

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

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-19437

**TRANSENERIX, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

11-2962080  
(I.R.S. Employer  
Identification No.)

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

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

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class                         | Trading Symbol(s) | Name of each exchange where registered |
|---|-------------------|--|
| Common Stock<br>\$0.001 par value per share | TRXC              | NYSE American                          |

Securities registered pursuant to Section 12(g) of the Act:

None  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No .

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No .

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No .

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

|                         |                          |                           |                                     |
|-------------------------|--------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/> | Accelerated filer         | <input checked="" type="checkbox"/> |
| Non-accelerated filer   | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                          | Emerging growth company   | <input type="checkbox"/>            |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes  No .

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On June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value (based on the average bid and asked price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was \$244.9 million.

The number of shares outstanding of the registrant's common stock as of March 12, 2020 was 46,089,766.

**Documents Incorporated By Reference:** Part III of this Annual Report on Form 10-K is incorporated by reference to our Definitive Proxy Statement on Schedule 14A to be filed in respect of our 2020 Annual Meeting of Stockholders.

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**TRANSENERIX, INC.**  
**ANNUAL REPORT ON FORM 10-K**

**DECEMBER 31, 2019**

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 21E of the Securities Exchange Act of 1934, as amended or the Exchange Act. Such forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Many factors could cause our actual operations or results to differ materially from the operations and results anticipated in forward-looking statements. These factors include, but are not limited to:

- our history of operating losses;
- our need to obtain additional funding to continue our operations;
- our ability to successfully transition from a research and development company to a company focused on market development activities and sales and distribution of our products;
- our ability to successfully develop, clinically test and commercialize our products;
- our ability to identify and pursue development of additional products;
- the timing and outcome of the regulatory review process for our products;
- competition from existing and new market entrants;
- the impact of foreign currency fluctuations on our financial results;
- our ability to attract and retain key management, marketing and scientific personnel;
- our ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights;
- changes in the health care and regulatory environments of the United States, Europe and other jurisdictions in which the Company operates; and
- other factors contained in the section entitled “Risk Factors” contained in this Annual Report.

We do not undertake any obligation to update our forward-looking statements, except as required by applicable law.

In this Annual Report we refer to TransEnterix, Inc. and its subsidiaries collectively as the “Company,” “it,” “we,” “our” or “us.” The Company’s subsidiaries are: TransEnterix Surgical, Inc., SafeStitch LLC, TransEnterix International, Inc.; TransEnterix Italia S.r.l.; TransEnterix Europe S.à.R.L.; TransEnterix Asia Pte. Ltd.; TransEnterix Taiwan Ltd; TransEnterix Japan KK, TransEnterix Israel Ltd. and TransEnterix Netherlands B.V.

## PART I

### ITEM 1. BUSINESS

#### Overview

TransEnterix is a medical device company that is digitizing the interface between the surgeon and the patient in laparoscopy to increase control and reduce surgical variability in today's value-based healthcare environment. We are focused on the market development for and commercialization of the Senhance® Surgical System, which digitizes laparoscopic minimally invasive surgery, or MIS. The Senhance Surgical System is the first and only digital, multi-port laparoscopic platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including 3 millimeter microlaparoscopic instruments, eye-sensing camera control and fully-reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy.

We believe that future outcomes of minimally invasive surgery will be enhanced through our combination of more advanced tools and robotic functionality, which are designed to:

- empower surgeons with improved precision, ergonomics, dexterity and visualization;
- offer high patient satisfaction and enable a desirable post-operative recovery; and
- provide a cost-effective robotic system, compared to existing alternatives today, for a wide range of clinical applications and operative sites within the healthcare system.

Our strategy is to focus on the market development, commercialization and further development of the Senhance System.

We further believe that:

- laparoscopic and robotic surgery will need to continue to evolve given the pressures of value-based healthcare and existing operating room inefficiencies, surgical variability and workforce challenges;
- with the Senhance System, surgeons can benefit from the haptic feedback, enhanced three-dimensional, high definition, or 3D HD, vision and open architecture consistent with current laparoscopic surgery procedures; and
- patients will continue to seek a minimally invasive option, offering minimal scarring and fewer incisions, for many common general abdominal and gynecologic surgeries, which desires are addressed by the Senhance System.

The Senhance System addresses these key challenges for laparoscopic surgeons and hospitals by delivering the benefits of robotics with improved control of the surgical field, enhanced visualization and camera control and improved ergonomics, coupled with the familiarity of laparoscopic motion and consistent per-procedure costs.

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan and select other countries.

- The Senhance System has a CE Mark in Europe for adult and pediatric laparoscopic abdominal and pelvic surgery, as well as limited thoracic surgeries excluding cardiac and vascular surgery.
- In the United States, we have received 510(k) clearance from the FDA for use of the Senhance System in laparoscopic colorectal and gynecologic surgery in a total of 28 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, we have received regulatory approval and reimbursement for 98 laparoscopic procedures.

During 2018 and 2019, we successfully obtained FDA clearance and CE Mark for our 3 millimeter diameter instruments, our Senhance ultrasonic system, our 3 millimeter and 5 millimeter hooks, and the Senhance articulating system. The 3 millimeter instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. The ultrasonic system is an advanced energy device used to deliver controlled energy to ligate and divide tissue, while minimizing thermal injury to surrounding structures. The Senhance articulating system was launched in Europe in November 2019 and we are evaluating our pathway forward to launch such a system in the United States with a planned submission for US clearance at the end of 2020.

In January 2020, we submitted an application to the FDA seeking clearance of the first machine vision system for our robotic surgery unit named Intelligent Surgical Unit (ISU™). Such Intelligent Surgical Unit was developed using the image analytics technology acquired from MST. The Company believes it is the first such FDA submission seeking clearance for machine vision technology in abdominal robotic surgery. On March 13, 2020, the Company announced that it has received FDA clearance for the Intelligent Surgical Unit.

We believe that future outcomes of minimally invasive laparoscopic surgery will be enhanced through our combination of more advanced tools and robotic functionality, which are designed to: (i) empower surgeons with improved precision, dexterity, visualization, and tools that help reduce the cognitive load on surgeons during surgery thus reducing surgeon fatigue; (ii) improve patient satisfaction and enable a desirable post-operative recovery; and (iii) provide a cost-effective robotic system, compared to existing alternatives today, for a wide range of clinical indications.

From our inception, we devoted a substantial percentage of our resources to research and development and start-up activities, consisting primarily of product design and development, clinical studies, manufacturing, recruiting qualified personnel and raising capital. We expect to continue to invest in research and development and market development as we implement our strategy. As a result, we will need to generate significant revenue in order to achieve profitability. The Company operates in one business segment.

On December 11, 2019, following receipt of approval from stockholders at a special meeting of stockholders held on the same day, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio of one-for-thirteen, or the Reverse Stock Split. Our common stock began trading on a split-adjusted basis on NYSE American on the morning of December 12, 2019. No fractional shares were issued in connection with the Reverse Stock Split. Instead, we rounded up each fractional share resulting from the reverse stock split to the nearest whole share. As a result of the Reverse Stock Split, our outstanding common stock decreased from approximately 261.9 million shares to approximately 20.2 million shares (without giving effect to the rounding up for each fractional share).

Unless otherwise noted, all share and per share data referenced in this Annual Report have been retroactively adjusted to reflect the Reverse Stock Split. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Annual Report, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

### **Restructuring**

Despite the number of advances and regulatory clearances received in 2018 and 2019, our Senhance System sales in 2019 were disappointing. Adoption of new technologies, particularly for capital intensive devices such as the Senhance System can be slow and uneven as market development and commercial development is time-consuming and expensive. We have determined to refocus our resources and efforts in 2020 on market development activities to increase awareness of:

- the benefits of the use of the Senhance System in laparoscopic surgery;
- the digitization of high volume procedures using the Senhance System;
- the indications for use, including pediatric indications of use in CE Mark territories; and
- the overall cost efficiency of the Senhance System

We intend to focus on markets with high utilization of laparoscopic techniques, including Japan, Western Europe and the United States. Our focus will be on (1) increasing the number of placements of the Senhance System, not necessarily through sales, but through leasing arrangements, (2) increasing the number of procedures conducted using the Senhance System quarter over quarter, and (3) solidifying key opinion leader support and publications related to the use of the Senhance System in laparoscopic procedures. During this period we will not focus on revenue targets.

During the fourth quarter of 2019, we announced the implementation of a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. Under the restructuring plan, we reduced headcount primarily in the sales and marketing functions and determined that the carrying value of our inventory exceeded the net realizable value due to a decrease in expected sales. The restructuring charges amounted to \$8.8 million, of which \$7.4 million was an inventory write down and was included in cost of product revenue and \$1.4 million related to employee severance costs and was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, during the fourth quarter of 2019. Future payments under the restructuring plan are expected to conclude in 2020.

During March 2020, we continued our restructuring with additional headcount reductions which resulted in \$0.8 million related to severance costs which are expected to be paid in 2020 and 2021.

### **Recent Financing Transactions**

The Company has engaged in a number of capital raising transactions in 2019 and 2020 to date. On August 12, 2019, the Company entered into a Controlled Equity Offering Sales Agreement, or the 2019 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which the Company may sell from time to time, at its option, up to an aggregate of \$25.0 million shares of the Company's

common stock, through Cantor, as sales agent, or the 2019 ATM Offering. The aggregate compensation payable to Cantor was 3.0% of the aggregate gross proceeds from each sale of the Company's common stock. The Company raised gross proceeds of \$7.2 million under the 2019 ATM Offering and net proceeds of \$7.0 million during the year ended December 31, 2019, and an additional \$11.2 million of net proceeds to date in 2020.

On September 4, 2019, the Company entered into an Underwriting Agreement, or the Underwriting Agreement, with Cantor. Subject to the terms and conditions of the 2019 Underwriting Agreement, the Company sold to Cantor, in a firm commitment underwritten offering, 2,153,846 shares of the Company's common stock. In addition, the Company granted Cantor a 30-day option to purchase 323,077 of additional shares of common stock. The Company raised \$18.8 million in gross proceeds and \$18.7 million in net proceeds under this offering. The option to purchase additional shares of common stock was not exercised.

On February 10, 2020, we entered into a purchase agreement, or the LPC 2020 Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which we have the right to sell to Lincoln Park up to an aggregate of \$25,000,000 in shares of our common stock, subject to certain limitations and conditions set forth in the LPC 2020 Purchase Agreement, including a limitation on the number of shares of common stock we can put to LPC and the pricing parameters for the sales. In consideration for entering into the LPC 2020 Purchase Agreement, we issued to Lincoln Park 343,171 shares of Common Stock as commitment shares. We also committed to issue up to an additional 171,585 shares of Common Stock to Lincoln Park on a pro rata basis based on the number of shares Common Stock purchased by Lincoln Park pursuant to the LPC 2020 Purchase Agreement.

On March 10, 2020, the Company closed a firm commitment underwritten public offering, or the 2020 Public Offering, pursuant to which it sold an aggregate of 14,121,766 Class A Units at a public offering price of \$0.68 per Class A Unit and 7,937,057 Class B Units at a public offering price of \$0.68 per Class B Units. Each Class A Unit consists of one share of the Company's common stock, one warrant to purchase one share of common stock that expires on the first anniversary of the date of issuance, or collectively, the Series C Warrants, and one warrant to purchase one share of common stock that expires on the fifth anniversary of the date of issuance, or collectively, the Series D Warrants. Each Class B Unit consists of one share of Series A Convertible Preferred Stock, par value \$0.01 per share, or the Series A Preferred Stock, convertible into one share of common stock, a Series C Warrant to purchase one share of Common Stock and a Series D Warrant to purchase one share of Common Stock. The Class A Units and Class B Units have no stand-alone rights and were not certificated or issued as stand-alone securities. The shares of common stock, Series A Preferred Stock, Series C Warrants and Series D Warrants are immediately separable. In addition, the underwriter for the 2020 Public Offering exercised its overallotment option to purchase 3,308,823 Series C Warrants and 3,308,823 Series D Warrants for an aggregate purchase price of \$60 thousand. The net proceeds to the Company were \$13.4 million.

## **Market Overview**

Over the past three decades, laparoscopic surgery has emerged as a minimally invasive alternative to open surgery. In laparoscopic surgery, multiple incisions are necessary to provide surgical access ports. Carbon dioxide gas insufflation is then used to create room in the body cavity, and long rigid instruments are introduced through ports placed in the incisions to perform surgical tasks. Millions of laparoscopic surgical procedures across a broad range of clinical applications are now performed each year worldwide, though many surgeries are still performed in an open fashion.

While laparoscopy has improved the invasive nature of many previously open procedures, it still has many limitations. Traditional, or rigid, laparoscopy still requires multiple incisions to achieve the visualization and instrument triangulation required to perform successful surgery. Rigid laparoscopy also creates physical challenges by forcing the surgeon's hands and arms into awkward angles, requiring the surgeon to hold instruments in fixed positions for long periods of time and requiring an assistant to stabilize and move a laparoscopic camera. Another challenge associated with rigid laparoscopic surgery is the creation of a cumbersome and potentially tissue-damaging fulcrum at the patient's abdominal wall where instruments are manipulated. Nearly all laparoscopic instruments are rigid instruments that lack internal articulation to enhance dexterity in complex tasks. Most laparoscopic surgeries are performed with two-dimensional, or 2-D, visualization of the operative field, making depth perception difficult.

Despite such limitations, traditional laparoscopy remains the prevalent technique in minimally invasive surgery. We believe that robotic devices that replicate laparoscopic motion are more comfortable for surgeons to adopt. Our Senhance System mimics laparoscopic surgery.

Robotic and computer-controlled assistance have developed as technologies that offer the potential to improve upon many aspects of the laparoscopic surgical experience. Hundreds of thousands of robotic-assisted surgical procedures are now performed each year worldwide, but they still represent a small fraction (less than 10%) of the total abdominal laparoscopic procedures performed. While initial widespread adoption of robotic-assisted surgery was focused on urologic and gynecologic procedures that were primarily performed in an open fashion prior to robotics, recently developed robotic approaches have been applied to many other

clinical applications, particularly in general surgery. Despite recent advances, we believe there remain many limitations associated with current robotic-assisted surgery systems used in connection with laparoscopic surgeries.

We digitize the surgical interface between the surgeon and the patient. We believe image analytics technology will help accelerate and drive meaningful adoption of the Senhance System and allow us to expand the Senhance System capabilities to add augmented intelligence and reality vision capabilities.

## **Product Overview**

We are addressing the challenges in laparoscopy and robotic-assisted surgery with technologically advanced products and product candidates that leverage the best features of both approaches to minimally invasive surgery, or MIS.

### **The Senhance Surgical System**

On September 18, 2015, the Company entered into a Membership Interest Purchase Agreement, or the Purchase Agreement, with Sofar S.p.A., or Sofar, as seller, pursuant to which the Company acquired the Senhance System and related assets and personnel, or the Senhance Acquisition. The closing occurred on September 21, 2015. For a description of the Senhance Acquisition and related transactions, see the disclosure titled “Senhance Acquisition and Related Transactions” under Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report.

The Senhance System is a multi-port robotic surgery system that allows up to four arms to control robotic instruments and a camera. The system builds on the success of laparoscopy by enhancing the traditional features that surgeons have come to expect from existing products and by addressing some of the limitations associated with robotic surgery systems for laparoscopic procedures. The Senhance System also offers responsible economics to hospitals through its robotic technology coupled with reusable standard instruments that yield minimal additional costs per surgery when compared to laparoscopy. The Senhance System has a CE Mark in Europe for laparoscopic abdominal and pelvic surgery, as well as limited thoracic operations excluding cardiac and vascular surgery. In April 2017, the Company submitted a 510(k) submission to the FDA for the Senhance System. On October 13, 2017, the Company received 510(k) clearance for the Senhance System for use in laparoscopic colorectal and gynecologic surgery. In May 2018, the indications for use expanded when we received 510(k) clearance from the FDA for use of the Senhance System in laparoscopic inguinal hernia and laparoscopic cholecystectomy surgery for a total of 28 indicated procedures. During 2018 and early 2019, we successfully obtained FDA clearance and CE Mark for a number of instruments used with the Senhance System, as described further below. In February 2020, we received CE Mark for the Senhance System and related instruments for pediatric use indications in CE Mark territories.

The Senhance System is available for sale in the United States, Europe, Japan, Taiwan and select other countries.

Key features of the Senhance System are:

- Fully Reusable, Autoclavable Instrumentation: the Senhance System offers standard instrumentation that is cleaned and sterilized using current autoclave technology that does not require additional, less standard sterilization methods, and that has no pre-set limitation on number of uses that require them to be disposed;
- Enhanced Vision, Eye Tracking Camera Control: the Senhance System is compatible with three-dimensional high definition, or 3D HD, vision technology providing the surgeon with additional depth and spatial relation of organs; tremor free view of the surgical field and is centered in the surgeon’s field of vision. Eye-tracking camera control, allows hands’ free, surgeon-controlled visualization;
- Haptic Feedback: the Senhance System’s haptic feedback feature heightening the surgeon’s sensing of pressure/tension throughout the surgical procedure, haptics provide the surgeon with the ability to feel the tissue response of the body during a procedure;
- Laparoscopic Motion: digital laparoscopy, maintaining familiar motions, tools and techniques that is similar to the motion used during traditional laparoscopic surgeries;
- Comfortable Ergonomics: ergonomic seating for the surgeon throughout the procedure to help reduce fatigue and risk of musculoskeletal injuries;
- E-Fulcrum: a digital fulcrum, setting a dynamic virtual pivot point that helps to potentially minimize incision trauma;
- Open-Platform Architecture: allows the use and integration of existing operating room technologies to maximize benefit from capital investments and support surgeon preference (e.g., trocars, electrosurgical units, insufflators, select vision systems, etc.); and

- View of the Sterile Field: the Senhance System offers the user an open view of the operating room and sterile field from the ergonomically-designed console.

The Senhance System is manufactured for us by third party contract manufacturers. We or our manufacturers acquire raw materials and components of the Senhance System from vendors, some of which are sole suppliers. We believe our relationships with our vendors and manufacturing contractors are good. We further believe that we have the manufacturing capacity and inventory reserves to meet our anticipated Senhance System sales for the foreseeable future. We are currently taking steps to develop redundant manufacturing and supply alternatives that will expand our manufacturing capacity to help meet future demand.

## **Instruments and Other Products**

### **Instruments**

During 2018 and 2019, we successfully obtained FDA clearance and CE Mark for our 3 millimeter diameter instruments, our Senhance ultrasonic system, our 3 millimeter and 5 millimeter hooks, and the Senhance articulating system. The 3 millimeter instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. The ultrasonic system is an advanced energy device used to deliver controlled energy to ligate and divide tissue, while minimizing thermal injury to surrounding structures. The Senhance articulating system was launched in Europe in November 2019 and we are evaluating a pathway to bring the instruments to the United States with a planned regulatory filing by the end of 2020. We currently offer approximately 40 instruments and accessories in our portfolio. We also have designed the Senhance System so that third-party manufactured instruments can be easily adapted for use.

### **SurgiBot System**

The Company has also developed the SurgiBot System. The SurgiBot System is a single-port system designed to utilize flexible instruments through articulating channels controlled directly by the surgeon, with robotic assistance, while the surgeon remains patient-side within the sterile field. In December 2017, we entered into an agreement with Great Belief International Limited, or GBIL, to advance the SurgiBot System towards global commercialization. The agreement transferred ownership of the SurgiBot System assets, while the Company retained the option to distribute or co-distribute the SurgiBot System outside of China. GBIL intends to have the SurgiBot System manufactured in China and obtain Chinese regulatory clearance from the China Food and Drug Administration while entering into a nationwide distribution agreement with China National Scientific and Instruments and Materials Company, or CSIMC, for the Chinese market. The agreement provided the Company with proceeds of at least \$29 million, of which \$15 million has been received to date. The remaining \$14.0 million, representing minimum royalties, will be paid beginning at the earlier of receipt of Chinese regulatory approval or March 2023.

## **Products in Development**

### **Instruments**

We continue to work on the development and regulatory clearance for articulating instruments for the Senhance System. In December 2018, we submitted a 510(k) submission to the FDA related to wristed instruments for the Senhance System. That 510(k) submission was withdrawn in 2019 to provide us additional time to pursue development efforts and clinical trials. We intend to submit a new 510(k) submission by the end of 2020.

### **MST Assets**

On October 31, 2018, we acquired the assets, intellectual property and highly experienced multidisciplinary personnel of Israel-based MST Medical Surgical Technologies, Inc., or MST. Through this acquisition we acquired MST's AutoLap™ technology, one of the only image-guided robotic scope positioning systems with FDA clearance and CE Mark. The AutoLap technology is a fully vetted technology used in over 1,500 surgeries in multiple specialties and accompanied by post-marketing publication and studies, a broad intellectual property portfolio and personnel with clinical, scientific and engineering experience. We believe MST's image analytics technology will accelerate and drive meaningful Senhance System developments and allow us to expand the Senhance System to add augmented, intelligent vision capability.

On July 3, 2019, we entered into a System Sale Agreement with GBIL to sell certain assets related to the AutoLap technology. On October 15, 2019, we entered into an Amended and Restated System Sale Agreement (the "Amended AutoLap Agreement") with GBIL to restructure the previously announced sale of certain AutoLap assets. Pursuant to the Amended AutoLap Agreement, the Company sold the AutoLap laparoscopic vision system, or AutoLap, and related assets to GBIL for \$17 million, all of which was received in 2019 in the form of \$16 million in cash and a payment by GBIL of \$1.0 million to settle certain Company obligations in China. The assets include inventory, spare parts, production equipment, testing equipment and certain intellectual property



specifically related to the AutoLap. In addition, the Company entered into a cross-license agreement with GBIL to retain rights to use any AutoLap-related intellectual property sold to GBIL, and to non-exclusively license additional intellectual property to the Buyer.

In January 2020, we submitted a 510(k) submission to the FDA for our Intelligent Surgical Unit that is designed to enable machine vision capabilities on the Senhance System. Such Intelligent Surgical Unit was developed using the MST image analytics technology that we retained. The Company believes it is the first such FDA submission seeking clearance for machine vision technology in abdominal robotic surgery. On March 13, 2020, the Company announced that it has received FDA clearance for the Intelligent Surgical Unit.

### **Business Strategy**

Our current strategy is to focus our resources on the market development of the Senhance System and related instruments.

We believe that:

- the Senhance System is easier to use in MIS laparoscopic surgery, particularly for surgeons well versed in laparoscopic technique;
- markets outside of the United States, particularly where laparoscopic surgery is more heavily utilized, such as Japan, may more readily adopt the use of the Senhance System;
- because of the capital-intensive nature of the purchase of a robotic system, we are exploring contracts with new hospitals that provide for the lease of the Senhance System;
- there are a number of hospitals and an increasing number of ambulatory surgery centers internationally and in the United States that can benefit from the addition of robotic-assisted MIS and, through the Senhance System, lower operational costs as contrasted with other robotic systems;
- with the Senhance System, surgeons can benefit from the security of haptic feedback, enhanced 3D HD vision and open-platform architecture consistent with current laparoscopic surgery procedures;
- patients continue to seek a minimally invasive option for many common general abdominal and gynecologic surgeries that are addressed by the Senhance System;
- the addition of advanced energy and 3 millimeter instruments for the Senhance System help to increase adoption of our products in the laparoscopic surgery market;
- leveraging haptic feedback, 3 millimeter instruments, independent arms and lower operating cost, the Senhance system is well suited for pediatric surgeries; and
- the enablement of image analytics technology, augmented intelligence and reality vision capabilities, such as the Intelligent Surgical Unit, will help accelerate and drive meaningful adoption of the Senhance System into the future and help clearly differentiate our offering in surgical robotics.

We intend to continue our development activities and seek 510(k) clearance and CE Mark for additional instruments, including the Senhance articulating system, in 2020 as we pursue our strategy.

### **Sales and Marketing**

At the end of 2019 we reduced our sales and marketing team as we shifted our focus to market development and promoting utilization of our current Senhance Systems. We utilize distributors in a number of jurisdictions where we do not sell directly. Our distribution agreements typically provide exclusivity in a specific territory or jurisdiction.

As of December 31, 2019, we have two training centers, one in Milan, Italy and the other at the Institute for Surgical Advancement at Florida Hospital Orlando and three research and development centers, one in Research Triangle Park, North Carolina, one in Milan, Italy and the other in Yokne'am Illit, Israel. We do not intend to increase the number of such centers in 2020.

We rely on customers of our sold and placed Senhance Systems to use the Senhance System on a consistent basis. We had six customers who accounted for 82% of sales in 2019 and twelve customers who accounted for 89% of sales in 2018.

### **Intellectual Property**

We believe that our intellectual property and expertise is an important competitive resource. Our experienced research and development team has created a substantial portfolio of intellectual property, including patents, patent applications, trade secrets and proprietary know-how. We maintain an active program of intellectual property protection, both to assure that the proprietary technology developed by us is appropriately protected and, where necessary, to assure that there is no infringement of our proprietary technology by competitive technologies.

The following summarizes our current patent and patent application portfolio.

As of December 31, 2019, the Company's patent portfolio includes 40 United States patents and approximately 92 patents issued outside the United States, and more than 140 patent applications filed in the United States and internationally. We own all right, title and interest in all but the 42 of our patents and patent applications that are exclusively licensed to us. We also hold non-exclusive licenses to an additional 6 U.S. and 4 non-U.S. patents.

