UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NORTH CAROLINA

ASHOK V. BANKLEY, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. TRANSENTERIX, INC., TODD M. POPE, and JOSEPH P. SLATTERY, Defendants.	)	CASE NO.: COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS 15 U.S.C. §§78j(b), 78t(a); 17 C.F.R. §240.10b-5 CLASS ACTION DEMAND FOR JURY TRIAL

Plaintiff Ashok V. Bankley ("Plaintiff"), by and through his undersigned attorneys, individually and on behalf of all others similarly situated, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls, announcements, and United States Securities and Exchange Commission ("SEC") filings; wire and press releases published by and regarding TransEnterix, Inc. ("TransEnterix" or the "Company"); analysts' reports and advisories about the Company; and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons who purchased or otherwise acquired TransEnterix stock between February 10, 2016 and May 10, 2016, inclusive (the "Class Period"), against TransEnterix and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 ("1934 Act"). These claims are asserted against TransEnterix and certain of its officers and/or directors who made materially false and misleading statements during the Class Period in press releases, analyst conference calls, and SEC filings.

2. TransEnterix is a medical device company that seeks to use flexible instruments and robotics to improve the outcomes of minimally invasive surgery. Of relevance here is the Company's focus on the development and commercialization of the SurgiBot System ("SurgiBot"), a single-port, robotically enhanced laparoscopic surgical platform. The surgical approach and motions used with the SurgiBot robotic device are intended to mimic established laparoscopic surgical techniques. The system utilizes flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, from within the sterile field. The flexible nature of the system is intended to allow multiple instruments to be introduced and deployed through a single incision. At a projected cost of $500,000, the SurgiBot was designed to be a lower-cost alternative

for the surgical robot industry, which is dominated by a surgical device called the da Vinci System, which costs approximately $2 million.

3. Prior to the start of the Class Period, on June 1, 2015, the Company issued a press release announcing that it had submitted its 510(k) application to the United States Food and Drug Administration ("FDA") for the SurgiBot.

4. According to the FDA, Section 510(k) of the Food, Drug, and Cosmetic Act requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification – commonly referred to within the industry as a "510(k)." This 90-day notification allows the FDA to determine whether the device is "substantially equivalent" to a device already placed into one of three classification categories, *i.e.*, whether the device is as safe and effective as similar, legally marketed products. Put simply, manufacturers use a 510(k) to demonstrate their devices are "substantially equivalent" to existing devices.

5. Specifically, medical device manufacturers are required to submit a 510(k) if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Until the FDA issues an order declaring a device to be substantially equivalent, a manufacturer may not proceed to market the device.

6. Describing the Company's 510(k), TransEnterix's June 1, 2015 press release stated, in relevant part:

> "TransEnterix is pleased to deliver on our commitment to file for 510(k) clearance for the SurgiBot System by mid-2015," said TransEnterix President and CEO, Todd M. Pope. "Robotically enhanced laparoscopy with the SurgiBot System represents the first surgical platform designed to address economic and clinical challenges associated with current laparoscopic and robotic options. We view the SurgiBot as a market-expanding technology with a compelling value for a wide variety of surgical facilities with the potential to deliver critical benefits to surgeons, hospitals and patients. We look forward to continuing our preparation to bring this innovative technology to the market upon FDA clearance."

7. During the Class Period, Defendants made numerous positive statements about the SurgiBot. For example, on February 10, 2016, the Company issued a press release announcing that

it had finalized its FDA submission related to the SurgiBot 510(k) application, with Company President and Chief Executive Officer ("CEO") Todd M. Pope ("Pope") commenting:

> We are pleased to have completed our response to the FDA and strengthened our balance sheet. ***We continue to expect FDA clearance for the SurgiBot System in the first quarter of this year, and our cash position allows us to accelerate our transition to commercializing both the ALF-X and the SurgiBot***.

8. After the market closed on April 20, 2016, Defendants shocked investors when the Company revealed that the FDA notified TransEnterix on April 19, 2016 that the FDA had determined the SurgiBot "does not meet the criteria for substantial equivalence based upon the data and information submitted by TransEnterix in its 510(k) submission."

