientific executive had ever entered into, Defendant Mahoney's Rule 10b5-1 plan executed the $9 million sale in a single trade, and thus was a "single trade plan"—a type of plan identified by academics as highly indicative of abuse and insider selling in order to capitalize on material non-public information and avoid losses. Among other things, single-trade plans are inconsistent with the original expectation that Rule 10b5-1 would govern trades made under a "regular, pre-established program," inconsistent with the traditional financial advice for exiting a concentrated equity position over time, and have been identified in academic literature as highly statistically correlated with the "opportunistic use" of Rule 10b5-1 plans to "avoid significant losses and foreshadow considerable stock price declines that are well in excess of industry peers." Indeed, of the Rule 10b5-1 plans disclosed by Boston Scientific, every prior plan adopted by Defendant Mahoney spread out trades over the duration of three or more months—as opposed to a single day.[4]

221. In addition, unlike every other Rule 10b5-1 plan Defendant Mahoney or any other Boston Scientific executive had ever entered into, the Rule 10b5-1 plan here had an extraordinarily short "effective cooling off" period—i.e., the time between the date the plan was entered into and the first sale under the plan. Here, Defendant Mahoney's November 3, 2020 trade was executed a mere 48 trading days after the adoption of the trading plan—a short cooling off period that is indicative of opportunistic trading to capitalize on material, non-public information. Moreover, Defendant Mahoney's Rule 10b5-1 trading plan was designed to terminate a mere 50 trading days after it was entered into on August 25, 2020—whereas all other plans adopted by other Boston

[4] Larcker, et al., Gaming the System: Three "Red Flags" of Potential 10b5-1 Abuse, Stanford Closer Look Series (Jan. 19, 2021).

Scientific executives, including every other plan adopted by Defendant Mahoney, terminated in the range of between three to 12 months following the adoption date. In sum, the trading plan adopted by Defendant Mahoney on August 25, 2020 was an extreme departure from Defendant Mahoney's prior trading history, the trading histories of all other Boston Scientific executives, and most executives at public companies—and no trading plan at Boston Scientific had ever terminated so close in time to the date of adoption, involved such a large dollar volume so close to the date of plan adoption, and sold such a large dollar volume all at once.

222. Moreover, Defendant Mahoney's $9 million November 3, 2020 sale occurred shortly after Defendants' false and misleading statements falsely touting Lotus Edge purported high reorder rates, utilization, and purported success in opening 150 U.S. Lotus accounts—a statement that was revealed to be false just a month later. Particularly telling, the Rule 10b5-1 plan was entered into just days after Boston Scientific falsely represented that the Company had achieved 138 Lotus accounts and was opening new ones, and Defendant Mahoney's November 3, 2020 trade occurred just four business days after Defendant Mahoney himself falsely touted "we're seeing strong results in the sites that are using Lotus in the U.S." The timing of Defendant Mahoney's November 3, 2020 trade, which occurred shortly after Defendants' false and misleading statements and exactly two weeks prior to Boston Scientific's November 17, 2020 revelation that the Company was discontinuing the Lotus platform, provides powerful evidence of scienter.

223. Twelfth, separate and apart from Defendant Mahoney's highly unusual Rule 10b5-1 trading plan and $9 million sale, the other Executive Defendants engaged in insider sales that further support their scienter. In fact, even though the Executive Defendants were motivated to conceal the truth in order to avoid experiencing losses they otherwise would have incurred, the

artificial inflation caused by the false statements alleged herein also enabled the Executive Defendants to reap substantial proceeds from their insider sales that were out of line with their prior sales, as set forth below:

	Class Period 2.06.19 - 11.16.20			Control Period 4.28.17 - 2.5.19		
Defendant	**Shares sold**	**Proceeds from sales**	**% of shares sold pursuant to plan adopted before Class Period**	**Shares sold**	**Proceeds from sales**	**% of shares sold pursuant to plan**
Kevin Ballinger	209,833	$8,065,882.30	11%	223,379	$7,153,793.33	89%
Daniel Brennan	173,946	$7,033,090.94	88%	152,367	$4,210,081.49	100%
Joseph Fitzgerald	252,147	$10,759,605.91	16%	85,227	$2,256,674.60	100%
Total Sales:		**$25,858,579.15**		**Total Sales:**	**$15,390,666.84**	
Excluding Pre-Class 10b5-1 Trading Plan Sales:		**$20,922,625.09**				

224. As shown above, the Executive Defendants noted above received over one-and-a-half times as much in proceeds from shares sold during the Class Period than through sales during the Control Period, even though the Class Period coincided with the initial onset of the pandemic and a decline in equity prices generally. The individual trades themselves are highly unusual as well. For example, shortly after leaving Boston Scientific—while knowing the Lotus franchise he had overseen for years had been a failure—Defendant Ballinger sold approximately $3.2 million and $2.5 million on August 6, 2020 and September 1, 2020, respectively—his largest single-block sales in history, both which were outside of any Rule 10b5-1 trading plan. Similarly, Defendant Fitzgerald garnered nearly five times the amount of proceeds from sales of shares during than Class Period than in the Control Period, selling approximately $4.8 million and $3.2 million on December 13, 2019 and September 11, 2020, respectively, in the largest blocks of sales he had

made up until that point. And Defendant Brennan sold shares during the Class Period that provided him with nearly twice the amount of proceeds as he had by selling shares in the Control Period.[5]

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

225. Throughout the Class Period, Defendants made a series of materially false and misleading statements about the Lotus Edge, its adoption by physicians, the product's costs and impact on Company margins, and market share. For example, Defendants attributed the device's purportedly growing adoption by surgeons as a result of the device's "ease of use" when, in truth, Boston Scientific knew the device was incredibly difficult to use and in fact was racing to develop a replacement for the Lotus Edge precisely because it was too difficult and "complex" to use. And while Defendants claimed throughout the Class Period that the Lotus Edge was "on track" to achieve the Company's publicly announced goal of securing 150 U.S. Lotus accounts—and purportedly achieved that goal in 2020—Defendants admitted after the Class Period that, in truth, Boston Scientific only secured "sub-100" accounts.

A. Defendants Tout The Lotus Edge's "Ease of Use" While Concealing That Physicians Were Rejecting The Device Because It Was Extraordinarily Difficult To Use

226. In connection with the commercial introduction of the Lotus Edge to the U.S. market, the Company released a five-episode video series titled "The Reveal Series: Lotus Edge and the New Era in TAVR Technology." In that video series and other similar videos published by Boston Scientific in connection with the Lotus Edge launch on social media and the Company's website, and which were publicly available throughout the Class Period, Defendant Meredith,

[5] The Company was not required to and did not publicly report any insider selling by Defendant Lisa or any sales by Defendant Ballinger after he left the Company in the middle of the Class Period (although sales of shares following his departure from the Company were publicly reported because they were publicly registered pursuant to Rule 144).

Defendant Ballinger, the head of Lotus sales Samuel Conaway, and other senior Boston Scientific executives made a series of statements about the Lotus Edge and its purported benefits over competitor devices. Specifically, the statements in the video series center on how the Lotus Edge was purportedly "simple" for doctors to use. For example, Defendant Ballinger highlighted that:

> The engineers have done a really good job making something that is very complex feel really simple for the end-users. That's what happens with the best types of engineering feats. The ability for the technology for doing some things that are very precise. And I think the Lotus Edge brings that experience to the physician.

227. Similarly, Sean Gilligan, a Lotus engineer, represented that the Lotus Edge's simplicity, ease-of-use, and valve repositionability led to better patient outcomes, stating:

> These are very sick patients but the environment for the whole staff is more relaxed. And I think leads itself to better outcomes overall. And that is a huge motivator. But you also want to equip operators who have to do these procedures with the best technology possible where there is the opportunity for the least amount of mistakes. Most of the technologies out there today you don't have the opportunity to do a re-do. The opportunity with the Lotus, is that you do.

228. The head of Lotus sales, Samuel Conway, acknowledged the setbacks with bringing the Lotus to market but reassured investors that those problems had been solved, explaining that "whenever you create these devices you have some hiccups along the way, some things you have to modify because we wanted to get the perfect device to marketplace." Another Boston Scientific engineer, Niamh Brew, stated that, in bringing the Lotus Edge to market, "we wanted to keep all the benefits of the repositionability, the mechanical expansion of the valve, and kind of build on it, make it a simpler device to use." And another Boston Scientific spokesperson, Dr. Dean Kereiakes, states that "I think the iterations that have been made in this second generation, with

Edge, really make it much easier as an operator. Making the procedure easier for the operator usually means the outcomes are better for the patient."[6]

229. These statements were consistent with and reinforced by Defendant Mahoney's statements before the Class Period touting the Lotus Edge as superior to the market leader, Edwards' Sapien device, based on the Lotus Edge's purportedly "superior ease of use" profile. As Defendant Mahoney told investors at a September 17, 2017 investor conference:

> We do think Lotus is better [than Sapien]. We think the mechanical properties and the way you can position the Lotus valve is very unique. It's very unique for complex patients and oftentimes as you build a lot of trust with cardiologist, we can help them out with their most complex cases. So we think the mechanical ease of use properties are differentiated. The PVL rates are best in class and the pacemaker rate continues to come down with Lotus Edge. So, we think we've got at least on par offering and I think superior ease of use characteristics of it.

