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

Date of Report (Date of Earliest Event Reported): August 6, 2014

TransEnterix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-19437	11-2962080
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
635 Davis Drive, Suite 300, Morrisville, North Carolina		27560
(Address of principal executive offices)		(Zip Code)

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

Not Applicable

Former name or former address, if changed since last report

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:

[ ] 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 (17 CFR 240.13e-4(c))

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Item 2.02 Results of Operations and Financial Condition.

Item 2.02 Results of Operations and Financial Condition.

On August 6, 2014, TransEnterix, Inc., a Delaware corporation (the "Company") issued a press release announcing financial results for the second quarter ended June 30, 2014. A copy of the press release is attached hereto as Exhibit 99.1.

Also on August 6, 2014, following the issuance of the press release referred to above, the Company conducted a conference call to discuss its operational and financial results for the second quarter ended June 30, 2014. The conference call transcript is furnished herewith as Exhibit 99.2 and incorporated herein by reference.

The information included herein and in Exhibit 99.1 and Exhibit 99.2 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 Statements and Exhibits.

Item 9.01 Financial Statements and Exhibits.

99.1 Press Release, dated August 6, 2014

99.2 Conference Call Transcript, dated August 6, 2014

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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 hereunto duly authorized.

TransEnterix, Inc.

August 11, 2014

By: Joseph P. Slattery

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

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Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated August 6, 2014
99.2	Conference Call Transcript dated August 6, 2014

Exhibit 99.1 – Press Release Dated August 6, 2014

TransEnterix, Inc. Reports Operating Results for the Second Quarter 2014

- Remain on track to file SurgiBot™ FDA 510(k) before year-end 2014
- Completed sale of 14.1 million shares of common stock and raised $52.5 million, net of issuance costs
- Completed uplisting to NYSE MKT in April 2014
- Launched fully flexible advanced energy device

RESEARCH TRIANGLE PARK, N.C., — (BUSINESS WIRE) — 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 its operating and financial results for the second quarter 2014.

“We continue to make significant progress in the development of the SurgiBot patient-side surgical robotic system and look forward to bringing this innovative solution to the market,” said Todd Pope, President and Chief Executive Officer of TransEnterix. “We remain focused on reaching our primary goal for 2014 of submitting our SurgiBot system FDA 510(k) application in the fourth quarter.”

Financial Results

Comparison of Selected Consolidated Financial Results (in thousands, except net loss per share)

	Three Months Ended June 30,	
	2014	**2013**
Total revenue	$ 113	$ 521
Net loss	$10,587	$4,285
Net loss per share	$ 0.18	$ 3.97
Weighted average common shares	59,673	1,078

Revenue was $113 thousand in the second quarter of 2014, representing a 78% decrease from revenue of $521 thousand in the second quarter of 2013. The decrease in revenue was due to lower sales volumes of the SPIDER® Surgical System as a result of the reduction in our U.S. sales force headcount. TransEnterix continues to primarily focus its resources on the development of the SurgiBot system.

Cost of goods sold was $238 thousand in the second quarter, compared with $1.2 million in the second quarter of 2013. The decrease was primarily the result of the reduction in sales as we limit sales of the SPIDER Surgical System to existing customers and the transfer of employees from manufacturing and quality departments to research and development and regulatory functions.

Research and development expenses were $7.9 million in the second quarter of 2014, compared with $2.2 million in the second quarter of 2013. The increase in expenses was attributable to higher personnel-related costs as we continue to increase headcount in our research and development and regulatory functions as well as an increase in other expenses related to product development of our SurgiBot system.

Sales and marketing expenses for the second quarter of 2014 were $461 thousand compared to $540 thousand in the second quarter of 2013. The decrease was primarily related to lower personnel-related costs as we reduced our direct sales and marketing personnel.

General and administrative expenses for the second quarter of 2014 were $1.9 million compared to $702 thousand in the second quarter of 2013. The increase was primarily due to increased costs associated with being a public company, greater costs associated with stock-based compensation and higher staffing costs.