9. Then, after the market closed on May 10, 2016, the Company further shocked the market when it announced that it was "reprioritiz[ing] its near-term regulatory efforts" and shelving the SurgiBot. Instead of pursuing approval and commercialization for the SurgiBot, which would require a new 510(k) submission, Defendants revealed the Company would now "focus [its] resources on the commercialization of and regulatory clearance for the ALF-X System." TransEnterix further stated that it would "delay any potential re-filing for the SurgiBot System" until after the Company could achieve 510(k) clearance for its other robotic surgical device, the ALF-X System (the "ALF-X"), despite the fact that it did not expect to submit a 510(k) for the ALF-X until the fourth quarter of 2016. Defendants also revealed that TransEnterix had "taken actions to reduce headcount and investment related to the SurgiBot."

10. During a conference call after the market closed on May 10, 2016, Defendant Joseph P. Slattery ("Slattery") stated that TransEnterix was "reduc[ing] head count investment in SurgiBot production and development" which "resulted in an annualized reduction in salaries of approximately $4 million." The next day, the *Triangle Business Journal* reported that TransEnterix "cut ties with an estimated 50 employees in the United States – about 40 percent of its workforce in this country."

11. In response to the Company-specific, negative news revealed in the Company's April 20, 2016 press release, the price of TransEnterix stock declined substantially. After closing at $4.74

on April 20, 2016, the stock opened at $1.57 per share on April 21, 2016, falling to a low of $1.28 and ultimately closing at $2.27, a decline of more than 50%, on abnormally high trading volume of more than 21.5 million shares. Then, in response to the negative news revealed after the market closed on May 10, 2016, the price of TransEnterix stock dropped again, falling more than 10% to close at $1.84 on May 11, 2016, on elevated trading volume of more than 5.5 million shares.

JURISDICTION AND VENUE

12. Jurisdiction is conferred by Section 27 of the 1934 Act, 15 U.S.C. §78aa. The claims asserted herein arise under Sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. §240.10b-5.

13. Venue is proper in this District pursuant to Section 27 of the 1934 Act. The violations of law complained of herein occurred in part in this District, including the dissemination of materially false and misleading statements complained of herein into this District. TransEnterix's headquarters are located in this District at 635 Davis Drive, Suite 300, Morrisville, North Carolina 27560.

14. 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 mails, interstate telephone communications, and the facilities of the national securities markets. TransEnterix trades in an efficient market on the New York Stock Exchange MKT ("NYSEMKT").

PARTIES

15. Plaintiff purchased TransEnterix stock as described in the attached certification and suffered damages as a result of the securities fraud alleged herein.

16. Defendant TransEnterix, Inc. is incorporated in Delaware and has its headquarters in this District. Shares of TransEnterix stock trade on the NYSEMKT under the ticker symbol "TRXC."

17. Defendant Todd M. Pope is and at all relevant times was President and CEO of TransEnterix.

18. Defendant Joseph P. Slattery is and at all relevant times was Executive Vice President and Chief Financial Officer of TransEnterix.

19. Defendants Pope and Slattery (collectively, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of TransEnterix's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and investors, *i.e.*, the market. They 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. Because of their positions with the Company and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

20. Defendants are liable for: (a) making false statements; or (b) failing to disclose adverse facts known to them about TransEnterix. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of TransEnterix stock was a success, as it: (a) deceived the investing public regarding TransEnterix's prospects and business; (b) artificially inflated the price of TransEnterix common stock; and (c) caused Plaintiff and other members of the Class, as defined below, to purchase TransEnterix stock at inflated prices and suffer economic loss when the revelations set forth herein reached the market.

CLASS ACTION ALLEGATIONS

21. 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 TransEnterix stock during the Class Period (the "Class"). Excluded from the Class are Defendants and their families; the officers and directors of the Company, at all relevant times; members of their immediate families

and their legal representatives, heirs, successors, or assigns; and any entity in which Defendants have or had a controlling interest.

22. 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. TransEnterix trades on the NYSEMKT and has more than 114 million shares outstanding, owned by hundreds, if not thousands, of persons.

23. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to members of the Class which predominate over questions that may affect individual Class members include:

(a) whether Defendants violated the 1934 Act;

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

(c) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) whether the price of TransEnterix stock was artificially inflated; and

(f) the extent of damages sustained by Class members and the appropriate measure of damages.

24. Plaintiff's claims are typical of those of the Class because Plaintiff and the other Class members sustained damages from Defendants' wrongful conduct.

25. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

26. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS ISSUED DURING THE CLASS PERIOD

27. On February 10, 2016, the Company issued a press release stating that it had finalized its FDA 510(k) submission for the SurgiBot and "***[c]ontinue[d] to anticipate SurgiBot FDA clearance by the end of the first quarter of 2016***." The press release also added:

> TransEnterix, Inc. (NYSE MKT: TRXC), a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery, today announced the following:
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> - Completes FDA Response. ***TransEnterix has successfully completed its response to the U.S. Food and Drug Administration (FDA) related to the pending 510(k) application submitted for clearance of the company's SurgiBot™ System***.
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> - Strengthens Balance Sheet. Since September 30, 2015, the Company has raised $18 million in net proceeds at an average price of $3.23 per share under its $25 million "at-the-market" (ATM) equity sales facility that was established in February 2015. There is no further availability under this facility. ***The proceeds from these sales will be utilized to continue to support investments for the commercialization of*** the ALF-X® system in Europe, as well as ***the SurgiBot in the United States, following FDA clearance***.
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> - Files New ATM Facility. Following the successful completion of the prior ATM facility, the Company has entered into a new ATM facility that allows it the option to raise up to $43.6 million in equity from time to time through January 2017. The Company has no obligation to sell any shares under this facility.
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> "We are pleased to have ***completed our response to the FDA*** and strengthened our balance sheet," said TransEnterix President and CEO, Todd M. Pope. "***We continue to expect FDA clearance for the SurgiBot System in the first quarter of this year, and our cash position allows us to accelerate our transition to commercializing*** both the ALF-X and ***the SurgiBot***."

28. On March 3, 2016, the Company reported its operating results for the fourth quarter and full year 2015. In a press release that day, the Company reiterated that it had "Submitted [its] 510(k) Application to the FDA for the SurgiBot™ System" and stated, in relevant part:

> "2015 was a transformative year for TransEnterix, as ***we are now positioned as a global surgical robotics company. In 2016, our focus will shift from product development to commercial execution***," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We will continue building the infrastructure to support the commercialization of the ALF-X in multiple countries that accept CE Mark, and ***we remain focused on achieving FDA clearance for the SurgiBot by the end of March, 2016, and preparing for a U.S. commercial launch***."

29. Under the heading "2016 Priorities and Expectations," the press release added:

> During 2016, the Company will continue to expand its sales and service infrastructure for the ALF-X System in Europe and the Middle East. ***Following SurgiBot FDA clearance, the Company intends to expand its U.S. sales and service infrastructure, develop training sites and work with key opinion leaders to gain clinical experience on SurgiBot***. The Company plans to submit a 510(K) application to the FDA for the ALF-X system in the fourth quarter of 2016 and capitalize on the U.S. market opportunity in 2017 with a dual-platform portfolio.

30. The March 3, 2016 release also added:

> The Company had cash and cash equivalents of approximately $38.4 million as of December 31, 2015, and approximately $47.1 million as of February 29, 2016. The Company expects its existing cash and cash equivalents to fund operations through the end of 2016. Pursuant to the disclosure requirements of the NYSE MKT Company Guide Section 610(b), the Company is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2015, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission expected to be filed on or about March 3, 2016, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to the Company's ability to continue as a going concern.