230. Similarly, Defendant Lisa told investors at a June 7, 2016 Jeffries Healthcare Conference that Lotus's "ease of use, which I think maybe gets underestimated sometimes" and the "best-in-class parvalvular leak rates and then the ease of use" were its primary competitive advantages and that Lotus "has been a nice growth story for us really driven by the outcomes and as well as the ease of use."

231. Defendants continued to tout the Lotus Edge's purported "ease of use" throughout the Class Period, and internal Company slide decks instructed Lotus sales representatives to "amplify ease of use" as a Lotus Edge marketing pitch even though, as Lotus sales representatives reported, the Lotus Edge was the "most complicated device on the planet." For example, at Boston Scientific's Investor Update at the 2019 TCT conference on September 27, 2019, Boston Scientific

[6] While the Lotus Edge promotional videos in which Dr. Kereiakes serves as a spokesperson for Boston Scientific state that the interviewees were not compensated, Dr. Kereiakes has in fact received tens of thousands of dollars in consulting fees from the Company, which also paid over $2.4 million in associated research funding for his work involving Lotus Edge.

quoted a spokesperson Dr. Rizik as stating that "Lotus Edge represents a broad spectrum therapy for valvular heart disease. Many TAVR operators, myself included, consider this first line therapy; others utilize it for their most complex aortic valve anatomies given its consistent performance. I believe its ease of use sets it apart, making Lotus Edge a superb choice for operators early in their TAVR experience."[7]

232. Defendants' statements that the Lotus Edge was made to "feel really simple for the end-users," a "simpler device to use" and offered doctors "ease-of-use" were materially false and misleading because, in truth, the Lotus Edge was incredibly complex and difficult to use, the flaws in the delivery system that had triggered recalls prior to the Class Period were unresolved, and its complexity rendered the product not commercially viable. These statements were also highly material to investors and analysts, who credited Defendants' representations in noting, for example, that "the U.S. Lotus launch is going well and doctor feedback in challenging cases has been especially positive," and that the benefits of the Lotus Edge included a "more simple implantation procedure" and the fact that it was purportedly "very easy to use with a more flexible shaft, and a simplified procedure."

233. But in truth, the fact that the Lotus Edge was incredibly complex and difficult to use was a core flaw in the device that persisted throughout the Class Period. For example, on November 17, 2020, when announcing the Lotus Edge was being discontinued and globally recalled, Defendants admitted the reason for the recall was due to the complexity of the delivery system which would require significant investment to redesign and re-launch the product. Specifically, Defendants admitted that "[t]he complexity of Lotus Edge delivery system has

[7] Dr. Rizik has received over $200,000 in consulting fees and other renumeration from Boston Scientific and over $790,000 in associated research funding from the Company.

resulted in the valves current niche role in the market despite our commercial efforts" and "that it's not prudent to sustain the level of investment required for delivery system change and the increase in burden of training and case support requirements."

234. In fact, at the time these statements were made, Boston Scientific was rushing to develop a replacement for the Lotus Edge precisely because it required "three hands to operate" (when surgeons only have two). Further, the fact that the Lotus Edge was hard to use was an issue well-known within the Company that "went all the way up" to the senior-most levels, and was a problem Boston Scientific was "throwing money" at to try to fix during the Class Period. The complexity of the Lotus Edge also caused Defendant Ballinger, Defendant McCarthy and Defendant Meredith and the head of Lotus sales, Samuel Conaway, to convene an emergency meeting with the entire Lotus sales team on Thanksgiving weekend of 2019 to provide additional training to avoid poor patient outcomes precisely due to the device's complexity.

235. Defendants' misrepresentations concerning the Lotus Edge's purported "ease of use" were further false and misleading because they omitted the highly material facts that the sales representatives who were in charge of overseeing Lotus procedures described the Lotus Edge as the "most complicated device on the planet," the device's complexity required extensive training that Boston Scientific failed to provide, and the complications in using the Lotus Edge delivery system led to an alarming rate of adverse events, including numerous patient deaths and injuries that far outpaced those of its two primary competitor devices.

236. Further, the representation in ¶228 that the "iterations" made to the Lotus Edge made it "easier to use" than the first-generation Lotus omitted the highly material facts that those iterations did not address the core problems with the delivery system that Defendants concluded required so much additional "training and case support" that the device was not commercially

viable. In addition, the representation in ¶231 that the Lotus Edge provided "consistent performance" was materially false and misleading because, in truth, the device's performance was highly inconsistent and led to patient injuries and deaths that far outpaced those of its competitors. In fact, rather than present a "superb choice for operators early in their TAVR experience," the unique complexities with the Lotus Edge and its flawed delivery system were so serious that the Lotus Edge was the worst choice for early TAVR operators.

B. Defendants Tell Investors They Are Conducting A Successful "Controlled" Launch To Ensure "Terrific" Patient Outcomes While Concealing That Egregiously Inadequate Training Led To Patient Injuries And Deaths

237. On February 6, 2019, the first day of the Class Period, Boston Scientific held its earnings conference call with investors to discuss its fourth quarter and year-end 2018 results. During the call, analysts asked a series of question about the available market share and demand for the Lotus Edge in light of competition from Edwards and Medtronic, and Defendants reassured investors that there will be "adequate demand" and sales of the Lotus Edge had been incorporated into the Company's $700 to $725 million annual guidance for Structural Heart. For example, in response to a question from an RBC analyst who asked "how you're going to be positioning Lotus given you just have a high-risk label," Mahoney answered:

> This has been a journey for us with Lotus, but the product characteristics are very unique, and we're excited about the long-term growth prospects of this platform…
>
> [W]e think the differentiated features [of Lotus], the repositionability of it, the best PVL in the marketplace, and also just the clinical experience of those who have been involved in our clinical trials. So we believe there will be adequate demand for Lotus in the marketplace and we want to obviously focus as we begin to launch this product in the second quarter on delivering excellent outcomes and strong experiences. This will be a key platform for us for many years.
>
> So we think the market's there.

238. In response to a follow-up question on Lotus from a Bank of America analyst inquiring why Boston Scientific was not immediately pursuing a "full blown" launch after FDA

approval, Defendant Mahoney clarified that, despite the "controlled" launch, Lotus Edge sales were going to contribute meaningfully to Boston Scientific's revenues that year:

> We think the approval will likely happen potentially early in the second quarter versus mid-year. So that's good, and that's very good, and our team deserves it. And that's reflected in the full structural hard guidance we gave at the $700 million, $725 million.
>
> And simply speaking, with the Lotus Valve, we want to ensure that we deliver this exceedingly well, to get out of the gate strong, to build up a strong reputation for the product in the U.S. And so like we've commented in the past, this is very unlike – it's not like a DES launch. It's similar to what we did with Watchman, similar to what we done in Acurate in Europe, where key training and proctoring will be part of it.
>
> And so, we're not going to launch in hundreds of centers out of the gate like we would with a DES launch. So it will be smartly planned, delivering excellent outcomes, building greater confidence with the physician community, leveraging Claret with protected TAVR, the only company that can do that, and building momentum. And so you'll see us, much like the Watchman launch, continue to open centers over time, deliver great outcomes, and similar to Watchman, we've increased utilization rates each quarter by doing so.

239. Analysts reacted positively to Defendants' statements and understood the Lotus Edge would provide immediate and material contributions to the Company's revenues, with Piper Jaffray analysts concluding that the "relaunch of Lotus in Europe in March and domestically early in Q2 (a couple months ahead of expectations) accounts for close to half of this ~$235M YOY increase" in annual Structural Heart revenue from the prior year's revenue of $475 million in 2018.

240. On April 24, 2019, the day after Boston Scientific announced that the U.S. Food and Drug Administration had approved the Lotus Edge for use in high-risk patients, the Company held its earnings call for the first quarter of 2019. On that call, Defendant Mahoney stated that, "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, such as heavy calcified native valves and bicuspid valves." Mahoney added that Lotus was part of Boston Scientific's "combined strength" in the structural heart space

that "position[s] us well to deliver on our guidance for $700 million to $725 million in structural heart revenue in 2019."

241. During the question-and-answer session of the April 24, 2019 earnings call, a SVB Leerink analyst asked how Boston Scientific planned to price the Lotus Edge as the U.S. market was going from a two-player market (i.e. Medtronic and Edwards) to a three-player market. While Mahoney declined to provide pricing specifics, he reassured investors that, "I think in the U.S., we're very confident in the capabilities of the Lotus valve. This is not a low-tier segment offering, and so you'll see Lotus priced at competitive rates with the market in the U.S." When the SVB Leerink analyst pressed for further detail on pricing, and whether the Lotus was priced at a discount in Europe, Mahoney answered:

> [A]t the end of the day, the valve does need to stand alone in terms of its clinical efficacy, safety, and the benefits. Doctors typically aren't going to choose a TAVI valve just because it costs less money. And so we're delivering very good outcomes with Acurate. You've seen a lot of the clinical data there, and also Lotus. So pricing obviously is important, but it's a different environment than drug-eluting stents.