Net loss in the second quarter of 2014 was $10.6 million compared to a net loss of $4.3 million in the second quarter of 2013. Net loss per common share was $0.18 in the second quarter of 2014 based on 59.7 million weighted average common shares outstanding compared to a net loss per share of $3.97 in the second quarter of 2013 based on 1.1 million weighted average common shares outstanding.

Cash and cash equivalents were $52.6 million as of June 30, 2014.

Public Offering of Common Stock

On April 14, 2014, we sold 12,500,000 shares of common stock at a public offering price of $4.00 per share for aggregate gross proceeds of $50.0 million in an underwritten firm commitment public offering. We also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,875,000 shares of common stock to cover overallotments. The common stock was offered and sold pursuant to a shelf registration statement registering an aggregate of $100 million of designated securities of the company. The closing of the public offering occurred on April 21, 2014. On April 30, 2014, the underwriters exercised a portion of their over-allotment option to acquire an additional 1,610,000 shares at the public offering price of $4.00 per share for aggregate additional gross proceeds of $6.4 million. The purchase of the over-allotment shares closed on May 5, 2014. Total proceeds were $52.5 million, net of issuance costs of $3.9 million. In conjunction with the April 14, 2014 public offering, our common stock began trading on the NYSE MKT under the ticker symbol “TRXC.”

Regulatory Update

In July 2014, we received feedback on our pre-submission filing with the U.S. Food and Drug Administration (“FDA”) regarding our planned 510(k) filing for the SurgiBot system. We are incorporating this feedback into our clinical and regulatory plan and anticipate that we will submit our SurgiBot system regulatory filings by the end of 2014.

Advanced Energy Device Launch

In April 2014, we announced the completion of the first human cases using our advanced energy Flex Ligating Shears. The Flex Ligating Shears are designed to deliver full flexibility to the surgeon while offering ligation and division with direct thermal energy in various laparoscopic surgical procedures. Advanced energy devices represent one of the most versatile and critical tools for surgeons in minimally invasive surgery. These devices deliver controlled energy to effectively ligate and divide tissue while greatly limiting bleeding in the operative field and minimizing thermal injury to surrounding structures. TransEnterix’s advanced energy device has been created for surgeons to use with the company’s existing SPIDER Surgical System. We intend to offer a similar device in the future for use with its SurgiBot system.

Conference Call

TransEnterix, Inc. will host a conference call on Wednesday, August 6, 2014 at 4:30 PM ET to discuss its second quarter operating and financial results. To listen to the conference call on your telephone, please dial (888) 312-3048 for domestic callers or (719) 325-2362 for international callers ten minutes prior to the start time. The call will be concurrently webcast. To access the live audio webcast or the archived recording, use the following link http://ir.transenterix.com/events.cfm.

Financial Statements

On September 3, 2013, SafeStitch Medical, Inc. (now TransEnterix, Inc.) and TransEnterix Surgical, Inc., formerly known as TransEnterix, Inc., consummated a merger transaction (the “Reverse Merger”) whereby TransEnterix Surgical, Inc. merged with a merger subsidiary of SafeStitch Medical, Inc., with TransEnterix Surgical, Inc. as the surviving entity in the merger. As a result of the merger, TransEnterix Surgical, Inc. became a wholly owned subsidiary of SafeStitch Medical, Inc. On December 6, 2013, SafeStitch Medical, Inc. changed its corporate name to TransEnterix, Inc.

The Reverse Merger has been accounted for as a reverse acquisition under which TransEnterix Surgical, Inc. was considered the acquirer of SafeStitch Medical, Inc. As such, the financial statements of TransEnterix Surgical, Inc. are treated as the historical financial statements of the combined company, with the results of SafeStitch Medical, Inc. being included from September 3, 2013.

About TransEnterix

TransEnterix is a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery. The company is focused on the development and commercialization of the SurgiBot™ system, a minimally invasive surgical robotic system that allows the surgeon to be patient-side within the sterile field. For more information, visit the company’s website at www.transenterix.com.