31. On March 3, 2016, the Company hosted a conference call to discuss its fourth quarter and full year 2015 financial results, with Pope and Slattery participating. During the call, Defendants made numerous statements regarding the status of the SurgiBot. For example, Pope stated, in relevant part:

> In the second quarter of 2015, we filed our 510(k) which was a big undertaking. It was a very extensive and comprehensive filing. We felt very good about it. As planned, we knew we'd hear back from the FDA with some of their feedback and questions, which we did in the Q3. ***And we've been taking the last quarter or two to really build up our answers to their questions. We've had a very proactive relationship with the FDA, very good. It continues to this day. And in the first quarter of 2016, we finalized our response and sent it back to the FDA***.
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> We built eight complete systems of the SurgiBot and over 1,200 instruments in support of this machine. ***So we really felt like we got good experience with our manufacturing. We continue to expect about Q1 FDA clearance, which would be later this month***. I just have to say, as I step back and look at 2015; it was a tremendous year for the company. We really hit all of our targets that we set out to and then we took on a new one with the acquisition of ALF-X and that's turned out to be tremendous. So we're really proud of 2015 and super excited as we turn the page to look toward 2016.
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> ***With the SurgiBot, following clearance, which we expect later this month***, we want to expand our U.S. sales and service infrastructure. We want to early on develop

> trainee sites and work with those sites to develop key opinion leaders and gain valuable clinical experience as you do any time you launch a new platform.
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> ***[W]ith SurgiBot following our FDA clearance***, our plans are as follows. We want to hire three area sales managers shortly after clearance. As we've been talking to you, we've been interviewing for a while. We've got a tremendous pipeline of candidates and we've got them lined up to be able to make those hires. And we want to go out and establish our commercial foundation. It always involves developing early clinical experience, making sure that the sites you sell into are willing to host other accounts and be a training site, you want to get a KOL or key opinion leader network, so they can go out and not only have a podium presence but a publication presence. And then we want to build a customer support infrastructure with service and the other things that go around early commercialization.

32. During the question and answer portion of the March 3, 2016 earnings call, Defendants were asked about the approval process for the Company's other key device, the ALF-X, and whether the Company had "some early discussions with the FDA on ALF-X and that's what's giving you the confidence to file it the end of this year?" In response, Pope made clear that the Company would need to get the SurgiBot approved first before seeking clearance for the ALF-X in the United States:

> Yes. We have not gone and had an official meeting with the FDA on the ALF-X. ***We want to finalize our work with SurgiBot with them and then turn our attention to that***. I think from what I'm speaking of is, being in the business 25 years, having a lot of products go through the 510(k) process and certainly coming on the back of the SurgiBot experience, we feel like we were going to have a good solid submission where a good ways there and we're just going to finalize some things throughout this year to be able to file.

33. When asked for some "color about your last interaction with the FDA," Pope stated, in relevant part:

> ***As we've characterized in the past, we filed, [the FDA] gave us their questions in a timely manner as we expected, we responded to their questions in a timely manner as they expected. And they confirmed that they received our questions and they're working through them. We have a good interaction with them. Any interaction over the prior month or a couple of weeks have just been clarifying questions. So everything continues to be on the path that we set out last year***.

34. Also on March 3, 2016, the Company filed with the SEC its 2015 annual report on Form 10-K (the "2015 10-K"), which was signed by Pope and Slattery and contained required Sarbanes-Oxley certifications signed by each of them stating, among other things, that the annual

report did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." Among other things, the 2015 10-K stated, in relevant part:

> The SurgiBot System is currently in development and is designed as a single-incision, patient-side robotic-assisted surgery system. The system is intended to bring many of the advantages of robotic assistance to single incision laparoscopic surgery while mitigating many of the drawbacks of existing robotic-assisted surgery systems. On June 1, 2015, the Company submitted its 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. In August 2015, the FDA requested additional information related to the SurgiBot System 501(k) submission. ***The Company responded to the additional information request in February 2016. The Company anticipates that it will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016, and thereafter intends to launch sales of the SurgiBot System during the second quarter of 2016***.

35. Approval and commercialization of the SurgiBot was critical to the Company's success, as the 2015 10-K noted that "[i]n the year ended December 31, 2015, the Company had no revenue and no U.S. customers, as we focused our efforts on the SurgiBot System development." As of December 31, 2015, the Company had accumulated a deficit of $182.9 million and a net loss of approximately $46.9 million. Indeed, the 2015 10-K included a statement by the Company's independent registered public accounting firm, BDO USA, LLP, that the Company's "recurring losses from operations" and failure to "generate[] significant revenue or positive cash flows from operations . . . raise substantial doubt about the Company's ability to continue as a going concern."