242. Defendants' representations in ¶¶237-41, that the Lotus Edge was "sought after by physicians and operators as a workhorse valve" and that there was "adequate demand" to support the Company's reported 2019 revenue guidance were false and misleading because, in truth, physicians did not view the Lotus Edge as a "workhorse valve" but as limited to only a few specialized cases for high-risk patients and there was in fact little to no demand for the product. To the contrary, Boston Scientific conducted surveys of TAVR physicians prior to the Lotus Edge launch documenting that the true maximum potential market for the Lotus Edge was, at best, 5 to 10% of all TAVR patients, and that the device faced extraordinary challenges to compete with Medtronic and Edwards to secure a meaningful portion of those 5 to 10% of total cases.

243. On May 29, 2019, Defendant Mahoney attended the Sanford C. Bernstein Strategic Decisions Conference. In response to an analyst's question to explain Boston Scientific's "[TAVR] strategy in the U.S., given your biggest competitors' head start and Lotus' current high-risk-only indication," Mahoney responded:

> Yeah, we're very excited. This has been the biggest investment of the company for a number of years now. And now we're entering the market that'll be well over $5 billion growing, call it double digits. And our U.S. business is extremely low. And so, at PCR last week, we're the only company globally that'll serve, we think, the full menu for a physician. So, many physicians like a super annular valve, more like a Medtronic offering, and more physicians prefer an intra-annular valve which is more like a Lotus valve. And these tables like the supra-annular valve, this is like intra-annular valve. So, we're the only company that offers both of those platforms. But we're also the only company that offers protected TAVI with our Claret device.
>
> And so seeing the reaction in Europe where we have now both valves in the marketplace and the flexibility not only for contracting but also the unique clinical benefits of Lotus with Claret, Acurate with Claret. It's very unique. And so, we're excited about bringing that to the U.S. market, just started in the Lotus launch, which is going well. And we'll start rolling the Acurate clinical trial in the U.S. the back half of 2019.

244. At the Company's Investor Day on June 26, 2019, Boston Scientific touted Lotus Edge and described the progress of the launch as "very positive." For example, at the conference, Shawn McCarthy, Boston Scientific General Manager for Structural Heart Valve, stated:

> Lotus Edge, we're extremely excited about our launch, obviously selling both in Europe and the U.S. And we 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. We have designed Lotus Edge to deliver the best-in-class PVL outcomes to nail your delivery exactly where you want it, never have a malposition, having superior stroke rates as seen in our study in REPRISE III, and also competitive pacemaker rates. And as you know, we're commercializing both in Europe and in the U.S. as we speak…
>
> Our focus is to drive sticky adoption, right, to make sure – as this product is different than original Lotus and it's unique because it's the only repositionable and retrievable valve on the planet. 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 and then soon after we'll start to increase the rate of new customers.
>
> Early indications I would suggest are very positive. We can share with you some anecdotes and some quotes. Some of you were at the TCT Conference in Chicago just a couple of weeks ago, but if I could share a couple of those key quotes with leading physicians in our marketplace. One of them suggested, with Lotus perfection is normal. We're normalizing perfection. And nothing else seals like Lotus Edge.

245. At the Company's next earnings call, on July 24, 2019, Defendant Mahoney updated investors regarding the Company's TAVR Portfolio, saying:

> The Lotus Edge controlled launch is going extremely well. Positive physician feedback highlights the benefit of complete control and drama free TAVR. We are on pace to open the 150 accounts in the first 12 months that we cited in Investor Day. And we'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.
>
> We see a significant opportunity in the high risk labeling we have today. And we're actively enrolling for our U.S. REPRISE IV clinical trial to expand the indication to intermediate risk patients.

246. With respect to Lotus Edge, Defendant Mahoney stated, "You'll see greater acceleration of Lotus Edge, which we're very pleased with the initial results, over the second quarter [of 2019]." When pressed by a Morgan Stanley analyst for details on the usage at the TAVR centers using Lotus, Mahoney said:

> 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. We're not going to provide kind of share data or usage data by account.
>
> But I would say, this has been a long time coming to bring this to market. And anecdotally, I would say doctors are pleasantly surprised by the unique features that it delivers. The controlled use of the device, the ability to reposition, and the elimination of the PBL. It's delivering on its promise.
>
> And given the investment that we've made, the time that it's taken, we're really focused on quality, strong patient outcomes, and proctoring. 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.

247. Defendant Mahoney and Defendant Meredith's statements above that the Lotus Edge Launch was "going extremely well," that the launch was "very positive," and that the Company was "on track" and "on pace to open the 150 accounts in the first 12 months" were materially false and misleading because, in truth, the launch had been a disaster, the Company was not "on pace" to open 150 U.S. accounts, and sales were about half of the Company's internal targets. Indeed, as Defendant Fitzgerald admitted at the end of the Class Period, the Company never secured 100 Lotus accounts before concluding the franchise had been a failure and would be shut down.

248. In addition, Defendant Mahoney's and Defendant McCarthy's statements in ¶244 are materially false and misleading because, rather conducting a controlled launch by ensuring the Company did the "exact work we will as a world-class organization to train physicians" and focusing on "quality, strong patient outcomes, and proctoring," the Lotus Edge lunch was conducted in a rushed, haphazard and "clinically unsafe" manner. For example, Boston Scientific sales and clinical representatives were required to attend less than half the number of Lotus Edge procedures before being "certified" to conduct cases on their own, while of the 21 Boston Scientific representatives who were in fact "qualified" to oversee TAVR procedures on their own were certified after having participated in five or fewer Lotus Edge procedures. By contrast, Medtronic and Edwards representatives would participate in between 50 to 75 procedures before being certified to oversee Sapien or CoreValve cases, while Boston Scientific itself required representatives participate in 75 to 100 procedures before being qualified to oversee Watchman cases—a device that was "super easy" compared to the Lotus Edge, which was the "most complicated device on the planet."

249. On August 8, 2019, Defendant Lisa, Vice President of Investor Relations and Lauren Tengler, Director of Investor Relations, presented at the Canaccord Genuity Growth Conference on behalf of Boston Scientific. When asked about the Lotus Edge rollout, and whether the Company was using any "discounting" strategies in selling Lotus, Tengler answered:

> [W]e're really excited early days of Lotus. We're doing a controlled release because we are seeing it used initially in more complex patients who are very well-suited, bicuspid, very heavily calcified native and A[ortic] S[tenosis]. So, physicians, I think, frankly, are probably a little skeptical kind of where this has been. And then they do these cases and have great outcomes. And there's a hashtag #dramafreeTAVR. So, we're excited about that. And then part of this controlled release is to make sure it doesn't stay niche in those more complex patients but that repositionability, retrievability, control all gets levered into your more plain vanilla cases as well.
>
> * * *
>
> So I think that you've seen very good price discipline in the TAVR market and that is always our playbook as well, is not to use discounting as a strategy. So we're selling Lotus on a differentiation, but there can be more flexibility on again kind of a commercial bundle or category shift with SENTINEL which will also sell stand-alone if you're using a different type of device, but then there can be a bundle if you're using Lotus or ACURATE.

250. Tengler's statements in ¶249 regarding the "healthy market" for Lotus and Boston Scientific's purported policy "not to use discounting as a strategy" were materially false and misleading when made because, in truth, Boston Scientific had in fact by this time initiated a strategy to offer discounts to TAVR centers because they were not purchasing the Lotus Edge and had resisted doing so in part because of its price. Specifically, as reported by FE 2, in order to boost stagnant Lotus Edge sales, Boston Scientific began to offer substantial incentives to TAVR centers to purchase Lotus Edge—including by selling the product on consignment and offering bulk order "discounts."

251. On September 5, 2019, Defendants Mahoney and Lisa attend the Wells Fargo Health Care Conference. The analyst hosting the conference asked Mahoney to discuss "the relaunch of LOTUS." Mahoney answered:

> It's so fun to see this finally coming together at years and years of investment and planning…
>
> LOTUS is going very well. We have spent a lot of time in LOTUS cases and we're spending a lot of time in that area. And we aim to open up about 150 centers during the first year. So, it's not going after every single hospital, but the results have been very strong. We're seeing very high reorder rates of LOTUS, and the launch really is going as planned as adjusted in 2019. Not as planned in 2016, where we had some challenges with it. But we're very pleased with it. And I think, at the end of the day, you've got doctors who are – who've been implanting Edwards or Medtronic for a while. And so I think what's important is you really can't come up with a kind of a me-too product. It has to be uniquely differentiated to make an impact and that's exactly what LOTUS is.
>
> And when you see physicians use it, and it literally eliminates P[ara] V[alvular] L[eak] like a surgery – surgical procedure would. And the flexibility that they have to position the valve is very unique versus our competition. And it requires that differentiation in order to make an impact in a market that has two strong competitors in it.
>
> So, we're seeing strong reorder rates with it.

252. Defendant Mahoney and Defendant Lisa's statements in ¶251 regarding the purportedly "very high reorder rates" and "strong reorder rates" for Lotus were materially false and misleading when made because, in truth, TAVR centers were not re-ordering Lotus. As reported by numerous former Boston Scientific employees, including FE 1 and FE 2, and confirmed by internal Company documents, there were virtually no re-orders for Lotus Edge, the TAVR centers that initially purchased Lotus Edge would use up their stock and not reorder, the sales "just weren't coming in," and "There was just really no one ordering more product based on usage so there was no organic growth in the sales."

