
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

**November 12, 2013
Date of Report (Date of earliest event reported)**

SAFESTITCH MEDICAL, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State of Other Jurisdiction
of Incorporation)

0-19437
(Commission
File Number)

11-2962080
(I.R.S. Employer
Identification Number)

**635 Davis Drive, Suite 300,
Morrisville, NC 27560**
(Address of principal executive offices) (Zip Code)

(919) 765-8400
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d- 2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e- 4(c))
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Item 2.02 Results of Operations and Financial Condition

On November 12, 2013, SafeStitch Medical, Inc., a Delaware corporation (“SafeStitch” or the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2013. A copy of the press release is attached hereto as Exhibit 99.1.

Also on November 12, 2013, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the financial results for the third quarter ended September 30, 2013. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.2 and incorporated herein by reference. A copy of the presentation slides of the conference call is furnished herewith as Exhibit 99.3 and incorporated herein by reference.

The information included herein and in Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statement and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2013
99.2	Conference call transcript, dated November 12, 2013
99.3	Presentation slides, dated November 12, 2013

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SAFESTITCH MEDICAL, INC.

By: /s/ Joseph P. Slattery
Name: Joseph P. Slattery
Title: EVP and Chief Financial Officer

Date: November 18, 2013

SafeStitch Medical, Inc. Reports Operating Results for the Third Quarter of 2013

- **Completes merger with TransEnterix, Inc., building foundation for growth**
- **Closes \$30.2 million financing, expanding shareholder base**
- **Pre-clinical testing for SurgiBot™ ongoing, expecting 2014 regulatory submissions**
- **Strengthens management team, appointing Joseph Slattery at Executive Vice President & CFO**
- **Company to change name to TransEnterix, Inc.**

RESEARCH TRIANGLE PARK, N.C., Nov. 12, 2013 (BUSINESS WIRE) – SafeStitch Medical, Inc. (“SafeStitch”) (OTCBB:SFES), which recently merged with TransEnterix, Inc. (“TransEnterix”), a medical device company that is pioneering the use of flexible instruments and robotics to improve how minimally invasive surgery is performed, today announced its operating results for the third quarter ended September 30, 2013.

Comparison of Selected Financial Results (in thousands, except per share data)

	Three Months Ended September 30,	
	2013	2012
Total revenue	\$ 362	\$ 531
Net loss	\$(11,265)	\$(3,670)
Net loss per common share	\$ (0.21)	\$ (0.68)
Weighted average common shares outstanding	52,921	5,391

Revenues were \$362,000 in the third quarter of 2013, representing a 32% decrease from revenues of \$531,000 in the third quarter of 2012. The decrease in revenue was primarily due to a reduction U.S. sales personnel, resulting in a decrease in sales of our SPIDER® Surgical System.

Net loss was \$11.3 million in the third quarter of 2013, compared to a net loss of \$3.7 million in the third quarter of 2012. Net loss per common share was \$0.21 in the third quarter of 2013 based on 52.9 million weighted average common shares outstanding compared to a net loss per common share of \$0.68 in the third quarter of 2012 based on 5.4 million weighted average common shares outstanding.

Cash and cash equivalents were \$23.8 million as of September 30, 2013.

On October 29, 2013, SafeStitch stockholders took action to approve changing the name of the company to “TransEnterix, Inc.” SafeStitch anticipates this name change to become effective in the fourth quarter of 2013, after which the common stock will trade on the OTCBB under the symbol “TRXC.”

“The recently completed merger of TransEnterix and SafeStitch and concurrent \$30.2 million financing provide us with a strong foundation for growth,” said Todd Pope, President and Chief Executive Officer of SafeStitch Medical, Inc. “We are enthusiastic about the market opportunity for our SurgiBot system and look forward to bringing this innovative surgical robotic solution to the market.”

Conference Call

SafeStitch Medical, Inc. will host a conference call on Tuesday, November 12, 2013 at 4:30 pm ET to discuss its third quarter financial results. To listen to the conference call on your telephone, please dial (866) 318-8617 for domestic callers or (617) 399-5136 for international callers approximately ten minutes prior to the start time. The call will be concurrently webcast. To access the live audio broadcast or the archived recording, use the following link www.transenterix.com/investors.php

Financial Statements

The merger between SafeStitch and TransEnterix is treated as a reverse acquisition for financial accounting and reporting purposes, with SafeStitch as the acquired entity and TransEnterix as the acquirer. As a result, the assets and liabilities and the historical operations that are reflected in the financial statements disclosed herein and filed with the SEC are those of TransEnterix until September 3, 2013, at which time the assets, liabilities and results of operations have been consolidated with the assets, liabilities and results of operations of SafeStitch.

About SafeStitch Medical, Inc. (TransEnterix)

SafeStitch Medical, Inc. (TransEnterix) is a medical device company that is pioneering the use of flexible instruments and robotics to improve how minimally invasive surgery is performed. The Company is focused on the development and commercialization of SurgiBot, a novel patient side minimally invasive surgical robotic system. For more information, visit the Company’s websites at www.transenterix.com and www.safestitch.com.

Forward Looking Statements

This press release includes statements relating to our efforts to gain favorable coverage decisions for our products that are based on our current beliefs and assumptions. These statements constitute “forward looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation

Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, whether the merger between SafeStitch and TransEnterix will be successful, whether the combined company will be successful in 2014 and beyond, the pace of adoption of our product technology by surgeons, the outcome of coverage and reimbursement decisions by the government and third party payors, the success and market opportunity of our continuing and new product development efforts, including the SurgiBot system, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. For a discussion of the most significant risks and uncertainties associated with SafeStitch's business, please review SafeStitch's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2012, the Form 8-K filed on September 6, 2013 and subsequent SEC reports. You are cautioned not to place undue reliance on these forward looking statements, which are based on SafeStitch's expectations as of the date of this press release and speak only as of the date of this press release. We undertake no obligation to publicly update or revise any forward looking statement, whether as a result of new information, future events or otherwise.