Forward Looking Statements

This press release includes statements relating to the SurgiBot system, our flexible energy device and our current regulatory and commercialization plans for these products. These statements and other statements regarding our future plans and goals 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, including whether we will successfully submit our SurgiBot system regulatory filings in the 2014 fourth quarter, and whether we will be able to bring the SurgiBot system to the market. Factors that could cause our results to differ materially from those described include, but are not limited to, whether the SurgiBot system’s 510(k) application(s) will be cleared by the U.S. FDA, 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 TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 5, 2014 as amended, and other filings we make with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward looking statements, which are based on our 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

Media Contact:
TransEnterix, Inc.

Mohan Nathan, 919-917-6559
mnathan@transenterix.com

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

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Sales	$ 113	$ 521	$ 206	$ 850
Operating Expenses				
Cost of goods sold	238	1,156	458	2,038
Research and development	7,882	2,165	12,893	4,946
Sales and marketing	461	540	867	1,052
General and administrative	1,913	702	3,527	1,387
Total Operating Expenses	10,494	4,563	17,745	9,423
Operating Loss	(10,381)	(4,042)	(17,539)	(8,573)
Other (Expense) Income				
Interest expense, net	(206)	(243)	(527)	(489)
Total Other (Expense) Income, net	(206)	(243)	(527)	(489)
Net Loss	$ (10,587)	$ (4,285)	$ (18,066)	$ (9,062)
Other comprehensive income (loss)	-	-	-	-
Comprehensive loss	$ (10,587)	$ (4,285)	$ (18,066)	$ (9,062)
Net loss per share — basic and diluted	$ (0.18)	$ (3.97)	$ (0.33)	$ (8.41)
Weighted average common shares outstanding — basic and diluted[1]	59,673	1,078	54,264	1,078

[1] Adjusted for 1:5 reverse stock split on March 31, 2014.

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

	June 30, 2014	December 31, 2013
Assets	(unaudited)	
Current Assets		
Cash and cash equivalents	$ 52,566	$ 10,014
Short-term investments	—	6,191
Accounts receivable, net	96	188
Interest receivable	2	68
Inventory, net	438	701
Other current assets	617	593
Total Current Assets	53,719	17,755
Restricted cash	250	375
Property and equipment, net	2,413	1,864
Intellectual property, net	2,491	2,741
Trade names, net	8	10
Goodwill	93,842	93,842
Other long term assets	72	127
Total Assets	$ 152,795	$116,714
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 3,616	$ 1,804
Accrued expenses	1,906	1,406
Note payable — current portion	4,052	3,879
Total Current Liabilities	9,574	7,089
Long Term Liabilities		
Note payable — less current portion	2,532	4,602
Total Liabilities	12,106	11,691
Commitments and Contingencies		
Stockholders' Equity		
Common stock $0.001 par value, 750,000,000 shares authorized at June 30, 2014 and December 31, 2013; 62,975,255 and 48,841,417 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively[(1)]	63	49
Additional paid-in capital	256,956	203,238
Accumulated deficit	(116,330)	(98,264)
Total Stockholders' Equity	140,689	105,023
Total Liabilities and Stockholders' Equity	$ 152,795	$116,714

[(1)] Adjusted for 1:5 reverse stock split on March 31, 2014.

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

	Six Months Ended June 30,	
	2014	2013
Operating Activities		
Net loss	$(18,066)	$(9,062)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	594	697
Amortization of debt issuance costs	44	53
Stock-based compensation	1,202	130
Loss on disposal of property and equipment	19	32
Changes in operating assets and liabilities:		
Accounts receivable	92	392
Interest receivable	66	16
Inventory	263	(82)
Other current and long term assets	(13)	(5)
Restricted cash	125	—
Accounts payable	1,812	159
Accrued expenses	500	227
Net cash and cash equivalents used in operating activities	(13,362)	(7,443)
Investing Activities		
Proceeds from sale and maturities of investments	6,191	907
Purchase of property and equipment	(910)	(150)
Net cash and cash equivalents provided by investing activities	5,281	757
Financing Activities		
Payment of debt	(1,897)	—
Proceeds from the issuance of common stock, net of issuance costs	52,506	—
Proceeds from exercise of stock options and warrants	24	—
Net cash and cash equivalents provided by financing activities	50,633	—
Net increase (decrease) in cash and cash equivalents	42,552	(6,686)