Several of our issued patents resulted from filings related to the Senhance System. These include 7 United States patents, and approximately 40 patents outside the United States. The earliest to expire U.S. and non-U.S. patents within this part of our portfolio will remain in force until 2027. The patent applications include over 90 that relate to the Senhance System or other features, instruments or components for robotic-assisted surgery. Our patents and applications that we acquired from MST relate to image analytics and robotic surgery, among other things. We intend to continue to seek further patent and other intellectual property protection in the United States and internationally, where available and when appropriate, as we continue our product development efforts.

Some of our issued patents and pending applications for the Senhance System, as well as associated technology and know-how, are exclusively licensed to TransEnterix Italia from the European Union. The license agreement with the European Union has a term which runs until the final licensed patent expires, unless the agreement is terminated earlier by mutual consent of the parties or for breach. The Company is currently in compliance with the terms of this license agreement.

### **Competition**

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more established and developed than ours.

There are many competitive offerings in the field of minimally invasive surgery. Several companies have launched devices that enable reduced incision or single incision laparoscopic surgery with or without robotic assistance. Our surgical competitors include, but are not limited to: Johnson & Johnson/Verb Surgical Inc., Medtronic plc, Intuitive Surgical Inc., and CMR Surgical Ltd. We are aware that more entrants anticipate introducing additional robotic-based instruments in the next few years.

In addition to surgical device manufacturer competitors, there are many products and therapies designed to reduce the need for or attractiveness of surgical intervention. These products and therapies may impact the overall volume of surgical procedures and negatively impact our business.

Our ability to compete may be affected by the failure to fully educate physicians in the use of our products and products in development, or by the level of physician expertise. This may have the effect of making our products less attractive. Among currently available surgical robotic systems, we expect the Senhance System to differentiate on the basis of overall attractiveness to laparoscopic surgeons due to its ability to provide robotic benefits while leveraging their laparoscopic training and experience lower per procedure costs when compared to other robotic systems on the market today; and we expect the Senhance System to differentiate, in most cases, its ability to provide the surgeon with valuable tactile feedback for increased security. Several medical device companies are actively engaged in research and development of robotic systems or other medical devices and tools used in minimally invasive surgery procedures. We cannot predict the basis upon which we will compete with new products marketed by others.

### **Government Regulation of our Product Development Activities**

The U.S. government and foreign governments regulate the medical device industry through various agencies, including but not limited to, the U.S. FDA, which administers the Federal Food, Drug and Cosmetic Act, or the FDCA. The design, testing, manufacturing, storage, labeling, distribution, advertising, and marketing of medical devices are subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by similar agencies in other

countries, including the European Union. Any device product that we develop must receive all requisite regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country.

### **Device Development, Marketing Clearance and Approval**

Medical devices are subject to varying levels of pre-market regulatory requirements. The FDA classifies medical devices into one of three classes: (i) Class I devices are relatively simple and can be manufactured and distributed with general controls; (ii) Class II devices are somewhat more complex and receive greater scrutiny from the FDA and have heightened regulatory requirements; and (iii) Class III devices are new, high risk devices, and frequently are permanently implantable or help sustain life and generally require a Pre-Market Approval, or PMA, by the FDA.

In the United States, a company generally can obtain permission to distribute a new medical device in one of two ways. The first applies to any device that is substantially equivalent to a device first marketed prior to May 1976, or to another device legally marketed after that date, but which is not subject to premarket approval (PMA) (described below). These devices are generally either Class I or Class II devices. To obtain FDA clearance to distribute the medical device, a company generally must submit a 510(k) notification and receive an FDA order finding substantial equivalence to a predicate device (pre-May 1976 device or post-May 1976 device is legally marketed and not subject to PMA) and permitting commercial distribution of that medical device for its intended use. A 510(k) notification must provide information supporting a claim of substantial equivalence to a single medical device, the predicate device, or multiple predicates in certain circumstances. If clinical data from human experience are required to support the 510(k) notification, these data must be gathered in compliance with the investigational device exemption, or IDE, regulations for investigations performed in the United States. The 510(k) process is normally used for products of the type that we are developing and propose to market and sell. The FDA review process for premarket notifications submitted pursuant to Section 510(k) of the FDCA takes, pursuant to statutory requirements, 90 days, but it can take substantially longer if the FDA has questions regarding the regulatory submission. It is possible for 510(k) clearance procedures to take from six to twelve months, depending on the concerns raised by the FDA and the complexity of the device. There is no guarantee that the FDA will “clear” a medical device for marketing, in which case the device cannot be distributed in the United States. There is also no guarantee that the FDA will deem the applicable device subject to the 510(k) process, as opposed to the more time-consuming and resource-intensive PMA process described below.

The second, more comprehensive, approval process applies to a new device that is not substantially equivalent to a predicate product or that is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices. For example, many implantable devices are subject to the approval process as a Class III device. Two steps of FDA approval are generally required before a company can market a product in the United States that is subject to PMA approval, as opposed to clearance, as a Class III device. First, a company must comply with IDE regulations in connection with any human clinical investigation of the device conducted in the United States. While the IDE regulations permit a company to undertake a clinical study of a “non-significant risk” device without formal FDA approval prior express FDA approval is required if the device is a significant risk device. Second, the FDA must approve the company’s PMA application, which typically contains, among other things, clinical information acquired under the IDE. Additionally, devices subject to PMA approval may be subject to an Advisory Panel review to obtain marketing approval and are required to pass a factory inspection in accordance with the current “good manufacturing practices” standards in order to obtain approval. The FDA will approve the PMA application if it finds there is reasonable assurance that the device is safe and effective for its intended use. The PMA process takes substantially longer than the 510(k) process, approximately one to two years or more.

However, in some instances the FDA may find that a device is new and not substantially equivalent to a predicate device but is also not a high risk device as is generally the case with Class III PMA devices. In these instances, the FDA may allow a device to be down classified from Class III to Class I or II. The de novo classification option is an alternate pathway to classify novel devices of low to moderate risk. A sponsor may submit a de novo classification request to the FDA for novel low to moderate risk devices without first being required to submit a 510(k) submission. These types of applications are referred to as “Evaluation of Automatic Class III Designation” or “de novo request.” In instances where a low to moderate risk device is deemed not substantially equivalent to a predicate device, the candidate device may be filed under a de novo request. FDA review of a de novo request may lead the FDA to identify the device as either a Class I or II device subject to the 510(k) regulatory pathway. Review times for de novo requests vary widely, and may take in excess of one year.

The Company believes the Senhance System and many related products are Class II devices as evidenced by the Company’s cleared 510(k) premarket notifications. The Company intends to further develop the product line by adding additional instrumentation to and expanding the capabilities of the Senhance System. At this time, the Company believes that the items under development are Class II devices subject to 510(k) premarket notification. The FDA might find that the 510(k) submission does not provide the evidence required to prove that the additional instruments or accessories for use with the Senhance System are substantially equivalent to marketed Class II devices. If that were to occur, the Company would be required to undertake the more complex and

costly PMA process or perhaps be considered for a de novo reclassification. For either the 510(k), de novo, or the PMA process, the FDA could require the Company to conduct clinical trials, which would take more time, cost more money and pose other risks and uncertainties. The Company does not believe it has any need to, and is not currently planning to conduct, any clinical trials.

If needed in the future, clinical studies conducted in the United States or used in any U.S. application on an unapproved medical device that presents a significant risk require approval from the FDA prior to initiation. Even when a clinical study has been approved by the FDA or deemed approved, the study is subject to factors beyond a sponsor's control, including, but not limited to, the fact that the institutional review board, or IRB, at a specified clinical site might not approve the study, might decline to renew approval, or might suspend or terminate the study before its completion. There is no assurance that a clinical study at any given site will progress as anticipated. In addition, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA that the product is safe and effective, a prerequisite for FDA approval of a PMA, or substantially equivalent in terms of safety and effectiveness to a predicate device, a prerequisite for clearance under Section 510(k). Even if the FDA approves or clears a device, it may limit its intended uses in such a way that manufacturing and distribution of the device may not be commercially feasible.

After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain serious adverse events, are authorized under various circumstances to withdraw the clearance or approval of the device, or require changes to a device, its manufacturing process or its labeling or require additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the PMA process is not permitted to make changes to the device which affect its safety or effectiveness without first submitting a supplement application to its PMA and obtaining FDA approval for that supplement, prior to marketing the modified device. In some instances, the FDA may require clinical trials to support a supplement application. A manufacturer of a device cleared through the 510(k) process must submit an additional premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source, labeling or manufacturing process. A change in the intended uses of a PMA device or a 510(k) device generally requires an approval supplement or newly cleared premarket notification or de novo request. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

### **Continuing FDA Regulation**

After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- quality system regulations that require manufacturers to follow stringent design, testing, process control, documentation and other quality assurance procedures;
- labeling regulations that prohibit the promotion of products for unapproved, i.e. "off label," uses and impose other restrictions on labeling;
- Medical Device Reporting, or MDR, regulations that require manufacturers to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- corrections and removal reporting regulations that require manufacturers to report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- requirements to conduct postmarket surveillance studies to establish continued safety data.

We are required to, and have, registered with the FDA as a medical device manufacturer. We must obtain all necessary permits and licenses to operate our business in all regions in which we do business. As manufacturers, we and our suppliers are subject to announced and unannounced inspections by the FDA to determine our compliance with the Quality System Regulation, or QSR, and other regulations.

In Europe, we comply with the requirements of the 93/42/EEC Medical Devices Directive, or MDD, and appropriately affix the CE Mark on our products to attest to such compliance. TransEnterix Italia S.R.L. is the legal manufacturer in the European Union. Our products marketed in the EU meet the "Essential Requirements" of the MDD relating to safety and performance. We have undergone verification of our regulatory compliance, or conformity assessment, by a Notified Body duly authorized by an EU country and must continue to do so as new products and changes to the products arise. The level of scrutiny of such assessment depends on the regulatory class of the product. We are subject to continued surveillance by our Notified Body and are required to

report any serious adverse incidents to the appropriate authorities. We also must comply with additional requirements of individual countries in which our products are marketed. In the European Union, we are required to maintain certain quality system certifications in order to sell products. These regulations require us or our manufacturers to manufacture products and maintain documents in a prescribed manner with respect to design, manufacturing, testing, labeling and control activities. As legal manufacturers, we and our suppliers are subject to announced and unannounced inspections by the European Notified Bodies and Competent Authorities.

In May 2020, the Medical Device Directive will be replaced by the updated European Medical Device Regulation, or 2017/745 (MDR), after a three year transition period. Any products that are currently certified to comply with the MDD will have to be re-evaluated by a designated Notified Body according to the new regulations after their certificates expire or in case of a substantial change. The new regulations will place new requirements regarding labeling, post-market surveillance, and technical documentation on all medical device manufacturers. In addition, Notified Bodies are undergoing the transition as well, leading to reduced capacity to take on new clients or review new medical devices for CE mark approvals or existing medical devices for substantial changes. Transition to the new regulations will take time and resources from our internal personnel and external consultants to gain compliance, which may reduce the resources available for market expansion and new product introductions.

### **Impact of Regulation**

Failure to comply with the applicable regulatory requirements can result in enforcement action by the FDA and other international regulatory bodies, which may include, among other things, any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refund or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for market access approvals of new products or modifications to existing products;
- withdrawing or suspending clearances or approvals that are already granted;
- criminal prosecution; and
- disgorgement of profits.

Further, the levels of revenues and profitability of medical device companies like us may be affected by the continuing efforts of government and third party payors to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls.

Therefore, we cannot assure you that any of our products will be considered cost effective, or that, following any commercialization of our products, coverage and reimbursement will be available or sufficient to allow us to manufacture and sell them competitively and profitably.

### **Health Care Regulation**

Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

In the United States, there have been, and we expect there to continue to be, a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. At the current time, our products are not defined as durable medical equipment. Non-DME devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. Instead, the hospital or health care provider is reimbursed based on the procedure performed and the inpatient or outpatient stay. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage as hospitals, ambulatory surgery centers and health care providers attempt to negotiate lower prices for products such as the ones we develop and sell.

In 2010, the Patient Protection and Affordable Care Act, or the Affordable Care Act, and the reconciliation law known as Health Care and Education Reconciliation Act, or the Reconciliation Act, and, with the Affordable Care Act, the 2010 Health Care Reform Legislation, were enacted into law. Due to ongoing legal challenges and changes to the 2010 Health Care Reform Legislation since its enactment, the Company cannot predict with certainty the long-term impact of federal health care legislation on its business.

The 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires certain manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or "transfers of value" provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. We have provided reports under the Open Payments Act to the Centers for Medicare & Medicaid Services since 2014. Amendments to the Open Payments Act expanded the categories of health care providers for which reporting is required. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

### **International Regulation and Potential Impact**

The Company has market development and commercial activities in a number of international markets and intends to focus on such markets in the near term. Some of these markets maintain unique regulatory requirements outside of or in addition to those of the FDA and the European Union. The Senhance System is CE marked, which is the basis to allow us to offer the product for sale in a number of jurisdictions, including select countries in Europe, the Middle East and Asia. Due to the variations in regulatory requirements within territories, the Company may be required to perform additional safety or clinical testing or fulfill additional agency requirements for specific territories. The Company may also be required to apply for registration using third parties within those territories and may be dependent upon the third parties' successful regulatory processes to file, register and list the product applications and associated labeling, which could lead to significant investments and resource use. These additional requirements may result in delays in international registrations and commercialization of our products in certain countries.

In addition, we are utilizing distributors and sales agents in various territories throughout Europe, the Middle East and Africa, and need to ensure that our activities, and the activities of our distributors and sales agents, are compliant with local law and U.S. laws governing the sales of medical devices. We have also established subsidiaries and contracted with third parties in Asia, including Japan and Taiwan, to seek regulatory approvals to offer our products in Asia. The laws governing the registration, approval, clearance and sales of medical devices, such as the Senhance System, in multiple jurisdictions are complex, and the failure to comply with such laws in any given jurisdiction could subject us to financial penalties or suspension or termination of our ability to sell our products in the applicable jurisdiction.

### **Employees**

As of December 31, 2019, we had 163 employees, including 160 full time employees. The Company considers its relationships with its employees to be good.

### **Corporate Information**

The Company's principal executive offices are located at 635 Davis Drive, Suite 300, Morrisville, NC 27560. The Company was originally incorporated on August 19, 1988 as a Delaware corporation.

As of December 31, 2019, the active subsidiaries of the Company are TransEnterix Surgical, Inc., SafeStitch LLC, TransEnterix International, Inc.; TransEnterix Italia S.r.l.; TransEnterix Europe S.à.R.L; TransEnterix Asia Pte. Ltd.; TransEnterix Taiwan Ltd; TransEnterix Japan KK; TransEnterix Israel Ltd. and TransEnterix Netherlands B.V.

### **Available Information**

The Company maintains a website at [www.transenterix.com](http://www.transenterix.com). We are not incorporating our website by reference into this Annual Report. Our Code of Business Conduct and Ethics, as reviewed and updated on October 24, 2019, is available on our website. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website as soon as practicable after electronic filing of such material with, or furnishing it to, the U.S. Securities and Exchange Commission, or the SEC.

## **ITEM 1.A. RISK FACTORS**

***We have a history of operating losses, and we may not be able to achieve or sustain profitability. In addition, we may be unable to continue as a going concern.***

We have a limited operating history. We are not profitable and have incurred losses since our inception. Management concluded that substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs as well as past recurring losses and an accumulated deficit. Our independent registered public accounting firm also included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2019 with respect to this uncertainty. Our net loss for the year ended December 31, 2019 was \$154.2 million, and our accumulated deficit as of December 31, 2019 was \$663.6 million. We believe that our existing cash and cash equivalents, together with cash received from product and instrument sales and leases will be sufficient to meet our anticipated cash needs into the fourth quarter of 2020.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we continue to develop and commercialize our products. We will continue to incur research and development and general and administrative expenses related to our operations, and sales and marketing expenses to support our commercial activities, as restructured. Even if we are successful in reducing our expenses or achieving profitability in the future, we may not be able to sustain profitability in subsequent periods.

***We will require substantial additional funding in the future, which may not be available to us on acceptable terms, or at all.***

We do not anticipate that the net proceeds of prior equity financings will be sufficient to support development of our products and product candidates and provide us with the necessary resources to commercialize the Senhance System and other products through the lengthy sales cycle. We intend to advance multiple additional products through clinical and pre-clinical development in the future. We believe we will need to raise substantial additional capital in order to continue our operations and achieve our business objectives.

We have two effective shelf registration statements. As of March 10, 2020, we had approximately \$5.5 million available for future financings under a shelf registration statement due to expire in May 2020. We have an additional shelf registration statement that was declared effective on February 10, 2020 registering up to \$150 million of our securities. As of the date of this Annual Report, we had approximately \$124 million available for future financings under such shelf registration statement. We cannot assure you that we will be successful in obtaining such additional financing on terms acceptable to the Company or at all.

Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of our Senhance System market development, commercialization and development activities;
- the costs and timing of seeking and obtaining FDA and other non-U.S. regulatory clearances and approvals for our products in development;
- the costs associated with our manufacturing capabilities;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, products and technologies;
- the economic and other terms and timing of our existing licensing arrangement and any collaboration, licensing or other arrangements into which we may enter in the future;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, quality systems and information technology systems; and
- our ability to maintain, expand and defend the scope of our intellectual property portfolio.

Until we generate a sufficient amount of revenue to finance our cash requirements, which may never occur, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution; and debt financing, if available, may involve restrictive covenants that limit our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our products or grant licenses on terms that may not be favorable to us.

***We announced that we are seeking strategic and financing alternatives. We may not be successful in achieving a suitable transaction.***

On October 17, 2019, we announced that we had engaged J.P. Morgan Securities LLC to assist the Board of Directors in considering strategic alternatives for the Company to enhance stockholder value, including, but not limited to a sale of the Company, a financing of the Company, a strategic partnership or collaboration or some other form of commercial relationship. In addition, we announced the implementation of a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. We may not be able to identify, successfully negotiate with and consummate a suitable transaction with a buyer or other commercial partner. We may not be able to raise the funds needed to operate the business for any specific period of time. If we are not successful in consummating a transaction or financing, our financial condition will be materially adversely affected.

***We have announced a restructuring plan to reduce our operating expenses. We may not achieve some or all of the expected benefits of our restructuring plan and the restructuring may adversely affect our business.***

Following the disappointing 2019 commercial results, we have determined to restructure our organization to focus on market development and increasing use of the Senhance System, rather than focusing on building our sales team. Our restructuring is designed to re-align our commercial organization through re-prioritization of certain geographical markets and to implement operational excellence through strategic reallocation of resources. We need to fully implement the restructuring plan while evaluating strategic alternatives. We may encounter unexpected costs while implementing the restructuring plan and may not be successful in reducing our operating expenses as much as needed. We may undertake additional restructurings in the future. Implementation of a restructuring plan is costly and disruptive to our business, and we may not be able to obtain the estimated cost savings and benefits that were initially anticipated in connection with our restructuring in a timely manner or at all. Additionally, as a result of any restructuring, we may experience a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods and may lose momentum in the sales of Senhance Systems. Reorganization and restructuring can require a significant amount of management and other employees' time and focus, which may divert attention from operating and growing our business. Any failure to properly execute the restructuring plans could result in total costs that are greater than expected and cause us not to achieve the expected long-term operational benefits and adversely affect our financial condition, operating results and future operations.

Under the restructuring plan, we determined that the carrying value of our inventory exceeded the net realizable value due to a decrease in expected sales. The restructuring charges amounted to \$8.8 million, of which \$7.4 million was an inventory write down based on management's estimates. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates. Significant items subject to such estimates and assumptions include identifiable intangible assets, contingent consideration, warrant liabilities, stock compensation expense, revenue recognition, accounts receivable reserves, excess and obsolete inventory reserves, inventory classification between current and non-current, and deferred tax asset valuation allowances. We cannot assure you that additional write downs or other charges related to any management estimates will not be needed.

***We are currently highly dependent on a single product, the Senhance System. We cannot give any assurance that the Senhance System can be successfully commercialized.***

We are currently highly dependent on the Senhance System, which is FDA cleared for sale in the United States, CE marked for sale in the European Union and other countries, and approved for sale and reimbursement in Japan. We began our selling efforts for the Senhance System in the fourth quarter of 2015 in Europe, in the fourth quarter of 2017 in the United States and in the second quarter of 2018 in Asia. We have had limited commercial success to date, particularly in 2019. We have determined to focus our energies on market development and increased usage of the Senhance Systems that have been purchased and placed. We cannot assure you that we will be able to successfully improve the commercialization of the Senhance System, for a number of reasons, including, without limitation, failure in our market development and sales efforts, the long sales cycle associated with the purchase of capital equipment, and the potential introduction by our competitors of more clinically effective or cost-effective alternatives. Failure to successfully commercialize the Senhance System would have a material and adverse effect on our business.

***The sales cycle for the Senhance System has been lengthy and unpredictable, which has made it difficult for us to forecast revenue and increased the magnitude of quarterly fluctuations in our operating results.***

Purchase of a surgical robotic system such as the Senhance System represents a capital purchase by hospitals and other potential customers. The capital purchase nature of the transaction, the complexity of our product, the relative newness of surgical robotics



and the competitive landscape requires us to spend substantial time and effort to assist potential customers in evaluating our robotic systems. We must communicate with multiple surgeons, administrative staff and executives within each potential customer in order to receive all approvals on behalf of such organizations. We face difficulty identifying and establishing contact with such decision makers. Even after initial acceptance, the negotiation and documentation processes can be lengthy. Additionally, our customers may have strict limitations on spending depending on the current economic climate or trends in healthcare management. We are also expanding the potential market for robotic surgical systems with our focus on laparoscopic surgery. Such expansion requires a different sales and marketing approach than a focus on open procedures. We have found that sales are extremely difficult and take substantial effort. In late 2019 we began leasing Senhance Systems to hospitals with lease terms ranging from twelve to twenty-four months or more. We began delivering these units during the first quarter of fiscal year 2020. We cannot assure you that these lease arrangements will lead to more sales of our Senhance System.

We currently have limited marketing, sales and distribution capabilities. We are focusing on market development efforts and have curtailed our sales force in the United States, and are focusing on select countries in Europe and in Japan. Sales efforts elsewhere are conducted through the use of independent contractor and distribution agreements with companies possessing established sales and marketing operations in the medical device industry. There can be no assurance that we will be successful in building our sales capabilities after this period of market development. To the extent that we enter into additional distribution, co-promotion or other arrangements, our product revenue is likely to be lower than if we directly market or sell our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products. If we are not successful in commercializing our existing and future products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have procedures in place to require our distributors and sales agents to comply with applicable laws and regulations governing the sales of medical devices in the jurisdictions where they operate. Failure to meet such requirements could subject us to financial penalties or the suspension or termination of the ability to sell our products in such jurisdiction.

***We expect our gross margins to vary over time, and changes in our gross margins could adversely affect our financial condition or results of operations.***

We began selling the Senhance System in 2015. Our gross margins have fluctuated from period to period, and we expect that they will continue to fluctuate in the future. Our gross margins have been and may continue to be adversely affected by numerous factors, including:

- service costs;
- changes in customer, geographic, or product mix;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;
- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor or other manufacturing-related costs, including impact of foreign exchange rate fluctuations for foreign-currency denominated costs;
- fluctuations in foreign currency exchange rates and changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the U.S.;
- inventory obsolescence and product recall charges; and
- market conditions.

If we are unable to offset the unfavorable impact of the factors noted above by increasing the volume of products shipped, reducing product manufacturing costs or otherwise, our business, financial condition, results of operations or cash flows may be materially adversely affected.

***Negative publicity, whether true or not, concerning us or our products could reduce market acceptance of our products and could result in decreased demand for the Senhance System.***

There have been social media and other publications regarding us and the Senhance System published from time to time since we started selling the Senhance System. Negative media and social media coverage, whether true or not, concerning our products or us could reduce market acceptance of the Senhance System.

***The spread of the coronavirus (COVID-19) has negatively impacted our operations.***

We have facilities located in the United States, Israel and Italy. The engineers and other employees working in those facilities may be at greater risk for exposure to and for contracting the coronavirus, COVID-19. A portion of our operations are in Milan, Italy and our Senhance Systems are manufactured at a contract manufacturing facility in Milan. With the quarantine in Northern Italy, the assembly of new units has been disrupted. In addition, on March 13, 2020, President Trump declared a national emergency in the United States, and other countries in which we operate have restrictions in place. A variety of travel restrictions, actual and pending, have caused a delay in our product installation and training activities in recent weeks, and are expected to continue. The COVID-19 pandemic could continue to harm our operations and negatively impact our financial condition.

***In order to compete successfully within the surgical robotics industry, we need to continue to evolve the Senhance System, including the innovations associated with the MST assets we acquired. Failure to develop, seek regulatory approval for and commercialize such developments could have a material adverse effect on our business and financial position.***

In order to compete successfully within the highly competitive surgical robotics industry, we need to continue to advance and innovate the Senhance System, including the innovations associated with the MST assets we acquired. Our focus currently is on harnessing the image technology acquired in the MST acquisition to advance the intelligence of the Senhance System to provide meaningful real-time data to surgeons. If we fail to develop such innovations, or fail to obtain regulatory approval or clearance for or successfully commercialize such innovations, such failure could have a material adverse effect on our business and financial position.