Investor Contact

Westwicke Partners
Mark Klausner, 443-213-0501
transenterix@westwicke.com

SafeStitch Medical, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Sales	\$ 362	\$ 531	\$ 1,212	\$ 1,741
Operating Expenses				
Cost of goods sold	2,059	1,077	4,096	3,465
Research and development	2,909	1,228	7,855	4,552
Sales and marketing	437	1,025	1,490	2,991
General and administrative	1,279	777	2,665	2,176
Merger expenses	2,891	—	2,891	—
Total Operating Expenses	9,575	4,107	18,997	13,184
Operating Loss	(9,213)	(3,576)	(17,785)	(11,443)
Other (Expense) Income				
Remeasurement of fair value of preferred stock warrant liability	(1,800)	—	(1,800)	—
Interest expense, net	(252)	(94)	(742)	(251)
Total Other (Expense) Income, net	(2,052)	(94)	(2,542)	(251)
Net Loss	\$(11,265)	\$(3,670)	\$(20,327)	\$(11,694)
Other comprehensive income (loss)	—	—	—	—
Comprehensive loss	\$(11,265)	\$(3,670)	\$(20,327)	\$(11,694)
Net loss per share - basic and diluted	\$ (0.21)	\$ (0.68)	\$ (0.95)	\$ (2.17)
Weighted average common shares outstanding - basic and diluted	52,921	5,391	21,409	5,391

SafeStitch Medical, Inc.
Consolidated Balance Sheets
(in thousands, except share amounts)

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	\$ 23,829	\$ 8,896
Short-term investments	1,104	907
Accounts receivable, net	294	536
Accounts receivable - related party	24	—
Interest receivable	10	16
Inventory, net	766	1,382
Other current assets	1,033	235
Total Current Assets	<u>27,060</u>	<u>11,972</u>
Restricted cash	375	375
Property and equipment, net	1,823	1,767
Intellectual property, net	2,866	3,241
Intangible assets	10	—
Goodwill	93,670	—
Other long term assets	129	205
Total Assets	<u>\$ 125,933</u>	<u>\$ 17,560</u>
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current Liabilities		
Accounts payable	\$ 2,567	\$ 515
Related party payable	—	6
Accrued expenses	1,078	538
Note payable - current portion	3,795	1,519
Total Current Liabilities	<u>7,440</u>	<u>2,578</u>
Long Term Liabilities		
Preferred stock warrant liability	—	109
Note payable - less current portion	5,604	8,481
Total Liabilities	<u>13,044</u>	<u>11,168</u>
Commitments and Contingencies		
Redeemable Convertible Preferred Stock		
Series A Redeemable Convertible Preferred Stock, \$0.001 par value, 5,734,402 shares authorized; and 5,696,261 shares issued and outstanding at December 31, 2012	—	19,885
Series B Redeemable Convertible Preferred Stock, \$0.001 par value, 11,504,298 shares authorized; and 11,489,972 shares issued and outstanding at December 31, 2012	—	40,016
Series B-1 Redeemable Convertible Preferred Stock, \$0.001 par value, 48,454,545 shares authorized; and 45,998,220 shares issued and outstanding at December 31, 2012	—	15,104
Stockholders' Equity (Deficit)		
Series B Convertible Preferred Stock, \$0.01 par value, 25,000,000 shares authorized, 7,569,704.4 shares issued and outstanding at September 30, 2013	30,197	—
Common stock \$0.001 par value, 225,000,000 and 113,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 167,504,447 and 4,674,495 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	168	5
Additional paid-in capital	172,757	1,288
Accumulated deficit	(90,233)	(69,906)
Total Stockholders' Equity (Deficit)	<u>112,889</u>	<u>(68,613)</u>
Total Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)	<u>\$ 125,933</u>	<u>\$ 17,560</u>

SafeStitch Medical, Inc.
Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	2013	2012
Operating Activities		
Net loss	\$(20,327)	\$(11,694)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	1,064	1,444
Amortization of debt issuance costs	78	23
Remeasurement of fair value of preferred stock warrant liability	1,800	(19)
Accretion/amortization of bond discount/premium	(1)	1
Stock-based compensation	484	274
Gain on disposal of property and equipment	32	4
Impairment loss on property and equipment	304	—
Changes in operating assets and liabilities:		
Accounts receivable	251	(232)
Interest receivable	6	(62)
Inventory	667	(282)
Other current and long term assets	(527)	(122)
Accounts payable	1,444	(351)
Related party payable	173	(10)
Accrued expenses	505	125
Net cash and cash equivalents used in operating activities	<u>(14,047)</u>	<u>(10,901)</u>
Investing Activities		
Purchase of investments	(1,104)	(4,702)
Proceeds from sale and maturities of investments	907	—
Cash received in acquisition of a business, net of cash paid	305	—
Purchase of property and equipment	(724)	(92)
Proceeds from sale of property and equipment	—	49
Net cash and cash equivalents used in investing activities	<u>(616)</u>	<u>(4,745)</u>
Financing Activities		
Proceeds from issuance of debt	1,998	4,000
Payment of debt	(601)	—
Proceeds from issuance of preferred stock, net of issuance costs	28,199	268
Proceeds from exercise of stock options	—	3
Net cash and cash equivalents provided by financing activities	<u>29,596</u>	<u>4,271</u>
Net increase (decrease) in cash and cash equivalents	<u>14,933</u>	<u>(11,375)</u>
Cash and Cash Equivalents, beginning of period	8,896	14,004
Cash and Cash Equivalents, end of period	<u>\$ 23,829</u>	<u>\$ 2,629</u>
Supplemental Disclosure for Cash Flow Information		
Interest paid	<u>\$ 625</u>	<u>\$ 219</u>
Supplemental Schedule of Noncash Investing and Financing Activities		
Issuance of preferred stock warrants and debt issuance costs	<u>\$ 128</u>	<u>\$ 63</u>
Conversion of bridge notes to preferred stock	<u>\$ 1,998</u>	<u>\$ —</u>
Conversion of preferred stock warrants to common stock warrants	<u>\$ 1,909</u>	<u>\$ —</u>

**SafeStitch Medical Third Quarter 2013 Results Conference Call
November 12, 2013**

Corporate Speakers

- | | | |
|----------------|--------------|----------|
| • Todd Pope | TransEnterix | EVP, CEO |
| • Joe Slattery | TransEnterix | CFO |

Participants

- | | | |
|-----------------|--------------------|----|
| • Mark Klausner | Westwicke Partners | IR |
|-----------------|--------------------|----|

PRESENTATION

Operator: Good day, ladies and gentlemen, and welcome to the SafeStitch Medical Third Quarter 2013 Results Conference Call. My name is Derrick and I'll be your operator for today. At this time, all participants are in a listen-only mode.
(Operator Instructions)

I would now like to turn the conference over to Mr. Mark Klausner of the Westwicke Partners. Please proceed.

Mark Klausner: Thanks, Derrick. Joining us on today's call are TransEnterix's President and Chief Executive Officer, Todd Pope, and its Executive Vice President and Chief Financial Officer, Joe Slattery. I would like to remind you that this call is being webcast live and recorded.

A replay of the event will be available later today on our website and will be available for at least 30 days following the call. In addition, we will be referring to slides that are being shown on the webcast. Those slides are also available for download through the webcast link. To access the webcast, please visit the Events link at ir.transenterix.com.

Before we begin, I'd like to remind you that SafeStitch Medical recently merged with TransEnterix and that shareholders have taken action to approve changing the name of the Company to TransEnterix, which is anticipated to occur in the fourth quarter.

I would also like to caution listeners that certain information discussed by management during this conference call will include forward-looking statements covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

Actual results could differ materially from those stated or implied by our forward-looking statements due to risks and uncertainties associated with the Company's business. The Company disclaims any obligation to update any forward-looking statements made during the course of this call.