Cash and Cash Equivalents, beginning of period	10,014	8,896
Cash and Cash Equivalents, end of period	$ 52,566	$ 2,210
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 337	$ 437

Exhibit 99.2

TRANSENTERIX

Moderator: Mark Klausner
August 6, 2014
3:30 pm CT

Operator: Good afternoon ladies and gentlemen and welcome to the TransEnterix 2014 second quarter conference call. As a reminder, this conference is being webcast live and recorded. It is now my pleasure to introduce your host Mr. Mark Klausner of Westwood Partners.

Mark Klausner: Thank you. Good afternoon and thanks for joining us today for TransEnterix second quarter 2014 conference call. Joining us on today's call are TransEnterix 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 event will be available for following the call on our website. To access the webcast please visit the Events link in the IR section of our website transenterix.com.

Before we begin I would like to caution listeners that certain information discussed by management during this conference call are forward-looking statements including statements related to the SurgiBot system, our flexible energy device, and our current regulatory and commercialization plans for these products covered under the Safe Harbor provisions of 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 including whether we will successfully submit our SurgiBot system regulatory filings in the fourth quarter of 2014 and whether we will be able to bring the SurgiBot system to the market.

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 undertakes no obligation to update information provided on this call.

For a discussion of risks and uncertainties associated with TransEnterix business, I encourage you to review the company's filings with the Securities and Exchange Commission including the annual report on Form 10-K for the year ended December 31, 2013 and the Form 10-Q for the quarter ended June 30, 2014 expected to be filed later today. With that it's my pleasure to turn the call over to TransEnterix President and Chief Executive Officer Todd Pope.

Todd Pope: Thank you and good afternoon. Thank you for joining us today to discuss our operating and financial results for the second quarter of 2014. On today's call I will provide a brief overview of our business and an update on the ongoing development of our SurgiBot system before handing the call over to Joe who will walk you through the financial results. Now I will briefly recap our priorities for the remainder of the year and then open up the line to take any questions.

As many of you know, TransEnterix is a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery. We are currently focused on the development of our SurgiBot system that allows the surgeons to be patient side within the sterile field.

In addition, SurgiBot is designed as a cost effective system with broad procedure applicability. We believe that our annual addressable market in the United States is approximately two million procedures.

The SurgiBot system builds upon the experience we gained from our Spider system, a manual surgical platform upon which the company was founded and over 3500 successful procedures have been performed to date. Our body of clinical evidence with the Spider has been gathered globally and we have developed significant knowledge and experience with flexible instruments and single port surgery across a variety of procedures.

While surgeons were enthusiastic about the single port capability, our true right and true left ergonomics, and the internal triangulation of the Spider system, they also communicated a desire for higher levels of strength, precision, and advanced vision capabilities. We determined that could best be addressed by roboticizing the Spider system and began development of the SurgiBot in 2012.

Now let's turn to the progress we have made over the past quarter and also provide an update on our development of SurgiBot. This past April we completed a public equity offering in which we sold 14.1 million shares of common stock at $4 per share resulting in net proceeds after offering costs of $52.5 million.

We believe this capital will be sufficient to fund the development and early commercialization of SurgiBot. Our financing was done in conjunction with an uplisting to the NYSE MKT where our stock now trades under the ticker symbol TRXC.

In the second quarter we also launched the world's first fully flexible advanced energy device, our Flex Ligating Shears. This product will compete in the over $3 billion market for advanced energy instruments. Our device which is currently being used on the Spider platform allows this critical aspect of surgery to be delivered with a flexible device rather than a rigid instrument.

Since our launch in mid-April there have been over 100 successful procedures performed with this device globally. The early results have been encouraging and surgeon feedback supports this device seals tissue extremely well with limited thermal spread. Surgeons have also commented on the benefits of single port access with full flexibility and 360 degree articulation which enables the device to reach areas where rigid instruments have difficulty.