***Fluctuations in foreign currency exchange rates may adversely affect our financial results.***

We conduct operations in several different countries, including the United States and throughout Europe, and portions of our revenues, expenses, assets and liabilities are denominated in U.S. dollars, Euros, and other currencies. Since our consolidated financial statements are presented in U.S. dollars, we must translate revenues, income and expenses, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. We have not historically hedged our exposure to foreign currency fluctuations. Accordingly, increases or decreases in the value of the U.S. dollar against the Euro and other currencies could materially affect our net operating revenues, operating income and the value of balance sheet items denominated in foreign currencies.

***Our global operations expose us to additional risks and challenges associated with conducting business internationally.***

The international nature of our business, particularly in Europe, Israel and Asia, may expose us to risks inherent in conducting foreign operations. These risks include:

- challenges associated with managing geographically diverse operations, which require an effective organizational structure and appropriate business processes, procedures and controls;
- the high cost of doing business in foreign jurisdictions, including compliance with international and U.S. laws and regulations that apply to our international operations;
- currency exchange and interest rate fluctuations and the resulting effect on our revenue and expenses, and the cost and risk of entering into hedging transactions, if we chose to do so in the future;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- potentially adverse tax consequences;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- compliance with additional regulations and government authorities in a highly regulated business;

- difficulties associated with staffing and managing foreign operations, including differing labor relations; and
- general economic and political conditions outside of the U.S.

The risks that we face in our international operations may continue to intensify as we further develop and expand our international operations.

***We effected a reverse stock split of our common stock on December 11, 2019, which may not achieve one or more of our objectives.***

On December 11, 2019, following receipt of approval from stockholders at a special meeting of stockholders held on the same day, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio of one-for-thirteen, or the Reverse Stock Split. We cannot predict with certainty the effect of the Reverse Stock Split upon the market price of our common stock. As such, it is possible that the market price of our shares may fluctuate and decline.

One objective of the Reverse Stock Split was to strengthen our strategic alternative considerations. However, there is no assurance that the per-share market price of our common stock after the Reverse Stock Split will attract institutional investors or investment funds, or meet investing guidelines of institutional investors or investment funds. It is possible that the reduced number of outstanding shares of our common stock following the Reverse Stock Split may adversely impact the liquidity of the shares of our common stock. Moreover, an increased number of stockholders may own odd lots (less than 100 shares) of our common stock following the Reverse Stock Split. These stockholders may face greater trading commissions for the sale of such shares and may have greater difficulty effecting such sales.

***Our stock price has been volatile and may experience additional fluctuation in the future.***

The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock. During the two year period ended December 31, 2019, the market price of our common stock fluctuated from a high of \$90.74 per share to a low of \$1.35 per share, after giving effect to the one-for-thirteen Reverse Stock Split effected on December 11, 2019. The market price of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- the announcement of favorable or unfavorable news regarding us, including our product development efforts and regulatory clearance activities;
- the achievement of commercial sales of our products;
- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;
- developments in surgical robotics;
- the results of product liability or intellectual property lawsuits;
- future issuances of common stock or other securities;
- the addition or departure of key personnel;
- the reduced volume of stock trades that may result as a consequence of the Reverse Stock Split;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

***Our stockholders have experienced dilution of their percentage ownership of our stock and may experience additional dilution in the future.***

We have raised significant capital through the issuance of our common stock and warrants and anticipate that we will need to raise substantial additional capital in order to continue our operations and achieve our business objectives. We have two effective shelf registration statements under which we have the current ability to raise up to approximately \$129.5 million in future financings, as well as our existing at-the-market, or ATM, offering and the recently announced equity line financing under which we may raise up to \$25 million through the issuance of common stock over 36 months. Any additional issuances under the ATM offering or equity line financing cannot commence until June 30, 2020. We cannot assure you that we will be able to sell shares or other securities in any offering at a price per share that is equal to or greater than the price per share paid by investors in previous offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in previous offerings. The future issuance of the Company's equity securities will further dilute the ownership of our outstanding common stock. The market price of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease and could cause you to lose some or all of your investment in our common stock.

***The exercise of our outstanding warrants will dilute stockholders and could decrease our stock price.***

The existence of our outstanding warrants, including the outstanding remaining Series B Warrants and the recently issued Series C Warrants and Series D Warrants, may adversely affect our stock price due to issuances of a large number of shares or the perception that such sales could occur. These factors also could make it more difficult to raise funds through future offerings of common stock or warrants, and could adversely impact the terms under which we could obtain additional equity capital. Exercise of outstanding warrants, or any future issuance of additional shares of common stock or other equity securities, including but not limited to options, warrants or other derivative securities convertible into our common stock, may result in significant dilution to our stockholders and may decrease our stock price.

***We issued 24,900,000 Series B Warrants in May 2017; the outstanding warrants must be revalued each reporting period. In addition, we owe contingent consideration to Sofar under the Purchase Agreement that is also revalued each reporting period. Such assessments involve the use of estimates that could later be found to differ materially from actual results.***

On April 28, 2017, we sold 24.9 million units, each consisting of approximately 0.077 shares of common stock, a Series A warrant to purchase approximately 0.077 shares of common stock, and a Series B warrant to purchase approximately 0.058 shares of common stock, at a public offering price of \$1.00 per unit for aggregate gross proceeds of \$24.9 million in an underwritten firm commitment public offering. As of December 31, 2017, all Series A warrants were exercised. The outstanding Series B Warrants contain provisions, often referred to as "down-round protection" that has led to adjustments of the exercise price and number of underlying warrant shares with respect to future issuances by the Company of its securities, including its common stock or convertible securities or debt securities. The "down-round protection" has led to and may continue to lead to additional adjustments of the exercise price and number of underlying warrant shares in the future. As of March 10, 2020, Series B Warrants to acquire 292,178 shares of common stock at an exercise price of \$0.68 per share were outstanding. In addition, the third tranche of the contingent consideration to be paid to Sofar under the Purchase Agreement remains outstanding, to be paid if the designated milestone is met.

The Series B Warrants and the contingent consideration are each recorded as a liability on our financial statements, and we are required to revalue each of the outstanding Series B Warrants and the contingent consideration at each reporting period. Such revaluations necessarily involve the use of estimates, assumptions, probabilities and application of complex accounting principles. Actual value at the time the Series B Warrants are exercised or the contingent consideration paid could vary significantly from the value assigned to such liabilities on a quarterly basis. We cannot assure you that the revaluation of the Series B Warrants and contingent consideration will equal the value in the future, and know that the actual value could be significantly different, which could have a material adverse effect on us.

***The surgical robotics industry is increasingly competitive, which can negatively impact our commercial opportunities.***

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address minimally invasive and robotic-assisted surgery, including new entrants in the competitive market. We are currently commercializing the Senhance System in the United States with FDA 510(k) clearance, in Europe which accepts a CE Mark, the Middle East and selected countries in Asia. We face significant competition in such markets. Many of our competitors, including Intuitive Surgical, have significantly greater financial, manufacturing, marketing and product development resources than we do. Some of the medical device companies we compete with or expect to compete with include Johnson & Johnson/Verb Surgical Inc., Medtronic plc, Intuitive Surgical Inc., and CMR Surgical Ltd. and a number of minimally invasive surgical device and robotic surgical device manufacturers and providers of products and therapies that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many other universities and private and

public research institutions are or may become active in research involving surgical devices for minimally invasive and robotic-assisted surgery.

We are also expanding the potential market for robotic surgical systems with our focus on laparoscopic surgery. Such expansion may lead to additional competition with companies with sufficiently higher resources than ours.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy, safety and reliability of our products;
- our ability to commercialize and market our cleared or approved products;
- the completion of our development efforts and receipt of regulatory clearance or approval for instruments and accessories to support the use of the Senhance System;
- the cost of ownership and use of our products in relation to alternative devices;
- the timing and scope of regulatory clearances or approvals, including any expansion of the indications of use for our products;
- whether our competitors substantially reduce the cost of ownership and use of an alternative device;
- our ability to protect and defend intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any cleared or approved products to the market;
- the availability of adequate coverage and reimbursement by third-party payors for the procedures in which our products are used;
- our ability to adapt to changes in the regulatory environment;
- the effectiveness of our sales and marketing efforts; and
- acceptance of future products by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than our products or future products, or that reach the market sooner than our products, we may not achieve commercial success. In addition, the medical device industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or products obsolete or less competitive.

We anticipate that the highly competitive surgical robotics environment can lead our competitors to attempt to slow or derail our commercial progress. We are using our best efforts to enter the commercial markets effectively and efficiently while maintaining compliance with all regulatory and legal requirements. Responding to the actions of our competitors will require the attention of our management and may distract the management team from its focus on our commercial operations and lead to increased costs of commercialization, which could have a negative impact on our financial position.

We also anticipate that the competitive surgical robotics environment will become more intense because of increased consolidation by companies in the health care industry looking to achieve cost reductions. Such consolidation may have an adverse effect on our business operations.

***We utilize distributors for a portion of our sales, which subjects us to a number of risks that could harm our business.***

We use distributors for sales and service of our products in certain foreign countries. If these relationships are terminated and not replaced, our revenues and/or ability to sell or service our products in the markets serviced by these distributors could be adversely affected. The actions of our distributors may affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if the distributor holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance. It may be difficult, expensive and time consuming for us to re-establish market access or regulatory compliance in such case.

***We face risks arising from sole suppliers of components and our ability to meet delivery schedules for sales of our products.***

The Senhance System is manufactured for us under contract by a third party manufacturer. We or our manufacturer acquire raw materials and components of the Senhance System from vendors, some of which are sole suppliers. Although we believe that we have the manufacturing capacity and inventory reserves to meet our anticipated Senhance System sales for the foreseeable future, we are currently taking steps to develop redundant manufacturing and supply alternatives. We cannot assure you that we will be successful in developing these redundant supply and manufacturing capabilities. If we are not successful, our business operations could suffer.

***Because our design, development and manufacturing capabilities are limited, we rely on third parties to design, develop, manufacture or supply some of our products. An inability to find additional or alternate sources for these services and products could materially and adversely affect our financial condition and results of operations.***

We have used third-party design and development sources to assist in the design and development of our medical device products. In the future, we may choose to use additional third-party sources for the design and development of our products. If these design and development partners are unable to provide their services in the timeframe or to the performance level that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the manner that we require.

Our ability to replace any then-existing manufacturer may be difficult because the number of potential manufacturers is limited and, in the case of Class III devices, the FDA must approve any replacement manufacturer before manufacturing can begin. The process of identifying and engaging new manufacturers may be time-consuming and costly. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all. This may adversely affect our product availability and, as a result, our business.

***Reliance on third parties to manufacture or supply some of our products may harm our business if such third parties do not meet regulatory and performance standards.***

Our products require precise, high quality manufacturing. We and our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with the quality systems regulations, current “good manufacturing practices” and other applicable government regulations and corresponding standards. If we or our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure by us or on the part of our design and development partners or contract manufacturers could delay product development or regulatory clearance or approval of our products, or commercialization of our products and future products, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on any third party for design, development or manufacturing could adversely affect our future profit margins.

***We sold our SurgiBot System assets in 2017, and we may not obtain the royalty income we anticipate from such sale.***

In December 2017, we transferred ownership of the SurgiBot System assets to GBIL. The agreements provide rights to the purchaser to manufacture, or have manufactured, the SurgiBot System in China, and provides exclusive distribution rights to the Chinese market. The agreement provides us with minimum royalties of \$14.0 million over a future five-year period. If the buyer is not successful in gaining Chinese regulatory approval or marketing the SurgiBot System, we will only receive such minimum royalties, decreasing the return on the funds expended in the development of the SurgiBot System.

***We had significant management changes in the fourth quarter of 2019. Such changes could divert attention from the operation of the business and create uncertainty.***

Joseph P. Slattery, our former chief financial officer, retired on December 31, 2019. In January 2020 we hired Brett Farabaugh as our interim Chief Financial Officer. A search is in process for a new chief financial officer but we may have difficulty recruiting a new chief financial officer with the current issues facing the Company.

On November 8, 2019, we announced the departure of Todd M. Pope as our president and chief executive officer, and as a member of our Board of Directors, and announced the appointment of Anthony Fernando as president and chief executive officer and his election to the Board of Directors. Any such significant management changes can divert focus away from the operation of the business and could create uncertainty in our personnel. We cannot assure you that the change in senior leadership will not have an adverse impact on the Company and its financial condition.

***We identified a material weakness in our internal control over financial reporting related to our preparation, documentation and review of the income tax provision in accordance with GAAP. We may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations.***

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2019, we identified a material weakness in our internal control over financial reporting related to our income tax provision and related accounting and disclosures. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2019, we did not maintain effective controls relating to the income tax accounting and disclosures for the significant components of deferred tax assets and liabilities related to a foreign non-recurring transaction.

Based on this finding, management is implementing a remediation plan to address the control deficiency that led to the material weakness. The remediation plan includes implementing specific review procedures, including strengthening our income tax control with improved documentation standards, technical oversight and training.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we are unable to successfully remediate our existing or any future material weakness in our internal control over financial reporting, or identify any additional material weaknesses that may exist, the accuracy and timing of our financial reporting may be adversely affected. Additionally, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports as well as applicable stock exchange listing requirements. We may be unable to prevent fraud, investors may lose confidence in our financial reporting, and our stock price may also decline. Our reporting obligations as a public company could place a significant strain on our management, operational and financial resources and systems for the foreseeable future and may cause us to fail to timely achieve and maintain the adequacy of our internal control over financial reporting.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate. Because of its inherent limitations, internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. As a result, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. We cannot assure you that the measures we are currently undertaking or may take in the future will be sufficient to maintain effective internal controls or to avoid potential future deficiencies in internal control, including material weaknesses. In addition, failing to maintain effective disclosure controls and internal controls over financial reporting could have a material and adverse effect on our business and operating results and could cause a decline in the price of our securities.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts, any of which could materially adversely affect our liquidity, business prospects and results of operations.

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third-party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***For our Senhance System, we rely on our license from the European Union, and any loss of our rights under such license agreement, or failure to properly prosecute, maintain or enforce the patent applications underlying such license agreement, could materially adversely affect our business prospects for the Senhance System.***

Some of the patents and patent applications in our patent portfolio related to the Senhance System are licensed to TransEnterix Italia under a license agreement with the European Union. Presently, we rely on such licensed technology for our Senhance System products and may license additional technology from the European Union or other third parties in the future. The EU license agreement gives us rights for the commercial exploitation of the licensed patents, patent applications and know-how, subject to certain provisions of the license agreement. Failure to comply with these provisions could result in the loss of our rights under the EU license agreement. Our inability to rely on these patents and patent applications which are the basis of certain aspects of our Senhance System technology would have an adverse effect on our business.

Further, our success will depend in part on the ability of us, the European Union and other third-party licensors to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights. We, the European Union or other third-party licensors may not successfully prosecute the patent applications which are licensed to us, may fail to maintain these patents, and may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than necessary to obtain an acceptable outcome from any such litigation. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could materially adversely affect our competitive business position, business prospects and results of operations.

***If we or our licensors are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

***If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.***

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. Because certain U.S. patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not



available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

Our strategy depends on our ability to promptly identify and seek patent protection for our discoveries. In addition, we may rely on third-party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time-consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to develop and use information that we regard as proprietary.

The issuance of a patent provides a presumption, but does not guarantee that it is valid. Any patents we have obtained, or obtain in the future, may be challenged or potentially circumvented. Moreover, the United States Patent and Trademark Office, or the USPTO, may commence interference proceedings involving our patents or patent applications. Any such challenge to our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, future court decisions may introduce uncertainty in the enforceability or scope of any patent, including those owned by medical device companies.

Our pending patent applications may not result in issued patents. The patent position of medical device companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties.

We cannot assure you that any patents that will issue, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our products, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our future products.

***Even if we obtain regulatory clearances or approvals for our products, the terms thereof and ongoing regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate anticipated revenues.***

Once regulatory clearance or approval has been granted, the cleared or approved product and its manufacturer are subject to continual review. Any cleared or approved product may be promoted only for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities clear or approve any of our products, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We and any outsourced manufacturers of our products are also required to comply with the FDA's QSR, or similar requirements of non-U.S. regulatory authorities which includes requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation as well as other quality system requirements and regulations from non-U.S. regulatory authorities. Further, regulatory agencies must approve our manufacturing facilities for Class III devices before they can be used to manufacture our products, and all manufacturing facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA, either before or after clearance or approval, or other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters, non-warning letters incorporating inspectional observations, or consent decrees;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;

- suspension or withdrawal of regulatory clearances or approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- refusal to clear or approve pending applications or premarket notifications; and
- import and export restrictions.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, the FDA and other non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory clearance or approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future products and we may not achieve or sustain profitability.

***We may be liable if the FDA or another regulatory agency concludes that we have engaged in the off-label promotion of our products.***

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of the Senhance System and our other products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, sales practices or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although we train our marketing and direct sales force to not promote our products for uses outside of their cleared uses and our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

***The regulatory approval and clearance processes are expensive, time-consuming and uncertain and may prevent us from obtaining approvals or clearances, as the case may be, for the commercialization of some or all of our products.***

Regulatory approval of a PMA or PMA, or supplement or clearance pursuant to a 510(k) premarket notification, or granting of a de novo request is not guaranteed, and the approval or clearance process, as the case may be, is expensive, uncertain and may, especially in the case of the PMA application, take several years. The FDA also has substantial discretion in the medical device clearance process or approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to repeat or perform additional development, standardized testing, pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA clearance or approval varies depending on the medical device candidate, the disease or condition that the medical device candidate is designed to address, and the regulations applicable to any particular medical device candidate. The FDA or other non-U.S. regulatory authorities can delay, limit or deny clearance or approval of a medical device candidate for many reasons, including:

- a medical device candidate may not be deemed to provide a reasonable assurance of safety or effectiveness, in the case of a PMA application;
- a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed predicate device through the 510(k) premarket notification process;
- a medical device candidate may not be deemed to be in conformance with applicable standards and regulations;
- FDA or other regulatory officials may not find the data from pre-clinical studies and clinical trials sufficient;
- FDA may not approve our processes or facilities or those of any of our third-party manufacturers for a Class III PMA device;

- other non-U.S. regulatory authorities may not approve our processes or facilities or those of any of our third-party manufacturers, thereby restricting export; or
- FDA or other non-U.S. regulatory authorities may change clearance or approval policies or adopt new regulations.

The laws governing the regulatory approval or clearance pathways in jurisdictions outside of the United States are complex. We need to ensure that our activities, and the activities of our distributors and agents, comply with such laws. If we do not comply with such laws, we may not be able to sell our products, including the Senhance System, in all jurisdictions we have targeted, which could have an adverse effect on our business operations and financial condition.

***Once our products are cleared or approved, modifications to our products may require new 510(k) clearances, de novo clearance, premarket approvals or new or amended CE Certificates of Conformity, and may require us to cease marketing or recall the modified products until clearances, approvals or the relevant CE Certificates of Conformity are obtained.***

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use requires a new 510(k) clearance or, possibly, a PMA or de novo clearance. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review such determinations. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA disagrees with our determinations for any future changes, or prior changes to previously marketed products, as the case may be, we may be required to cease marketing or to recall the modified products until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. In October 2017, the FDA issued guidance documents addressing when to submit a new 510(k) due to modifications to 510(k) cleared products and the criteria for evaluating substantial equivalence. The interpretation of the guidance documents by the FDA staff could lead to instances where the FDA disagrees with the Company's decision regarding a change, and could result in warning letters and other enforcement actions.

***Even after clearance or approval for our products is obtained, we are subject to extensive post-market regulation by the FDA and other regulators. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.***

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market studies. These studies can be very expensive and time-consuming to conduct. Failure to complete such studies in a timely manner could result in the revocation of clearance or approval and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States. The FDA has broad enforcement powers, and any regulatory enforcement actions or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

We are also required to comply with the FDA's QSR, which covers the methods used in, and the facilities and controls used for, the design, manufacture, quality assurance, labeling, packaging, sterilization, storage, shipping, installation and servicing of our marketed products. The FDA enforces the QSR through periodic announced and unannounced inspections of manufacturing facilities. In addition, in the future, regulatory authorities and/or customers may require specific packaging of sterile products, which could increase our costs and the price of our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In Europe, the advertising and promotion of our products is subject to the MDD, as well as other European Economic Area, or EEA, Member State legislation governing the advertising and promotion of medical devices. The MDR, which will replace the MDD in May 2020 after a three-year transition period, will impose significant additional premarket and post-market certification requirements on medical devices marketed in the EU. EEA Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare providers harming our business, operating results and financial condition. If we are unable to obtain

timely, updated post-market certifications for our products under the MDR, or experience difficulty scheduling with a Notified Body, our business prospects in the EU could be materially adversely affected, which could have a material adverse effect on our financial results.

***If one of our products, or a malfunction of one of our products, causes or contributes to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to the FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations.

All manufacturers bringing medical devices to market in the EEA are legally bound to report any incident that led or might have led to the death or serious deterioration in the state of health of a patient, user or other person, and which the manufacturer's device is suspected to be a contributory cause, to the competent authority in whose jurisdiction the incident occurred. In such case, the manufacturer must file an initial report with the relevant competent authority, which would be followed by further evaluation or investigation of the incident and a final report indicating whether further action is required. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

***A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.***

The FDA and similar foreign governmental authorities such as the competent authorities of the EEA countries have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues.

Any future recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

***U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.***

Legislative changes could significantly alter the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products. In addition, FDA regulations and guidance could be revised or reinterpreted by the FDA in ways that could significantly affect our business and our products. Any new regulations or revisions, or reinterpretations of existing regulations, may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be.

***Even if we receive regulatory clearance or approval to market our products, the market may not be receptive to our products, which could undermine our financial viability.***

Even if our products obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. We have experienced minimal sales of our Senhance System, to date. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;

- safety and efficacy of our products;
- physician training in the use of our products;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support; and
- price of our future products, both in absolute terms and relative to alternative treatments.

If applicable, availability of coverage and reimbursement from government and other third-party payors can also impact the acceptance of our product offerings.

***If we fail to attract and retain key management and professional personnel, we may be unable to successfully commercialize or develop our products.***

We will need to effectively manage our operational, sales and marketing, development and other resources in order to successfully pursue our commercialization and research and development efforts for our existing and future products. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel. If we are not successful in retaining and recruiting highly qualified personnel, our business may be harmed as a result.

***We may be subject, directly or indirectly, to federal and state anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Our business activities are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician payment transparency laws. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

***Current legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.***

In the United States, there have been, and we expect there to continue to be, a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. While many of the proposed policy changes require congressional approval to implement, we cannot assure you that reimbursement payments under governmental and private third-party payor programs to health care providers will remain at levels comparable to present levels or will be sufficient to cover the costs allocable to patients eligible for reimbursement under these programs. Any changes that lower reimbursement rates under Medicare, Medicaid or private payor programs could negatively affect our business.

To the extent that any of our products are deemed to be durable medical equipment, or DME, they may be subject to distribution under Medicare's Competitive Acquisition regulations, which could adversely affect the amount that we can seek from payors. Non-DME devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage as hospitals and health care providers attempt to negotiate lower prices for products such as the ones we develop and sell.

With the continued uncertainty regarding the status of the 2010 Health Care Reform Legislation, at this time, the Company is not certain as to the impact of federal health care legislation on its business.

Further, the 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires certain manufacturers of certain drugs, biologics, and devices that are reimbursed by Medicare, Medicaid and the Children's Health Insurance Program to report annually certain payments or "transfers of value" provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. We provided reports under

the Open Payments Act to the Centers for Medicare & Medicaid Services, or CMS. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation.

We are unable to predict what additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. Any cost containment measures or other health care system reforms that are adopted could have a material and adverse effect on our ability to commercialize our existing and future products successfully.

***We may become subject to potential product liability claims, and we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the design, testing, manufacture, sale and distribution of our products and each of our product candidates that we are seeking to introduce to the market. Surgical medical devices involve significant risks of serious complications, including bleeding, nerve injury, paralysis, infection, and even death. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or in our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damages award, we may have to pay the excess of this award out of our cash reserves, which could significantly harm our financial condition. If longer-term patient results and experience indicate that our products or any component of a product causes tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. A product liability claim, even one without merit, could harm our reputation in the industry, lead to significant legal fees, and result in the diversion of management's attention from managing our business.

***If we experience an intrusion of or disruption to our information technology systems, we may be harmed.***

We rely on sophisticated information technology systems to operate our business. Our systems are subject to cyber-attacks, viruses, worms, malicious software programs, outages, equipment malfunction or constraints, software deficiencies, human error and other malicious intrusions, which may materially disrupt our business and compromise our data. We may not be able to anticipate and prevent such disruptions or intrusions, and we may not be able to mitigate them when and if they occur. Our ability to effectively operate our business and comply with applicable laws and regulations may be materially impaired by any such disruption or intrusion. Furthermore, we may incur significant costs in responding to any such disruption or intrusion and remedying our systems. In such event we may also be subject to litigation and other potential liability, which could materially impact our business and financial condition. Moreover, a breach or disruption of our information technology systems could damage our reputation.

#### **ITEM 1.B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our principal corporate office is located at 635 Davis Drive, Suite 300, Morrisville, North Carolina. We lease this facility, which consists of 37,328 square feet. In June 2019, the Company entered into a lease amendment extending the term of the lease for a period of twelve months commencing on January 1, 2020 and expiring on December 31, 2020, with no remaining renew rights or options to extend the term of the lease.

Our Italian research and development and demonstration facilities are located at Viale dell'Innovazione 3, 20126 Milan, Italy. We lease these facilities, which consist of 11,273 square feet, for a six-year term ending on July 31, 2022, under a lease that commenced on May 12, 2016.