253. In addition, at the September 5, 2019 Wells Fargo Healthcare Conference, in response to an analyst's question about the Lotus Edge launch being a "deliberate rollout,"

Defendant Mahoney responded that it is "absolutely true" the Company was doing a "deliberate" and "controlled" launch of the Lotus Edge. Defendant Lisa also stated that, "given the differentiation of LOTUS and that predictability and control, you are seeing kind of out of the gate site trying it in their most complex patients, those with heavy calcification or bicuspid patients as well. 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."

254. Defendant Mahoney's and Defendant Lisa's statements in ¶253 are materially false and misleading because rather than conducting a "deliberate" and "controlled" launch focused on "ensuring terrific outcomes," in truth, the launch was "clinically unsafe" because Boston Scientific sales representatives and clinical support staff received woefully inadequate training, including receiving a fraction of the training required to oversee far simpler procedures with devices offered by Medtronic and Edwards and the "super easy" Watchman device that Boston Scientific sold.

255. On September 27, 2019, Defendants Lisa, Ballinger, and Ian Meredith presented on behalf of Boston Scientific at the Transcatheter Cardiovascular Therapeutics Scientific Symposium, one of the industry's leading annual events. Defendant Ballinger said there was "a lot of good momentum" for structural heart valves and that "[w]e're encouraged on LOTUS" because "[t]he early stages of the launch is now going very, very well." Defendant Ballinger said that Boston Scientific was "on track to open 150 accounts" by April 2020 and that "we'll plan to be in 150 or more accounts" by then.

256. Further, when asked when the LOTUS launch would enter a "full commercial" launch as opposed to a "controlled launch," Defendant Ballinger represented that the Company had already entered a "full launch." Specifically, Defendant Ballinger told analysts the launch of

the Lotus Edge was controlled to ensure physicians received "exceptional proctoring" and "training:"

> Just on the US LOTUS launch, so what I would say is the ramp has now accelerated and the mode that we predicted in terms of the – so opening the number of accounts per month that we predicted at full launch. And so we purposely, over the course of the summer, were more in a self-constrained, limited market evaluation mode. And we started loosening that obviously in the July and August timeframe with a stronger ramp and now September. We've launched about the number of accounts that we think is appropriate to ensure that we do exceptional proctoring, training, and giving the product the best chance possible to stick and get the attention that we need.

257. Defendant Ballinger's statement in ¶256 is materially false and misleading because, rather than launch Lotus Edge in a "self-constrained, limited market evaluation mode" by limiting the number of accounts "appropriate to ensure…exceptional proctoring, training," in truth, the Lotus Edge launch was conducted in a "clinically unsafe" manner with woefully inadequate representative and clinical support training.

258. Defendant Ballinger also addressed the fact that Edwards and Medtronic received FDA approval for lower-risk indications for their respective devices on August 16, 2019, but reassured investors and dismissed this new indication as causing "very little distraction."

> Yeah. So I think really I would say September, this past month, and we're now almost into October was really the – what I would call the full launch mode in terms of opening the number of accounts we plan to on a go-forward basis per month. So we're kind of at that clip now fully ramp through LME and launching the rest of the multiple next months will look like September in terms of account openings.
>
> I'd say there's been very little distraction by this low risk expansion, and I think you gave wildly different views on what that all means. But I think – the one thing about LOTUS and I've talked a lot about this before is even for the staunchest CoreValve or SAPIEN users, for the most part we hear them say LOTUS has a role, after using it, then they say that even more strongly after using it, LOTUS has a place.
>
> Now what does that mean in terms of share? Well, it varies by account. So some users, we're already seeing will adopt this as a mainline therapy, front-line workhorse product. Others are kind of dipping their toe in the water around more

> complex cases. So it's an interesting dynamic; in all my years in this space, you typically would go and launch a product and typically it'd be first used in relatively simple patients and you work your way up from there. And it's flipped on its head with LOTUS that in many situations it's used in the absolute toughest of the tough cases, where they literally reserve that patient like this – we need a LOTUS here. And so – and it might be their first experience. And so I guess, the good news is I think pretty frequently where they might have a perception that it's a complicated device, they use it five times, it is not a complicated device and it actually takes stress out of the procedure.

259. Defendant Ballinger's statements that the launch had been going "very, very well" and that Boston Scientific was "on track" to achieve 150 accounts in the first year of the launch were false and misleading because, in truth, the launch was a disaster and the Company was nowhere close to being on track to securing 150 accounts. Further, Defendant Ballinger's statement that the Company had entered into "full launch" mode in September 2020 was misleading because, while the Company had entered into "full launch" mode, the Company had transitioned to "full launch" mode because of the lack of sales during the controlled launch and was desperately trying to improve its numbers. As reported by FE 2, the Company transitioned to a "full launch" because the "controlled launch" was not going as planned, and began offering "bulk" rates to TAVR centers in order to get them to purchase Lotus Edge and demonstrate to investors that product was being accepted by physicians—when, in truth, the Company's Lotus sales were less than half of internal targets.

C. Defendants Continue To Tout The Launch's Success Even As the Company Missed Sales Targets, Had "Zero Orders," And Convened An Emergency Companywide Sales Meeting Because The Franchise Was In Crisis

260. On October 23, 2019, Boston Scientific held its earnings call for the third quarter of 2019. In his opening remarks, Mahoney said, "The LOTUS Edge launch is going extremely well and we're building momentum in both the US and Europe." He continued, "We remain on pace to open 150 accounts in our first 12 months in the US."

261. During the question-and-answer session, an analyst from Evercore directly asked Defendant Mahoney to specify whether structural heart "really changed trajectory" because of "underlying TAVR market growth" or "standalone Boston outperformance." In his response, Mahoney highlighted Lotus and ACURATE:

> We'[re] very excited [where] we are with Lotus. We haven't seen a tremendous change in terms of market growth, but the outcomes with LOTUS have been very favorable. We think it offers some very compelling differentiation versus our competition. And we're really on track with our opening the 150 accounts really per our plan.
>
> And I made comments on ACURATE before. So I think the combination of all these things within cardiology are going to lead to nicely above growth versus the BSX overall average as you look forward to 2020 and it's really that strategy of diversification and new complex coronary and structural heart that's working.

262. Defendant Mahoney's statement in ¶¶260-61 that Boston Scientific was "on track" with "opening the 150 accounts really per our plan" was materially false and misleading when made because, in truth, at the time, did not have success opening new accounts on a pace that would meet the April 2020 deadline, and its actual Lotus Edge sales were approximately half of internal targets.

263. In addition, during the question-and-answer session, a Stifel Nicolaus analyst asked whether investors would "expect to see a step-up or an acceleration in Lotus utilization into 2020." In response, Defendant Meredith stated:

> So, the limited market release is going very well. It's on track and the plans haven't changed thus far. We see this will have an impact on the ability to take in more patients, there'll be fewer exclusions. Probably 5% of patients are being excluded on vessel size. But the rollout of Lotus Edge of course is a planned controlled release. And in the short term, it will be determined by training.

264. Defendant Meredith's statement above that the Lotus Edge rollout was a "planned controlled release" that was "determined by training" was materially misleading because it omitted

the highly material facts that the launch was rushed, haphazard, and "clinically unsafe" because of woefully deficient clinical and sales representative training.

265. Less than one week later, on November 5, 2019, Boston Scientific filed its Form 10-Q for the third quarter of 2019, certified by Defendants Mahoney and Brennan. In the Form 10-Q, Boston Scientific said, the "year-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies, including our Acurate™ Transcatheter Aortic Valve Replacement (TAVR), our Lotus Edge™ Aortic Valve System as well as our Sentinel™ Cerebral Embolic Protection System purchased as part of our Claret acquisition in the third quarter of 2018."

266. Defendant Boston Scientifics statements, which were certified by Defendants Mahoney and Brennan, as the Lotus Edge's contributions to net sales were materially false and misleading when made. In truth, the Lotus Edge was not meeting sales expectations and Defendants knew, or recklessly disregarded, that Boston Scientific had failed to achieve its target reorder rates for the device and failed to expand its customer base with new customer accounts.

267. Later than same month, on November 12, 2019, Defendant Lisa attended the Credit Suisse Healthcare Conference on behalf of Boston Scientific. In response to a question concerning when there will be an "inflection point" for Boston Scientific in TAVR, Lisa said, "[W]e're really pleased with how the [Lotus] 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. The advantage here is that it's always repositionable and always retrievable." Reiterating how "pleased" the Company was with Lotus, Lisa continued, "We are on target to get to 150 centers we talked about opening in the US by Q1 of 2020."

268. Defendant Lisa's statement in ¶¶267 that Boston Scientific was "really pleased" with the Lotus launch and that the Company was "on target to get 150 centers" were materially false and misleading when made because, in truth, Boston Scientific sales were less than half of internal targets and Boston Scientific was not on a pace that would meet the April 2020 deadline for 150 accounts—indeed, Boston Scientific never even opened 100 accounts, and determined to shut down the business after failing to meet that target. As recounted by FE 1, Lotus Edge sales numbers "just weren't coming in" and management "freaked out." As FE 1 explained, "There was just really no one ordering more product based on usage so there was no organic growth in the sales."