36. On March 11, 2016, the Company filed a prospectus relating to the sale of 15,543,413 shares of TransEnterix common stock by SOFAR S.p.A., which received those shares as part of the consideration paid by the Company for the acquisition of the ALF-X surgical robotic system. On March 11, 2016, the Company also filed a prospectus relating to the sale of 42,759,127 shares of TransEnterix common stock, "registered for the account of the investors" who acquired shares of TransEnterix common stock in the Company's 2013 private financing, which included Slattery.

37. Discussing the SurgiBot, both prospectuses stated, in relevant part:

> On June 1, 2015, we submitted our 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. ***In August 2015, the FDA requested additional information related to the SurgiBot System 510(k) submission. We responded to that additional information request in February***

> ***2016. We anticipate that we will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016 and thereafter intend to launch sales of the SurgiBot System during the second quarter of 2016***.

38. On March 24, 2016, the Company issued a press release to provide an "Update on [its] SurgiBot FDA 510(k) Submission Process." The press release stated that the Company had received an update from the FDA on the status of the 510(k) submission for the SurgiBot, and also stated, in relevant part:

> ***The FDA advised the Company that it has not yet concluded the review of the Company's 510(k) submission and provided an update on the status of the filing. The Company has updated its timing expectations and now expects to receive a decision from the FDA by mid-April, 2016. The Company previously expected a decision from the FDA in the first quarter of 2016.***
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> ***"We have been engaged in constructive dialogue with the FDA throughout the entire submission process," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We appreciate the proactive exchange with the FDA and look forward to their decision, and continue to expect clearance for the SurgiBot***."

39. After the market closed on April 20, 2016, Defendants shocked investors when the Company issued a press release stating that it received a response from the FDA on the SurgiBot 510(k) submission. The press release stated, in relevant part:

> TransEnterix, Inc. (NYSE MKT:TRXC) today announced that the United States Food and Drug Administration ("FDA") notified the Company on April 19, 2016 that the FDA has determined that the SurgiBot™ System does not meet the criteria for substantial equivalence based upon the data and information submitted by TransEnterix in its 510(k) submission.
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> "The FDA's decision is extremely disappointing. We are in the process of reviewing all aspects of the FDA's communication," said Todd M. Pope, President and CEO of TransEnterix. "We will work to complete this review, and will provide an update on the regulatory strategy for the SurgiBot System together with our first quarter 2016 financial and operating results during our quarterly conference call on May 10, 2016."

40. As set forth above, on this news the price of TransEnterix stock dropped suddenly. After closing at $4.74 on April 20, 2016, the stock opened at $1.57 per share on April 21, 2016, fell to a low of $1.28 and ultimately closed at $2.27, a decline of more than 50%, on abnormally high trading volume of more than 21.5 million shares.

41. After the market closed on May 10, 2016, the Company issued a press release, filed its quarterly report on Form 10-Q (the "1Q2016 10-Q"), and hosted a conference call. In the press release, the Company stated, in relevant part:

> As previously announced, the Company received a Not Substantially Equivalent ("NSE") letter from the U.S. Food and Drug Administration ("FDA"). The Company expects to have further discussions with the FDA, but currently believes that a new 510(k) submission would be required to obtain clearance. The Company has evaluated the operational and financial feasibility of pursuing 510(k)s for SurgiBot and ALF-X concurrently, and has decided to reprioritize its near-term regulatory efforts and focus on the ALF-X 510(k) submission. As a result, in the 2016 second quarter, the Company has taken actions to reduce headcount and investment related to the SurgiBot.

42. In the 1Q2016 10-Q, the Company stated, in relevant part:

> Our current strategy is to focus our resources on the commercialization of and regulatory clearance for the ALF-X System. In order to obtain a clearance for the SurgiBot System, we believe that a new 510(k) application would need to be submitted after further interactions with the FDA. Based on this belief, we have evaluated the operational and financial feasibility of pursuing two 510(k) applications in parallel and have elected to focus our near term efforts on the 510(k) submission for the ALF-X System and to delay any potential re-filing for the SurgiBot System until after we achieve ALF-X System clearance in the U.S.