For a discussion of risks and uncertainties associated with TransEnterix's business, I encourage you to review SafeStitch's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2012, the Form 8-K filed on September 6, 2013, the Form 10-Q for the quarter ended September 30, 2013, which the Company plans to file with the SEC on or about November 14, 2013, and any subsequent SEC reports.

With that, it's my pleasure to turn the call over to TransEnterix's CEO, Todd Pope.

Todd Pope: Thank you, Mark. Since this is our first public conference call subsequent to the merger of SafeStitch and TransEnterix, today I'd like to provide you with an overview of the history of TransEnterix, where we stand today as a combined Company, and our outlook for the future. Prior to my presenting our corporate overview, Joe will review our financial results for the third quarter.

Joe?

Joe Slattery: Thanks, Todd, and good afternoon, everyone. Before reviewing the financial results, I'd like to provide some background on the numbers we will be discussing. On September 3, 2013, SafeStitch Medical, Inc. consummated a merger with TransEnterix, Inc.

The merger is being treated as a reverse acquisition for financial accounting and reporting purposes, with SafeStitch as the acquired entity and TransEnterix as the acquirer. As a result, the assets and liabilities and historical operations that will be discussed are those of TransEnterix through September 3 and of the merged entity thereafter.

For the third quarter, we reported revenues of \$362,000, down 32% compared to the third quarter of last year, primarily due to lower US sales headcount, resulting in a decrease in sales of our Spider Surgical System. As Todd will discuss in detail shortly, our primary focus going forward will be on the development and commercialization of SurgiBot. As such, as we have begun limiting sales of our Spider System to existing customers.

Cost of goods sold was \$2.1 million in the third quarter, an increase from \$1 million in the prior year's quarter. The increase was largely related to an uptick in the reserve for obsolete inventory of \$0.7 million, for raw material inventory that we do not anticipate utilizing given the change in our Spider System commercial approach and associated manufacturing property and equipment impairment charges of \$0.3 million to reflect the change in the estimate of useful lives.

Research and development expenses were \$2.9 million for the third quarter, an increase of \$1.7 million over the prior year's quarter, primarily due to activities associated with SurgiBot development.

Sales and marketing expenses decreased to \$0.4 million for the third quarter. The \$0.6 million decrease in expenses from the prior year's quarter was mainly due to \$0.4 million in lower personnel-related costs, as we decreased our direct sales and marketing personnel, and reduced expenditures for demonstration products of \$0.1 million.

General and administrative expenses increased by \$0.5 million to \$1.3 million for third quarter, up from \$0.8 million in the three months ended September 30, 2012. The increase in expenses was primarily due to an increase in general and administrative expenses incurred by SafeStitch from the date of the merger through September 30, 2013.

Other expense for the third quarter of 2013 was \$2.1 million, compared to \$94,000 for the prior-year quarter. The increase of \$2 million was largely related to the remeasurement of the fair value of preferred stock warrant liability prior to the effective date of the merger of \$1.8 million and an increase in interest expense of \$0.1 million as a result of the issuance of term debt of \$4 million in January 2012 and \$6 million in December 2012. That loss was \$11.3 million in the third quarter of 2013, compared to a net loss of \$3.7 million in the third quarter of 2012.

Net loss per common share was \$0.21 in the third quarter of 2013, based on 52.9 million weighted average common shares outstanding, compared to a net loss per share of \$0.68 in the third quarter of 2012, based on 5.4 million weighted average common shares outstanding. Cash and cash equivalents were \$23.8 million as of September 30, 2013.

I'd now like to turn the call back over to Todd. Todd?

Todd Pope: Thanks, Joe. I'd now like to walk you through our corporate presentation, and will be referring to slides on the webcast. I'm excited to have the opportunity today to share the TransEnterix story with you. Let's first take a look at the focus of TransEnterix going forward which will primarily be on surgical robotics. Today, we live in a world that surgical robotics are firmly entrenched, although the majority of the procedures really fall within three procedures — prostate, hysterectomy, and cholecystectomy, which is gallbladder removal.

As we look to develop a new robot, the feedback that we received from the market was that technology should really focus on a few things, primarily being a patient-side robotic platform. With this, they would like to have a robotic platform that's more cost effective than current options available today and offer a broad procedure applicability other than the three primary procedures mentioned earlier. We're going to be talking about how our Company has changed focus to be able to address these needs.

Our market is large. We look at US laparoscopic markets in our addressable market of being about two million procedures. We'll highlight those later in the presentation. And the opportunity in this market really has given us a strong vision of where we want to go and it's enabled us to recruit a very strong management team and those around them.

If you take a look at the Company history, TransEnterix was founded back in 2006. I joined shortly thereafter. We really focused on a single port surgery system, a platform that could be best-in-class. Well, we named that product Spider, and over the coming three or four years after 2006 we really focused on concept to commercialization. In 2009, we received clearance of our 510(k) to begin marketing the Spider Surgical System. The year after that, we received our CE Mark and began a targeted rollout in Europe and in the Middle East.

Today, we've had over 3,000 successful procedures with the Spider. It's been a great clinical body of evidence, we've learned a tremendous amount, and we then got feedback from the market that asked if we could we incorporate some changes and transform the Spider into a surgical robot. We started focusing on SurgiBot in 2012. We began our design certification and pre-clinical labs in 2013. And most recently, in September, merged with SafeStitch Medical.

If we take a look at our merger with SafeStitch, I want to talk about why this was effective for both parties. The transaction closed about 60 days ago. SafeStitch is a publicly-traded medical device company. They have one product that's approved, both in the US and Europe, the Hernia Stapler, which is a fine product. And they've spent much of their time focusing on a project using flexible endoluminal technology to go after obesity and GERD.

This really was synergistic with TransEnterix as we also use flexible technology in all of our systems, and our fastest-growing procedure is the sleeve gastrectomy in the obesity market.

The board of directors and the investors that were with SafeStitch and have since joined the new Company, TransEnterix, have had a great track record over the past three decades in developing, leading, and founding high-growth med-tech companies. At close of the transaction, we raised \$30 million, from both existing TransEnterix and SafeStitch shareholders, and our combined entity going forward will be called TransEnterix.

If you think about both companies leading up to this point, they were really focused on less invasive surgery, and we've often times in the medical profession equated surgical progress with less invasiveness. On the left-hand side of this slide, you see what was a traditional cholecystectomy incision.

For many, many years, large procedures required large incisions and the surgeons were able to put their hands in the abdomen. In the late 1980s, laparoscopic surgery was introduced and they used rigid trocars, or access ports, and rigid instruments, and that's become a very big and growing business over the past 20 years.

What we tried to focus on with our early product development at TransEnterix is taking this concept of rigid laparoscopy and making it flexible. You'll see from the picture on the right that is the actual picture of our first patient that had a sleeve gastrectomy on their two-week post follow-up. Interestingly, it's the same procedure that the patient in the middle had that required six trocars. So, you can see the benefit pictorially there of less invasive medicine.

As we recount the Spider Surgical System, when we started the Company, we got a lot of feedback from surgeons that they saw the benefit of single-port surgery, but the instrumentation really lacked what they were looking for. And they asked us to develop a certain set of criteria into the product, and we did that.