269. On November 14, 2019, at the Stephens Nashville Investment Conference, Defendant Lisa discussed the Lotus Edge launch, telling investors:

> And so we're seeing docs kind of test drive it in very complex, challenging cases like those with bicuspid leaflets or very heavy calcification, and they're seeing very good results. 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. It's just a different method of deployment than physicians are used to in the U.S.

270. Defendant Lisa statement above is materially false and misleading because, rather than "taking our time to get to 150 accounts in the first year launch to make sure that everything is proctored and trained" was materially false and misleading because, in truth, the Company was not focused on making sure everything was proctored and trained properly. To the contrary, the launch was conducted in a "clinically unsafe" manner, including because Boston Scientific sales and clinical support staff received woefully inadequate training that was out-of-line with industry standards and Boston Scientific's own standards for far more "easy" and simple devices. Further, Defendant Lisa's statement that the Lotus Edge procedure was "not harder" than other TAVR procedures was materially misleading because, in truth, the Lotus Edge device was the "most

complicated device on the planet" and, as Defendants admitted after the end of the Class Period, so extraordinarily complex that it was not commercially viable.

271. On November 19, 2019, Defendants Lisa and Brennan appeared on behalf of Boston Scientific at the Stifel Health Care Conference. At the conference, Brennan told investors that, "Lotus is ramping kind of per plan." Then, when asked if the "two-valve strategy" was "just because different strokes for different folks or is this something more specific" for the Company, Brennan responded, "We have both in Europe today… which is a nice place for that to play out as it comes to the U.S. And both valves can operate in workhorse valve territory and they both have benefits on the edges of that … It's playing out well in Europe and we're excited to bring it to the U.S." Then, when asked if Structured Heart could reach $1 billion in 2020, Brennan said, "[I]f you look at the different growth drivers there, we would expect that Lotus, as we continue to go at a controlled rollout pace and enter new accounts, will continue to grow."

272. Defendant Brennan's and Defendant Lisa's statements in ¶271 that the Company expected Lotus to "enter new accounts" and "continue to grow" was materially false and misleading when made because, in truth, Lotus was failing and not growing at all. Defendant Brennan knew, or recklessly disregarded, that existing customers were not reordering Lotus devices and that the Company was not adding new accounts. Furthermore, the statement in ¶271 was false and misleading because Lotus' sales numbers were already a disappointment, and came in less than half than the Company's internal targets.

273. In fact, as FE 9 reported, the Company's Lotus facility in Penang, Malaysia was shut down in March 2020 because there were "zero orders" for Lotus at the end of 2019 and in 2020. Defendant Brennan's statements that the Company was "very pleased" about the "launch and growth" of Lotus Edge during the launch were materially false and misleading because, at the

time they omitted the fact that Boston Scientific held an emergency company-wide meeting on Thanksgiving weekend in November 2019 precisely because sales were not growing and there had been a spike in adverse events and patient deaths in TAVR procedures using Lotus Edge.

274. On December 4, 2019, Defendant Lisa and Tengler attended the Evercore ISI HealthCONx Conference on behalf of Boston Scientific. When asked to comment on the commercial launch for Lotus Edge in the U.S., Lisa said:

> [O]n Lotus, we are really encouraged by the initial uptake. It's a really differentiated valve, the only one where you can always reposition and fully retrieve. There's never a point of no return. It's great control, very predictable.
>
> And there's a hashtag drama-free TAVR, which we know that LOTUS enables you to do. We think that physicians understandably were skeptical. It's been a long time coming. And we've seen them I think being really pleased with the results in very tough cases out of the gate with how the valve has performed and seeing a real need to have it on the shelf.

Regarding account openings and orders, Lisa claimed, "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."

275. The next day, on December 5, 2019, Defendant Lisa represented Boston Scientific at the Piper Jaffray Healthcare Conference. When asked to identify what "should really kind of drive things for Boston [in 2020]," Lisa said, "Lotus Edge launching in the US and Europe this year is a big driver." In response to the analyst's question about whether the Lotus launch was "on track," Lisa responded:

> [W]e're really pleased with how the Lotus launch is going. And we're not giving specifics in terms of dollars or accounts. And we 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. But I think one point of evidence is we grew mid-teens in interventional cardiology in Q3, which was a clear acceleration…
>
> So, pleased with how Lotus is going. It's a differentiated valve. It's not a me-too. It's the only one that's always fully repositionable and retrievable. There's a #dramafreeTAVR. You can get it exactly where you need it to be. It's well-suited

> in heavily calcified patients or bicuspid patients. It's getting tried out in those tough cases and doing very well. So, we're really pleased with how LOTUS is doing.

276. Defendant Lisa's statements in ¶¶274-75 that Defendants were "really pleased with how the Lotus launch is going," that Lotus had been a "big driver" of the Company's financial results, and that the Company was "on track" secure 150 centers were materially false and misleading when made because, in truth, Lotus sales were dismal and the Company had just weeks before convened a companywide sales meeting because the launch was in crisis.

D. Defendants Falsely Tout The Company's "Steady" Progress In Securing 150 U.S. Accounts In Order To Renegotiate Boston Scientific's Credit Agreements And Raise $2 Billion from Public Investors

277. On January 14, 2020, Defendant Mahoney attended the J.P. Morgan Healthcare Conference on behalf of Boston Scientific. As he presented a slideshow, Mahoney said, "in TAVR, we're very pleased with the Lotus Edge launch and growth."

278. Defendant Mahoney's statement in ¶277 that "we're very pleased with the LOTUS Edge launch and growth" was materially false and misleading when made because, in truth, the launch was failing and Lotus Edge accounts were not growing but were stagnant. In fact, the Company's Lotus facility in Penang, Malaysia was shut down in March 2020 because there were "zero orders" for Lotus at the end of 2019 and in 2020. Defendant Mahoney's statements that the Company was "very pleased" about the "launch and growth" of Lotus Edge during the launch were materially false and misleading because they omitted the fat that Boston Scientific held an emergency company-wide meeting on Thanksgiving weekend in November 2019 precisely because sales were not growing and there had been a spike in adverse events and patient deaths in TAVR procedures using Lotus Edge.

279. During the Company's next earnings call on February 5, 2020, Boston Scientific announced its fourth quarter 2019 and full year 2019 financial results. In his opening remarks,

Mahoney said, "Turning to TAVR, we 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." He added, "Our super annular valve offering, Acurate neo, grew mid-teens in the quarter and we look forward to the launch of the next-generation Acurate neo2 in Europe midyear."

280. During the question-and-answer session of the call, a Morgan Stanley analyst asked Mahoney to speak about his "confidence" in Lotus. Mahoney answered:

> Lotus is doing very well in the market. It's kind of on plan for 150 accounts. So you'll see a full year impact of Lotus and expect to see each quarter greater impact there. Our Symetis valve, Acurate is doing well. It grew above the company average and grew about mid-teens in the fourth quarter. And we expect to see neo2 launching in the second half. So, the whole basket of structural heart will be big.

281. In response to a question from an Evercore analyst regarding whether the structural heart "cadence" would be the same as 2019 in 2020, Brennan answered, "as you look at the Lotus launch, that's obviously a very controlled rollout that we've had and that should gain momentum over time."

282. Defendants Mahoney and Brennan's statements in ¶¶279-81 that Defendants "continue to be pleased with the launch and progress of Lotus Edge," "Lotus is doing very well in the market," and "the whole basket of structural heart will be big" were materially false and misleading because, in truth, the Lotus launch was not only failing, as existing customers did not reorder the device and the Company struggled to sign new accounts on to use the Lotus, but Defendants were already taking steps to shut down production of the Lotus, beginning with a component manufacturing facility in Penang, Malaysia. In fact, there were "zero orders" for the Lotus Edge throughout 2019 and 2020 and, because the facility was "getting zero orders" for Lotus at the end of 2019, and no work was being done, the plant was shut down by March 2020, before the onset of the COVID-19 pandemic.

283. Defendants Mahoney and Brennan's statements in ¶¶279-81 that Lotus Edge was "on track" and "on plan" for 150 accounts by April 2020 were materially false and misleading because, in truth, Defendants already knew that the Lotus was performing poorly by the end of 2019, when Boston Scientific missed its sales targets and reorder rate goals for Lotus Edge.

284. A few weeks after the February 2020 earnings call, Boston Scientific filed its Form 10-K for the fourth quarter and full year 2019, certified by Defendants Mahoney and Brennan, on February 25, 2020. In the Form 10-K, Boston Scientific said, "This year-over-year increase [in net sales of Interventional Cardiology products] was primarily driven by strong sales growth in our structural heart therapies, including our Acurate™ Transcatheter Aortic Valve Replacement (TAVR), our Lotus Edge™ Aortic Valve System as well as our Sentinel™ Cerebral Embolic Protection System."

285. Defendant Boston Scientific's statements in ¶284, certified by Defendants Mahoney and Brennan, were materially false and misleading when made because, in truth, far from being a "strong" sales growth driver, Lotus Edge was failing to achieve any organic growth. Indeed, at the end of 2019, as FE 1 reported, the numbers were "just weren't coming in" and "there was just really no one ordering more product based on usage so there was no organic growth in the sales."

286. Two days after Boston Scientific filed its Form 10-K for 2019, on February 25, 2020, Defendant Lisa attended the SVB Leerink Global Healthcare Conference on behalf of the Company. In her presentation, Defendant Lisa stated, "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."