In addition, surgeons have experienced improved visualization when compared to market leading products as a result of no plume of smoke in the surgical field. Our primary objective with the limited release of the Flex Ligating Shears is to demonstrate the utility of the product in a variety of surgeries.

Later this month in conjunction with the International Federation for the Surgery of Obesity World Congress in Montreal, Canada, a live Spider sleeve gastrectomy utilizing our Flex Ligating Shears will be performed by Dr. Helmuth Billy of Ventura, California and broadcast into the conference. This represents a great opportunity for us to continue to raise awareness of our products with surgeons who treat obesity and metabolic disorders.

We intend to have the Flex Ligating Shears available for the SurgiBot at launch. We feel this capability will help to create value in multiple procedural areas where advanced energy is a critical tool.

Now turning to our development of the SurgiBot. We have been refining our regulatory strategy for SurgiBot over the past year. In the fourth quarter of 2013 we had an in-person meeting with the FDA to discuss our regulatory strategy for the SurgiBot system. Following this meeting we prepared our presubmission FDA filing which was submitted in the first quarter of 2014.

Our objective for the presubmission filing was to obtain specific feedback from the agency. We received this written feedback in July which we have incorporated into our planning. We now intend to move directly to file our 510(k) without conducting human clinical trials.

We are enthusiastic about this modification to our regulatory plan as we believe it significantly reduces the execution risk of our submission. We remain confident that we are on track to meet our goal of submitting our 510(k) by year end. I will now hand the call over to Joe who will walk you through the numbers.

Joe Slattery: Thanks Todd. Before reviewing the financial results I'd like to provide some background on the numbers we will be discussing today. On September 3, 2013 TransEnterix, Inc. and SafeStitch Medical, Inc. merged. The historical results being discussed are those of TransEnterix through September 3, 2013 and of the merged entity thereafter.

We reported revenue of $113,000 in the second quarter of 2014 as compared to revenue in the prior year period of $521,000. The decrease in revenue was attributable to a planned decline in U.S. sales volume as we reduced the size of our Spider sales force and limited Spider sales to existing customers, a result of our decision to focus the majority of our resources on the development of the SurgiBot system.

Cost of goods sold was $238,000 in the second quarter, a decrease from $1.2 million in the prior year's quarter. The decrease was primarily the result of the reduction in sales as we limit sales of the Spider surgical system to existing customers and the transfer of employees from manufacturing and quality departments to research and development and regulatory functions.

Research and development expenses were $7.9 million in the second quarter of 2014 compared with $2.2 million in the second quarter of 2013. The increase in R&D spend was attributable to higher personnel related expenses as we added additional employees to our research and development team and regulatory team as well as an increase in other expenses related to our continued development of the SurgiBot system.

Sales and marketing expenses declined to $461,000 for the second quarter in comparison to $540,000 in the prior year period. The decrease in expenses was mostly related to lower personnel costs as we reduced our direct sales and marketing personnel and allocated fewer resources to the Spider system.

General and administrative expenses were $1.9 million in the second quarter of 2014 as compared to $702,000 in the prior year period. The increase in expenses was due to increased costs associated with being a public company, larger costs associated with stock based compensation, and higher staffing costs. Net loss was $10.6 million in the second quarter of 2014 compared to a net loss of $4.3 million in the second quarter of 2013.

Turning to the balance sheet, we finished the quarter with $52.6 million in cash and cash equivalents. During the second quarter of 2014 our cash burn was $8.6 million which included $959,000 of debt service and $723,000 of property, plant, and equipment investment. I will now hand the call back to Todd who will give an update on our priorities for the balance of the year.

Todd Pope: Thank you Joe. As we look toward the remainder of 2014 our primary objective is to complete our FDA 510(k) submission for the SurgiBot and we remain on track to achieve this goal. We expect to file for CE Mark shortly thereafter.