First of all, all single-port surgery products need to create triangulation. The camera needs to be in the middle and instruments need to come from the left and right to create a triangle. That's the way surgery is done laparoscopically. All systems on the market today create that triangulation at the abdominal wall of the patient so the instruments actually cross through the abdomen, and it puts a lot of torque throughout the surgery on the abdominal wall, which can cause soreness post-op.

Our system, as you can see on the picture on the right, the triangulation actually occurs at the end of our system, which is intra-abdominal, so what's going up against the patient's abdominal wall is a small shaft that remains stationary during the procedure. So, our internal triangulation is achieved, and it's an important difference about our system.

We also took the rigid access ports and instruments and made them flexible, and we use those for dissection and retraction throughout the procedure. And most importantly, we allow the surgeon — as you see the inset there on the left, the surgeon's right hand actually controls the instrument tip that is the right instrument tip that is inside the patient, and the left is the left.

Some of the competition out there actually asks the surgeon's right hand to control the left tip. And this was the opposite of what they had been used to over the last 20 years of laparoscopic surgery and really hindered other competing platforms around single-port adoption.

We fixed those three issues on the left. We also had a low profile port that easily fit through the umbilicus of patients. As we've stated before, we've done over 3,000 procedures. We've had a broad procedural mix. We've had bariatric surgery performed with the Spider, primarily sleeve gastrectomy. We've had cholecystectomy, colorectal surgery, urology and GYN.

As we thought about, in 2012, how to advance the Company to the next level, we got a lot of feedback from the surgeons that said, "We love many things about your system. It's very effective in surgery and we've got a good clinical base of evidence, but we would really like to see some of the advantages that are starting to be incorporated by the robotic platform."

With robotics, you're able to get increased strength, which is very helpful in multiple surgeries. You're able to increase your precision. You're able to get an ergonomic setup for the surgeon during surgery. And certainly, current robotic platforms have introduced 3D vision. So, we took a look at our experience with the Spider over the prior three years, both with regulatory, quality, manufacturing, our domestic and international distribution. It took all those learnings and really wanted to roll and roboticize the Spider.

Now, as we think about looking at the surgical robotics market as a whole, some of those benefits, we could look at those a little closer. As we say, on the left-hand side there, you're able to improve your dissection and retraction strength with the robotic platform. Often times, removing heavy viscera — organs inside the abdomen, sometimes with bariatric patients a liver can weigh eight to 10 pounds — to be able to move that manually is difficult; robotically, much easier.

Also, you have competing priorities in surgery. Often times, in addition to strength in dissection, you need enhanced precision. You've got very good visualization, so you want to be able to take the surgeons' slight movements with their hands and translate those one-to-one inside the abdomen of the patient. Robotics allows you to do that.

The surgeon is put in more of a comfortable situation, not only through long hours in the OR, which is helpful, but it really reduces tremor. Often times, laparoscopic surgery puts surgeons in awkward physical positions during the surgery, and that can cause a wear-down of their small muscle groups in their arms and shoulders. This has improved with robotics. And lastly, 3D visualization has been very helpful.

So, those are all categories, features and benefits of robotics surgery that we wanted to honor and make sure we incorporate into the SurgiBot. And there's a few more that they wanted to see over and above that. So, as you take a look at our platform, you see an operating table there, the Endodrive that we point out there on the left-hand side of the slide is the part that goes into the patient. You see it's very similar to our experience in design with the Spider.

The flex instruments there, on the back, the surgeon will actually stand at patient-side and be able to have their hands on instruments that are actually inside the patient, which allows them ultimate control and tactile feedback.

Our positioning arm, we only need one arm for our robotic platform, and it's low profile. It can stay out of the way and not only provide stability but the ability for the surgeon to move the device throughout the abdomen, which is a very important benefit of ours. And then you see our cart is quite small. We've worked with many OR room circulators to make sure our system can be unobtrusive and fit into the OR environment. And then, when it's not used, it can be put in the corner and not be in the way, it doesn't have to dominate an entire OR and take up that valuable space, and it can be moved from OR to OR very easily.

Now, as we think about some of the things we incorporated in the SurgiBot that are not present in current robotic platforms, I think this is a very interesting slide I want to spend a moment on. As you see in the picture here, surgeons with our system will be scrubbed in. This is the exact position they have been used to over the past 20 years of laparoscopic surgery. They're standing there, hands on the instruments.

This does a couple of things. It provides ultimate control for them to be able to control the instrument patient-side. If there are any complications, they're there patient-side, already scrubbed in, they can take care of them immediately and not have to worry about leaving the room to get scrubbed in. And lastly, surgeons being able to hold the instruments give them tactile feedback. They're used to having their instruments go up against tissue, press, grab, and that gives them tactile feedback that's very important in discerning tissue.

Similar to our last platform, we have flexible instruments in articulating channels. We do have a 3D scope that we're developing for our camera. It is able to be steered inside the patient, but, most importantly, it will be the first camera system that offers a flexible back end. One problem when you reduce the ports with surgery, there's several hands having to be at the same position.

The assistant, as you see there to the left of the surgeon, can stand off to the side with a flexible shaft of our 3D/HD camera and control it without being in the way, which is a great breakthrough we're excited about. As we talked about in the last slide, our system is small and mobile. It's nimble, moving it not only around the OR but to different ORs.

This next point is quite important. As we talked about, the majority of procedures that are done over the past years with robotic surgery have been prostate, hysterectomy, and gallbladder removal. In each one of those, you have a focal target organ space about the size of a softball, so you can focus on that area and you don't have to move your robotic system around.

As we looked to fulfilling one of the promises of the SurgiBot, which is broader procedure applicability, we're going to get into procedures around bariatrics and colorectal eventually that you'll need to be able to move your robotics system intraoperatively to different quadrants. It's very important to have that capability.

The surgeon, with one push of a button, can unlock the system and sweep the system to the left, the right, to the upper quadrant, to the lower quadrant, intraoperatively, which is a very important feature that we've incorporated in the SurgiBot that we think will unlock future potential for many more procedures that are being done today.

And last, on this slide, but certainly not least, cost effectiveness is going to be important. We will have a significant cost savings from current robotic platforms for the capital acquisition.

As we think about the key stakeholders within the environment that we'll be operating in, we've spoken quite a bit about surgeons — that's on the left-hand side — we don't need to revisit that. When surgeons have those benefits, they're transferable to the patient. Patients have had a lot of benefit over the last past 20 years with minimally-invasive surgery moving to more and more procedures. And certainly, current robotic platforms have had patient benefits.

As you look at the hospital, certainly, ROIs have been looked at for healthcare facilities when they're looking to make an acquisition. They certainly want to look at, does it make sense to add robotic capabilities? And they not only think about this as a strategic asset to talk with patients about visiting their hospital for these services, but certainly, surgeons. It's important for surgeons to be able to train on the newest technology. Hospitals look at this as both a strategic asset for surgeon recruitment and retention.