287. Pressed for details about whether centers are "add[ing] LOTUS to the shelf" or "just replacing whatever they have with Lotus," Lisa responded, "So we're on track we said to hit 150 centers opened in the first year and that typically we are seeing Lotus Edge added as a third valve."

288. Defendant Lisa's statements in ¶286 that Boston Scientific was "really excited about Lotus Edge and how it's going and the opportunity in front of it" were materially false and misleading when made because, in truth, the Lotus Edge was performing very poorly, the Company had previously convened an emergency companywide sales meeting over Thanksgiving weekend 2019 because the launch was in crisis and, by 2020, management "freaked out" because the reorders "just weren't coming in" and "there was just really no one ordering more product based on usage so there was no organic growth in the sales."

289. Furthermore, Defendant Lisa's statement in ¶286 was materially false and misleading because Defendants were already shutting down Lotus Edge component manufacturing facilities in Penang, Malaysia, the opposite of what a business would do if it felt "excited" about its product with an "opportunity in front of it." In fact, there were "zero orders" for the Lotus Edge throughout 2019 and 2020 and, because the facility was "getting zero orders" for Lotus at the end of 2019, and no work was being done, the plant was shut down by March 2020, before the onset of the COVID-19 pandemic and at the same time Defendant Lisa appeared at the SVB Leerink Conference.

290. Defendant Lisa's statement in ¶286 that Lotus Edge was "on track… to hit 150 centers opened" by April 2020 was also materially false and misleading because, in truth, Boston Scientific was not "on track" to hit that target, and indeed, never secured 100 U.S. accounts. In truth, the actual Lotus sales targets and reorder rate targets were half of Boston Scientific's internal targets.

291. On March 3, 2020, Defendants Brennan and Lisa presented at the Cowen Health Care Conference on behalf of Boston Scientific. In response to a question about what "tailwinds" Boston Scientific was experiencing, Brennan answered, "our successes should be built on the momentum that we have with the launches" including "Lotus in the U.S., Lotus in Europe."

292. Then, regarding Boston Scientific's stated goal of entering 150 TAVR centers, Brennan claimed, "qualitatively, 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." When pressed by the analyst hosting the conference on the cadence of getting to 150 centers and whether it was "back half weighted," Brennan denied that it was, answering:

> 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. It is a little different than a traditional kind of balloon expandable or self-expanding valve. We want to make sure that people have the right proctor in place to do that before they're off doing it on their own and that's what we're doing.

293. In response, the analyst hosting the conference asked Brennan, "when [do] you start kind of putting the pedal on the launch – or pushing the pedal down in terms of giving the launch some gas or is that just going to continue to be kind of a deliberate center-by-center?" Brennan answered:

> The danger is you try and go too fast and you lose your way relative to proctoring and then you put outcomes and procedures not where we want them to be. 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.

294. Defendant Brennan's statements in ¶292 that the Lotus was "on track" to obtain accounts at 150 centers and that the launch was "going well" were materially false and misleading because, in truth, the Lotus launch was failing, as Defendants had already begun to shut down manufacturing facilities for components of Lotus because there were "zero orders" for the product

In truth, there were "zero orders" for the Lotus Edge throughout the end of 2019 and 2020 and, because the Penang facility was "getting zero orders" for Lotus at the end of 2019, the plant was shut down by March 2020.

295. Further, Defendant Brennan's statements in ¶¶292-93 are materially false and misleading because, rather than placing "heavy emphasis on proctoring and making sure that folks are 100% able and ready to use the valve" and "making sure that everybody is proctored, ready to go," in truth, the launch was rushed and conducted in a "clinically unsafe" manner due to poor Boston Scientific sales representative training.

296. On March 11, 2020, Defendant Mahoney participated in the Barclays Virtual Global Healthcare Conference on behalf of Boston Scientific. In response to "what you are seeing in the TAVR business," Mahoney stated:

> It's one of the biggest investment areas in the company. We're the only company and we're looking long term here. So, as the short term, in 2020, we're essentially on our planned goals on Lotus of 150 accounts open in the first year. Lots of focus on training in the U.S. Europe requires a little bit less of it, because the doctors are more familiar with Lotus in Europe, and we're seeing excellent PVL and many 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. But we're the only company that has the intra-annular valve which is Lotus Edge and Acurate. And what's important is we have a nice product cadence behind each one of those platforms. And there's a lot of clinical work being done in intermediate risk within Lotus Edge and we're also starting our clinical trials in the US with Acurate.
>
> And then we'll have our Acurate neo2 approved hopefully for the second half of 2020, which allow us to open up more accounts in Europe. And as I said, we've started the enrollment in the US. So, overall, that [TAVR] category is growing nicely for us and we're building momentum and more capabilities internally.

297. Defendant Mahoney's statement in ¶296 that "we're looking long term here" was materially misleading because, in reality, Defendants were not looking long term and had already begun. Indeed, there were "zero orders" for the Lotus Edge at the Company's Penang facility throughout 2019 and 2020 and the plant was shut down in early 2020. Further, Defendant

Mahoney's statement in ¶296 that "we're essentially on our planned goals on Lotus of 150 accounts open in the first year" was materially false and misleading because, in truth, Boston Scientific was not remotely on track to hit that target and, in fact, never obtained 100 accounts before concluding the franchise was doomed and would be shut down.

298. In addition, Defendant Mahoney's statement in ¶296 that there was a "focus on training in the U.S." and that the Company was getting "smarter and better as we proctor new physicians in the U.S." was materially misleading because it omitted the highly materially facts that sales and clinical support training for Boston Scientific Lotus Edge representatives was woefully deficient and contrary to industry standards. The statement was also materially misleading because it omitted the highly material facts that, by 2020, Boston Scientific only had 21 clinical or sales representatives who had been certified to oversee Lotus Edge procedures, many of who had only participated in five Lotus Edge procedures such certification—leaving them woefully ill-equipped to handle complications arising from the most "complicated device on the planet."

299. On April 29, 2020, Boston Scientific held its earnings call for the first quarter of 2020. Defendant Mahoney claimed, "the ongoing launch of Lotus Edge in the U.S. and Japan has been challenged by COVID-19 restrictions that limit proctor travel and the delivery of training, but we do look forward to the recovery in procedure volumes." A slide deck prepared by the Company in connection with the earnings call contained a similar statement.

300. Defendants Mahoney's statement in ¶299 was materially misleading when made because, rather than pursue the ongoing launch of Lotus, the Company had by this time shut down at least one facility that manufactured component parts for the device in Penang, Malaysia and had concluded to exit the business. Further, rather than face "challenges" from the COVID pandemic,

the launch had been a failure since long before the pandemic, had severely underperformed the Company's internal targets for the past year, and had been unsuccessful for reasons having nothing to do with the pandemic. In fact, there was "zero orders" for the Lotus Edge throughout 2019 and 2020 and, because the facility was "getting zero orders" for Lotus at the end of 2019, the plant was shut down by March 2020.

301. On July 29, 2020, Boston Scientific held its earnings call for the second quarter of 2020. In prepared remarks, Defendant Mahoney stated the following:

> In TAVR, we continue to roll our Acurate neo2 US trial and plan for a limited market release in Europe in the second half. Lotus Edge continues to see strong utilization within existing accounts, while new account openings and geographic expansion did slow in second quarter due to COVID impacts and a slowdown in physician training. June and July results with Lotus Edge are encouraging, and we continue to enroll REPRISE IV, and we 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.

302. During the question-and-answer session, an analyst from Morgan Stanley asked Mahoney about the impact of COVID-19 on launches reliant upon proctoring. Mahoney stated:

> The procedures that have been – the new launches that have been impacted more significantly, specifically in second quarter, although we have seen improvement in the second half of June and the full month of July really are products like Lotus and EXALT-D, which do require, Lotus, another level of physician training when you're opening up new centers. So we have seen some improvement in that very recently. But the current centers are using the device quite consistently.

303. Further, in response to a question from an analyst from J.P. Morgan who asked about Boston Scientific's progress in navigating the pandemic, noting the relative weakness in Structural from April to June and the fact that many of the patients for Structural Heart procedures—including Lotus Edge—"can't be put off forever, as you mentioned a couple of times." In light of that fact, the analyst wanted to know whether investors would see a recovery in that area of the business where the "trend would catch up" to some of the other performance

metrics. In response, Defendant Mahoney affirmatively stated that the Lotus procedures had already increased, and that the Company had already seen new account openings:

> [A]s I mentioned before, the TAVR new openings were impacted more significantly in the second quarter. So we are starting to see the gates open up a bit more in terms of new account openings with Lotus, and we're going to be launching the ACURATE neo2 device in Europe in the second half. So we have seen improvement, again, in our TAVR – our structural heart portfolio, particularly in June and July from second quarter.

304. Defendant Mahoney's statements in ¶¶301-03 that "Lotus Edge continues to see strong utilization" and that the Company was "starting to see the gates open up a bit more in terms of new account openings with Lotus" were materially false and misleading when made because, in truth, Boston Scientific was not starting to see any increase in new accounts or experiencing strong utilization for Lotus Edge. In fact, Boston Scientific had months before shut down its manufacturing facility in Penang because there were "zero orders" for Lotus.