Our Israeli research and development facilities are located at Ha-Tsmikha Street 1, Yokne'am Illit, Israel. We lease these facilities, which consist of 5,597 square feet, for a five-year term ending on April 14, 2024, under a lease that commenced on April 15, 2019.

Our Japanese office is located at 1-3-5 Kojimachi Chiyoda-ku, Mikuni Building, 5th Floor, Tokyo, Japan. We lease this facility, which consists of 737 square feet, for a five-year term ending on April 24, 2023, under a lease that commenced on April 25, 2018.

Our Swiss administrative office is located at Via Serafino Balestra 12, Lugano, Switzerland. We lease this facility, which consists of 3,208 square feet, for a five-year term ending on June 30, 2023, under a lease that commenced on July 1, 2018.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Since April 2, 2014, our common stock has been listed on the NYSE American. Our trading symbol is "TRXC."

As of March 12, 2020, there were approximately 64 record holders of our common stock (counting all shares held in single nominee registration as one stockholder) and 1 record holder of our preferred stock.

**Sales of Equity Securities and Use of Proceeds.**

The Company did not re-purchase any of its common stock during the quarter ended December 31, 2019.

**ITEM 6. SELECTED FINANCIAL DATA**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.



## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with our "Risk Factors" and our consolidated financial statements and the related notes to our consolidated financial statements included in this Annual Report. The following discussion contains forward-looking statements. See cautionary note regarding "Forward-Looking Statements" at the beginning of this Annual Report.*

### Overview

TransEnterix is a medical device company that is digitizing the interface between the surgeon and the patient in laparoscopy to increase control and reduce surgical variability in today's value-based healthcare environment. The Company is focused on the market development for and commercialization of the Senhance® Surgical System, which digitizes laparoscopic minimally invasive surgery, or MIS. The Senhance System is the first and only digital, multi-port laparoscopic platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including 3 millimeter microlaparoscopic instruments, eye-sensing camera control and reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy.

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan and select other countries.

- The Senhance System has a CE Mark in Europe for adult and pediatric laparoscopic abdominal and pelvic surgery, as well as limited thoracic surgeries excluding cardiac and vascular surgery.
- In the United States, the Company has received 510(k) clearance from the FDA for use of the Senhance System in laparoscopic colorectal and gynecologic surgery in a total of 28 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, the Company has received regulatory approval and reimbursement for 98 laparoscopic procedures.

During 2018 and 2019, we successfully obtained FDA clearance and CE Mark for our 3 millimeter diameter instruments, our Senhance ultrasonic system, our 3 millimeter and 5 millimeter hooks, and the Senhance articulating system. The 3 millimeter instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. The ultrasonic system is an advanced energy device used to deliver controlled energy to ligate and divide tissue, while minimizing thermal injury to surrounding structures. The Senhance articulating system was launched in Europe in November 2019 and we are evaluating our pathway forward to launch such a system in the United States with a planned submission for US clearance at the end of 2020.

In January 2020, we submitted an application to the FDA seeking clearance of the first machine vision system for robotic surgery (Intelligent Surgical Unit). The Company believes it is the first such FDA submission seeking clearance for machine vision technology in abdominal robotic surgery. On March 13, 2020, the Company announced that it has received FDA clearance for the Intelligent Surgical Unit.

In February 2020, we received CE Mark for the Senhance System and related instruments for pediatric use indications in CE Mark territories.

On October 17, 2019, the Company announced that it has engaged J.P. Morgan Securities LLC to assist the Board of Directors in considering strategic alternatives for the Company to enhance stockholder value, including, but not limited to a sale of the Company, a financing of the Company, a strategic partnership or collaboration or some other form of commercial relationship. In addition, the Company announced the implementation of a restructuring plan to reduce operating expenses as it continues the global market development of the Senhance platform.

On October 31, 2018, the Company acquired the assets, intellectual property and highly experienced multidisciplinary personnel of MST Medical Surgical Technologies, Inc., or MST, an Israeli-based medical device company. Through this acquisition, the Company acquired MST's AutoLap™ technology, one of the only image-guided robotic scope positioning systems with FDA clearance and CE Mark. The Company believes MST's image analytics technology will accelerate and drive meaningful Senhance System developments, and allow it to expand the Senhance System to add augmented, intelligent vision capability. On October 15, 2019, the Company announced the sale of certain AutoLap assets, as discussed in the "Sale of AutoLap Assets" section below.

The Company has also developed the SurgiBot System, a single-port, robotically enhanced laparoscopic surgical platform. In December 2017, the Company entered into an agreement with Great Belief International Limited, or GBIL, to advance the SurgiBot System towards global commercialization. The agreement transferred ownership of the SurgiBot System assets, while the Company retained the option to distribute or co-distribute the SurgiBot System outside of China. GBIL intends to have the SurgiBot System

manufactured in China and obtain Chinese regulatory clearance from the China Food and Drug Administration while entering into a nationwide distribution agreement with China National Scientific and Instruments and Materials Company for the Chinese market. The agreement provides the Company with proceeds of at least \$29 million, of which \$15 million has been received to date. The remaining \$14.0 million, representing minimum royalties, will be paid beginning at the earlier of receipt of Chinese regulatory approval or March 2023.

The Company believes that future outcomes of minimally invasive laparoscopic surgery will be enhanced through its combination of more advanced tools and robotic functionality, which are designed to: (i) empower surgeons with improved precision, dexterity and visualization; (ii) improve patient satisfaction and enable a desirable post-operative recovery; and (iii) provide a cost-effective robotic system, compared to existing alternatives today, for a wide range of clinical indications.

From our inception, we devoted a substantial percentage of our resources to research and development and start-up activities, consisting primarily of product design and development, clinical studies, manufacturing, recruiting qualified personnel and raising capital. We expect to continue to invest in research and development and market development as we implement our strategy.

Since inception, we have been unprofitable. As of December 31, 2019, we had an accumulated deficit of \$663.6 million.

Due to a decline in market conditions and changes in our forecast, the Company tested its goodwill and in-process research & development, or IPR&D, for potential impairment as of September 30, 2019. During the third quarter of 2019, the Company determined that the carrying value of both its goodwill and IPR&D were impaired, and recorded impairment charges of \$79.0 million and \$7.9 million, respectively.

We operate in one business segment.

On December 11, 2019, following receipt of approval from stockholders at a special meeting of stockholders held on the same day, the Company filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock at a ratio of one-for-thirteen, or the Reverse Stock Split. The Company's common stock began trading on a split-adjusted basis on NYSE American on the morning of December 12, 2019. No fractional shares were issued in connection with the Reverse Stock Split. Instead, the Company rounded up each fractional share resulting from the reverse stock split to the nearest whole share. As a result of the Reverse Stock Split, the Company's outstanding common stock decreased from approximately 261.9 million shares to approximately 20.2 million shares (without giving effect to the rounding up for each fractional share).

Unless otherwise noted, all share and per share data referenced in this Annual Report have been retroactively adjusted to reflect the Reverse Stock Split. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Annual Report, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

## **Restructuring**

Despite the number of advances and regulatory clearances received in 2018 and 2019, the Company's Senhance System sales in 2019 were disappointing. Adoption of new technologies, particularly for capital intensive devices such as the Senhance System can be slow and uneven as market development and commercial development is time-consuming and expensive. The Company has determined to refocus its resources and efforts in 2020 on market development activities to increase awareness of:

- the benefits of the use of the Senhance System in laparoscopic surgery;
- the digitization of high volume procedures using the Senhance System;
- the indications for use, including pediatric indications of use in CE Mark territories;
- the overall cost efficiency of the Senhance System

We intend to focus on markets with high utilization of laparoscopic technique, including Japan, Western Europe and the United States. Our focus will be on (1) increasing the number of placements of the Senhance System, not necessarily through sales, but through leasing arrangements, (2) increasing the number of procedures conducted using the Senhance System quarter over quarter, and (3) solidifying key opinion leader support and publications related to the use of the Senhance System in laparoscopic procedures. During this period we will not focus on revenue targets, especially in the United States.

During the fourth quarter of 2019, we announced the implementation of a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. Under the restructuring plan, we reduced headcount primarily in the sales and marketing functions and determined that the carrying value of our inventory exceeded the net realizable value due

to a decrease in expected sales. The restructuring charges amounted to \$8.8 million, of which \$7.4 million was an inventory write down and was included in cost of product revenue and \$1.4 million related to employee severance costs and was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, during the fourth quarter of 2019. Future payments under the restructuring plan are expected to conclude in 2020.

During March 2020, we continued our restructuring with additional headcount reductions which resulted in \$0.8 million related to severance costs which are expected to be paid in 2020 and 2021.

## **Debt Transactions**

On May 23, 2018, the Company and its domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement, or the Hercules Loan Agreement, with several banks and other financial institutions or entities from time to time party to the Loan Agreement, or collectively, the Lender, and Hercules Capital, Inc., as administrative agent and collateral agent, or the Agent. Under the Hercules Loan Agreement, the Lender agreed to make certain term loans to the Company in the aggregate principal amount of up to \$40.0 million. Funding of the first \$20.0 million tranche occurred on May 23, 2018, or the Initial Funding Date. On October 23, 2018, the Lender funded the second tranche of \$10.0 million under the Hercules Loan Agreement. The Company was entitled to make interest-only payments until December 1, 2020, and at the end of the interest-only period, the Company would have been required to repay the term loans over an eighteen-month period based on an eighteen-month amortization schedule, with a final maturity date of June 1, 2022. The term loans were required to be repaid if the term loans are accelerated following an event of default.

On May 7, 2019, the parties executed an amendment to the Hercules Loan Agreement, or the Hercules Amendment, effective April 30, 2019, under which the Hercules Loan Agreement was amended to eliminate the availability of the Tranche III loan facility, add a new Tranche IV loan facility of up to \$20.0 million, revise certain financial covenants and make other changes. The availability of advances under the Tranche IV Loan was not milestone-based, rather the Company could request advances in minimum \$5.0 million increments at any time during the period from July 1, 2019 through December 31, 2020, subject to the funding discretion of the Lender. The monthly trailing six month net revenue financial covenant was amended to be tested quarterly and to change the projected net revenue percentage to be met for the six months ending on the last day of each fiscal quarter. If such quarterly financial covenant was not achieved as of the last day of any fiscal quarter, as tested on the thirtieth day after quarter end, the Company must have complied with the waiver conditions in the Hercules Amendment from such test date until the next quarterly test date. The Amendment was treated as a debt modification for accounting purposes.

In connection with the entry into an agreement to sell certain AutoLap assets, the Company commenced discussions with the Agent in order to obtain the required consent of the Agent and the Lender with respect to such AutoLap assets sale. In connection with obtaining such consent, the Company entered into the Consent and Second Amendment to the Loan and Security Agreement on July 10, 2019, or the Hercules Second Amendment. Under the Hercules Second Amendment, in consideration for the consent to the sale of, and the release of the Lender's security interest on, the AutoLap assets, the Company reduced its indebtedness under the Hercules Loan Agreement by repaying \$15.0 million of the \$30.0 million of outstanding indebtedness thereunder, without any prepayment penalties, amendment fee or acceleration of the end of term charges, and received adjustments to the quarterly financial covenants and related waiver conditions to reflect the decreased outstanding indebtedness. The Amendment was treated as a debt modification for accounting purposes.

Under the Hercules Second Amendment, the applicable waiver condition for fiscal year 2019 was changed to maintenance of unrestricted cash equal to \$7.0 million.

The term loans bore interest at a rate equal to the greater of (i) 9.55% per annum, or the Fixed Rate, and (ii) the Fixed Rate plus the prime rate (as reported in The Wall Street Journal) minus 5.00%. On the Initial Funding Date, the Company was obligated to pay a facility fee of \$0.4 million, recorded as a debt discount. The Company also incurred other debt issuance costs totaling \$1.1 million in conjunction with its entry into the Hercules Loan Agreement. In addition, the Company was permitted to prepay the term loans in full at any time, with a prepayment fee of 3.0% of the outstanding principal amount of the loan in the first year after the Initial Funding Date, 2.0% if the prepayment occurred in the second year after the Initial Funding Date and 1.0% thereafter. Upon prepayment of the term loans in full or repayment of the term loans at the maturity date or upon acceleration, the Company was required to pay a final fee of 6.95% of the aggregate principal amount of term loans funded. The final payment fee was accreted to interest expense over the life of the term loan and included within notes payable on the consolidated balance sheet.

The Company's obligations under the Hercules Loan Agreement were guaranteed by all current and future material foreign subsidiaries of the Company and were secured by a security interest in all of the assets of the Company and their current and future domestic subsidiaries and all of the assets of their current and future material foreign subsidiaries, including a security interest in the intellectual property. The Hercules Loan Agreement contained customary representations and covenants that, subject to

exceptions, restricted the Company's and its subsidiaries' ability to do the following, among other things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that were not related to its existing business. Under the terms of the Hercules Loan Agreement, the Company was required to maintain cash and/or investment property in accounts which perfected the Agent's first priority security interest in such accounts in an amount equal to the lesser of (i) (x) 120% of the then-outstanding principal balance of the term loans, including accrued interest and any other fees payable under the agreement to the extent accrued and payable plus (y) an amount equal to the then-outstanding accounts payable of the Company on a consolidated basis that were more than 90 days past due and (ii) 80% of the aggregate cash of the Company and its consolidated subsidiaries. The Agent was granted the option to invest up to \$2.0 million in any future equity offering broadly marketed by the Company to investors on the same terms as the offering to other investors.

On November 4, 2019, the Company entered into a payoff letter with the Agent pursuant to which the Company terminated the Hercules Loan Agreement, as amended. The Company determined it was in the best interests of the Company to pay down the debt and terminate the Hercules Agreement to simplify the Company's balance sheet and provide additional flexibility as the Board of Directors continued to evaluate strategic and financial alternatives for the Company. Under the payoff letter, the Company repaid all amounts owed under the Hercules Loan Agreement totaling approximately \$16.4 million, which included end of term fees of \$1.4 million, and Hercules released all security interests held on the assets of the Company and its subsidiaries, including, without limitation, on the intellectual property assets of the Company. The Company recognized a loss of \$1.0 million on the extinguishment of notes payable, which is included in interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

In connection with its entrance into the Hercules Loan Agreement in 2018, the Company repaid its existing loan and security agreement, or the Innovatus Loan Agreement, with Innovatus Life Sciences Lending Fund I, LP, or Innovatus. The Company recognized a loss of \$1.4 million on the extinguishment of notes payable which was included in interest expense on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2018. The Company paid \$0.7 million in final payment obligations and \$0.3 million in prepayment fees under the Innovatus Loan Agreement upon repayment. For a description of the Innovatus Loan Agreement, see "Notes to Consolidated Financial Statements – Note 13. Notes Payable."

## **Financing Transactions**

### **May 2017 Public Offering**

On April 28, 2017, we entered into an underwriting agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, relating to an underwritten public offering of an aggregate of 24.9 million Units, each consisting of approximately 0.077 shares of the Company's Common Stock, a Series A Warrant to purchase approximately 0.077 shares of Common Stock and a Series B Warrant to purchase approximately 0.058 shares of Common Stock at an offering price to the public of \$1.00 per Unit. Certain of the Company's officers, directors and existing stockholders purchased approximately \$2.5 million of Units in the public offering. The closing of the public offering occurred on May 3, 2017. The net proceeds to the Company from the offering were approximately \$23.2 million, prior to any exercise of the Series A Warrants or Series B Warrants, after deducting underwriting discounts and commissions and estimated offering expenses paid by the Company. The net proceeds to the Company from the exercise of all of the Series A Warrants and the Series B Warrants exercised prior to December 31, 2019 were approximately \$37.6 million.

Each Series A Warrant had an initial exercise price of \$13.00 per share and was able to be exercised at any time beginning on the date of issuance, and from time to time thereafter, through and including the first anniversary of the issuance date, unless terminated earlier as provided in the Series A Warrant. Receipt of 510(k) clearance for the Senhance System on October 13, 2017, triggered the acceleration of the expiration date of the Series A Warrants to October 31, 2017. As of December 31, 2017, all of the Series A Warrants had been exercised.

Each Series B Warrant had an initial exercise price of \$13.00 per share and may be exercised at any time beginning on the date of issuance and from time to time thereafter through and including the fifth anniversary of the issuance date, or by May 3, 2022. As of December 31, 2019, Series B Warrants representing approximately 1.2 million shares had been exercised.

The exercise prices and the number of shares issuable upon exercise of the outstanding Series B Warrants are subject to adjustment upon the occurrence of certain events, including, but not limited to, stock splits or dividends, business combinations, sale of assets, similar recapitalization transactions, or other similar transactions. The Series B Warrants are subject to adjustment in the event that the Company issues or is deemed to issue shares of common stock for less than the then applicable exercise price of the Series B Warrants. Such adjustments occurred in August, September, November, and December 2019 due to sales under the 2019 Sales Agreement and the Underwriting Agreement at prices less than the then applicable exercise price of the Series B Warrants. See "Notes to Consolidated Financial Statements - Note 16 Warrants." The exercisability of the Series B Warrants may be limited if,

upon exercise, the holder or any of its affiliates would beneficially own more than 4.99% of our common stock. If, at any time Series B Warrants are outstanding, any fundamental transaction occurs, as described in the Series B Warrants and generally including any consolidation or merger into another corporation, the consummation of a transaction whereby another entity acquires more than 50% of the Company's outstanding voting stock, or the sale of all or substantially all of its assets, the successor entity must assume in writing all of the obligations to the Series B Warrant holders. Additionally, in the event of a fundamental transaction, each Series B Warrant holder will have the right to require the Company, or its successor, to repurchase the Series B Warrants for an amount of cash equal to the Black-Scholes value of the remaining unexercised portion of such Series B Warrants.

On December 15, 2017, we filed a registration statement on Form S-3 (File No. 333-222103) to register shares of common stock underlying outstanding Series B Warrants previously issued as part of the Company's May 3, 2017 public offering. The new registration statement replaced the registration statement on Form S-3 that expired on December 19, 2017 with respect to these securities. On January 26, 2018, we filed an Amendment No. 1 to such registration statement on Form S-3 to update the information in the registration statement. The registration statement covers up to 736,914 shares of common stock underlying the then-outstanding Series B Warrants. This registration statement on Form S-3 was declared effective on January 29, 2018. On February 7, 2020, we filed a new registration statement (File No. 333-236337) to register 2,500,000 additional shares of common stock to cover the "down-round protection" adjustments made to the Series B Warrant Shares pursuant to sale prices below the then-current exercise price. This registration statement on Form S-3 was declared effective on February 13, 2020.

On February 24, 2020, the Company entered into a Series B Warrants Exchange Agreement, or the Exchange Agreement, with holders of Series B Warrants. Under the terms of the Exchange Agreement, each Series B Warrant was canceled in exchange for 0.61 of a share of common stock. The Warrant holders participating in the exchange held 3,373,900 of the 3,638,780 Series B Warrants then outstanding, and received an aggregate of 2,040,757 shares of common stock, leaving 264,880 Series B Warrants outstanding to acquire 160,226 shares of common stock.

### **Lincoln Park Purchase Agreement**

On February 10, 2020, we entered into a purchase agreement, or the LPC 2020 Purchase Agreement, with Lincoln Park, pursuant to which we have the right to sell to Lincoln Park up to an aggregate of \$25,000,000 in shares of our common stock, subject to certain limitations and conditions set forth in the LPC 2020 Purchase Agreement, including a limitation on the

number of shares of common stock we can put to LPC and the pricing parameters for the sales. In consideration for entering into the LPC 2020 Purchase Agreement, we issued to Lincoln Park 343,171 shares of Common Stock as commitment shares. We also committed to issue up to an additional 171,585 shares of Common Stock to Lincoln Park on a pro rata basis based on the number of shares Common Stock purchased by Lincoln Park pursuant to the LPC 2020 Purchase Agreement.

### **At-the-Market Offerings**

On December 28, 2018, we entered into an At-the-Market Equity Offering Sales Agreement, or the 2018 Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which we could offer and sell, through Stifel, up to approximately \$75.0 million in shares of common stock in an at-the-market offering, or the 2018 ATM Offering. All sales of shares were to be made pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. Stifel would have received a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2018 Sales Agreement. Effective August 12, 2019, the Company terminated the 2018 Sales Agreement. The Company sold no shares of its common stock under the 2018 Sales Agreement.

On August 12, 2019, the Company entered into a Controlled Equity Offering Sales Agreement, or the 2019 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which the Company may sell from time to time, at its option, up to an aggregate of \$25.0 million shares of the Company's common stock, through Cantor, as sales agent, or the 2019 ATM Offering. Pursuant to the 2019 Sales Agreement, sales of the common stock were made under the Company's previously filed and currently effective Registration Statement on Form S-3. The aggregate compensation payable to Cantor was 3.0% of the aggregate gross proceeds from each sale of the Company's common stock. The Company raised gross proceeds of \$7.2 million under the 2019 ATM Offering and net proceeds of \$7.0 million during the year ended December 31, 2019, and an additional \$11.6 million of gross proceeds and \$11.2 million of net proceeds to date in 2020.

On September 4, 2019, the Company entered into an Underwriting Agreement, or the Underwriting Agreement, with Cantor. Subject to the terms and conditions of the 2019 Underwriting Agreement, the Company sold to Cantor, in a firm commitment underwritten offering, 2,153,846 shares of the Company's common stock, or the Firm Commitment Offering. In addition, the Company granted Cantor a 30-day option to purchase 323,077 of additional shares of common stock. The Company raised \$18.8 million in gross proceeds under this offering. The option to purchase additional shares of common stock was not exercised.

The following table summarizes the total sales under the 2019 ATM Offering and Firm Commitment Offering for the period indicated (in thousands except for share and per share amounts):

|                                   | 2019<br>ATM Offering<br>For the year ended<br>December 31, 2019 | Firm Commitment<br>Offering<br>For the year ended<br>December 31, 2019 | Total<br>December 31, 2019 |
|-----------------------------------|---|--|----------------------------|
| Total shares of common stock sold | 1,374,686   | 2,153,846  | 3,528,532                  |
| Average price per share           | \$ 5.23   | \$ 8.73  | \$ 7.37                    |
| Gross proceeds                    | \$ 7,193  | \$ 18,796  | \$ 25,989                  |
| Commissions earned by Cantor      | \$ 212  | \$ —   | \$ 212                     |
| Net Proceeds                      | \$ 6,981  | \$ 18,796  | \$ 25,777                  |

Since January 1, 2020, the Company has raised, under the 2019 ATM Offering, net proceeds of \$11.2 million through the sale of 6,687,846 shares of common stock.

### 2020 Public Offering

On March 10, 2020, the Company closed an underwritten public offering (the "2020 Public Offering") with Ladenburg Thalmann & Co. Inc. as underwriter and sold an aggregate of 14,121,766 Class A Units at a public offering price of \$0.68 per Class A Unit and 7,937,057 Class B Units at a public offering price of \$0.68 per Class B Unit. Each Class A Unit consists of one share of the Company's common stock, one warrant to purchase one share of common stock that expires on the first anniversary of the date of issuance (the "Series C Warrants"), and one warrant to purchase one share of common stock that expires on the fifth anniversary of the date of issuance (the "Series D Warrants"). Each Class B Unit consists of one share of Series A Convertible Preferred Stock, par value \$0.01 per share (the "Series A Preferred Stock"), convertible into one share of common stock, a Series C Warrant to purchase one share of common stock and a Series D Warrant to purchase one share of common stock. The Class A Units and Class B Units have no stand-alone rights and were not certificated or issued as stand-alone securities. The shares of common stock, Series A Preferred Stock, Series C Warrants and Series D Warrants are immediately separable. In addition, the underwriter for the public offering exercised an overallotment option allowing it to purchase 3,308,823 additional Series C Warrants and 3,308,823 additional Series D Warrants at the closing.

Each Series C Warrant included in the Units has an exercise price of \$0.68 per share, and each Series D Warrant included in the Units has an exercise price of \$0.68 per share. The Series C Warrants and the Series D Warrants are exercisable at any time on or after the date of issuance until their respective expiration dates.

The exercise prices and the number of shares issuable upon exercise of each of the Series C Warrants and Series D Warrants are subject to adjustment upon the occurrence of stock splits or dividends, business combinations, similar recapitalization transactions, or other similar transactions. The exercisability of the Series C Warrants and Series D Warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.99% of the Common Stock. If, at any time Series C Warrants or Series D Warrants are outstanding, any fundamental transaction occurs, as described in the Warrants and generally including any consolidation or merger into another corporation, the consummation of a transaction whereby another entity acquires more than 50% of the Company's outstanding voting stock, or the sale of all or substantially all of its assets, the successor entity must assume in writing all of the obligations to the holders of the Series C Warrants and Series D Warrants. Additionally, in the event of a fundamental transaction, each holder of the Series C Warrants and Series D Warrants will have the right to require the Company, or its successor, to repurchase the Series C Warrants and Series D Warrants it holds for an amount of cash equal to the Black-Scholes value of the remaining unexercised portion of such Series C Warrants or Series D Warrants, as applicable.