And if we unpack the addressable market of hospitals a little bit further, you can see here that hospitals in the United States, we have over 5,000, and we break them down in this pie chart by bed size. You can see there's 1,500 under 50; about 2,000 between the 50 to 200; almost 1,000 between 200 and 400 beds; and then the large tertiary centers of over 400 beds make up almost 500 of those. Today, each one of these segments are participating in the robotic surgery movement.

But the fact remains that over two-thirds of these hospitals do not have a robotic platform. They've chosen not to participate or can't afford to. So, we think that's an addressable market that the SurgiBot will hit very nicely.

And one important point at the bottom of this slide, not many people talk about surgery centers today as it relates to robotics, but there are over 5,000 surgery centers in the United States today that perform over 22 million procedures. Certainly not all will be a candidate for the SurgiBot, but we think this is an untapped market that you're going to hear more about with the price point that we'll be entering in.

But also, the way we think about hospitals, in addition to bed size segmentation, do they currently have a robotic platform or not? Those on the left, that have chosen not to have robotic capability, we've talked to many of those over the past year.

Often times, they would like to have robotic capabilities; they've decided not to because the acquisition price was too steep or maybe they felt like their procedure volume wasn't heavy enough to get the return on investment. We think we're going to be an answer for many of those hospitals that have chosen not to acquire robotics up to this point.

Surgery centers, we've talked about, we feel like it's a large untapped market. And also, we believe that as you look at the robotic penetration globally it's a large untapped market OUS. There have been pockets that have been able to participate, but it's fairly underpenetrated. We've had good success in learnings with our current Spider platform in Europe and in the Middle East. We've talked to a lot of folks around the world, and there's a high interest in our platform outside the US.

To transition over to the hospitals that do have current robotic capability, they have made the investment, they understand the strategic value. It certainly makes them a competitive differentiator to have robotic surgery. And many of these hospitals have chosen to acquire more than one, which shows it's working within their four walls.

Certainly, the pressure that all of healthcare continues to be under, I think return on investment expectations will continue to be ratcheted up. And the ability for these hospitals to take advantage of the investment they've made, proliferate their robotic offerings with something like SurgiBot, is of great interest to many of the hospitals we've talked about that do have robotics. So, we believe that on both sides of the fence here people that do not have robotics but people that have made the investment is fertile ground for the SurgiBot as we go forward.

Revisiting our original slide, when we talked about two million procedures, I just wanted to show how we think about these. These are targeted laparoscopic procedures done in the US. Bariatric surgery is over 160,000 procedures and the sleeve gastrectomy is the fastest-growing procedure in the world today.

Many of you are aware of the correlation that was presented by the Cleveland Clinic and in the New England Journal of Medicine about the people that have sleeve gastrectomies and bypass, nine out of 10 of those had their type two diabetes symptoms resolved. So, bariatric surgery is on the high growth path.

Gallbladder is over a million in the US alone, certainly pressure on reimbursement, but a procedure that is done widely and has started to be done with a robotic capability. Colorectal surgery, approaching 400,000 procedures in the US, we've got a nice history with the Spider with colorectal surgery. And lastly, certain GYN and urology procedures, we think, will be ideal for the SurgiBot. So that's how we build up our two million target procedures in the US that we think are very amenable to the SurgiBot.

We think about our revenue model. It will be familiar to many of you. We'll have a capital equipment component. We'll certainly have instruments that both will have a disposable component and a reusable, reposable component, and then we'll have service for our capital equipment. This should be familiar to many of you.

As we think about going forward, our commercial pathway this year has seen us in a design finalization and beginning our pre-clinical testing. We've worked with regulatory bodies and had a pre-submission meeting with the FDA. In 2014, we anticipate beginning our first human procedures and we'll file our regulatory submissions. And we anticipate regulatory clearance in 2015 and a global launch, both inside the US and outside.

The management team, you've heard a little bit from me today and Joe Slattery. I've spent the past 23 years in the med-tech segment with Boston Scientific and with Johnson & Johnson and with multiple divisions within those companies. I most recently was the CEO of Cordis, a large multi-billion-dollar division of J&J, prior to coming here to TransEnterix.

Joe Slattery, whom you heard from earlier, came to us from Baxano most recently. He has a lot of public company experience, not only operationally, but board representation. He spent over 10 years being a part of the team that built Digene and took them public and had a very successful business.

Rich Mueller is our Chief Operating Officer. We recruited Rich from NuVasive. He's got a long history in developing and launching innovative products. NuVasive, when he joined the company, they were doing less than \$20 million; and over his five years, they launched almost 80 products and grew to over \$500 million. And they're a public-traded med-tech company, so we think his success and skill sets are very transferrable.

Mohan Nathan is our Vice President of Global Marketing. He joined us over three years ago. He was at Intuitive Surgical prior to that, a director of marketing in the urology franchise. And he was at Johnson & Johnson prior to Intuitive.

And Tammy Carrea is our Vice President of Quality and Regulatory. She has over 20 years experience in both of those functions, all in med-tech, and has spent the previous 10 years at Sichel Technologies prior to joining TransEnterix.

So, we feel like we've got a very strong team and each one of these folks have a great support group around them that we've been able to recruit here to RTP North Carolina and we're really excited about our team and our capability to execute.

As you think about the board of directors, we've just simply got a stellar board. This group that came together from TransEnterix and SafeStitch has surgeons on it, it has entrepreneurs, many people that have invested, founded, led, taken public, and had successful M&A in med-tech over the last three decades. It's a tremendous board. And coupled with our healthcare investors that are highlighted at the bottom of the slide, I couldn't be happier with the team around us and the way they've supported this Company.

As we come to the close of my presentation, I think it's hopefully obvious for each of you to see why my enthusiasm is high. We feel like the market opportunity has lined up very well with our technology and our direction. And when all those things align, you're just left to execute. So, we're very excited about it.

Well, let me just close by thanking all of you for taking the time out of your day to join us on the call. We're very enthusiastic about the combination of SafeStitch and TransEnterix and the opportunities in front of us as a newly combined Company. We sincerely appreciate your interest and look forward to updating you on our progress in the next quarter. Thank you.

Operator: Ladies and gentlemen, that concludes today's conference. We thank you for your participation. You may now disconnect. Have a great day.

A large, faint, light blue watermark of the TransEnterix logo is visible in the background of the slide.

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Through Innovation*

Any statements contained in this presentation that do not describe historical facts, including statements about the beliefs and expectations of SafeStitch Medical, Inc. ("SafeStitch") and TransEnterix, Inc. ("TransEnterix"), may constitute forward-looking statements as that term is defined by the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expect," "anticipate," "future," "intend," "plan," "believe," "estimate," "confident" and similar statements. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties that may cause actual results to differ materially from expectations.