305. On August 19, 2020, Defendants Brennan and Defendant Lisa attended a Virtual Fireside Chat with Credit Suisse on behalf of Boston Scientific. During the interview, the analyst hosting the event asked Defendant Brennan about the Company's progress in opening 150 accounts, asking, "[H]ave we crossed that threshold at this point?" Defendant Brennan deferred to Defendant Lisa and Tengler, who stated, "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."

306. The statements by Tengler on behalf of Boston Scientific in ¶305 that Boston Scientific was "on track pre-COVID" and "you can expect our work to be similar in the next 12 months" were materially false and misleading when made. In truth, Boston Scientific was not "on track" with new account openings but had never even reach "sub-100" accounts in the United States before Boston Scientific determined it would abandon the business, as Defendant Fitzgerald subsequently admitted.

307. Later that month, Defendants Mahoney and Brennan attended the Morgan Stanley Global Healthcare Conference on behalf of Boston Scientific on September 16, 2020. When asked about Boston Scientific's equity raise the prior quarter and whether it signaled that Boston Scientific needed the capital to "urgently go out and do deals because you're feeling not as good about the core portfolio," Mahoney stated: "When [we] did the equity raise, it was a bit of a different era with COVID, so we're concerned about that and we didn't want to be, as you said, flat footed on the defense over the next 18 months with our ability to leverage that venture portfolio and other opportunities."

308. Then, the analyst said, "I've got this thesis that I don't think you'll agree with, but I'm going to throw it out there anyway. This dynamic that Lotus was supposed to be a much bigger product … and it's not and that has sort of forced the company to sort of shift things around or it created a void in the [Long Range Plan]" to get to 6 to 9% organic growth. Mahoney adamantly disagreed and stated, "No. 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." Mahoney also said:

> 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. So, Lotus is important for us, but we have other tailwinds to support the company.

309. Later that same day, the analyst followed up on the status of the Lotus, stating, "obviously the Lotus… you're taking share, but it's tough to take share from the incumbents, [Medtronic and Edwards]." Mahoney responded, "We're very confident in the performance of the [Lotus] device, the infrastructure that we have around it."

310. Defendant Mahoney's statements in ¶¶307-09 that "Lotus will continue to be an important product for us," that "Lotus remains a key growth driver for us," and "Lotus is important for us" were materially false and misleading when made because, in truth, Defendants were planning to recall and cancel the platform, had already shut down a manufacturing facility in Penang, Malaysia and lay off hundreds of workers. Further, Defendant Mahoney's statement in ¶308 that "we're starting to do more account openings, the reorder rate for existing users is quite high" was materially false and misleading when made because, in truth, there were "zero orders" for Lotus throughout late 2019 and 2020, sales were less than half of the Company's internal targets, and, as Defendant Fitzgerald later admitted, Boston Scientific determined to shut down the business once the Company had reached "sub-100" accounts.

311. On September 28, 2020, Boston Scientific issued a press release announcing the launch of the Acurate neo2 in Europe. In the press release, Defendant Fitzgerald is quoted as saying, "We believe having this differentiated valve with the enhanced sealing technology will further drive favorable market experience and growth." He then added, "Combined with the Lotus Edge™ Aortic Valve System and Sentinel™ Cerebral Protection System to protect the brain against the risk of TAVI-related stroke, the Acurate neo2 valve represents the natural evolution of our complementary dual-valve TAVI toolkit that covers the needs of a wide range of patient cases."

312. Defendant Fitzgerald's statements in ¶311 that Lotus would be "combined" with Acurate in Boston Scientific's "complementary dual-valve TAVI toolkit" was materially false and misleading because Boston Scientific had already determined to recall and cancel Lotus and indeed, had closed a Lotus production facility in Penang, Malaysia earlier that year.

E. Defendants Falsely Declare That Boston Scientific Had Secured 150 Accounts In The United States And That The Lotus Edge Continued to "Gain Momentum"

313. On October 15, 2020, Defendants Fitzgerald, Meredith, and Lisa attended the Transcatheter Cardiovascular Therapeutics Conference on behalf of Boston Scientific. In prepared remarks, Defendant Fitzgerald said he was "really excited about [Boston Scientific's] ability" to "continu[e] our Lotus Edge launch in the U.S. and Japan and getting neo2 launched … despite the challenges with COVID around the globe."

314. With respect to Lotus Edge, Fitzgerald stated, "I'm proud to announce that we have opened more than 150 accounts in the U.S." Further, he told investors, "I know we are accelerating our momentum in our REPRISE IV medium risk indication trial."

315. Then, unexpectedly, Defendants disclosed that Boston Scientific "taking the opportunity here to reset the timing expectations" and was not expecting an intermediate indication for Lotus Edge until 2024, and that FDA approval and U.S. commercialization of ACURATE neo2 would be in 2024. Although concealed these facts had been concealed from investors throughout the Class Period, FE 4 recounted that enrollment problems for REPRISE IV were in large part due to physicians rejecting the device because of its complexity and the poor patient outcomes they were experiencing including based on the experience of a TAVR center in Atlanta.

316. Nevertheless, despite announcing a three-year delay in the intermediate risk indication for Lotus Edge, Defendants continued to reassure analysts about the sustainability and success of the Lotus franchise, and represented that the franchise was in fact "gaining momentum." For example, an analyst from Morgan Stanley asked about the Lotus Edge's rollout globally. Fitzgerald responded:

> [L]et's start with US. We – I consider that we just annualized our launch COVID sat right in the middle of that first 12 months of launch. But 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. We've got an improved version of iSLEEVE that will hit the US for an LMR in November…
>
> 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.

317. Defendants Fitzgerald's statement in ¶316 that "our launch is gaining momentum" and that Boston Scientific was "expanding our footprint" with Lotus were materially false and misleading when made because, in truth, as Defendants later admitted, Boston Scientific had already determined to abandon the business and had done so when Lotus reached "sub-100" accounts.

318. On October 28, 2020, Boston Scientific held its earnings call for the third quarter of 2020. In his prepared remarks, Defendant Mahoney highlighted the Company's "continued U.S and Japan rollout of Lotus Edge and U.S. intermediate risk trial enrollment" highlighting the Company's dual-valve strategy and "distinct benefits" of the Lotus Edge, including the "predictable control with a platform that may be fully recaptured and repositioned at any time."

319. During the question-and-answer session, an analyst from Wells Fargo pointedly asked Mahoney if, "at a high level, from an ROI perspective, does it still make sense to develop two TAVR platforms?" Mahoney responded reassured investors that Boston Scientific had concluded that it was, stating:

> 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.

320. Defendant Mahoney's statements in ¶319 reassuring investors concerning Boston Scientific's "two-valve strategy" and the "strong results" in sites using the Lotus Edge that were "using it quire regularly" was misleading when made because, in truth, Defendants had determined to abandon the business, had closed down a Lotus component manufacturing facility in Penang,

Malaysia months earlier, and had done so because the business was failing and sales had consistently underperformed, not even reaching half of Boston Scientific's internal targets, since the launch was initiated a year earlier. Defendant Mahoney's statement in ¶319 that "we're seeing strong results in the sites that are using Lotus" is also materially false and misleading because Defendants had received numerous reports from physicians that the Lotus was difficult to use, the device's complicated delivery system had resulted in numerous patient injuries and deaths, and that the Company had held an emergency company-wide meeting of its Lotus sales force in Thanksgiving 2019 precisely because the device was difficult to use and physicians were having poor results.

F. Defendants' False Statements About Boston Scientific's Financial Results

321. By concealing the Lotus Edge's failure until November 17, 2020, Defendants avoided reporting charges that it be required to disclose upon cancellation of Lotus platform. Indeed, on November 17, 2020, Defendants announced that they would take a $225-$300 million charge associated with the cancellation of the Lotus platform, and in fact have since recorded charges of $182 million in Lotus restructuring costs.

322. The Company's concealment of the Lotus failure caused Boston Scientific to materially overstate its earnings per share ("EPS") during the Class Period beginning in the first quarter of 2020, once Defendants made the decision to shut down the Lotus platform. In delaying the recall and cancellation, Boston Scientific avoided reporting an EPS loss of an additional $0.13 for the quarter in which the charge was not disclosed. Significantly, by concealing this charge, Boston Scientific was able to publicly disclose the costs associated with the Lotus shutdown during the fourth quarter of 2020, when the incurring those charges would not require Boston Scientific to report a quarterly EPS loss. These financial results were filed in press releases announcing the Company's quarterly earnings and in Forms 10-K and Form 10-Q filed with the SEC were

materially false and misleading due to the Company's failure to reveal the Lotus failure, which resulted in overstatements in the Company's EPS beginning in the first quarter of 2020 as follows:

Reporting Period[8]	**Reported GAAP EPS**	**True EPS With Lotus Charge**
First Quarter 2020	$0.01	($0.12)
Second Quarter 2020	($0.11)	($0.24)
Third Quarter 2020	($0.12)	($0.25)
Fourth Quarter 2020	$0.01	$0.01

323. By delaying disclosure of the recall and cancellation of Lotus Edge, these overstatements had a dramatic impact on the Company's reported financial results. The concealment of the Lotus Edge's failure permitted the Defendants to artificially inflate the Company's EPS, avoid reporting a loss or an even more drastic quarterly loss during a time when investors were particularly concerned about the Company's performance given the onset of the pandemic, and enabled Boston Scientific to publicly disclose the charge during a quarter when doing so would still enable the Company to report a profit and positive EPS for the quarter.