I would remind you that we have had significant experience with the FDA as our Spider device was cleared in 2009 for general abdominal surgical use. Since the Spider has been on the market we have had substantial positive clinical experience across a broad range of procedures in the U.S., Europe, and the Middle East. We are incorporating this experience into our ongoing clinical and regulatory efforts and ultimately into our 510(k) submission for the SurgiBot.

We will also be engaged in a number of activities over the second half of 2014 that will lay the foundation for clinical validation and initial commercialization in 2015.

Some of these activities include building SurgiBot units for use in our testing as well as in our preclinical studies, performing final integration of the entire system, running verification tests including biocompatibility, sterilization validation, transit, aging, functional testing, electrical safety testing, and software validation.

And we are recruiting sales leadership as we prepare for the commercial launch in 2015. We believe the plan we have put in place will allow us to meet our goal of submitting our 510(k) for SurgiBot by the end of 2014 and look forward to sharing additional details regarding our progress on upcoming calls. With that I'd like to turn it over to the operator and now take your questions.

Operator: Thank you. If you would like to ask a question please signal by pressing Star 1 on your telephone keypad. If you are using a speakerphone please make sure your mute function is turned off to allow your signal to reach our equipment. Again, press Star 1 to ask a question. We will pause for just a moment to allow everyone the opportunity to signal for questions. We'll take our first question from Rick Wise with Stifel.

Rick Wise: Afternoon, how are you doing? It sounds like, you know, major milestone ahead in the fourth quarter with the FDA filing on track. Can you talk a little bit about the fact that you're not going to need to do any human testing?

Help us understand, I mean, that seems like an important thing and it sounds like the FDA is comfortable with the filing. Can you just give us a little more color there Todd about the filing and that discussion and why that didn't go down that path?

Todd Pope: Sure Rick. You know, as we think about our primary goal for the company is to achieve regulatory clearance for the SurgiBot and we want to do that as quickly as possible.

You know, very few 510(k)s require clinical data, very few. And so we wanted to be conservative when we set up our initial timeline expectations until we had more information. We've had significant dialogue with the FDA as we outlined. We met with them in Q4 of '13, we put in our presubmission, and now we have gotten a response. And we believe our best path to clearance is to proceed right to filing the 510(k).

So we anticipate we'll do our first cases, they'll be commercial cases shortly after approval. So this is what we were hoping for and this is a good outcome for us.

Rick Wise: That's great. And in terms of your international initiatives, could you just update us a little more. And I apologize, I'm sort of hopping between two calls here. I apologize if you talked about it but just give us a little more clarity about what is happening there in commercializing SurgiBot and, you know, what's next there on the international front.

Todd Pope: Right, well we're right now in our regulatory filing phase and the CE Mark will follow shortly after our 510(k) submission. And so that process will follow and then, you know, we'll be prepared, you know, to launch in 2015 not only in the U.S. but where CE Mark is required also.

Rick Wise: And, you know, to the extent that you can Todd, talk about just ongoing physician interaction. I mean, obviously you're limited in what you can do now without an approved device in the U.S. but can you give us any color on ongoing discussions and, you know, getting ready for hopefully for approval and just any reactions that you can share with us?

Todd Pope: Sure, I think the way I would describe, you know, our interactions with key opinion leaders from around the world is robust. We have got a, you know, plan that we bring folks in to the headquarters quite often. We continue to talk with them. We're working with people that have seen the Spider and seen early versions of the SurgiBot and folks that haven't interacted with us in the past.

We're doing that both in the U.S., Europe, and in the Middle East with key opinion leaders. And the feedback we continue to get is very positive. People really like the thought of laparoscopic surgery being able to be benefited by our system.

The fact that these laparoscopic surgeons can scrub in and be in a sterile field, have a tactile feedback, have their hands on the instruments is a great — it's a great feature. They're really excited about that. You know, the price point has obviously gotten a lot of people's attention. We can really hopefully proliferate robotic advantages a little bit deeper than it has been done today.

So the feedback we get continues to be positive and, you know, confirmational. And we also are reaching out to hospitals along the way. We're meeting with hospital executives, IHDN leadership, and, you know, surgery centers to continue to talk to them about their needs and tell them about what we're bringing to the market and the early feedback continues to be very positive.