Potential risks and uncertainties include the risks outlined in this presentation and SafeStitch's filings with the U.S. Securities and Exchange Commission, including the benefits and opportunities of surgical robotics, whether the merger between SafeStitch and TransEnterix will be successful, whether the combined company will be successful in 2014 and beyond, the pace of adoption of our product technology by surgeons, the outcome of coverage and reimbursement decisions by the government and third party payors, the success and market opportunity of our continuing and new product development efforts, including the SurgiBot system, the effect on our business of existing and new regulatory requirements, and other economic and competitive factors. SafeStitch and TransEnterix caution readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. We do not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.

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Financial Overview

Joe Slattery

Executive Vice President & CFO



*Advancing Surgery
Through Innovation*

Focus

- Surgical robotics

Technology

- Developing patient-side robotic platform: SurgiBot

Solution

- Addresses unmet needs in today's robotic offerings
 - Cost effective
 - Broad procedure applicability

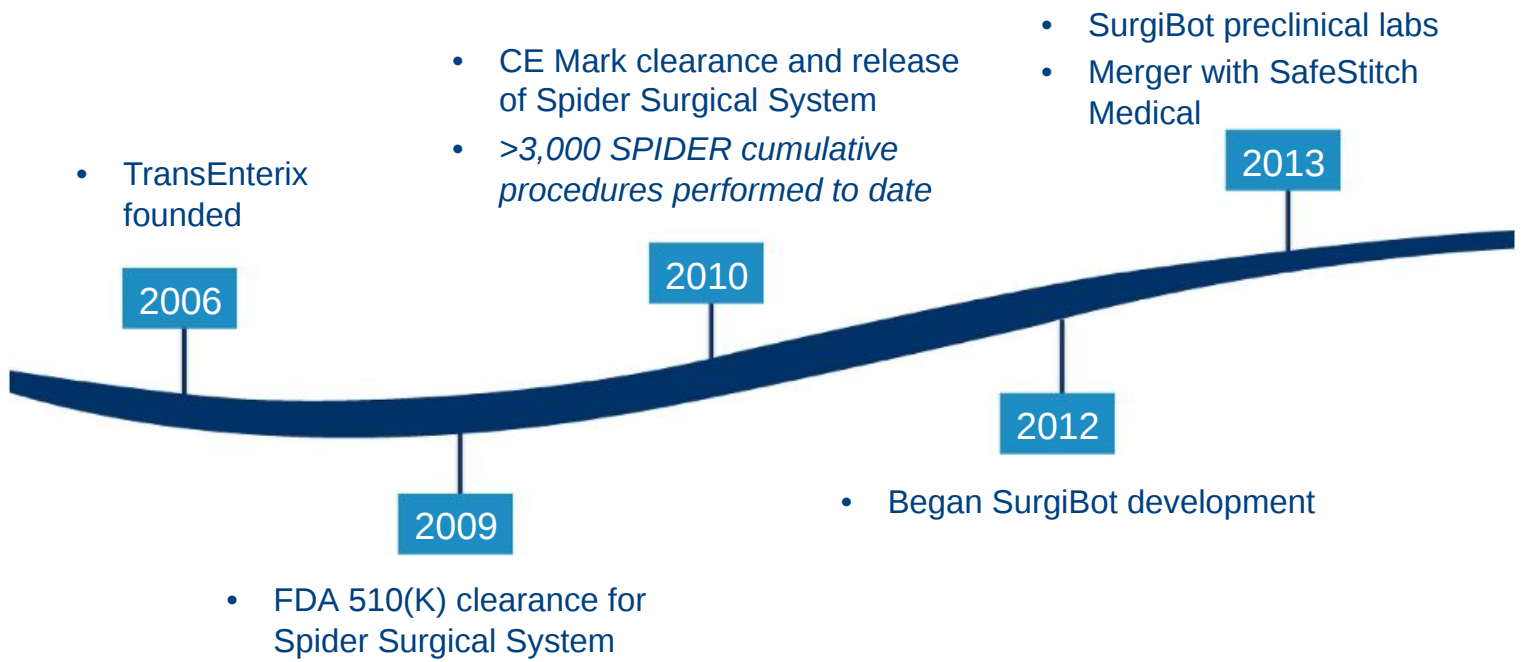
Market

- Large addressable market – ~2M US procedures

Team

- Strong management team

Company History





- Transaction closed on September 4, 2013
- About SafeStitch
 - Publicly-traded, development stage medical device company (OTCBB: SFES)
 - Obesity and GERD-focused, flexible endoluminal instrumentation
- Board and investors with demonstrated success in leading high-growth healthcare companies
- \$30M in financing raised from existing TransEnterix and SafeStitch shareholders
- Combined entity will be called TransEnterix, Inc.



Open
Surgery



Rigid
Laparoscopy
(1989)



Flexible
Laparoscopy
(2010)