The shares of Series A Preferred Stock rank on par with the shares of the common stock with regard to dividend rights and distributions of assets upon liquidation, dissolution or winding up of the Company. With certain exceptions, as described in the Series A Certificate of Designation, the shares of Series A Preferred Stock have no voting rights. However, as long as any shares of Series A Preferred Stock remain outstanding, the Series A Certificate of Designation provides that the Company shall not, without the affirmative vote of holders of a majority of the then outstanding shares of Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Series A Certificate of Designation, (b) amend the Company's certificate of incorporation or other charter documents in any manner that adversely affects

any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Each share of Series A Preferred Stock is convertible at any time at the holder's option into one share of common stock, which conversion ratio will be subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations and other similar transactions as specified in the Series A Certificate of Designation. Notwithstanding the foregoing, the Series A Certificate of Designation further provides that the Company shall not effect any conversion of the shares of Series A Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series A Preferred Stock (together with such holder's affiliates and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or 9.99% at the election of the holder prior to the date of issuance) of the shares of Common Stock then outstanding. At the holder's option, upon notice to the Company, the holder may increase or decrease this beneficial ownership limitation not to exceed 9.99% of the shares of Common Stock then outstanding, with any such increase becoming effective upon 61 days' prior notice to the Company.

The net proceeds to the Company from the 2020 Public Offering were approximately \$13.4 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

## **MST Acquisition and Related Transactions**

### ***Purchase Agreement***

On September 23, 2018, the Company entered into an Asset Purchase Agreement, or the MST Purchase Agreement, with MST Medical Surgery Technologies Ltd., an Israeli private company, or MST, and two of the Company's wholly owned subsidiaries, as purchasers of the assets of the Seller, including the intellectual property assets, or collectively, the Buyers. The closing of the transactions contemplated by the MST Purchase Agreement occurred on October 31, 2018, pursuant to which the Company acquired MST's assets consisting of intellectual property and tangible assets related to surgical analytics with its core image analytics technology designed to empower and automate the surgical environment, with a focus on medical robotics and computer-assisted surgery. The core technology acquired under the MST Purchase Agreement is a software-based image analytics information platform powered by advanced visualization, scene recognition, artificial intelligence, machine learning and data analytics.

Under the terms of the MST Purchase Agreement, at the closing the Buyers purchased substantially all of the assets of MST. The acquisition price consisted of two tranches. At or prior to the closing of the transaction the Buyers paid \$5.8 million in cash and approximately 242,310 shares of the Company's common stock, or the Initial Shares. A second tranche of \$6.6 million in additional consideration was payable in cash, stock or cash and stock, at the discretion of the Company, within one year after the closing date.

On August 7, 2019, the Company notified MST that the Company would satisfy the payment of additional consideration of \$6.6 million due to MST under the MST Purchase Agreement by issuing shares of the Company's common stock, as permitted by the MST Purchase Agreement. The number of shares issued to MST as the additional consideration was 370,423 shares of common stock, or the Additional Consideration Shares. In accordance with the provisions of the MST Purchase Agreement, the number of Additional Consideration Shares was calculated based on the volume-weighted average of the closing prices of the Company's common stock as quoted on the NYSE American for the ninety (90) day period ended August 6, 2019.

### ***Sale of AutoLap Assets***

On July 3, 2019, the Company entered into a System Sale Agreement with GBIL to sell certain assets related to the AutoLap technology. On October 15, 2019, the Company amended the prior AutoLap Sale Agreement with GBIL. Pursuant to the amended agreement the Company sold the AutoLap laparoscopic vision system, or AutoLap, and related assets to GBIL. The assets include inventory, spare parts, production equipment, testing equipment and certain intellectual property specifically related to the AutoLap. The purchase price was \$17.0 million, all of which was received in 2019 in the form of \$16 million in cash and a payment by GBIL of \$1.0 million to settle certain Company obligations in China. Under the amended AutoLap Agreement, the Company entered into a cross-license agreement with GBIL to retain rights to use any AutoLap-related intellectual property sold to GBIL, and to non-exclusively license additional intellectual property to GBIL. The Company recorded a \$16 million gain on the sale of the AutoLap assets during the year ended December 31, 2019, which represented the proceeds received in excess of the carrying value of the assets, less contract costs.

### ***Registration Rights and Lock-Up Agreements***

In connection with the closing under the MST Purchase Agreement, or the MST Acquisition, the Company and MST entered into a lock-up agreement dated October 31, 2018, or the Lock-Up Agreement, pursuant to which MST agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Initial Shares for six months following the closing date of the MST Purchase Agreement. As of the date of this Annual Report, 75% of the Initial Shares are free from the lock-up restrictions. For the remaining 25% of the Initial Shares, the Lock-Up Agreement provides that all of the Initial Shares will be released from the lock-up restrictions on May 1, 2020, or earlier upon certain other conditions. The Additional Consideration Shares were released from the lock-up restrictions on February 7, 2020.

In connection with the MST Acquisition, the Company also entered into a Registration Rights Agreement, dated as of October 31, 2018, with MST, pursuant to which the Company agreed to register the Initial Shares and Additional Consideration Shares, or collectively, the Securities Consideration, such that such Securities Consideration is eligible for resale following the end of the lock-up periods described above. All of the Securities Consideration is eligible to be sold by the holders without restriction under Rule 144, therefore the Registration Rights Agreement has expired.

## **Senhance Acquisition and Related Transactions**

### ***Membership Interest Purchase Agreement and Amendment***

On September 21, 2015, the Company announced that it had entered into a Membership Interest Purchase Agreement, dated September 18, 2015, or the Purchase Agreement, with Sofar S.p.A., or Sofar, as the seller, Vulcanos S.r.l., as the acquired company, and TransEnterix International, Inc., a wholly owned subsidiary of the Company as the Buyer. The closing of the transactions contemplated by the Purchase Agreement occurred on September 21, 2015. The Buyer acquired all of the membership interests of the acquired company from Sofar, and changed the name of the acquired company to TransEnterix Italia S.r.l. On the closing date, pursuant to the Purchase Agreement, the Company completed the strategic acquisition from Sofar of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery now known as the Senhance System, or the Senhance Acquisition.

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of 1,195,647 shares of the Company's common stock, or the Sofar Consideration, and approximately \$25.0 million U.S. Dollars and €27.5 million Euro in cash consideration, or the Cash Consideration. The Sofar Consideration was issued in full at closing of the acquisition; the Cash Consideration was or will be paid in four tranches, with U.S. \$25.0 million paid at closing and the remaining Cash Consideration of €27.5 million to be paid in three additional tranches based on achievement of negotiated milestones. On December 30, 2016, the Company and Sofar entered into an Amendment to the Purchase Agreement to restructure the terms of the second tranche of the Cash Consideration. Under the Amendment, the second tranche was restructured to reduce the contingent cash consideration by €5.0 million in exchange for the issuance of 286,360 shares of the Company's common stock with an aggregate fair market value of €5.0 million, which were issued on January 4, 2017. The price per share was \$18.252 and was calculated based on the average of the closing prices of the Company's common stock on ten consecutive trading days ending one day before the execution of the Amendment.

As of December 31, 2019, the Company has paid all Cash Consideration due under the second tranche and approximately €2.4 million of the €2.5 million due under the fourth tranche. The third tranche, consisting of €15.0 million, has not yet been paid and is subject to certain sales revenue milestones. The fourth tranche of the Cash Consideration is payable in installments by December 31 of each year as reimbursement for certain debt payments made by Sofar under an existing Sofar loan agreement in such year.

The Purchase Agreement contains customary representations and warranties of the parties and the parties have customary indemnification obligations, which are subject to certain limitations described further in the Purchase Agreement.

### ***Registration Rights***

In connection with the Senhance Acquisition, we also entered into a Registration Rights Agreement, dated as of September 21, 2015, with Sofar, pursuant to which we agreed to register the Securities Consideration shares for resale following the end of the lock-up periods. The resale Registration Statement has been filed and is effective.

## **Results of Operations**

### **Revenue**

In 2019, our revenue consisted of product and service revenue primarily resulting from the sale of a total of four Senhance Systems in Europe (one) and Asia (three), and related instruments, accessories and services for current and prior year system sales. The



Company also recognized \$1.3 million during the year ended December 31, 2019 related to a 2017 system sale for which revenue was deferred until the first clinical use of the system, which occurred in the second quarter of 2019. In 2018, our revenue consisted of product and service revenue primarily resulting from the sale of a total of fifteen Senhance Systems in Europe (eleven), Asia (one) and the United States (three), and related instruments, accessories and services.

Product, instrument and accessory revenue for the year ended December 31, 2019 decreased to \$7.1 million compared to \$23.3 million for the year ended December 31, 2018. The \$16.2 million decrease was the result of the revenue recognized on the sale of four Senhance Systems versus fifteen in the prior year, as well as instruments and accessories. Services revenue for the year ended December 31, 2019 increased to \$1.4 million from \$0.8 million for the year ended December 31, 2018 due to the increase in the number of Senhance Systems under service contracts.

We expect to experience some variability in the number and trend, and average selling price, of units sold given the early stage of commercialization of our products.

### **Cost of Revenue**

Cost of revenue consists primarily of costs related to contract manufacturing, materials, and manufacturing overhead. We expense all inventory obsolescence provisions related to normal manufacturing changes as cost of revenue. The manufacturing overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment depreciation and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. We expect cost of revenue to increase in absolute dollars to the extent our revenues grow and as we continue to invest in our operational infrastructure to support anticipated growth.

Product cost for the year ended December 31, 2019 increased to \$16.4 million as compared to \$14.2 million for the year ended December 31, 2018. This \$2.2 million increase over the prior year period was the result of the \$7.4 million inventory write-down under our restructuring plan, increased personnel costs totaling \$1.7 million, \$0.6 million in increased standard cost variances, \$0.3 million in increased travel, freight, and supplies costs, and a \$1.5 million reserve for obsolete inventory offset by \$9.1 million in lower product costs caused by decreased sales.

Service cost for the year ended December 31, 2019 increased to \$4.3 million as compared to \$2.0 million for the year ended December 31, 2018. This \$2.3 million increase over the prior year period was the result of increased field service costs of \$1.7 million for repairs and maintenance on a greater cumulative number of installed Senhance Systems, and a \$0.6 million increase in personnel costs due to increased headcount.

### **Research and Development**

Research and development, or R&D, expenses primarily consist of engineering, product development and regulatory expenses incurred in the design, development, testing and enhancement of our products and legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products. In future periods, we expect R&D expenses to increase moderately, but at a reduced rate due to the restructuring, as we continue to invest in additional regulatory approvals as well as new products, instruments and accessories to be offered with the Senhance System. R&D expenses are expensed as incurred.

R&D expenses for the year ended December 31, 2019 increased 3% to \$22.5 million as compared to \$21.8 million for the year ended December 31, 2018. The \$0.7 million increase primarily relates to higher personnel costs totaling \$1.6 million driven by higher headcount as a result of the MST acquisition offset by \$0.5 million in lower technology fees, \$0.2 million in lower consulting costs, and \$0.2 million in lower testing and validation costs. R&D expenses for the year ended December 31, 2019 also include an impairment of IPR&D in the amount of \$7.9 million that is presented separately in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

### **Sales and Marketing**

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshows, marketing clinical studies and consulting expenses. We expect sales and marketing expenses to decrease significantly as we refocus our resources and efforts on market development activities pursuant to our restructuring plan.

Sales and marketing expenses for the year ended December 31, 2019 increased 9% to \$28.0 million compared to \$25.7 million for the year ended December 31, 2018. The \$2.3 million increase was primarily related to increased personnel related costs of \$0.8 million, increased travel of \$0.8 million and increased product demonstration and trade show costs of \$0.7 million as we increased our U.S. sales and marketing efforts as we focused on the commercialization of the Senhance System.

## **General and Administrative**

General and administrative expenses consist of personnel costs related to the executive, finance and human resource functions, as well as professional service fees, legal fees, accounting fees, insurance costs, and general corporate expenses. In future periods, we expect general and administrative expenses to decrease due to the restructuring.

General and administrative expenses for the year ended December 31, 2019 increased 35% to \$18.8 million compared to \$13.9 million for the year ended December 31, 2018. The \$4.9 million increase was primarily due to increased personnel costs of \$1.5 million, increased consulting and outside services costs of \$1.3 million, increased taxes, licenses, and fees of \$0.4 million, increased facilities costs of \$0.2 million, decreased travel costs of \$0.1 million and a bad debt charge of \$1.6 million. The Company recorded the bad debt charge due to uncertainty regarding collectability on a 2018 system sale in North Africa.

## **Restructuring Charge**

During the fourth quarter of 2019, we announced the implementation of a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. Under the restructuring plan, we reduced headcount primarily in the sales and marketing functions and determined that the carrying value of our inventory exceeded the net realizable value due to a decrease in expected sales. The restructuring charges amounted to \$8.8 million, of which \$7.4 million was an inventory write down and was included in cost of product revenue and \$1.4 million related to employee severance costs and was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, during the fourth quarter of 2019.

During March 2020, we continued our restructuring with additional headcount reductions which resulted in \$0.8 million related to severance costs which are expected to be paid in 2020 and 2021.

## **Gain from Sale of AutoLap Assets, Net**

The gain from the sale of AutoLap assets, net to GBIL was \$16.0 million for the year ended December 31, 2019, as further explained in the "Overview" section. The gain represented the difference between the purchase price of \$17 million and a \$1 million liability incurred as a result of entering into the sale.

## **Gain from Sale of SurgiBot Assets, Net**

The gain from the sale of SurgiBot assets, net to GBIL was \$11.8 million for the year ended December 31, 2018, as further explained in the "Overview" section.

## **Amortization of Intangible Assets**

Amortization of intangible assets for the year ended December 31, 2019 decreased to \$10.3 million compared to \$10.9 million for the year ended December 31, 2018. The \$0.6 million decrease was primarily the result of a lower Euro to Dollar exchange rate.

## **Impairment of Goodwill and IPR&D Assets**

The Company typically tests goodwill for impairment annually as of year-end, however, due to market conditions as well as reduced forecasts, we tested our goodwill and IPR&D carrying values as of September 30, 2019.

Pursuant to ASU 2017-04, a company must record a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value. The Company generally determines the fair value of its reporting unit using two valuation methods: the "Income Approach — Discounted Cash Flow Analysis" method, and the "Market Approach — Guideline Public Company Method."

Under the "Income Approach — Discounted Cash Flow Analysis" method, the key assumptions consider projected sales, cost of sales, and operating expenses. These assumptions were determined by management utilizing the Company's internal operating plan, growth rates for revenues and operating expenses, and margin assumptions. An additional key assumption under this approach is the discount rate, which is determined by looking at current risk-free rates of capital, current market interest rates, and the evaluation of risk premium relevant to the business segment. If our assumptions relative to growth rates were to change or were incorrect, our fair value calculation may change.

Under the "Market Approach — Guideline Public Company Method," the Company identified several publicly traded companies, which it believed had sufficiently relevant similarities. Similar to the income approach discussed above, sales, cost of sales,

operating expenses, and their respective growth rates are key assumptions utilized. The market prices of the Company's common stock and other guideline companies are additional key assumptions. If these market prices increase, the estimated market value would increase. If the market prices decrease, the estimated market value would decrease.

The results of these two methods were weighted based upon management's evaluation of the relevance of the two approaches. In the 2019 evaluation, management determined that the income and market value approach should be weighted 50%-50%. In addition, management considered the decline in both our stock price and market capitalization after the September 30, 2019 measurement date as relevant factors in the analysis.

As of September 30, 2019, the Company determined that the goodwill associated with the business was impaired, and recorded impairment charges of \$79.0 million. The impairment charge resulted from decreased sales and estimated cash flows and a significant decline in the Company's stock price. The Company also recognized a \$7.9 million impairment charge to its IPR&D as it concluded that under the market value approach, the fair value of the IPR&D was lower than the carrying value.

No charge for goodwill and intangible asset impairment was required for the year ended December 31, 2018.

#### **Change in Fair Value of Contingent Consideration**

The change in fair value of contingent consideration in connection with the Senhance Acquisition was a \$9.6 million decrease for the year ended December 31, 2019 compared to a decrease of \$1.0 million for the year ended December 31, 2018. The net \$8.6 million decrease was primarily due to a significant reduction in the Company's five-year revenue forecast.

#### **Change in Fair Value of Warrant Liabilities**

The change in fair value of Series B Warrants issued in April 2017 was a decrease of \$2.2 million for the year ended December 31, 2019 compared to an increase of \$14.3 million for the year ended December 31, 2018. The net \$16.5 million decrease in change in fair value of warrant liabilities for the year ended December 31, 2019 over the year ended December 31, 2018 includes re-measurement associated with the warrants exercised during the year ended December 31, 2019 and 2018, and the outstanding warrants at December 31, 2019. The decrease in value at December 31, 2019 was primarily the result of the decrease in the stock price at December 31, 2019 versus December 31, 2018.

#### **Acquisition Related Costs**

Acquisition related costs of \$0.6 million for the year ended December 31, 2018 were incurred in connection with the MST Acquisition.

#### **Reversal of Transfer Fee Accrual**

In connection with the Senhance Acquisition, the Company recorded an accrual of \$3.0 million in the third quarter of 2015 for the potential assessment of additional transfer fees that could be assessed during a three year period. In September 2018, the Company determined that the accrual was no longer required and reversed the accrual.

#### **Interest Income**

Interest income for the year ended December 31, 2019 was \$0.6 million compared to \$1.4 million for the year ended December 31, 2018. The decrease of \$0.8 million was due to less cash and short-term investments on hand during the year ended December 31, 2019 earning less interest.

#### **Interest Expense**

Interest expense for the year ended December 31, 2019 was \$4.6 million compared to \$4.2 million for the year ended December 31, 2018. The Company incurred a \$1.4 million loss on extinguishment of debt, classified as interest expense, during the second quarter of 2018 as compared to a \$1.0 million loss on extinguishment of debt for the year ended December 31, 2019. This decrease in loss on extinguishment of debt was offset by greater interest incurred on the higher average principal balance of notes payable during 2019 as compared to 2018.

#### **Income Tax Benefit**

Income tax benefit consists primarily of taxes related to the amortization of purchase accounting intangibles in connection with the Italian taxing jurisdiction for TransEnterix Italia as a result of the acquisition of the Senhance System. We recognized \$3.1 million and \$3.4 million of income tax benefit for the years ended December 31, 2019 and 2018, respectively.

## **Liquidity and Capital Resources**

### **Going Concern**

The Company's consolidated financial statements are prepared using U.S. generally accepted accounting principles ("GAAP") applicable to a going concern, which contemplate the realization of assets and liquidation of liabilities in the normal course of business. The Company had an accumulated deficit of \$663.6 million as of December 31, 2019 and has working capital of \$14.9 million as of December 31, 2019. The Company has not established sufficient sales revenues to cover its operating costs and requires additional capital to proceed with its operating plan. In October 2019, the Company announced the implementation of a restructuring plan to reduce operating expenses. During March 2020, the Company continued the restructuring efforts with additional headcount reductions. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. In order to continue as a going concern, the Company will need, among other things, additional capital resources. The Company believes that its existing cash and cash equivalents from recent financings, together with cash received from product and instrument sales and leases will be sufficient to meet its anticipated cash needs into the fourth quarter of 2020.

Traditionally, the Company has raised additional capital through equity offerings. Management's plan to obtain such resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into a strategic collaboration, entry into an out-licensing arrangement or provision of additional distribution rights in some or all of our markets. In addition, as discussed below, the Company has engaged J.P. Morgan Securities LLC to assist it in considering strategic alternatives, including a fundamental business combination transaction. If the Company is unable to obtain adequate capital through one of these methods, it would need to reduce its sales and marketing and administrative expenses, delay research and development projects, including the purchase of equipment and supplies, and take other steps to reduce its expenses until it is able to obtain sufficient funds. If such sufficient funds are not received on a timely basis, the Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. Management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. The ability to successfully resolve these factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date that these financial statements are issued. The consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

### **Sources of Liquidity**

Our principal sources of cash to date have been proceeds from public offerings of common stock, private placements of common and preferred stock, incurrence of debt, the sale of equity securities held as investments and asset sales.

We currently have two effective shelf registration statements on file with the SEC. The first shelf registration statement was declared effective by the SEC on May 19, 2017 and registered up to \$150.0 million of debt securities, common stock, preferred stock, or warrants, or any combination thereof for future financing transactions. The second shelf registration statement was declared effective by the SEC on February 10, 2020, and also registers up to \$150.0 million of debt securities, common stock, preferred stock, or warrants, or any combination thereof for future financing transactions. We have raised or have reserved for issuance under such registration statements approximately \$170.5 million since 2017. As of March 10, 2020, the Company had approximately \$5.5 million available under the first effective shelf registration statement, which is due to expire in May 2020. As of the date of this Annual Report, the Company has approximately \$124 million available for future financings under the second shelf registration statement.

For a discussion of our recent equity financings, see "Financing Transactions" above in this Management's Discussion and Analysis and Results of Operations, and for a discussion of the 2019 sale of the AutoLap Assets, see "MST Acquisition and Related Transactions - Sale of AutoLap Assets" above in this Management's Discussion and Analysis of Financial Condition and Results of Operations.

At December 31, 2019, we had cash and cash equivalents, excluding restricted cash, of approximately \$9.6 million.

On October 17, 2019, the Company announced that it has engaged J.P. Morgan Securities LLC to assist the Board of Directors in considering strategic alternatives for the Company to enhance stockholder value, including, but not limited to a sale of the Company, a financing of the Company, a strategic partnership or collaboration or some other form of commercial relationship. In addition, the Company announced the implementation of a restructuring plan to reduce operating expenses as it continues the global market development of the Senhance platform. The Company is continuing to evaluate all potential alternatives, including pursuit of financing opportunities.

### **Consolidated Cash Flow Data**

|  | Years Ended December 31, |           |
|--|--------------------------|-----------|
|  | 2019                     | 2018      |
| (in millions)  |                          |           |
| Net cash (used in) provided by                               |                          |           |
| Operating activities   | \$ (73.5)                | \$ (48.5) |
| Investing activities   | 67.6                     | (53.5)    |
| Financing activities   | (5.6)                    | 26.5      |
| Effect of exchange rate changes on cash and cash equivalents | 0.4                      | (0.5)     |
| Net decrease in cash, cash equivalents and restricted cash   | \$ (11.1)                | \$ (76.0) |

### **Operating Activities**

For the year ended December 31, 2019, cash used in operating activities of \$73.5 million consisted of a net loss of \$154.2 million and cash used for working capital of \$12.8 million, offset by non-cash items of \$93.5 million. The non-cash items primarily consisted of \$86.9 million in goodwill and IPR&D impairment, \$11.5 million of stock-based compensation expense, \$11.5 million of net amortization of intangible assets, debt discount and debt issuance costs and short-term investments discount, \$2.2 million of depreciation, \$1.6 million of bad debt expense, \$1.0 million loss on debt extinguishment, \$8.9 million related to the write-down of obsolete inventory, and \$0.8 million in interest expense on deferred consideration related to the MST Acquisition, offset by \$16.0 million gain from sale of AutoLap assets, \$9.6 million change in fair value of contingent consideration, \$3.2 million deferred income tax benefit, and \$2.2 million change in fair value of warrant liabilities. The decrease in cash from changes in working capital included \$16.4 million increase in inventories, \$1.2 million decrease in accrued expenses, \$1.0 million decrease in deferred revenue, \$0.7 million decrease in accounts payable, and \$0.7 million increase in other current and long term assets, offset by \$6.1 million decrease in accounts receivable and \$1.0 million increase in other long term liabilities. The decrease in cash from changes in working capital was primarily driven by an increase in manufacturing activities combined with decreased Senhance System sales in the current year.

For the year ended December 31, 2018, cash used in operating activities of \$48.5 million consisted of a net loss of \$61.8 million and cash used for working capital of \$5.9 million, offset by non-cash items of \$19.2 million. The non-cash items primarily consisted of \$14.3 million change in fair value of warrant liabilities, \$11.2 million of net amortization of intangible assets, debt discount and debt issuance costs and short-term investment discount, \$9.0 million of stock-based compensation expense, \$2.4 million of depreciation, and \$1.4 million loss on debt extinguishment, offset by \$11.8 million gain from sale of SurgiBot assets, \$3.0 million reversal of transfer fee, \$3.4 million deferred income tax benefit, and \$1.0 million change in fair value of contingent consideration. The decrease in cash from changes in working capital included \$2.1 million increase in inventories, \$7.2 million increase in accounts receivable, and \$0.3 million increase in other current and long term assets, offset by \$0.8 million increase in accounts payable, \$2.1 million increase in accrued expenses and \$0.8 million increase in deferred revenue.

### **Investing Activities**

For the year ended December 31, 2019, net cash provided by investing activities was \$67.6 million. This amount primarily consists of \$65.0 million proceeds from maturities of short-term investments and \$16.0 million in proceeds related to the sale of the AutoLap assets, offset by \$12.9 million purchase of short-term investments and \$0.4 million purchases of property and equipment.

For the year ended December 31, 2018, net cash used in investing activities was \$53.5 million. This amount primarily consists of \$55.4 million purchase of short-term investments, \$5.8 million payment for acquisition of MST and \$0.8 million purchases of property and equipment, offset by \$4.5 million proceeds related to the sale of the SurgiBot assets and proceeds from maturities of short-term investments of \$4.0 million.

### **Financing Activities**

For the year ended December 31, 2019, net cash used in financing activities was \$5.6 million. This amount was primarily related to \$31.4 million payment of notes payable and \$0.5 million related to the taxes withheld on restricted stock unit, or RSU, awards, offset by \$25.8 million in proceeds from the issuance of common stock and warrants and \$0.5 million in proceeds from the exercise of stock options and warrants.

For the year ended December 31, 2018, net cash provided by financing activities was \$26.5 million. This amount was primarily related to \$28.5 million in proceeds from the issuance of debt, which was partially offset by \$15.3 million in payment of debt, \$12.4 million in proceeds from the exercise of stock options and warrants and \$3.0 million received for shares issued related to the sale of the SurgiBot assets, offset by \$1.7 million related to the taxes withheld on RSU awards and \$0.8 million payment of contingent consideration.