Rick Wise: But the basic bottom line is it sounds like all the timelines you've laid out are, you know, remain on track as planned as expected.

Todd Pope: Absolutely.

Rick Wise: Thank you very much.

Todd Pope: Thank you Rick.

Operator: We'll take our next question from Glenn Novarro with RBC Capital Markets.

Glenn Novarro: Hi, good afternoon. Two questions for you. First, I know this wasn't going to be part of the regulatory filing but in the past you've said you'd like to do some first in man cases, most likely occurring outside the U.S. in the third quarter. Is that still the plan is my first question.

Todd Pope: No, we really are going to wait until we have regulatory clearance and then we'll commercialize the product and that's when we'll be out doing our first cases.

Glenn Novarro: Okay good. And then as a follow-up, as you've discussed with — had dialogue with the FDA, have you also been discussing the label for the device? I think the goal was to have kind of a broad general surgery claim so can you give us any update on kind of the label that you may receive from the FDA?

Todd Pope: Yes we continue to feel confident about our predicate device being our own Spider and we think the experience we have garnered from those 3500 cases and the data that has been generated will keep us on track for our intended use.

Glenn Novarro: Okay thank you.

Todd Pope: Thanks Glenn.

Operator: As a reminder, if you would like to ask a question you may do so by pressing Star 1. We'll hear next from Larry Keusch with Raymond James.

Larry Keusch: Good afternoon guys. Todd I just want to follow up on the — on Glenn's question regarding the labeling. The Spider as you mentioned in your prepared comments had a general abdominal use label and so with your 510(k) labeling or filing I should say for SurgiBot, do you anticipate that, you know, same claim around the device?

Todd Pope: Yes Larry, we plan to submit data with our filing to support that label. So no changes in our intentions there.

Larry Keusch: Okay and, you know, I guess again, you know, you had been contemplating doing some clinical cases in case you did hear back from the FDA that there was going to be some clinical evidence necessary for this filing. Obviously now you're not intending to do that with the feedback from the agency.

So I guess the other question is you haven't changed the timeline for your filing but why wouldn't that be now speeded up a bit since you don't have to do any of those clinical cases prior to that submission?

Todd Pope: Well, you know, when you think about all the elements that go into a 510(k), you know, we have to plan those and we've had them planned for some time to get our submission into Q4. Some of those things, you know, verification testing, a lot of biocompatibility studies, sterilization, validations, we have to do our transit testing, all of our aging studies, functional testing, electrical safety, preclinical software.

So there's so many things that go into it, I think oftentimes people put a lot of weight on, you know, human clinical trials or preclinical but the fact that we don't feel like we need to do human clinical trials doesn't necessarily change the day.

We just believe what it really does, it just helps us clarify our timelines and reduce the risk but it doesn't really meaningfully change the timeframe because so many other things go into a submission.

Larry Keusch: Okay got it. And then last one for you is if you could just again help us understand when you gain FDA clearance for the SurgiBot, again and let's assume it's sort of a general abdominal claim, are you still anticipating that, you know, sort of the initial uses will be in choleys and, you know, something like sleeve gastrectomies?

And if you could fold into your comments any thoughts around, you know, the issues around power morcellators and what that may or may not do to the applicability of this device in hysterectomies.

Todd Pope: Sure, well as we, you know, think about once we have regulatory clearance we want to move fairly quickly to commercialize the product, you know. And obviously as our calls go on over the coming quarters we will discuss our commercialization strategy a little bit closer.

As we think about all the learnings that we've had with the Spider, yes many of the cases that we have had with the Spider have been in bariatrics and cholecystectomy and some other areas too in the abdomen. But we believe that, you know, the SurgiBot will certainly be able to do well in those procedures. And I think with its increased strength and precision and 3D vision, you know, some other procedures certainly may be enabled.

And, you know, with GYN and hysterectomy it has never been a real big part of our early plans but certainly in the future I think we'll watch what has happened with the morcellator and that's kind of new news this week with that, the product being taken off by one of the big companies off the market.