VIII. LOSS CAUSATION

324. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Boston Scientific common stock and operated as a fraud or deceit on Class Period purchasers of Boston Scientific common stock by failing to disclose and misrepresenting the adverse facts detailed herein, including that (1) Boston Scientific's commercial launch of the Lotus Edge in the U.S. was not "on track"; and (2) that Boston Scientific's two-valve TAVR strategy was failing. As a result of Defendants' misrepresentations and omissions, the price of Boston Scientific common stock

[8] The Company's false and misleading 2020 EPS results were published in press releases and quarterly reports filed under Forms 8-K and Forms 10-Q as follows: First Quarter: April 29, 2020 and May 6, 2020; Second Quarter: July 29, 2020 and August 5, 2020; Third Quarter: October 28, 2020 and November 5, 2020.

declined significantly as the prior artificial inflation came out of the Company's stock price on October 15, 2020 and November 17, 2020. Defendants' misstatements and omissions were the proximate cause of those stock price declines and the losses suffered by Class members. The disclosures that corrected the market price of Boston Scientific shares and reduced the artificial inflation caused by Defendants' materially false and misleading statements and omissions are summarized in the chart below, which identifies each corrective disclosure event, the price declines in Boston Scientific shares resulting from the event as compared to the prior day's close, and the percentage decline:

Date	**Event**	**Price Change**	**% Change**
10/15/20	Lotus Edge intermediate risk indication delay	$40.62 to $39.00	-3.99%
11/17/20	Lotus Edge recall	$38.03 to $35.03	-7.89%

325. As a result of their purchases of Boston Scientific common stock during the Class Period, Lead Plaintiffs and the other Class members suffered economic loss, i.e., damages, under the federal securities laws. Defendants' materially false and misleading statements caused Boston Scientific common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as $42.23 per share on September 2, 2020.

326. By concealing from investors the adverse facts detailed herein, Defendants presented a misleading picture of Boston Scientific's business and prospects. As true facts about the Company were revealed to the market, the price of Boston Scientific common stock fell significantly. These declines removed the inflation from the price of Boston Scientific common stock, causing real economic loss to investors who had purchased Boston Scientific common stock during the Class Period.

327. The declines in the price of Boston Scientific common stock after the corrective disclosures came to light were a direct result of Defendants' fraudulent misrepresentations being

revealed to investors and the market. The timing and magnitude of the price declines in Boston Scientific common stock negate any inference that the loss suffered by Lead Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct.

328. The economic loss, i.e., damages, suffered by Lead Plaintiffs and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Boston Scientific common stock and the subsequent significant decline in the value of Boston Scientific common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

IX. PRESUMPTION OF RELIANCE

329. At all relevant times, the market for Boston Scientific common stock securities was an efficient market for the following reasons, among others:

(a) Boston Scientific stock met the requirements for listing and was listed and actively traded on the New York Stock Exchange, a highly efficient and automated market;

(b) Boston Scientific filed periodic public reports with the SEC and the New York Stock Exchange;

(c) Boston Scientific regularly publicly communicated with investors via established market-communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Boston Scientific was followed by securities analysts employed by numerous major brokerage firms, who wrote reports that were distributed to the sales forces and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

330. As a result of the foregoing, the market for Boston Scientific securities promptly digested current information regarding Boston Scientific from all publicly available sources and reflected that information in the price of Boston Scientific securities. Under these circumstances, all purchasers of Boston Scientific securities during the Class Period suffered similar injury through their purchase of Boston Scientific securities at artificially inflated prices, and the presumption of reliance applies.

331. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class' claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Boston Scientific's business—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Lotus Edge, as alleged above, that requirement is satisfied here.

X. THE STATUTORY SAFE HARBOR DOES NOT APPLY TO DEFENDANTS' FALSE AND MISLEADING STATEMENTS

332. The statements alleged herein to be materially false and misleading are not subject to the protections of the PSLRA's statutory Safe Harbor for forward-looking statements because

(a) they are not forward looking; (b) they are subject to exclusion; or (c) even if purportedly forward-looking, Defendants cannot meet the requirements for invoking the protection, i.e., identifying the statements as forward looking and demonstrating that the statements were accompanied by meaningful cautionary language.

333. Many of the statements were misleading in light of omissions of material present or historical facts and cannot be considered forward-looking.

334. Under the PSLRA's statutory Safe Harbor for written statements, a forward-looking statement is protected if it is identified as such and "accompanied by meaningful cautionary language." 15 U.S.C. § 78u-5(c)(1)(A)(i). An oral forward-looking statement must be accompanied by a cautionary statement that it is forward-looking, that actual results may differ materially and that additional information concerning risk factors is contained in a readily available written document. In addition, the oral statement must: (i) identify the written document, or portion thereof, that contains such factors; and (ii) the referenced written documents must contain meaningful cautionary language. 15 U.S.C. § 78u-5(c)(2)(B).

335. The Safe Harbor excludes from protection all forward-looking statements that are included in financial statements purportedly prepared in compliance with Generally Accepted Accounting Principles ("GAAP"), including those filed with the SEC on Form 8-K. 15 U.S.C. § 78u-5(b)(2)(A).

336. Statements of historical fact, current condition or a mixture thereof are not "forward-looking" and thus not protected by the Safe Harbor.

337. To the extent any of the statements were identified as forward-looking statements, they do not fall within the protections of the Safe Harbor because they lacked specific, meaningful cautionary statements identifying important factors that could cause actual results to differ

materially from those in the purportedly forward-looking statements. A warning that identifies a potential risk, but implies that such a risk had not materialized, i.e., states that something might occur but does not state that something actually has already occurred, is not meaningful and does not fall within the protections of the Safe Harbor.

338. Meaningful risk disclosures must also be substantive and tailored to the forward-looking statement they accompany. Many of Defendants' purported risk disclosures remained unchanged over the course of the Class Period, despite the fact that such risks had in fact materialized, which change in circumstance was material to the reasonable investor. Defendants' risk disclosures were therefore neither substantive nor tailored and do not satisfy the requirements of the Safe Harbor.

339. Nor were the historic or present-tense statements made by Defendants assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

340. Defendants' forward-looking statements also do not fall within the protections of the Safe Harbor because they had no reasonable basis. Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false or misleading and/or the forward-looking statement was authorized and/or approved by an executive officer of Boston Scientific, who knew that those statements were false or misleading when made.

XI. CLASS ACTION ALLEGATIONS

341. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Boston

Scientific common stock during the Class Period, i.e., from February 6, 2019 through November 16, 2020, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants; members of the immediate families of the Individual Defendants; Boston Scientific's subsidiaries and affiliates; any person who is or was an officer or director of Boston Scientific during the Class Period; any entity in which any Defendant has a controlling interest; and the legal representatives, heirs, successors and assigns of any such excluded person or entity.

342. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. The Company's stock is actively traded on the NYSE and there are more than 1.4 billion shares of Boston Scientific common stock outstanding. While the exact number of Class members is unknown at this time, and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Boston Scientific or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

343. Common questions of law and fact predominate and include:

(a) whether Defendants violated the Exchange Act and SEC Rule 10b-5;

(b) whether Defendants omitted and/or misrepresented material facts;

(c) whether Defendants knew or recklessly disregarded that their statements were false;

(d) whether Defendants' statements and/or omissions artificially inflated the price of Boston Scientific common stock; and

(e) the extent and appropriate measure of damages.

344. Lead Plaintiff's claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

345. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

346. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XII. COUNTS

COUNT I

For Violation of Section 10(b) of the Exchange Act And Rule 10b-5 Against All Defendants

347. Lead Plaintiff repeat and reallege every allegation above as if fully stated in this Count.

348. This Count is asserted on behalf of all members of the Class against all Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

349. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were materially misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

350. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (iii) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of Boston Scientific common stock during the Class Period.

351. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Boston Scientific common stock. Lead Plaintiff and the Class would not have purchased Boston Scientific common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

352. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of Boston Scientific common stock during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against the Executive Defendants

353. Lead Plaintiff repeat and reallege every allegation above as if fully stated in this Count.

354. This Count is asserted on behalf of all members of the Class against the Executive Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

355. During the Class Period, the Executive Defendants acted as controlling persons of Boston Scientific within the meaning of Section 20(a) of the Exchange Act. By virtue of their

positions and their power to control public statements about Boston Scientific, the Executive Defendants had the power and ability to control the actions of Boston Scientific and its employees. Boston Scientific violated Section 10(b) of the Exchange Act and Rule 10b-5, as set forth above. By reason of such conduct, the Executive Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

356. Wherefore, Lead Plaintiffs pray for judgment as follows:

(a) Determining that this action is a proper class action, certifying Lead Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Lead Counsel as class counsel;

(b) Awarding compensatory damages in favor of Lead Plaintiff and the other members of the class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest;

(c) Awarding Lead Plaintiffs' reasonable costs and expenses incurred in this action, including attorneys' fees and expenses; and

(d) Awarding such equitable, injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

357. Lead Plaintiff demands a trial by jury.

Dated: June 4, 2021

Respectfully submitted,

/s/ *Michael Blatchley*

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