## Operating Capital and Capital Expenditure Requirements

We intend to spend substantial amounts on commercial activities, on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings, strategic collaborations, other funding transactions or a fundamental business combination transaction. There can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. If we are unable to obtain the necessary capital, we will need to pursue a plan to license or sell our assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

Cash and cash equivalents held by our foreign subsidiaries totaled \$1.5 million at December 31, 2019, including restricted cash. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiaries. If these funds are needed in the United States, we believe that the potential U.S. tax impact to repatriate these funds would be immaterial.

## Hercules Loan Agreement

On May 23, 2018, the Company and its domestic subsidiaries, as co-borrowers, entered into the Hercules Loan Agreement with several banks and other financial institutions or entities from time to time party to the Hercules Loan Agreement and Hercules Capital, Inc., or Hercules, as administrative agent and collateral agent. Effective April 30, 2019, the Hercules Loan Agreement was amended to eliminate the availability of the Tranche III loan facility, add a new Tranche IV loan facility of up to \$20 million, revise certain financial covenants and make other changes. On July 10, 2019, the Company entered into the Consent and Second Amendment to the Loan and Security Agreement on July 10, 2019, or the Hercules Second Amendment. Under the Hercules Second Amendment, in consideration for the consent to the sale of, and the release of the Lender's security interest on, the AutoLap assets, the Company reduced its indebtedness under the Hercules Loan Agreement by repaying \$15.0 million of the \$30.0 million of outstanding indebtedness thereunder, without any prepayment penalties, amendment fee or acceleration of the end of term charges, and received adjustments to the quarterly financial covenants and related waiver conditions to reflect the decreased outstanding indebtedness. On November 4, 2019, the Company entered into a payoff letter with the Agent pursuant to which the Company terminated the Hercules Loan Agreement, as amended. The Company determined it was in the best interests of the Company to pay down the debt and terminate the Hercules Agreement to simplify the Company's balance sheet and provide additional flexibility as the Board of Directors continues to explore strategic and financial alternatives for the Company. Under the payoff letter, the Company repaid all amounts owed under the Hercules Loan Agreement totaling approximately \$16.4 million, which included end of term fees of \$1.4 million, and Hercules released all security interests held on the assets of the Company and its subsidiaries, including, without limitation, on the intellectual property assets of the Company. Please see the description of the Hercules Loan Agreement above in the "Notes to the Consolidated Financial Statements - Note 13. Notes Payable."

## Innovatus Loan Agreement

On May 10, 2017, the Company and its domestic subsidiaries, as co-borrowers, entered into the Innovatus Loan Agreement with Innovatus Life Sciences Lending Fund I, LP, as lender and collateral agent. Please see the description of the Innovatus Loan Agreement above in this "Management's Discussion and Analysis of Financial Condition and Results of Operations - Debt Refinancing."

In connection with the entry into the Hercules Loan Agreement, the proceeds of which were used to repay the Innovatus Loan, we were obligated to pay final payment and prepayment fees under the Innovatus Loan Agreement. The final payment fee obligation was \$1.0 million and was paid during the year ended December 31, 2018.

## Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2019 (in millions):

|                                       | Payments due by period |                     |              |              |            |
|---------------------------------------|------------------------|---------------------|--------------|--------------|------------|
|                                       | Total                  | Less than<br>1 year | 1 to 3 years | 3 to 5 years | Thereafter |
| Operating leases                      | \$ 2.8                 | \$ 1.4              | \$ 1.2       | \$ 0.2       | \$ —       |
| License, supply and vendor agreements | \$ 9.1                 | \$ 5.6              | \$ 1.3       | \$ 1.1       | \$ 1.1     |
| Total contractual obligations         | \$ 11.9                | \$ 7.0              | \$ 2.5       | \$ 1.3       | \$ 1.1     |

During 2019, the Company fully repaid its outstanding indebtedness to Hercules Capital, and all related liens and encumbrances

have been terminated. As of December 31, 2019, the third tranche contingent consideration that may be paid under the Purchase Agreement with Sofar upon the achievement of milestones is €15.0 million. Due to uncertainty regarding the timing and amount of future payments related to this liability, the amount is excluded from the contractual obligations table above.

Operating lease amounts include future minimum lease payments under all our non-cancelable operating leases with an initial term in excess of one year. We rent office space in North Carolina under an operating lease which expires in 2020. In Italy, we rent space for research and development and demonstration facilities under an operating lease which expires in 2022. In Israel, we rent space for research and development under an operating lease which expires in 2024. In Japan, we rent office space under an operating lease which expires in 2023. In Switzerland, we rent office space under an operating lease which expires in 2023. This table does not include obligations for any lease extensions.

License, supply and third party vendor agreements include agreements assumed as part of the Senhance Acquisition and other third party vendor agreements.

### **Off-Balance Sheet Arrangements**

As of December 31, 2019, we did not have any off-balance sheet arrangements.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations set forth above under the headings “Results of Operations” and “Liquidity and Capital Resources” have been prepared in accordance with U.S. GAAP and should be read in conjunction with our financial statements and notes thereto appearing in Item 8 of this Annual Report. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our critical accounting policies and estimates, including identifiable intangible assets and goodwill, business acquisitions, in-process research and development, contingent consideration, warrant liabilities, stock-based compensation, inventory, revenue recognition and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. A more detailed discussion on the application of these and other accounting policies can be found in Note 2 in the Notes to the Consolidated Financial Statements which are included in Item 8 of this Annual Report. Actual results may differ from these estimates under different assumptions and conditions.

While all accounting policies impact the financial statements, certain policies may be viewed as critical. Critical accounting policies are those that are both most important to the portrayal of financial condition and results of operations and that require management’s most subjective or complex judgments and estimates. Our management believes the policies that fall within this category are the policies on accounting for identifiable intangible assets and goodwill, business acquisitions, in-process research and development, contingent consideration, warrant liabilities, stock-based compensation, inventory, revenue recognition and income taxes.

### **Identifiable Intangible Assets and Goodwill**

Identifiable intangible assets consist of purchased patent rights recorded at cost and developed technology acquired as part of a business acquisition recorded at estimated fair value. Intangible assets are amortized over 5 to 10 years. We periodically evaluate identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence of potential impairment exists by performing either a qualitative evaluation or a quantitative assessment. The qualitative evaluation is an assessment of factors, including industry, market and general economic conditions, market value, and future projections to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill.

As of December 31, 2018, we elected to bypass the qualitative assessment and calculated the fair value of our sole reporting unit based on our market capitalization, which exceeded the carrying amount. Accordingly, no charge for goodwill impairment was required as of December 31, 2018. During the third quarter of 2019, the Company’s stock price declined significantly as a result of decreased sales and estimated cash flows. As of September 30, 2019, goodwill was deemed to be fully impaired, and the Company recorded an impairment charge of \$79.0 million.

A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows; a sustained, significant decline in the Company’s

stock price and market capitalization; a significant adverse change in legal factors or in the business climate; adverse assessment or action by a regulator; and unanticipated competition. Key assumptions used in the annual goodwill impairment test are highly judgmental and include selection of comparable companies and amount of control premium. Any change in these indicators or key assumptions could have a significant negative impact on the Company's financial condition, impact the goodwill impairment analysis or cause the Company to perform a goodwill impairment analysis more frequently than once per year.

### **Business Acquisitions**

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification (“ASC”) 805, “Business Combinations.” ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, “Fair Value Measurements,” as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) and certain acquisition-related restructuring charges impacting the target company are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

### **In-Process Research and Development**

In-process research and development (“IPR&D”) assets represent the fair value assigned to technologies that were acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. During the year ended December 31, 2019, the Company also did an impairment analysis related to its IPR&D, and concluded that under the market value approach, the fair value of its IPR&D was lower than the carrying value and recorded an impairment charge of \$7.9 million.

The IPR&D from MST was acquired on October 31, 2018.

### **Contingent Consideration**

Contingent consideration is recorded as a liability and measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration at each reporting date will be updated by reflecting the changes in fair value in our statements of operations and comprehensive loss.

### **Warrant Liabilities**

For the Series B Warrants, the warrants are recorded as liabilities and are revalued at each reporting period. The change in fair value is recognized in the consolidated statements of operations and comprehensive loss. The selection of the appropriate valuation model and the inputs and assumptions that are required to determine the valuation requires significant judgment and requires management to make estimates and assumptions that affect the reported amount of the related liability and reported amounts of the change in fair value. Actual results could differ from those estimates, and changes in these estimates are recorded when known. As the warrant liability is required to be measured at fair value at each reporting date, it is reasonably possible that these estimates and assumptions could change in the near term.



## **Stock-Based Compensation**

We recognize as expense, the grant-date fair value of stock options and other stock based compensation issued to employees and non-employee directors over the requisite service periods, which are typically the vesting periods. We use the Black-Scholes-Merton model to estimate the fair value of our stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies as well as the Company's historical volatility. The expected term of options granted by us has been determined based upon the simplified method, because we do not have sufficient historical information regarding our options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of common stock; therefore, the expected dividend yield is assumed to be zero. We estimate forfeitures based on our historical experience and adjust the estimated forfeiture rate based upon actual experience.

## **Inventory**

Inventory, which includes material, labor and overhead costs, is stated at the lower of cost, determined on a first-in, first-out basis, or net realizable value. We record reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Any inventory on hand at the measurement date in excess of the Company's current requirements based on anticipated levels of sales is classified as long-term on the Company's consolidated balance sheets. The Company's classification of long-term inventory requires us to estimate the portion of on hand inventory that can be realized over the upcoming twelve months.

## **Revenue Recognition**

Our revenue consists of product revenue resulting from the sale of systems, system components, instruments and accessories, and service revenue. We account for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities.

Our system sale arrangements generally contain multiple products and services. For these bundled sale arrangements, we account for individual products and services as separate performance obligations if they are distinct, which is if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. Our system sale arrangements include a combination of the following performance obligations: system(s), system components, instruments, accessories, and system service. Our system sale arrangements generally include a five-year period of service. The first year of service is generally free and included in the system sale arrangement and the remaining four years are generally included at a stated service price. We consider the service terms in the arrangements that are legally enforceable to be performance obligations. Other than service, we generally satisfy all of the performance obligations up-front. System components, system accessories, instruments, accessories, and service are also sold on a standalone basis.

We recognize revenues as the performance obligations are satisfied by transferring control of the product or service to a customer. We generally recognize revenue for the performance obligations at the following points in time:

- *System sales.* For systems and system components sold directly to end customers, revenue is recognized when we transfer control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. For systems sold through distributors, with the distributors responsible for installation, revenue is recognized generally at the time of shipment. Our system arrangements generally do not provide a right of return. The systems are generally covered by a one-year warranty. Warranty costs were not material for the periods presented.
- *Instruments and accessories.* Revenue from sales of instruments and accessories is recognized when control is transferred to the customers, which generally occur at the time of shipment, but also occur at the time of delivery depending on the customer arrangement. Accessory products include sterile drapes used to help ensure a sterile field during surgery, vision products such as replacement endoscopes, camera heads, light guides, and other items that facilitate use of the Senhance Surgical System.

- *Service.* Service revenue is recognized ratably over the term of the service period as the customers benefit from the service throughout the service period. Revenue related to services performed on a time-and-materials basis is recognized when performed.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which we separately sell the products or services. Due to limited sales to date, standalone selling prices are not yet directly observable. We estimate the standalone selling price using the market assessment approach considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer, and market conditions. We regularly review standalone selling prices and update these estimates if necessary. Transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which the revenue has not yet been recognized. A significant portion of this amount relates to service obligations performed under our system sales contracts that will be invoiced and recognized as revenue in future periods.

We invoice our customers based on the billing schedules in our sales arrangements. Contract assets for the periods presented primarily represent the difference between the revenue that was recognized based on the relative selling price of the related performance obligations and the contractual billing terms in the arrangements. Deferred revenue for the periods presented was primarily related to service obligations, for which the service fees are billed up-front, generally annually. The associated deferred revenue is generally recognized ratably over the service period.

In connection with assets recognized from the costs to obtain a contract with a customer, we have determined that sales incentive programs for our sales team do not meet the requirements to be capitalized as we do not expect to generate future economic benefits from the related revenue from the initial sales transaction.

### **Income Taxes**

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets or liabilities for the temporary differences between financial reporting and tax basis of our assets and liabilities, and for tax carryforwards at enacted statutory rates in effect for the years in which the asset or liability is expected to be realized. The effect on deferred taxes of a change in tax rates is recognized in income during the period that includes the enactment date. In addition, valuation allowances are established when necessary to reduce deferred tax assets and liabilities to the amounts expected to be realized.

On December 22, 2017, the Tax Cuts and Jobs Act (“Tax Legislation”) was enacted into law, which reduced the U.S. federal corporate income tax rate to 21% for tax years beginning after December 31, 2017. As a result of the newly enacted tax rate, we adjusted our U.S. deferred tax assets as of December 31, 2017, by applying the new 21% rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately \$36.1 million.

The Tax Legislation also implements a territorial tax system. Under the territorial tax system, in general, our foreign earnings will no longer be subject to tax in the U.S. As part of transition to the territorial tax system the Tax Legislation includes a mandatory deemed repatriation of all undistributed foreign earnings that are subject to a U.S. income tax. We estimate that the deemed repatriation will not result in any additional U.S. income tax liability as we estimate we currently have no undistributed foreign earnings.

U.S. shareholders are subject to tax on global intangible low-taxed income (GILTI) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, *Accounting for Global Intangible Low-Taxed Income*, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred. As of December 31, 2019, no GILTI tax has been recorded.

In a referendum held on May 19, 2019, Swiss voters adopted the Federal Act on Tax Reform and AVS Financing (TRAF). TRAF introduces major changes in the Swiss tax system by abolishing certain current preferential tax regimes and replacing them with new measures that are in line with international standards. The referendum did not have a material impact on the Company’s 2019 tax provision. The Company will continue to evaluate the impact of these provisions in future periods as the enactment process is completed.

### **Recent Accounting Pronouncements**

See “Note 2. Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements in “Item 8. Financial Statements and Supplementary Data” of this Annual Report for a full description of recent accounting pronouncements including

the respective expected dates of adoption and effects on our Consolidated Balance Sheets and Consolidated Statements of Operations and Comprehensive Loss.

**ITEM 7.A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## **Report of Independent Registered Public Accounting Firm**

Stockholders and Board of Directors  
TransEnterix, Inc.  
Morrisville, North Carolina

### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of TransEnterix, Inc. (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 16, 2020 expressed an adverse opinion thereon.

### **Change in Accounting Principle**

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in the year ended December 31, 2019 upon adoption of Accounting Standards Codification Topic 842, *Leases*, using the modified retrospective method.

### **Going Concern Uncertainty**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2013.

Raleigh, North Carolina  
March 16, 2020

## **Report of Independent Registered Public Accounting Firm**

Stockholders and Board of Directors  
TransEnterix, Inc.  
Morrisville, North Carolina

### **Opinion on Internal Control over Financial Reporting**

We have audited TransEnterix, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes and our report dated March 16, 2020 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9.A., "Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness regarding management's failure to design and maintain controls over the Company's income tax accounting and disclosures for the significant components of deferred tax assets and liabilities related to a foreign non-recurring transaction has been identified and described in management's assessment. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2019 financial statements, and this report does not affect our report dated March 16, 2020 on those financial statements.

### **Definition and Limitations of Internal Control over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Raleigh, North Carolina

March 16, 2020

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

|  | December 31,<br>2019 | December 31,<br>2018 |
|--|----------------------|----------------------|
| <b>Assets</b>  |                      |                      |
| <b>Current Assets</b>  |                      |                      |
| Cash and cash equivalents  | \$ 9,598             | \$ 21,061            |
| Short-term investments   | —                    | 51,790               |
| Accounts receivable, net   | 620                  | 8,560                |
| Inventories  | 10,653               | 10,941               |
| Interest receivable  | —                    | 26                   |
| Other current assets   | 7,084                | 9,205                |
| <b>Total Current Assets</b>  | <b>27,955</b>        | <b>101,583</b>       |
| Restricted cash  | 969                  | 590                  |
| Inventories, net of current portion  | 7,594                | —                    |
| Property and equipment, net  | 4,706                | 6,337                |
| Intellectual property, net   | 28,596               | 39,716               |
| In-process research and development  | 2,470                | 10,747               |
| Goodwill   | —                    | 80,131               |
| Other long term assets   | 2,489                | 203                  |
| <b>Total Assets</b>  | <b>\$ 74,779</b>     | <b>\$ 239,307</b>    |
| <b>Liabilities and Stockholders' Equity</b>  |                      |                      |
| <b>Current Liabilities</b>   |                      |                      |
| Accounts payable   | \$ 3,579             | \$ 4,433             |
| Accrued expenses   | 8,553                | 9,619                |
| Deferred revenue – current portion   | 818                  | 1,733                |
| Contingent consideration – current portion   | 73                   | 72                   |
| Deferred consideration - MST Acquisition   | —                    | 5,962                |
| <b>Total Current Liabilities</b>   | <b>13,023</b>        | <b>21,819</b>        |
| <b>Long Term Liabilities</b>   |                      |                      |
| Deferred revenue – less current portion  | 27                   | 109                  |
| Contingent consideration – less current portion  | 1,011                | 10,565               |
| Notes payable, net of debt discount  | —                    | 28,937               |
| Warrant liabilities  | 2,388                | 4,636                |
| Net deferred tax liabilities   | 1,392                | 4,720                |
| Other long term liabilities  | 1,403                | —                    |
| <b>Total Liabilities</b>   | <b>19,244</b>        | <b>70,786</b>        |
| <b>Commitments and Contingencies (Note 21)</b>   |                      |                      |
| <b>Stockholders' Equity</b>  |                      |                      |
| Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2019 and December 31, 2018; 20,691,301 and 16,641,999 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively | 21                   | 17                   |
| Additional paid-in capital   | 720,484              | 676,572              |
| Accumulated deficit  | (663,600)            | (509,406)            |
| Accumulated other comprehensive (loss) income  | (1,370)              | 1,338                |
| <b>Total Stockholders' Equity</b>  | <b>55,535</b>        | <b>168,521</b>       |
| <b>Total Liabilities and Stockholders' Equity</b>  | <b>\$ 74,779</b>     | <b>\$ 239,307</b>    |

*See accompanying notes to consolidated financial statements.*



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

|   | Year ended December 31, |             |
|---|-------------------------|-------------|
|   | 2019                    | 2018        |
| Revenue:  |                         |             |
| Product   | 7,104                   | 23,268      |
| Service   | 1,427                   | 834         |
| Total revenue   | 8,531                   | 24,102      |
| Cost of revenue:  |                         |             |
| Product   | 16,439                  | 14,162      |
| Service   | 4,292                   | 2,009       |
| Total cost of revenue   | 20,731                  | 16,171      |
| Gross (loss) profit   | (12,200)                | 7,931       |
| Operating Expenses (Income)   |                         |             |
| Research and development  | 22,468                  | 21,823      |
| Sales and marketing   | 28,014                  | 25,736      |
| General and administrative  | 18,758                  | 13,854      |
| Amortization of intangible assets   | 10,301                  | 10,868      |
| Change in fair value of contingent consideration  | (9,553)                 | (1,011)     |
| Restructuring and other charges   | 1,374                   | —           |
| Goodwill impairment   | 78,969                  | —           |
| In-process research and development impairment  | 7,912                   | —           |
| Acquisition related costs   | —                       | 647         |
| Loss (gain) from sale of SurgiBot assets, net   | 97                      | (11,840)    |
| Gain from sale of AutoLap assets, net   | (15,965)                | —           |
| Reversal of transfer fee accrual  | —                       | (2,994)     |
| Total Operating Expenses  | 142,375                 | 57,083      |
| Operating Loss  | (154,575)               | (49,152)    |
| Other Income (Expense)  |                         |             |
| Change in fair value of warrant liabilities   | 2,248                   | (14,320)    |
| Interest income   | 582                     | 1,400       |
| Interest expense  | (4,613)                 | (4,208)     |
| Other (expense) income  | (967)                   | 1,126       |
| Total Other Expense, net  | (2,750)                 | (16,002)    |
| Loss before income taxes  | \$ (157,325)            | \$ (65,154) |
| Income tax benefit  | 3,124                   | 3,377       |
| Net loss  | \$ (154,201)            | \$ (61,777) |
| Comprehensive loss  |                         |             |
| Foreign currency translation loss   | (2,708)                 | (3,690)     |
| Comprehensive loss  | \$ (156,909)            | \$ (65,467) |
| Net loss per common share - basic and diluted   | \$ (8.69)               | \$ (3.88)   |
| Weighted average number of shares used in computing net loss per common share - basic and diluted | 17,737                  | 15,938      |

*See accompanying notes to consolidated financial statements.*

**TransEnterix, Inc.**  
**Consolidated Statements of Stockholders' Equity**  
(in thousands)

|   | Common Stock |        | Treasury Stock |        | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive (Loss) Income | Total Stockholders' Equity |
|---|--------------|--------|----------------|--------|----------------------------|---------------------|---|----------------------------|
|   | Shares       | Amount | Shares         | Amount |                            |                     |   |                            |
| <b>Balance, December 31, 2017</b>                                   | 15,329       | \$ 16  | —              | \$ —   | \$ 621,446                 | \$ (447,640)        | \$ 5,028                                      | \$ 178,850                 |
| Stock-based compensation  | —            | —      | —              | —      | 9,039                      | —                   | —   | 9,039                      |
| Issuance of common stock and warrants, net of issuance costs        | —            | —      | —              | —      | 279                        | —                   | —   | 279                        |
| Issuance of common stock for MST Acquisition                        | 242          | 0      | —              | —      | 8,300                      | —                   | —   | 8,300                      |
| Exercise of stock options and warrants                              | 889          | 1      | —              | —      | 36,171                     | —                   | —   | 36,172                     |
| Award of restricted stock units                                     | 82           | 0      | —              | —      | —                          | —                   | —   | —                          |
| Return of common stock to pay withholding taxes on restricted stock | —            | —      | 41             | 1      | (1,663)                    | —                   | —   | (1,662)                    |
| Cancellation of treasury stock                                      | —            | —      | (41)           | (1)    | —                          | —                   | —   | (1)                        |
| Issuance of common stock related to sale of SurgiBot assets         | 100          | 0      | —              | —      | 3,000                      | —                   | —   | 3,000                      |
| Cumulative effect of change in accounting principle (Note 2)        | —            | —      | —              | —      | —                          | 11                  | —   | 11                         |
| Other comprehensive loss  | —            | —      | —              | —      | —                          | —                   | (3,690)                                       | (3,690)                    |
| Net loss  | —            | —      | —              | —      | —                          | (61,777)            | —   | (61,777)                   |
| <b>Balance, December 31, 2018</b>                                   | 16,642       | \$ 17  | —              | \$ —   | \$ 676,572                 | \$ (509,406)        | \$ 1,338                                      | \$ 168,521                 |
| Stock-based compensation  | —            | —      | —              | —      | 11,508                     | —                   | —   | 11,508                     |
| Issuance of common stock, net of issuance costs                     | 3,571        | 4      | —              | —      | 25,773                     | —                   | —   | 25,777                     |
| Issuance of common stock consideration to MST                       | 370          | 0      | —              | —      | 6,599                      | —                   | —   | 6,599                      |
| Exercise of stock options and warrants                              | 38           | 0      | —              | —      | 538                        | —                   | —   | 538                        |
| Award of restricted stock units                                     | 70           | 0      | —              | —      | —                          | —                   | —   | —                          |
| Return of common stock to pay withholding taxes on restricted stock | —            | —      | 15             | 0      | (499)                      | —                   | —   | (499)                      |
| Cancellation of treasury stock                                      | —            | —      | (15)           | 0      | —                          | —                   | —   | —                          |
| Cumulative effect of change in accounting principle (Note 2)        | —            | —      | —              | —      | (7)                        | 7                   | —   | —                          |
| Other comprehensive loss  | —            | —      | —              | —      | —                          | —                   | (2,708)                                       | (2,708)                    |
| Net loss  | —            | —      | —              | —      | —                          | (154,201)           | —   | (154,201)                  |
| <b>Balance, December 31, 2019</b>                                   | 20,691       | \$ 21  | —              | \$ —   | \$ 720,484                 | \$ (663,600)        | \$ (1,370)                                    | \$ 55,535                  |