So we'll just have to watch and see how that does affect things but that has never been a huge part of our initial ramp assumption. So I think we'll have — the two million cases in the U.S. that we think are good targets for us, a small percentage lie there so we don't really think that's going to affect our outcomes.

Larry Keusch: Okay thanks very much and excellent news regarding the FDA.

Todd Pope: Yes it really is, thank you so much.

Operator: We'll take our next question from Jeffery Cohen with Ladenburg Thalmann.

Jeffrey Cohen: Hello, hi Joe and Mark, how are you?

Todd Pope: Hello, how are you doing?

Jeffrey Cohen: That's a great update, thank you very much, just a few brief questions. What's the size of the organization now, total employees?

Joe Slattery: A little over 100.

Jeffrey Cohen: Okay and how is that going to look as you head into commercialization in '15?

Joe Slattery: Well we'll probably have considerable growth before then, you know 150, something like that by the time we get to launch.

Jeffrey Cohen: Okay and could you talk a little bit about what might happen to the R&D spend through and after commercialization into '16 and '17?

Joe Slattery: Yes I can give you some color on that. You know, as we go into the next quarter or two it should amp up. We have a lot of one-time testing costs. Obviously it won't be the extent that we would have had if we had also done human clinicals so there's some cost savings there.

You know, there are a series of costs that will titrate back over the next couple of years first associated with, you know, the initial setup and verification testing and then the clinical work. So it should be quite a bit lower next year and then fall even further the following year. I can't really go into much more detail than that.

Jeffrey Cohen: Okay that's helpful, thanks. And one more if I may. Could you talk a little bit about the instrumentation and if there's any other instrumentation that you're currently working on?

Todd Pope: Yes, I mean, the instrumentation that we've had on the market out there really is a broad set, you know, of instruments. We've talked about them in the past and I think what we're most excited about adding to that kind of armamentarium is the Ligating Shears and we talked about that in our prepared remarks.

We're getting great feedback on that. That is a very big market and it's growing about twice the rate of the general surgery instrumentation market. So we're excited to lean into that with the SurgiBot to have Flexible Ligating Shears.

So in addition to the, you know, instruments that we already have on the market we look forward to replicating those with the SurgiBot and then the Ligating Shears will be a great addition.

Jeffrey Cohen: Okay super. Thanks very much, it's a great update.

Todd Pope: Thank you Jeff.

Operator: We'll take our next question from Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson: Hey good afternoon.

Todd Pope: Hi Bruce.

Bruce Jackson: So most of my questions have been answered but I was hoping maybe you could give us a little bit of color on the discussions with the FDA, maybe talk about some of the topics they were interested in and maybe if you want to speculate on the receptivity to your application when it goes in.

Todd Pope: Well, you know, as we have described on the call earlier today, you know, we've had numerous interactions with the FDA over the past year, talked about our face to face meeting, our presubmission, and then the response. And, you know, we've been prepared to share with you guys the plans, you know, regarding the upcoming 510(k) submission.

> But we really don't want to go into the details of any specific communications back and forth with the FDA. We feel like we've followed a very thorough outline, we've gotten very good feedback, and we feel like we have a good plan going forward. And we have some risk reduction with the news we've, you know, garnered today and shared with you. So I think we'll probably leave it at that as far as specifics.

Bruce Jackson: That's great, thanks for the update.

Todd Pope: Okay Bruce, thank you.

Operator: We'll hear again from Larry Keusch with Raymond James. Caller, your line is open.

Larry Keusch: Sorry about that, mute button. Now that you don't have to do the clinical work in front of the submission, Joe how much was that contemplated to cost? Said another way, what do you think your savings are by not having to do that?

Joe Slattery: It's a few hundred thousand dollars of savings over the, you know, spread over the third and fourth quarter.

Larry Keusch: Okay great, thank you.

Operator: At this time there are no additional questions in the queue.

Mark Klausner: Okay well we want to thank all of you for joining us for the call today. We look forward to staying in touch with you in future calls. Thank you.

Operator: That does conclude today's conference. Thank you for your participation.

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