Spider Surgical System

Enabling Flexible Laparoscopy

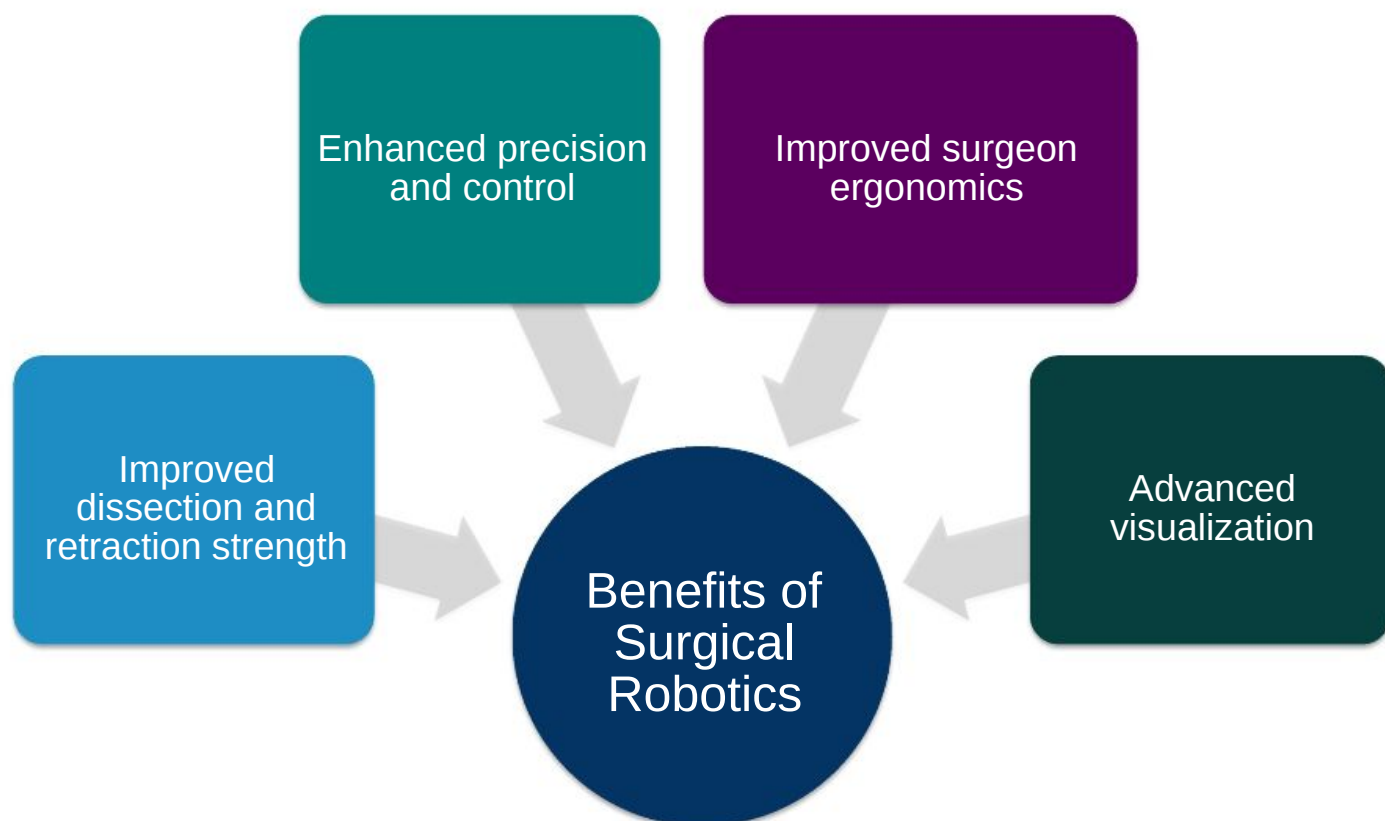


- Internal (intra-abdominal) triangulation
- Flexible, articulating instruments for dissection and retraction
- True left/right instrumentation
- Lower profile port of access
- Over 3,000 procedures performed
- Broad procedural mix

The text 'SurgiBot™' in a bold, blue, sans-serif font. A large, faint, light blue version of the 'T' icon from the TransEnterix logo is visible in the background behind the text.

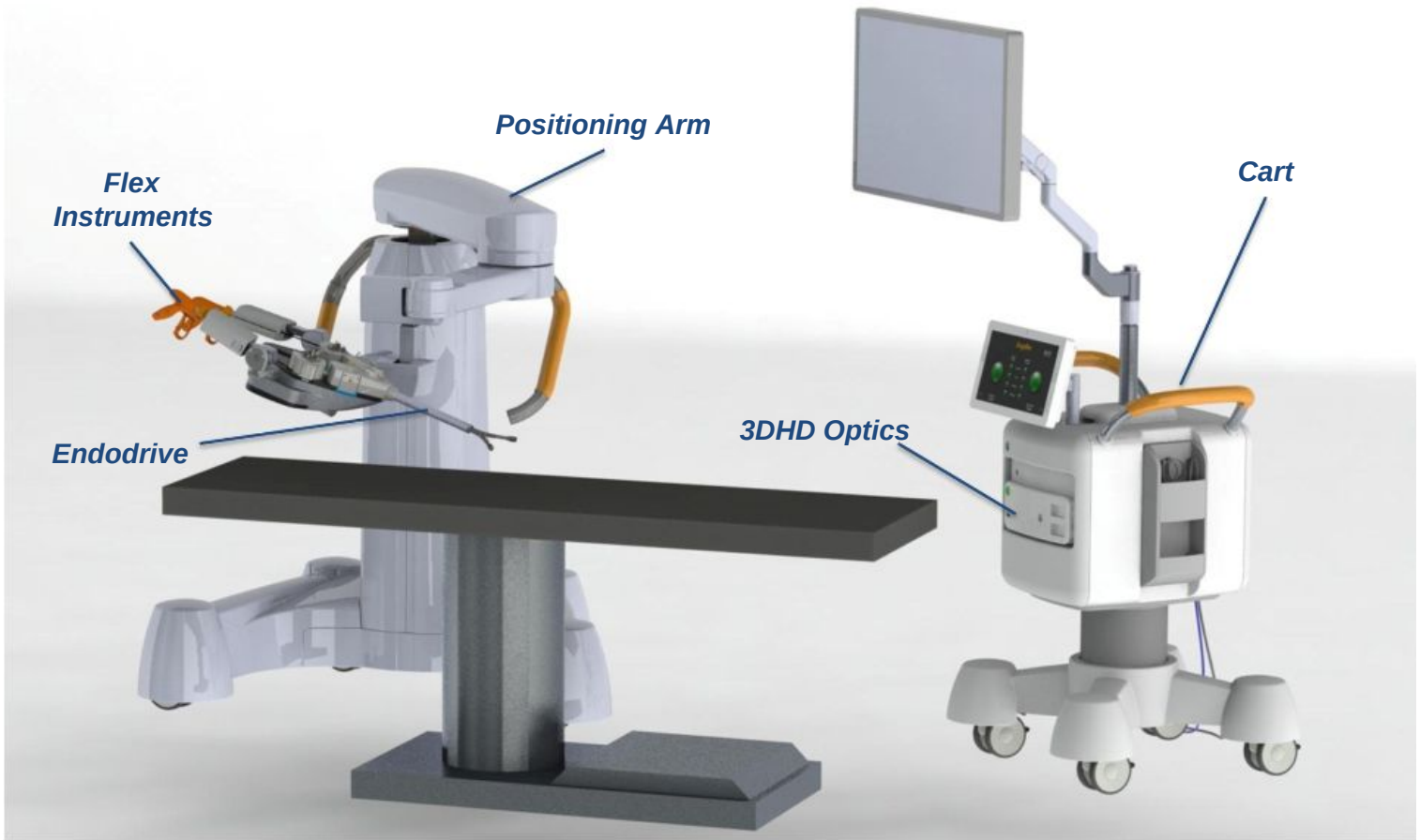
SurgiBot™

*Innovative, Minimally Invasive
Robotic Platform*



SurgiBot

First Patient-side Robotic Platform



SurgiBot

First Patient-side Robotic Platform

Surgeon scrubbed-in

Flexible, articulating channels & instruments

Flexible & steerable 3DHD

Small, mobile platform

Easily repositioned for multi-quadrant surgery

Cost effective platform



Hospitals and Surgical Centers

- Attractive ROI for many health care facilities, relative to competing robotic platforms
- Strategic asset for surgeon and patient recruitment

Surgeons

- Precision of robotic surgery
- Advanced 3D visualization
- Scrubbed-in patient-side
- Ergonomics/reduced fatigue