43. The 1Q2016 10-Q also stated that during the first quarter 2016 ended March 31, 2016, but prior to the negative news regarding the SurgiBot reaching the market, the Company sold more than 9 million shares of stock for total gross proceeds of more than $32 million through "at-the-market" offerings covered by a 2015 sales agreement and a 2016 sales agreement with Cantor Fitzgerald & Co., as well as the Company's shelf registration statement. Specifically, under the terms of the 2015 sales agreement, TransEnterix sold 5,710,200 shares at an average price per share of $3.23 for gross proceeds of $18,454,000. Pursuant to the 2016 sales agreement, TransEnterix sold 3,427,500 shares at an average price of $4.11 for gross proceeds of $14,084,000.

44. During the May 10, 2016 conference call, Pope stated, in relevant part:

> In June of 2015, we've submitted our 510(k) application, which was an extensive compilation of documentation and testing results. As is typical in the 510(k) process, within 60 days, we received the request for additional information from the FDA, called an AI, and immediately undertook the actions necessary to respond to their request. The 510(k) process gives the company up to six months to respond to an AI. And we submitted our response in February 2016.
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> In total, over the course of the submission we provided over 11,000 pages of requested material to the FDA. After a total of 138 days of FDA review, we received

> the NSE for the SurgiBot. The reason stated by the FDA for this decision included items that we believe we had adequately addressed through the interactive period.
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> Since receiving the NSE, we've been analyzing the FDA's response together with regulatory counsel. I have personally interacted with the Director of the Division of Surgical Devices of the FDA, along with the Director of the CDRH for the FDA, to request an in-person meeting to review the topics raised in the NSE, which they have agreed to, but has not yet been scheduled.
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> The current situation is as follows. This 510(k) file is now considered closed by the agency. We do expect further discussions with the FDA to help inform our future regulatory strategy for both SurgiBot and ALF-X. As it stands today, we believe that a new 510(k) would need to be submitted for SurgiBot.
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> Based on this belief, we've evaluated the operational and financial feasibility of pursuing two 510(k)s concurrently and have elected to focus our efforts on the 510(k) submission for the ALF-X. In anticipation of clearance, we have been investing substantially in continuing development and production efforts for SurgiBot. This week we have taken significant actions to reduce infrastructure in these areas of the business.
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> These actions put us in a stronger financial position to allow us to fully focus on ALF-X commercialization and prepare the FDA 510(k) submission for ALF-X, while also investing in expanding the capabilities of the ALF-X platform.

45. During the question and answer portion of the call, Pope stated that "over the last three years," the landscape for FDA approval of the SurgiBot had "changed," which implied that the Company's 510(k) submission for the SurgiBot failed to account for such changes. Specifically, Pope stated, in relevant part:

> Two parts, I'll kind of start a little bit with kind of our takeaways from our recent NSE. I do think as we think about robotically-assisted surgical device, the way the FDA is classifying these, RASD, they're more complex and comprehensive than some 510(k). So I think in some regard, focus on the 90-day clock in the 510(k), some point can work against you in a large complicated submission.
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> I certainly think as we think back on our interaction over the last three years, certain things have changed with the landscape. I think there's more scrutiny on robotics. Certainly, there was a public forum last summer for two days. And there's been three or four guidance documents released during that time that affects robotics products.
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> So I think we're a little smarter now. We certainly have those takeaways. But as we focus on your question on ALF-X, as we think about U.S. 510(k) submission, we certainly think we're better positioned. First of all, the ALF-X has a CE Mark, had that for several years. We've got clinical data. We've got several systems out in clinical use. We have multiple publications from multiple specialties. So, we just think we're going in to the ALF-X filing in a different and stronger position than we were with SurgiBot.

46. As set forth above, on this news, the price of TransEnterix stock dropped the following day. After closing at $2.06 per share on May 10, 2016, the stock fell more than 10% to close at $1.84 on May 11, 2016, on elevated trading volume of more than 5.5 million shares.