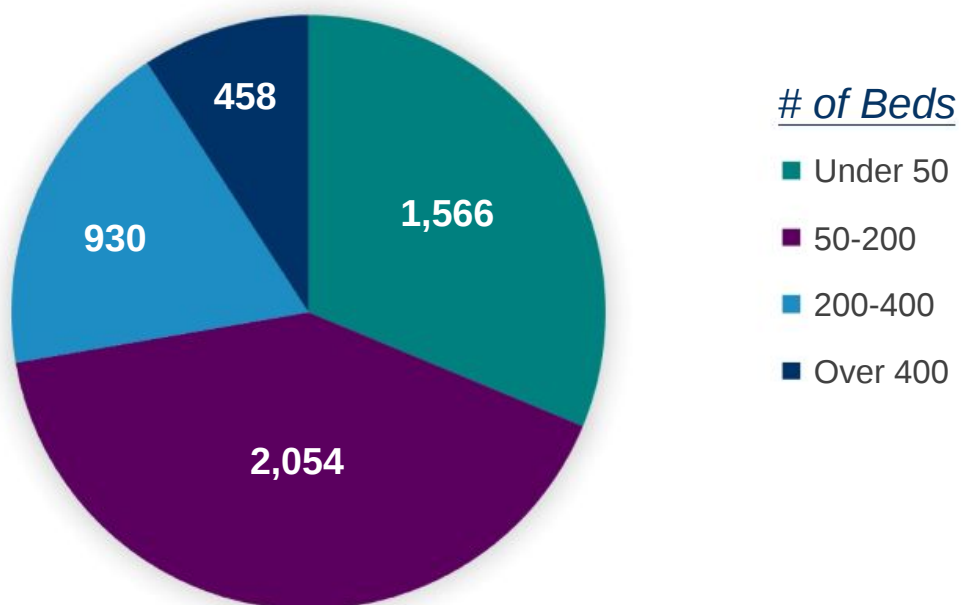
Patients

- Advances minimally invasive surgery



SurgiBot[™]

Over 5,000 Hospitals in the United States



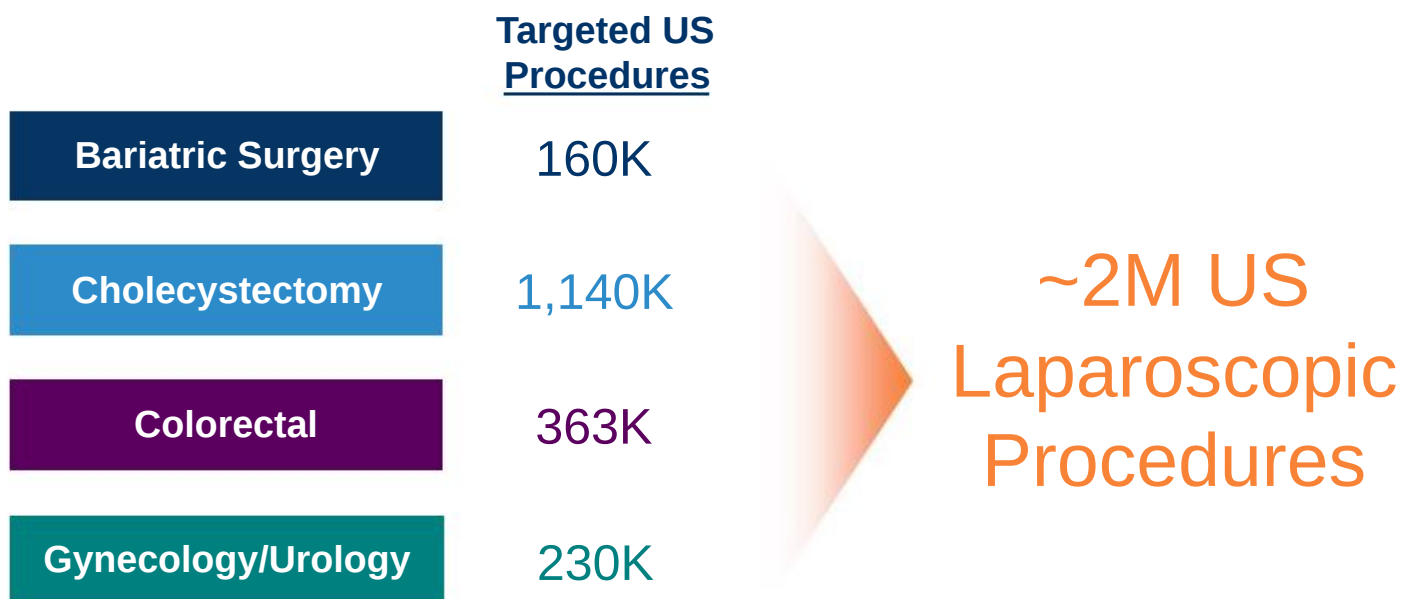
Additionally over **5,000** surgery centers in US

Hospitals without Robotic Capability

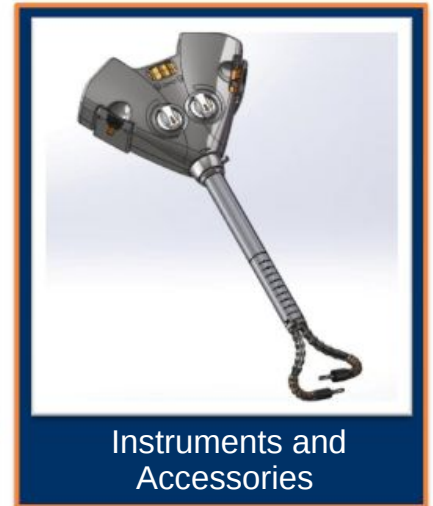
- Current robotic offerings are not cost effective
 - Price
 - Procedure volume
- Surgery centers – untapped market for robotics
- Large underpenetrated OUS opportunity

Hospitals with Robotic Capability

- Invested in the strategic and competitive value of robotic surgery
- ROI expectations changing/under pressure
- Potential for diversification of robotic solutions
 - Procedures
 - Price
 - Facilities



Source: Millennium Research Group US Markets Laparoscopic Devices 2014
Note: Company Estimate of Outside US addressable market = US opportunity



2013

- Design & Pre-clinical Testing
- Pre-submission FDA Meeting

2014

- First Human Procedures
- Regulatory Submissions

2015

- Regulatory Clearances
- Global Launch

Prior Experience

Todd M. Pope

President and Chief Executive Officer



Joe Slattery

EVP and Chief Financial Officer



Richard Mueller

Chief Operating Officer



Mohan Nathan

Vice President of Global Marketing



Tammy Carrea

Vice President, Quality and Regulatory Affairs



Board of Directors

- **Paul LaViolette**
 - Chairman of TransEnterix
 - Partner, SV Life Sciences
- **Todd Pope**
 - President and Chief Executive Officer, TransEnterix
- **Dennis Dougherty**
 - Founder, Intersouth Partners
- **David Milne**
 - Managing Partner, SV Life Sciences
- **William Starling**
 - Managing Director, Synergy Life Science Partners
- **Phillip Frost, M.D.**
 - CEO and Chairman of OPKO Health
 - Chairman of Teva Pharmaceuticals
- **Jane Hsiao, Ph.D., MBA**
 - Former Chairman of SafeStitch
 - Vice Chairman and CTO of OPKO Health
- **Aftab Kherani, M.D.**
 - Principal of Aisling Capital
- **Richard Pfenniger, Jr.**
 - Former Chairman/CEO of Continucare
 - Former CEO of Whitman Education Group

Healthcare Investors



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