47. The true facts, which were known by Defendants but concealed from the investing public during the Class Period, were as follows:

(a) Defendants' Class Period statements omitted disclosure of key aspects of the Company's business, specifically deficiencies within the Company's 510(k) submission regarding the SurgiBot, including communications with the FDA that undermined the likelihood that the SurgiBot 510(k) would receive FDA clearance;

(b) Defendants' Class Period statements omitted information regarding whether the SurgiBot possessed substantial equivalence to existing robotic surgical devices, leaving investors unable to accurately assess the validity of Defendants' repeated Class Period statements that the Company's SurgiBot 510(k) was likely to achieve FDA clearance;

(c) without 510(k) clearance, the Company would be unable to commercialize the SurgiBot in 2016 and suffer negative impacts on the Company's ability to obtain approval and commercialization in the United States of its other robotic surgery platform, the ALF-X; and

(d) as a result of the foregoing, Defendants' statements regarding the Company's outlook and expected financial performance were false and misleading and lacked a reasonable basis when made.

48. As a result of Defendants' false statements and material omissions, TransEnterix stock traded at artificially inflated prices during the Class Period. After the above revelations were revealed to the market, however, the price of TransEnterix stock declined significantly as the artificial inflation was removed.

ADDITIONAL SCIENTER ALLEGATIONS

49. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading, knew that such statements or documents would be issued or disseminated to the

investing public, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding TransEnterix, their control over and/or receipt and/or modification of allegedly materially misleading misstatements, and/or their associations with the Company, which made them privy to confidential proprietary information concerning TransEnterix, participated in the fraudulent scheme alleged herein.

LOSS CAUSATION/ECONOMIC LOSS

50. 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 TransEnterix stock and operated as a fraud or deceit on Class Period purchasers of TransEnterix stock by failing to disclose and misrepresenting the adverse facts detailed herein. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market on April 20 and May 10, 2016, the price of TransEnterix stock fell precipitously as the prior artificial inflation came out. As a result of their purchases of TransEnterix stock during the Class Period, Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws when the truth about TransEnterix was revealed through the disclosures specified herein, which removed the artificial inflation from the price of TransEnterix common stock.

51. By failing to disclose to investors the adverse facts detailed herein, Defendants presented a misleading picture of TransEnterix's business and prospects. Defendants' false and misleading statements had the intended effect and caused TransEnterix stock to trade at artificially inflated levels throughout the Class Period.

52. As a direct result of the disclosure identified herein, the price of TransEnterix stock fell precipitously. This removed the artificial inflation from the price of TransEnterix stock, causing real economic loss to investors who had purchased TransEnterix stock at artificially inflated prices during the Class Period.

53. The price declines on April 21 and May 11, 2016 were a direct result of the nature and extent of Defendants' fraud being revealed to investors and the market through the after-hours disclosures on April 20 and May 10, 2016. The timing and magnitude of the price declines in TransEnterix stock negate any inference that the losses suffered by Plaintiff and the other Class members were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of TransEnterix stock and the subsequent significant decline in the value of TransEnterix stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

PRESUMPTION OF RELIANCE

54. At all relevant times, the market for TransEnterix stock was an efficient market for the following reasons, among others:

(a) TransEnterix stock met the requirements for listing and was listed and actively traded on the NYSEMKT, a highly efficient and automated market;

(b) as a regulated issuer, TransEnterix filed periodic public reports with the SEC;

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

(d) TransEnterix was followed by securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

55. As a result of the foregoing, the market for TransEnterix stock promptly digested current information regarding TransEnterix from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of TransEnterix stock during the Class Period suffered similar injury through their purchase of TransEnterix stock at artificially inflated prices and a presumption of reliance applies under the fraud-on-the-market doctrine.

56. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court's holding in *Affiliated Ute Citizens 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 the Company's business operations and financial prospects – 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 Defendants' material Class Period omissions regarding, among other things, the SurgiBot, that requirement is satisfied here.

NO SAFE HARBOR

57. The "Safe Harbor" warnings accompanying TransEnterix's reportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with Generally Accepted Accounting Principles, including those filed with the SEC on Form 8-K, they are excluded from the protection of the statutory Safe Harbor. *See* 15 U.S.C. §78u-5(b)(2)(A).

58. Defendants are also liable for any false and misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of TransEnterix who knew that the FLS was false. In addition, the FLS were contradicted by existing, undisclosed material facts that were

required to be disclosed so that the FLS would not be misleading. Finally, most of the purported Safe Harbor warnings were themselves misleading because they warned of "risks" that had already materialized or failed to provide meaningful disclosures of the relevant risks.

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE 1934 ACT AND RULE 10b-5 AGAINST ALL DEFENDANTS

59. Plaintiff incorporates ¶¶1-58 by reference.

60. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were 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.

61. Defendants violated Section 10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts 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; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and other Class members in connection with their purchases of TransEnterix stock during the Class Period.

62. In addition to the duties of full disclosure imposed on Defendants as a result of their affirmative false and misleading statements to the public, Defendants had a duty to promptly disseminate truthful information with respect to TransEnterix's operations and performance that would be material to investors in compliance with the integrated disclosure provisions of the SEC, including with respect to the Company's revenue and earnings trends, so that the market price of the Company's stock would be based on truthful, complete, and accurate information. SEC Regulations S-X (17 C.F.R. §210.01, *et seq.*) and S-K (17 C.F.R. §229.10, *et seq.*).

63. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other Class members have suffered damages in connection with their respective purchases and sales of TransEnterix stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for TransEnterix stock and experienced loses when the artificial inflation was released from TransEnterix stock as a result of the revelations and stock price decline detailed herein. Plaintiff and the other Class members would not have purchased TransEnterix 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.

64. By virtue of the foregoing, TransEnterix and the Individual Defendants have each violated Section 10(b) of the 1934 Act, and Rule 10b-5 promulgated thereunder.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE 1934 ACT AGAINST ALL DEFENDANTS

65. Plaintiff incorporates ¶¶1-58 by reference.

66. The Individual Defendants acted as controlling persons of TransEnterix within the meaning of Section 20(a) of the 1934 Act. By reason of their controlling positions with the Company, and their ownership of TransEnterix common stock, the Individual Defendants had the power and authority to cause TransEnterix to engage in the wrongful conduct complained of herein. TransEnterix controlled the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring that this action is a proper class action, designating Plaintiff as Lead Plaintiff, and certifying Plaintiff as a Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members 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 thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such equitable, injunctive, or other relief as deemed appropriate by the Court.

JURY DEMAND

67. Plaintiff demands a trial by jury.

DATED: June 2, 2016

McDANIEL & ANDERSON, L.L.P.
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(NC State Bar No. 5025)

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Attorneys for Plaintiff

CERTIFICATION OF NAMED PLAINTIFF PURSUANT TO FEDERAL SECURITIES LAWS

The undersigned declares, as to the claims asserted under the federal securities laws, that:

Plaintiff has reviewed the initial complaint filed in this action.

Plaintiff did not purchase and/or acquire the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in any private action under the federal securities laws.

Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary. I understand that this is not a claim form, and that my ability to share in any recovery as a member of the class is not dependent upon execution of this Plaintiff Certification.

Plaintiff's transactions in the security that is the subject of this action during the Class Period are as follows:

Purchases:

Name of Company	Date(s) Purchased	# Shares Purchased	Cost/Share
TRXC	April 11, 2016	2,400	$5.18
	April 11, 2016	400	$5.25
	April 11, 2016	400	$5.20
	April 11, 2016	200	$5.16
	April 11, 2016	1,600	$5.275

Sales:

Name of Company	Date(s) Sold	# Shares Sold	Proceeds/Share
TRXC	April 21, 2016	2,400	$1.49
	April 21, 2016	1,000	$1.82225
	April 21, 2016	1,600	$1.47225

During the three (3) years prior to the date of this certification, Plaintiff has not sought to serve or served as a class representative in an action filed under the federal securities laws except for the following (if any):

Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this *1st* day of June, 2016 in Glen Allen (City), Virginia (State).

(Signature) X Ashok V. Bankley

(Print Name) ASHOK V. BANKLEY