*See accompanying notes to consolidated financial statements.*

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

|  | Twelve Months Ended<br>December 31, |             |
|--|-------------------------------------|-------------|
|  | 2019                                | 2018        |
| <b>Operating Activities</b>  |                                     |             |
| Net loss   | \$ (154,201)                        | \$ (61,777) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities: |                                     |             |
| Gain from sale of AutoLap assets, net  | (15,965)                            | —           |
| Loss (gain) from sale of SurgiBot assets, net  | 97                                  | (11,840)    |
| Goodwill and in-process research and development impairment                                      | 86,881                              | —           |
| Depreciation   | 2,166                               | 2,420       |
| Amortization of intangible assets  | 10,301                              | 10,868      |
| Amortization of debt discount and debt issuance costs  | 1,513                               | 725         |
| Amortization of short-term investment discount   | (327)                               | (351)       |
| Stock-based compensation   | 11,508                              | 9,039       |
| Inventory write-down related to restructuring  | 7,408                               | —           |
| Inventory write-down   | 1,523                               | —           |
| Bad debt expense   | 1,634                               | —           |
| Interest expense on deferred consideration - MST acquisition                                     | 756                                 | —           |
| Deferred tax benefit   | (3,224)                             | (3,377)     |
| Loss on extinguishment of debt   | 1,006                               | 1,400       |
| Change in fair value of warrant liabilities  | (2,248)                             | 14,320      |
| Change in fair value of contingent consideration   | (9,553)                             | (1,011)     |
| Reversal of transfer fee accrual   | —                                   | (2,994)     |
| Changes in operating assets and liabilities, net of effect of acquisition:                       |                                     |             |
| Accounts receivable  | 6,083                               | (7,225)     |
| Interest receivable  | 26                                  | 54          |
| Inventories  | (16,404)                            | (2,145)     |
| Other current and long term assets   | (655)                               | (325)       |
| Accounts payable   | (668)                               | 767         |
| Accrued expenses   | (1,180)                             | 2,134       |
| Deferred revenue   | (959)                               | 825         |
| Other long term liabilities  | 998                                 | —           |
| Net cash and cash equivalents used in operating activities                                       | (73,484)                            | (48,493)    |
| <b>Investing Activities</b>  |                                     |             |
| Proceeds from sale of AutoLap assets   | 15,965                              | —           |
| Purchase of short-term investments   | (12,883)                            | (55,439)    |
| Proceeds from maturities of short-term investments   | 65,000                              | 4,000       |
| Payment for acquisition of a business  | —                                   | (5,800)     |
| Proceeds related to sale of SurgiBot assets, net   | —                                   | 4,496       |
| Purchase of property and equipment   | (437)                               | (770)       |
| Proceeds from sale of property and equipment   | —                                   | 32          |
| Net cash and cash equivalents provided by (used in) investing activities                         | 67,645                              | (53,481)    |
| <b>Financing Activities</b>  |                                     |             |
| Payment of notes payable   | (31,425)                            | (15,305)    |
| Proceeds from issuance of debt and warrants, net of issuance costs                               | —                                   | 28,507      |
| Payment of contingent consideration  | —                                   | (770)       |
| Proceeds from issuance of common stock and warrants, net of issuance costs                       | 25,777                              | 279         |
| Taxes paid related to net share settlement of vesting of restricted stock units                  | (499)                               | (1,662)     |
| Proceeds from issuance of common stock related to sale of SurgiBot assets                        | —                                   | 3,000       |
| Proceeds from exercise of stock options and warrants   | 538                                 | 12,403      |
| Net cash and cash equivalents (used in) provided by financing activities                         | (5,609)                             | 26,452      |
| Effect of exchange rate changes on cash and cash equivalents                                     | 364                                 | (433)       |
| Net (decrease) increase in cash, cash equivalents and restricted cash                            | (11,084)                            | (75,955)    |
| Cash, cash equivalents and restricted cash, beginning of period                                  | 21,651                              | 97,606      |
| Cash, cash equivalents and restricted cash, end of period  | \$ 10,567                           | \$ 21,651   |

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

| Supplemental Disclosure for Cash Flow Information                                    |    |       |           |
|--|----|-------|-----------|
| Interest paid  | \$ | 2,187 | \$ 1,730  |
| Supplemental Schedule of Non-cash Investing and Financing Activities                 |    |       |           |
| Transfer of inventories to property and equipment                                    | \$ | 486   | \$ 2,160  |
| Transfer of property and equipment to inventories                                    | \$ | 323   | \$ 637    |
| Reclass of warrant liability to common stock and additional paid-in capital          | \$ | —     | \$ 23,774 |
| Cashless exercise of warrants  | \$ | —     | \$ 4,272  |
| Issuance of common stock related to MST acquisition                                  | \$ | 6,600 | \$ 8,300  |
| Proceeds from sale of AutoLap assets exchanged for settlement of Company obligations | \$ | 1,000 | \$ —      |
| Deferred consideration - MST acquisition   | \$ | —     | \$ 5,962  |

*See accompanying notes to consolidated financial statements.*

**TransEnterix, Inc.****Notes to Consolidated Financial Statements****1. Organization and Capitalization**

TransEnterix, Inc. (the "Company") is a medical device company that is digitizing the interface between the surgeon and the patient in laparoscopy to increase control and reduce surgical variability in today's value-based healthcare environment. The Company is focused on the market development for and commercialization of the Senhance™ System, which digitizes laparoscopic minimally invasive surgery. The Senhance System allows for robotic precision, haptic feedback, surgeon camera control via eye sensing and improved ergonomics while offering responsible economics.

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan and select other countries.

- The Senhance System has a CE Mark in Europe for adult and pediatric laparoscopic abdominal and pelvic surgery, as well as limited thoracic surgeries excluding cardiac and vascular surgery.
- In the United States, the Company has received 510(k) clearance from the FDA for use of the Senhance System in laparoscopic colorectal and gynecologic surgery in a total of 28 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal hernia and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, the Company has received regulatory approval and reimbursement for 98 laparoscopic procedures.

During 2018 and 2019, the Company successfully obtained FDA clearance and CE Mark for the Company's 3 millimeter diameter instruments, Senhance ultrasonic system, 3 millimeter and 5 millimeter hooks, and the Senhance articulating system. The 3 millimeter instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. The ultrasonic system is an advanced energy device used to deliver controlled energy to ligate and divide tissue, while minimizing thermal injury to surrounding structures. The Senhance articulating system was launched in Europe in November 2019 and the Company is evaluating its pathway forward to launch such a system in the United States with a planned submission for U.S. clearance at the end of 2020.

The Senhance System is a multi-port robotic surgery system that allows multiple robotic arms to control instruments and a camera. The system features advanced technology to enable surgeons with haptic feedback and the ability to move the camera via eye movement.

On October 31, 2018, the Company acquired the assets, intellectual property and highly experienced multidisciplinary personnel of MST Medical Surgical Technologies, Inc., or MST, an Israeli-based medical technology company. Through this acquisition the Company acquired MST's AutoLap™ assets and technology, one of the only image-guided robotic scope positioning systems with FDA clearance and CE Mark. The Company believes MST's image analytics technology will accelerate and drive meaningful Senhance System developments, and allow the Company to expand the Senhance System to add augmented, intelligent vision capability. See Note 3 for a description of the acquisition transaction. The Company sold the AutoLap assets, while retaining the core technology, in October 2019. See Note 3 for a description of the asset sale. On January 14, 2020, the Company announced that it had filed a 510(k) submission with the U.S. Food and Drug Administration for its Intelligent Surgical Unit (ISU™) for use with the Senhance System. The Company believes it is the first such FDA submission seeking clearance for machine vision technology in abdominal robotic surgery. On March 13, 2020, the Company announced that it has received FDA clearance for the Intelligent Surgical Unit.

The Company has also developed the SurgiBot System, a single-port, robotically enhanced laparoscopic surgical platform. In December 2017, the Company entered into an agreement with Great Belief International Limited, or GBIL, to advance the SurgiBot System towards global commercialization. The agreement transferred ownership of the SurgiBot System assets to GBIL, while the Company retained the option to distribute or co-distribute the SurgiBot System outside of China. GBIL intends to manufacture the SurgiBot System in China, obtain Chinese regulatory clearance from the National Medical Products Administration ("NMPA"), and commercialize in the Chinese market. The agreement provides the Company with proceeds of at least \$29.0 million, of which \$15.0 million has been received to date. The remaining \$14.0 million represents minimum royalties and will be paid beginning at the earlier of receipt of Chinese regulatory approval or March 2023. The Company recorded a gain during the year ended December 31, 2018 based on the cash proceeds (excluding future royalties) in excess of the carrying value of the assets sold.

On September 18, 2015, the Company entered into a Membership Interest Purchase Agreement, (the "Purchase Agreement") with Sofar S.p.A., ("Sofar") as seller, Vulcanos S.r.l. ("Vulcanos"), as the acquired company, and TransEnterix International, Inc.

(“TransEnterix International”), a direct, wholly owned subsidiary of the Company that was incorporated in September 2015, as buyer. The closing of the transactions occurred on September 21, 2015 (the “Closing Date”) pursuant to which the Company acquired all of the membership interests of Vulcanos from Sofar (now known as the “Senhance Acquisition”), and changed the name of Vulcanos to TransEnterix Italia S.r.l (“TransEnterix Italia”). The Senhance Acquisition included all of the assets, employees and contracts related to the Senhance System. See Note 3 for a description of the related transactions.

On September 3, 2013, TransEnterix Surgical, Inc. a Delaware corporation (“TransEnterix Surgical”), and SafeStitch Medical, Inc., a Delaware corporation (“SafeStitch”) consummated a merger transaction whereby TransEnterix Surgical merged with a merger subsidiary of SafeStitch, with TransEnterix Surgical as the surviving entity in the merger (the “Merger”). As a result of the Merger, TransEnterix Surgical became a wholly owned subsidiary of SafeStitch. On December 6, 2013, SafeStitch changed its name to TransEnterix, Inc. and increased the authorized shares of common stock from 225,000,000 to 750,000,000, and authorized 25,000,000 shares of preferred stock, par value \$0.01 per share.

As used herein, the term “Company” refers to the combination of SafeStitch and TransEnterix Surgical after giving effect to the Merger, and includes TransEnterix Surgical, Inc., SafeStitch LLC, TransEnterix International, Inc.; TransEnterix Italia S.r.l.; TransEnterix Europe S.à.R.L; TransEnterix Asia Pte. Ltd.; TransEnterix Taiwan Ltd.; TransEnterix Japan KK; TransEnterix Israel Ltd. and TransEnterix Netherlands B.V.

## **2. Summary of Significant Accounting Policies**

### **Basis of Presentation**

The accompanying Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and include the accounts of the Company and its direct and indirect wholly owned subsidiaries, SafeStitch LLC, TransEnterix Surgical, Inc., TransEnterix International, Inc., TransEnterix Italia S.r.l., TransEnterix Europe S.à.R.L; TransEnterix Asia Pte. Ltd.; TransEnterix Taiwan Ltd.; TransEnterix Japan KK; TransEnterix Israel Ltd. and TransEnterix Netherlands B.V. All material inter-company accounts and transactions have been eliminated in consolidation.

On December 11, 2019, following receipt of approval from stockholders at a special meeting of stockholders held on the same day, the Company filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company’s common stock at a ratio of one-for-thirteen, or the Reverse Stock Split. The Company’s common stock began trading on a split-adjusted basis on NYSE American on the morning of December 12, 2019. No fractional shares were issued in connection with the Reverse Stock Split. Instead, the Company rounded up each fractional share resulting from the reverse stock split to the nearest whole share. As a result of the Reverse Stock Split, the Company’s outstanding common stock decreased from approximately 261.9 million shares to approximately 20.2 million shares (without giving effect to the rounding up for each fractional share).

Unless otherwise noted, all share and per share data referenced in the consolidated financial statements and the notes thereto have been retroactively adjusted to reflect the Reverse Stock Split. As a result of the Reverse Stock Split, certain amounts in the consolidated financial statements and the notes thereto may be slightly different than previously reported due to rounding of fractional shares, and certain amounts within the consolidated balance sheets were reclassified between common stock and additional paid-in capital.

### **Going Concern**

The Company's consolidated financial statements are prepared using U.S. GAAP applicable to a going concern, which contemplate the realization of assets and liquidation of liabilities in the normal course of business. The Company had an accumulated deficit of \$663.6 million as of December 31, 2019, and has working capital of \$14.9 million as of December 31, 2019. The Company has not established sufficient sales revenues to cover its operating costs and requires additional capital to proceed with its operating plan. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. In order to continue as a going concern, the Company will need, among other things, additional capital resources.

Traditionally, the Company has raised additional capital through equity offerings. Management's plan to obtain such resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into a strategic collaboration, entry into an out-licensing arrangement or provision of additional distribution rights in some or all of our markets. In addition, the Company may consider fundamental business combination transactions. If the Company is unable to obtain adequate capital through one of these methods, or if expected capital from existing agreements is not received when due, or at all, it would need to reduce its sales and marketing and administrative expenses and delay research and development projects, including the purchase of equipment and supplies, until it is able to obtain sufficient funds. If such sufficient funds are not received on a timely basis, the

Company would then need to pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. However, management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. The ability to successfully resolve these factors raise substantial doubt about the Company's ability to meet its existing obligations, and to continue as a going concern within one year from the date that these financial statements are issued. The consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include identifiable intangible assets and goodwill, contingent consideration, warrant liabilities, stock compensation expense, revenue recognition, accounts receivable reserves, excess and obsolete inventory reserves, inventory classification between current and non-current, and deferred tax asset valuation allowances.

### **Cash and Cash Equivalents and Restricted Cash**

The Company considers all highly liquid investments with original maturities of 90 days or less at the time of purchase to be cash equivalents.

Restricted cash at December 31, 2019 and 2018 includes \$1.0 million and \$0.6 million, respectively, in cash accounts held as collateral primarily under the terms of an office operating lease, credit cards, automobile leases, and a performance guarantee required by the government of a country in which a Senhance System was sold in 2018.

### **Short-term Investments**

Short-term investments are considered to be "held-to-maturity" and are carried at amortized cost using the effective interest method. As of December 31, 2018, short-term investments consisted of \$51.8 million in U.S. government securities, all of which matured in less than a year. There were no short-term investments as of December 31, 2019.

The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period. The Company determined that its debt securities should be classified as held-to-maturity as of December 31, 2018. The Company had no debt securities as of December 31, 2019. This classification as of December 31, 2018 was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as the investments mature within six months and the underlying cash invested in these securities is not required prior to the investments maturity. Due to the short-term maturities of these instruments, the amortized cost approximated the related fair values, which was based on level 1 inputs as defined in Note 5. As of December 31, 2018, the gross holding gains and losses were immaterial.

The Company reviews its short-term investments for other-than-temporary impairment if the cost exceeds the fair value. No such impairment was recorded during the years ended December 31, 2019 or 2018.

### **Concentrations and Credit Risk**

The Company's principal financial instruments subject to potential concentration of credit risk are cash and cash equivalents, including amounts held in money market accounts. The Company places cash deposits with a federally insured financial institution. The Company maintains its cash at banks and financial institutions it considers to be of high credit quality; however, the Company's domestic cash deposits may at times exceed the Federal Deposit Insurance Corporation's insured limit. Balances in excess of federally insured limitations may not be insured. The Company has not experienced losses on these accounts, and management believes that the Company is not exposed to significant risks on such accounts.

The Company's accounts receivable are derived from sales to customers located throughout the world. The Company evaluates its customers' financial condition and, generally, requires no collateral from its customers. The Company provides reserves for potential credit losses and recorded a bad debt charge totaling \$1.6 million during the year ended December 31, 2019. The Company had eight customers who constituted 85% of the Company's net accounts receivable at December 31, 2019. The Company had five customers who constituted 89% of the Company's net accounts receivable at December 31, 2018. The Company had six customers who accounted for 82% of sales in 2019 and twelve customers who accounted for 89% of sales in 2018.

### **Accounts Receivable**

Accounts receivable are recorded at net realizable value, which includes an allowance for estimated uncollectible accounts. The allowance for uncollectible accounts was determined on a customer specific basis based on deemed collectability.

### **Inventories**

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or net realizable value. Inventory costs include direct materials, direct labor, and normal manufacturing overhead. The Company records reserves, when necessary, to reduce the carrying value of inventory to its net realizable value. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Any inventory on hand at the measurement date in excess of the Company's current requirements based on anticipated levels of sales is classified as long-term on the Company's consolidated balance sheets. The Company's classification of long-term inventory requires it to estimate the portion of on hand inventory that can be realized over the upcoming twelve months.

### **Identifiable Intangible Assets and Goodwill**

Identifiable intangible assets are recorded at cost, or when acquired as part of a business acquisition, at estimated fair value. Certain intangible assets are amortized over 5 to 10 years. Similar to tangible personal property and equipment, the Company periodically evaluates identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Intellectual property consists of purchased patent rights and developed technology acquired as part of a business acquisition. Amortization of the patent rights is recorded using the straight-line method over the estimated useful life of the patents of 10 years. Amortization of the developed technology is recorded using the straight-line method over the estimated useful life of 5 to 7 years.

The Company continues to operate in one segment, which is considered to be the sole reporting unit and therefore, goodwill is tested for impairment at the enterprise level. Indefinite-lived intangible assets, such as goodwill, are not amortized.

The Company typically tests goodwill for impairment annually, however, market conditions as well as reduced forecasts required that the Company test its goodwill carrying value as of September 30, 2019.

Subsequent to the adoption of Accounting Standards Update ("ASU") 2017-04 *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, a company must record a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value. The Company generally determines the fair value of its reporting unit using two valuation methods: the "Income Approach — Discounted Cash Flow Analysis" method, and the "Market Approach — Guideline Public Company Method."

Under the "Income Approach — Discounted Cash Flow Analysis" method the key assumptions consider projected sales, cost of sales, and operating expenses. These assumptions were determined by management utilizing the Company's internal operating plan, growth rates for revenues and operating expenses, and margin assumptions. An additional key assumption under this approach is the discount rate, which is determined by looking at current risk-free rates of capital, current market interest rates, and the evaluation of risk premium relevant to the business segment. If the Company's assumptions relative to growth rates were to change or were incorrect, the fair value calculation may change.

Under the "Market Approach — Guideline Public Company Method" the Company identified several publicly traded companies, which it believed had sufficiently relevant similarities. Similar to the income approach discussed above, sales, cost of sales, operating expenses, and their respective growth rates are key assumptions utilized. The market prices of the Company's common stock and other guideline companies are additional key assumptions. If these market prices increase, the estimated market value would increase. If the market prices decrease, the estimated market value would decrease.

The results of these two methods were weighted based upon management's evaluation of the relevance of the two approaches. In the 2019 evaluation, management determined that the income and market value approach should be weighted 50%-50%. In addition, management considered the decline in both the Company's stock price and market capitalization after the September 30, 2019 measurement date as relevant factors in the analysis.

The Company also performed a recoverability test on the intellectual property and concluded that there was no impairment as of September 30, 2019 or December 31, 2019.



During the third quarter of 2019, the Company determined that the goodwill associated with the business was impaired, and recorded impairment charges of \$79.0 million. The impairment charge resulted from decreased sales and estimated cash flows and a significant decline in the Company's stock price. The Company also recognized a \$7.9 million impairment charge to its IPR&D as it concluded that under the market value approach, the fair value of the IPR&D was lower than the carrying value.

No impairment existed at December 31, 2018.

### **In-Process Research and Development**

In-process research and development ("IPR&D") assets represent the fair value assigned to technologies that were acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

The IPR&D for the Senhance System was acquired on September 21, 2015. On October 13, 2017, upon receiving FDA clearance and the ability to commercialize the products associated with the IPR&D assets, the assets were deemed definite-lived, reclassified to intellectual property and are now amortized based on their estimated useful lives.

The IPR&D from MST was acquired on October 31, 2018.

The Company performed an impairment test of its IPR&D at the end of the third quarter 2019 as recent events and changes in market conditions indicated that the asset might be impaired.

The impairment test consisted of a comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of the IPR&D exceeds its fair value, an impairment loss is recognized in an amount equal to that excess.

Significant judgment is applied when testing for impairment. This judgment includes developing cash flow projections, selecting appropriate discount rates, identifying relevant market comparables, and incorporating general economic and market conditions.

During the third quarter of 2019, the Company concluded that the fair value determined by the market value approach, was lower than the carrying value. As a result, the Company recognized a \$7.9 million impairment charge to its IPR&D. The company performed its annual impairment assessment at December 31, 2019 and no additional impairment was required.

### **Property and Equipment**

Property and equipment consists primarily of machinery, manufacturing equipment, demonstration equipment, computer equipment, furniture, and leasehold improvements, which are recorded at cost.

Depreciation is recorded using the straight-line method over the estimated useful lives of the assets as follows:

|  |                                       |
|--|---------------------------------------|
| Machinery, manufacturing and demonstration equipment | 3-5 years                             |
| Computer equipment                                   | 3 years                               |
| Furniture  | 5 years                               |
| Leasehold improvements                               | Lesser of lease term or 3 to 10 years |

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

### **Impairment of Long-Lived Assets**

The Company reviews its long-lived assets for possible impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine the recoverability of its long-lived assets, the Company

evaluates the probability that future estimated undiscounted net cash flows will be less than the carrying amount of the assets. If such estimated cash flows are less than the carrying amount of the long-lived assets, then such assets are written down to their fair value. The Company's estimates of anticipated cash flows and the remaining estimated useful lives of long-lived assets could be reduced in the future, resulting in a reduction to the carrying amount of long-lived assets.

### **Contingent Consideration**

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, future Euro-to-USD exchange rates, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

### **Warrant Liabilities**

The Company's Series B Warrants (see Note 16) are measured at fair value using a simulation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected volatility, holding cost and the risk-free interest rate for the term of the warrant (see Note 5). The warrant liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss. The selection of the appropriate valuation model and the inputs and assumptions that are required to determine the valuation requires significant judgment and requires management to make estimates and assumptions that affect the reported amount of the related liability and reported amounts of the change in fair value. Actual results could differ from those estimates, and changes in these estimates are recorded when known. As the warrant liability is required to be measured at fair value at each reporting date, it is reasonably possible that these estimates and assumptions could change in the near term.

### **Translation of Foreign Currencies**

The functional currency of the Company's operational foreign subsidiaries is predominantly the Euro. The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items are translated at the average exchange rates prevailing during the period. The cumulative translation effect for a subsidiary using a functional currency other than the U.S. dollar is included in accumulated other comprehensive income or loss as a separate component of stockholders' equity.

The Company's intercompany accounts are denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany receivables that the Company considers to be of a long-term investment nature are recorded as a cumulative translation adjustment in accumulated other comprehensive income or loss as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany receivables from a foreign subsidiary for which the Company anticipates settlement in the foreseeable future are recorded in the consolidated statements of operations and comprehensive loss. The net gains and losses included in net loss in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2019 and 2018 were not significant.

### **Business Acquisitions**

Business acquisitions are accounted for using the acquisition method of accounting in accordance with ASC 805, "Business Combinations." ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, "Fair Value Measurements," as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) and certain acquisition-related restructuring charges impacting the target company are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

### **Risk and Uncertainties**

The Company is subject to a number of risks similar to other similarly-sized companies in the medical device industry. These risks include, without limitation, the Company's ability to continue as a going concern, the historical lack of profitability; the Company's ability to raise additional capital; the liquidity and capital resources of its partners; its ability to successfully develop, clinically test and commercialize its products; the timing and outcome of the regulatory review process for its products; changes in the health care and regulatory environments of the United States, the European Union, Japan, Taiwan and other countries in which the Company operates or intends to operate; its ability to attract and retain key management, marketing and scientific personnel; its ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights; its ability to successfully transition from a research and development company to a marketing, sales and distribution concern; competition in the market for robotic surgical devices; and its ability to identify and pursue development of additional products.

## Revenue Recognition

The Company adopted ASC Topic 606, *Revenue from Contracts with Customers* (the "New Revenue Standard"), on January 1, 2018. The Company's revenue consists of product revenue resulting from the sale of systems, system components, instruments and accessories, and service revenue. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities.

The Company's system sale arrangements generally contain multiple products and services. For these bundled sale arrangements, the Company accounts for individual products and services as separate performance obligations if they are distinct, which is if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. The Company's system sale arrangements include a combination of the following performance obligations: system(s), system components, instruments, accessories, and system service. The Company's system sale arrangements generally include a five years period of service. The first year of service is generally free and included in the system sale arrangement and the remaining four years are generally included at a stated service price. The Company considers the service terms in the arrangements that are legally enforceable to be performance obligations. Other than service, the Company generally satisfies all of the performance obligations up-front. System components, system accessories, instruments, accessories, and service are also sold on a standalone basis.

The Company recognizes revenues as the performance obligations are satisfied by transferring control of the product or service to a customer. The Company generally recognizes revenue for the performance obligations as follows:

- **System sales.** For systems and system components sold directly to end customers, revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. For systems sold through distributors, for which distributors are responsible for installation, revenue is recognized generally at the time of shipment. The Company's system arrangements generally do not provide a right of return. The systems are generally covered by a one-year warranty. Warranty costs were not material for the periods presented.
- **Instruments and accessories.** Revenue from sales of instruments and accessories is recognized when control is transferred to the customers, which generally occurs at the time of shipment, but also occurs at the time of delivery depending on the customer arrangement. Accessory products include sterile drapes used to help ensure a sterile field during surgery, vision products such as replacement endoscopes, camera heads, light guides, and other items that facilitate use of the Senhance System.
- **Service.** Service revenue is recognized ratably over the term of the service period as the customers benefit from the service throughout the service period. Revenue related to services performed on a time-and-materials basis is recognized when performed.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. Due to limited sales to date, standalone selling prices are not directly observable. The Company estimates the standalone selling price using the market assessment approach considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer, and market conditions. The Company regularly reviews standalone selling prices and updates these estimates if necessary.

The following table presents revenue disaggregated by type and geography:

|                                | Year Ended<br>December 31, |                  |
|--------------------------------|----------------------------|------------------|
|                                | 2019                       | 2018             |
|                                | (in thousands)             |                  |
| <b>U.S.</b>                    |                            |                  |
| Systems                        | \$ 90                      | \$ 2,556         |
| Instruments and accessories    | 108                        | 967              |
| Services                       | 338                        | 255              |
| <b>Total U.S. revenue</b>      | <b>536</b>                 | <b>3,778</b>     |
| <b>Outside of U.S. ("OUS")</b> |                            |                  |
| Systems                        | 5,459                      | 16,193           |
| Instruments and accessories    | 1,447                      | 3,552            |
| Services                       | 1,089                      | 579              |
| <b>Total OUS revenue</b>       | <b>7,995</b>               | <b>20,324</b>    |
| <b>Total</b>                   |                            |                  |
| Systems                        | 5,549                      | 18,749           |
| Instruments and accessories    | 1,555                      | 4,519            |
| Services                       | 1,427                      | 834              |
| <b>Total revenue</b>           | <b>\$ 8,531</b>            | <b>\$ 24,102</b> |

The Company recognizes sales by geographic area based on the country in which the customer is based.

Transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which the revenue has not yet been recognized. A significant portion of this amount relates to service obligations performed under the Company's system sales contracts that will be invoiced and recognized as revenue in future periods. Transaction price allocated to remaining performance obligations was approximately \$3.7 million as of December 31, 2019.

The Company invoices its customers based on the billing schedules in its sales arrangements. Contract assets for the periods presented primarily represent the difference between the revenue that was recognized based on the relative selling price of the related performance obligations and the contractual billing terms in the arrangements. Contract assets are included in accounts receivable and totaled \$0.2 million and \$0.2 million as of December 31, 2019 and 2018, respectively. Deferred revenue for the periods presented was primarily related to service obligations, for which the service fees are billed up-front, generally annually. The associated deferred revenue is generally recognized ratably over the service period. The Company did not have any significant impairment losses on its contract assets for the periods presented. Revenue recognized from deferred revenue attributable to warranty and maintenance agreements totaled \$1.0 million for the year ended December 31, 2019. The Company also recognized \$1.3 million during the year ended December 31, 2019, half of which was deferred at December 31, 2018, related to a 2017 system sale where revenue was deferred until its first clinical use, which occurred in the second quarter of 2019. Revenue recognized from deferred revenue for the year ended December 31, 2018 totaled \$0.4 million.

In connection with assets recognized from the costs to obtain a contract with a customer, the Company determined that the sales incentive programs for its sales team do not meet the requirements to be capitalized as the Company does not expect to generate future economic benefits from the related revenue from the initial sales transaction.

#### Cost of Revenue

Cost of revenue consists of contract manufacturing, materials, labor and manufacturing overhead incurred internally to produce the products. Shipping and handling costs incurred by the Company are included in cost of revenue. During the year ended December 31, 2019, the Company recorded a \$7.4 million inventory write-down as part of a restructuring plan and a \$1.5 million charge for inventory obsolescence related to certain system components.

#### Research and Development Costs

Research and development expenses primarily consist of engineering, product development and regulatory expenses, incurred in the design, development, testing and enhancement of our products. Research and development costs are expensed as incurred.

#### Reversal of Transfer Fee Accrual

In connection with the Senhance acquisition, the Company recorded an accrual of \$3.0 million in the 2015 third quarter for the potential assessment of additional transfer fees that could be assessed during a three year period. In September 2018, the Company determined that the accrual was no longer required and reversed the accrual.

### **Stock-Based Compensation**

The Company follows ASC 718 “Stock Compensation”, which provides guidance in accounting for share-based awards exchanged for services rendered and requires companies to expense the estimated fair value of these awards over the requisite service period.

The Company recognizes compensation expense for stock-based awards based on estimated fair values on the date of grant for awards. The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The fair value of restricted stock units is determined by the market price of the Company’s common stock on the date of grant. The expense associated with stock-based compensation is recognized on a straight-line basis over the requisite service period of each award.

The Company records as expense the fair value of stock-based compensation awards, including stock options and restricted stock units. Compensation expense for stock-based compensation was approximately \$11,508,000 and \$9,039,000 for the years ended December 31, 2019 and 2018, respectively.

### **Income Taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets or liabilities for the temporary differences between financial reporting and tax basis of the Company’s assets and liabilities, and for tax carryforwards at enacted statutory rates in effect for the years in which the asset or liability is expected to be realized. The effect on deferred taxes of a change in tax rates is recognized in income during the period that includes the enactment date. In addition, valuation allowances are established when necessary to reduce deferred tax assets and liabilities to the amounts expected to be realized.

On December 22, 2017, the Tax Cuts and Jobs Act (“Tax Legislation”) was enacted into law, which reduced the U.S. federal corporate income tax rate to 21% for tax years beginning after December 31, 2018. As a result of the newly enacted tax rate, the Company adjusted its U.S. deferred tax assets as of December 31, 2018, by applying the new 21% rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately \$36.1 million, resulting in no impact to the consolidated statement of operations and comprehensive loss.

The Tax Legislation also implements a territorial tax system. Under the territorial tax system, in general, the Company's foreign earnings will no longer be subject to tax in the U.S. As part of transition to the territorial tax system the Tax Legislation includes a mandatory deemed repatriation of all undistributed foreign earnings that are subject to a U.S. income tax. The Company has determined that the deemed repatriation applicable to the year ended December 31, 2018 did not result in an additional U.S. income tax liability as it has no undistributed foreign earnings.

The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income (“GILTI”), states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI as a period expense in the year the tax is incurred.

In a referendum held on May, 19 2019, Swiss voters adopted the Federal Act on Tax Reform and AVS Financing (TRAF). TRAF introduces major changes in the Swiss tax system by abolishing certain current preferential tax regimes and replacing them with new measures that are in line with international standards. The referendum did not have a material impact on the Company’s 2019 tax provision. The Company will continue to evaluate the impact of these provisions in future periods as the enactment process is completed.

### **Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

### **Segments**

The Company operates in one business segment—the research, development and sale of medical device robotics to improve minimally invasive surgery. The Company’s chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the

Company's consolidated operating results. Approximately 19% and 54% of the Company's total consolidated assets are located within the U.S. as of December 31, 2019 and 2018, respectively. The remaining assets are mostly located in Europe and are primarily related to the Company's facility in Italy, and include goodwill (as of December 2018 only), intellectual property, in-process research and development, other current assets, property and equipment, cash, accounts receivable, other long-term assets and inventory of \$60.5 million and \$111.0 million at December 31, 2019 and 2018. Total assets outside of the U.S. excluding goodwill amounted to 81% and 34% of total consolidated assets at December 31, 2019 and 2018, respectively. The Company recognizes sales by geographic area based on the country in which the customer is based. For the years ended December 31, 2019 and 2018, 6% and 16%, respectively, of net revenue were generated in the United States; 39% and 78% were generated in Europe; and 55% and 6% were generated in Asia.

### **Impact of Recently Issued Accounting Standards**

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The adoption of this ASU should not have a material impact on the consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-based Payments*. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The Company adopted ASU 2018-07 on January 1, 2019, whereby the accounting for share-based payments for non-employees and employees will be substantially the same. With the adoption of ASU 2018-07, the Company recorded a charge to accumulated deficit of \$7 thousand.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The amendments in this update are intended to simplify the accounting for certain equity-linked financial instruments and embedded features with down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under the new guidance, a down round feature will no longer need to be considered when determining whether certain financial instruments or embedded features should be classified as liabilities or equity instruments. That is, a down round feature will no longer preclude equity classification when assessing whether an instrument or embedded feature is indexed to an entity's own stock. In addition, the amendments clarify existing disclosure requirements for equity-classified instruments. These amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The adoption of this ASU did not have a material impact on the consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for most leases. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842), Targeted Improvements*, which amends the guidance to add a method of adoption whereby the issuer may elect to recognize a cumulative effect adjustment at the beginning of the period of adoption. ASU 2018-11 *Leases (Topic 842), Targeted Improvements*, does not require comparative period financial information to be adjusted. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement.

ASU 2016-02 defines a lease as a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration. To determine whether a contract conveys the right to control the use of the identified asset for a period of time, the customer has to have both (i) the right to obtain substantially all of the economic benefits from the use of the identified asset and (ii) the right to direct the use of the identified asset. A contract does not contain an identified asset if the supplier has a substantive right to substitute such asset ("the leasing criteria"). As part of the adoption of ASC 842, the Company performed an assessment of the impact that the new lease recognition standard will have on its consolidated financial statements. The Company's leases relate to office equipment, company owned vehicles and corporate offices, all of which are classified as operating leases and include fixed payments. The Company does not have any material leases, individually or in the aggregate, classified as a finance leasing arrangement under the new lease recognition standard.

On January 1, 2019, the Company adopted ASU No. 2016-02, applying the package of practical expedients to leases that commenced before the effective date whereby the Company elected to not reassess the following: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. The Company also elected, for all classes of underlying assets, to not separate non-lease components from lease components and instead to account for them as a single component. The Company elected to apply the transition provisions as of January 1, 2019, the date of adoption, using the effective date approach, and recorded lease ROU assets and related liabilities on its balance sheet

without restating prior periods. Many of the Company's leases include base rental periods coupled with options to renew or terminate the lease, generally at the Company's discretion. In evaluating the lease term, the Company considers whether renewal is reasonably certain. To the extent a significant economic incentive exists to renew the lease, the option is included within the lease term. Based on the Company's leases, renewal options generally do not provide a significant economic incentive and are therefore excluded from the lease term. The ROU asset is included in other long-term assets on the consolidated balance sheets. The current portion of operating lease liabilities are presented within accrued liabilities while the non-current portion of operating lease liabilities are presented within other long term liabilities on the consolidated balance sheets and represents the present value of the remaining lease payments, discounted using the Company's incremental borrowing rate, which ranges between 6.1% and 8.5% based on the terms of the lease. The weighted average discount rate as of December 31, 2019 was 7.8%. As a result of the adoption of ASU 2016-02, other long-term assets increased by \$1.8 million, accrued expenses increased by \$0.5 million, and other long-term liabilities increased by \$1.2 million. There was no change to the Company's consolidated statements of operations and comprehensive loss or cash flows as a result of the adoption of ASU 2016-02.

As of December 31, 2019, the right-of-use asset totaled \$2.3 million and is included within other long term assets on the consolidated balance sheet and the lease liability totaled \$2.5 million, of which \$1.1 million is classified as current within accrued expenses and \$1.4 million is classified as non-current and makes up the full balance of other long term liabilities on the consolidated balance sheet. Operating lease costs for the year ended December 31, 2019 totaled \$1.4 million and are included within operating expenses in the consolidated statement of operations and comprehensive loss. Rent expense for the year ended December 31, 2018 was approximately \$1.2 million. The weighted average remaining lease term for operating leases as of December 31, 2019 was 2.6 years. Total cash paid for operating leases during the year ended December 31, 2019 was \$1.7 million and is included within cash flows from operating activities within the consolidated statement of cash flows.

The following table presents the minimum lease payments as of December 31, 2019 (in thousands):

|   |                 |
|---|-----------------|
| January 1, 2020 to December 31, 2020                  | \$ 1,372        |
| January 1, 2021 to December 31, 2021                  | 716             |
| January 1, 2022 to December 31, 2022                  | 454             |
| January 1, 2023 to December 31, 2023                  | 207             |
| January 1, 2024 to December 31, 2024                  | 28              |
| Thereafter  | —               |
| <b>Total minimum lease payments</b>                   | <b>\$ 2,778</b> |
| Less: Amount of lease payments representing interest  | (266)           |
| <b>Present value of future minimum lease payments</b> | <b>\$ 2,512</b> |

The following table presents the minimum lease payments as of December 31, 2018 (in thousands):

|                                      |                 |
|--------------------------------------|-----------------|
| January 1, 2019 to December 31, 2019 | \$ 929          |
| January 1, 2020 to December 31, 2020 | 399             |
| January 1, 2021 to December 31, 2021 | 385             |
| January 1, 2022 to December 31, 2022 | 175             |
| January 1, 2023 to December 31, 2023 | 38              |
| Thereafter                           | —               |
| <b>Total minimum lease payments</b>  | <b>\$ 1,926</b> |

### 3. Acquisitions

#### *MST Medical Surgery Technologies Ltd. Acquisition*

On September 23, 2018, the Company entered into an Asset Purchase Agreement (the "MST Purchase Agreement") with MST Medical Surgery Technologies Ltd., an Israeli private company (the "Seller"), and two of the Company's wholly owned subsidiaries, as purchasers of the assets of the Seller, (collectively, the "Buyers"). The closing of the transactions occurred on October 31, 2018, pursuant to which the Company acquired the Seller's assets consisting of intellectual property and tangible assets related to surgical analytics with its core image analytics technology designed to empower and automate the surgical environment, with a focus on medical robotics and computer-assisted surgery. The core technology acquired under the MST Purchase Agreement is a software-

based image analytics information platform powered by advanced visualization, scene recognition, artificial intelligence, machine learning and data analytics.

Under the terms of the MST Purchase Agreement, at the closing the Buyers purchased substantially all of the assets of the Seller. The acquisition price consisted of two tranches. At or prior to the closing of the transaction the Buyers paid \$5.8 million in cash and the Company issued approximately 242,310 shares of the Company's common stock (the "Initial Shares"). A second tranche of \$6.6 million in additional consideration was payable in cash, stock or cash and stock, at the discretion of the Company, within one year after the closing date. On August 7, 2019, the Company notified MST that the Company would satisfy the additional consideration payment of \$6.6 million by issuing shares of TransEnterix common stock. The number of shares issued to MST was 370,423 (the "Additional Consideration Shares" and, together with the Initial Shares, the "Securities Consideration").

The MST Purchase Agreement contains customary representations and warranties of the parties and the parties have customary indemnification obligations, which are subject to certain limitations described further in the MST Purchase Agreement.

In connection with the closing under the MST Purchase Agreement (the "MST Acquisition"), the Company and the Seller entered into a Lock-Up Agreement, dated October 31, 2018, pursuant to which the Seller agreed, subject to certain exceptions, not to sell, transfer or otherwise convey any of the Initial Shares for six months following the Closing Date. As of the date of this report, 75% of the Initial Shares are free from the lock-up restrictions. For the remaining 25% of the Initial Shares, the Lock-Up Agreement provides that all of the Initial Shares will be released from the lock-up restrictions on May 1, 2020, or earlier upon certain other conditions. The Additional Consideration Shares were released from the lock-up restrictions on February 7, 2020.

In connection with the MST Acquisition, the Company also entered into a Registration Rights Agreement, dated as of October 31, 2018, with MST, pursuant to which the Company agreed to register the Securities Consideration such that such Securities Consideration is eligible for resale following the end of the lock-up periods described above. All of the Securities Consideration is eligible to be sold by the holders without restriction under Rule 144, therefore the Registration Rights Agreement has expired. The MST Purchase Agreement was accounted for as a business combination utilizing the methodology prescribed in ASC 805. The purchase price for the acquisition was allocated to the assets acquired and liabilities assumed based on their estimated fair values.

The following table summarizes the acquisition date fair value of the consideration (in thousands).

|   |    |               |
|---|----|---------------|
| Stock consideration                     | \$ | 8,300         |
| Cash consideration                      |    | 5,800         |
| Present value of deferred consideration |    | 5,900         |
| Other consideration                     |    | 314           |
| Total consideration                     | \$ | <u>20,314</u> |

The value of the stock consideration was determined based on the fair value of the stock on the closing date, adjusted for a lack of marketability discount related to the Lock-Up Agreement. The value of the deferred consideration was determined based on the present value of the future payment using a market interest rate.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on October 31, 2018, the date of acquisition (in thousands):

|                                     |    |               |
|-------------------------------------|----|---------------|
| Property and equipment              | \$ | 43            |
| In-process research and development |    | 10,633        |
| Goodwill                            |    | 9,638         |
| Net assets acquired                 | \$ | <u>20,314</u> |

The Company allocated \$10.6 million of the purchase price to identifiable intangible assets of in-process research and development that met the separability and contractual legal criterion of ASC 805. IPR&D is principally the estimated fair value of the MST technology which had not reached commercial technological feasibility nor had alternative future use at the time of the acquisition and therefore the Company considered IPR&D, with assigned values to be allocated to the IPR&D assets acquired.

Goodwill is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition arises largely from synergies expected



from combining the intellectual property acquired from MST with the Company's existing intellectual property as well as acquired employees. The goodwill is deductible for income tax purposes.

The following unaudited pro forma information presents the combined results of operations for the year ended December 31, 2018, as if the Company had completed the MST Acquisition at the beginning of fiscal 2018. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma consolidated financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs.

|                    | <u>Year Ended December 31,</u>                            |          |
|--------------------|---|----------|
|                    | <u>2018</u>   |          |
|                    | (In thousands except<br>per share amounts)<br>(unaudited) |          |
| Revenue            | \$  | 24,170   |
| Net loss           |   | (64,365) |
| Net loss per share | \$  | (0.31)   |

During the year ended December 31, 2018 no revenue and a net loss of \$0.4 million associated with MST's operations are included in the consolidated financial statements.

On July 3, 2019 the Company entered into a System Sale Agreement with GBIL to sell certain assets related to the AutoLap technology. On October 15, 2019, the Company amended the prior AutoLap Sale Agreement with GBIL. Pursuant to the amended agreement the Company sold the AutoLap laparoscopic vision system, or AutoLap, and related assets to GBIL. The assets include inventory, spare parts, production equipment, testing equipment and certain intellectual property specifically related to the AutoLap. The purchase price was \$17.0 million, all of which was received in 2019 in the form of \$16 million in cash and a commitment by GBIL to pay \$1.0 million to settle certain Company obligations in China. GBIL subsequently paid the obligation. Under the amended AutoLap Agreement, the Company entered into a cross-license agreement with GBIL to retain rights to use any AutoLap-related intellectual property sold to GBIL, and to non-exclusively license additional intellectual property to GBIL. The Company recorded a \$16.0 million gain on the sale of the AutoLap assets during the year ended December 31, 2019, which represented the proceeds received in excess of the carrying value of the assets, less contract costs.

#### *Senhance Surgical Robotic System*

On September 21, 2015, the Company completed the strategic acquisition, through its wholly owned subsidiary TransEnterix International, from Sofar, of all of the assets, employees and contracts related to the advanced robotic system for minimally invasive laparoscopic surgery now known as the Senhance System.

Under the terms of the Purchase Agreement, the consideration consisted of the issuance of (i) 1,195,647 shares of the Company's common stock (the "Securities Consideration") and (ii) approximately \$25.0 million U.S. Dollars and €27.5 million Euro in cash consideration (the "Cash Consideration").

On December 30, 2016, the Company and Sofar entered into an Amendment to the Purchase Agreement (the "Amendment") to restructure the terms of the second tranche of the Cash Consideration (the "Second Tranche"). The initial Securities Consideration was issued in full at the closing of the Senhance Acquisition; under the Amendment, the Second Tranche of the Cash Consideration was restructured, and an additional issuance of 286,360 shares of the Company's common stock with an aggregate fair market value of €5.0 million occurred in January 2017. Following the Amendment, the total Cash Consideration was \$25.0 million U.S. Dollars and approximately €22.5 million Euro, of which all but €15.1 million Euro has been paid as of December 31, 2019. The majority of the remaining Cash Consideration to be paid is the third tranche of the Cash Consideration (the "Third Tranche") of €15.0 million which shall be payable upon achievement of trailing revenues from sales or services contracts of the Senhance System of at least €25.0 million over a calendar quarter.

The fourth tranche of the Cash Consideration of €2.5 million was payable in installments by December 31 of each year as reimbursement for certain debt payments made by Sofar under an existing Sofar loan agreement in such year, with payments beginning as of December 31, 2017. As of December 31, 2019, the Company had paid €2.4 million of the fourth tranche.

The Third Tranche payments will be accelerated in the event that (i) the Company or TransEnterix International is acquired, (ii) the Company significantly reduces or suspends selling efforts of the Senhance System, or (iii) the Company acquires a business that offers alternative products that are directly competitive with the Senhance System. The remaining amounts due to Sofar are included in contingent consideration as of December 31, 2019 and 2018.

The Purchase Agreement contains customary representations and warranties of the parties and the parties have customary indemnification obligations, which are subject to certain limitations described further in the Purchase Agreement.

#### 4. Cash, Cash Equivalents, and Restricted Cash

Cash, cash equivalents and restricted cash consist of the following:

|                                 | December 31,<br>2019 | December 31,<br>2018 |
|---------------------------------|----------------------|----------------------|
|                                 | (In thousands)       |                      |
| Cash                            | \$ 9,596             | \$ 1,485             |
| Money market                    | 2                    | 19,576               |
| Total cash and cash equivalents | \$ 9,598             | \$ 21,061            |
| Restricted cash                 | 969                  | 590                  |
| Total                           | \$ 10,567            | \$ 21,651            |

Restricted cash at December 31, 2019 and 2018 includes \$1.0 million and \$0.6 million, respectively, in cash accounts held as collateral primarily under the terms of an office operating lease, credit cards, automobile leases, and a performance guarantee required by the government of a country in which a Senhance System was sold in 2018.

#### 5. Fair Value

The Company held certain assets and liabilities that are required to be measured at fair value on a recurring basis. These assets and liabilities include cash and cash equivalents, restricted cash, contingent consideration and warrant liabilities. ASC 820-10 (“Fair Value Measurement Disclosure”) requires the valuation using a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company’s own assumptions, consistent with reasonably available assumptions made by other market participants. The Company did not have any transfers of assets and liabilities between Level 1, Level 2, and Level 3 of the fair value hierarchy during the years ended December 31, 2019 and 2018.

For assets and liabilities recorded at fair value, it is the Company’s policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data and therefore, are based primarily upon estimates, are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

As prescribed by U.S. GAAP, the Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy.

The determination of where an asset or liability falls in the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures and based on various factors, it is possible that an asset or liability may be classified differently from period to period. However, the Company expects changes in classifications between levels will be rare.

The carrying values of accounts receivable, short-term investments, interest receivable, accounts payable, and certain accrued expenses at December 31, 2019 and 2018, approximate their fair values due to the short-term nature of these items. The Company's notes payable balance also approximates fair value as of December 31, 2018, as the interest rate on the notes payable approximates the rates available to the Company as of this date.

The following are the major categories of assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

| <b>December 31, 2019</b>                        |   |  |  |                  |  |
|---|---|--|--|------------------|--|
| (In thousands)<br>(unaudited)                   |   |  |  |                  |  |
| <b>Description</b>                              | <b>Quoted Prices in<br/>Active Markets for<br/>Identical Assets<br/>(Level 1)</b> | <b>Significant Other<br/>Observable Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable Inputs<br/>(Level 3)</b> | <b>Total</b>     |  |
| <b>Assets measured at fair value</b>            |   |  |  |                  |  |
| Cash and cash equivalents                       | \$ 9,598  | \$ —   | \$ —   | \$ 9,598         |  |
| Restricted cash                                 | 969   | —  | —  | 969              |  |
| <b>Total Assets measured at fair value</b>      | <b>\$ 10,567</b>  | <b>\$ —</b>  | <b>\$ —</b>  | <b>\$ 10,567</b> |  |
| <b>Liabilities measured at fair value</b>       |   |  |  |                  |  |
| Contingent consideration                        | \$ —  | \$ —   | \$ 1,084   | \$ 1,084         |  |
| Warrant liabilities                             | —   | —  | 2,388  | 2,388            |  |
| <b>Total liabilities measured at fair value</b> | <b>\$ —</b>   | <b>\$ —</b>  | <b>\$ 3,472</b>  | <b>\$ 3,472</b>  |  |
| <b>December 31, 2018</b>                        |   |  |  |                  |  |
| (In thousands)                                  |   |  |  |                  |  |
| <b>Description</b>                              | <b>Quoted Prices in<br/>Active Markets for<br/>Identical Assets<br/>(Level 1)</b> | <b>Significant Other<br/>Observable Inputs<br/>(Level 2)</b> | <b>Significant<br/>Unobservable Inputs<br/>(Level 3)</b> | <b>Total</b>     |  |
| <b>Assets measured at fair value</b>            |   |  |  |                  |  |
| Cash and cash equivalents                       | \$ 21,061   | \$ —   | \$ —   | \$ 21,061        |  |
| Restricted cash                                 | 590   | —  | —  | 590              |  |
| <b>Total Assets measured at fair value</b>      | <b>\$ 21,651</b>  | <b>\$ —</b>  | <b>\$ —</b>  | <b>\$ 21,651</b> |  |
| <b>Liabilities measured at fair value</b>       |   |  |  |                  |  |
| Contingent consideration                        | \$ —  | \$ —   | \$ 10,637  | \$ 10,637        |  |
| Warrant liabilities                             | —   | —  | 4,636  | 4,636            |  |
| <b>Total liabilities measured at fair value</b> | <b>\$ —</b>   | <b>\$ —</b>  | <b>\$ 15,273</b>   | <b>\$ 15,273</b> |  |

The Company's financial liabilities consisted of contingent consideration potentially payable to Sofar related to the Senhance Acquisition in September 2015 (Note 3). This liability is reported as Level 3 as estimated fair value of the contingent consideration related to the acquisition requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome. The decrease in fair value of the contingent consideration of \$9.6 million for the year ended December 31, 2019 was primarily due to a change in the Company's long-term forecast. The decrease in fair value of the contingent consideration of \$1.0 million for the year ended December 31, 2018 was primarily due to the impact of foreign currency exchange rates and changes in the Company's long-range forecast. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statements of operations and comprehensive loss.

On April 28, 2017, the Company sold 24.9 million units (the "Units"), each consisting of approximately 0.077 shares of the Company's Common Stock, a Series A warrant to purchase approximately 0.077 shares of Common Stock with an exercise price of \$13.00 per share (the "Series A Warrants"), and a Series B warrant to purchase approximately 0.058 shares of Common Stock with an exercise price of \$13.00 per share (the "Series B Warrants," together with the Series A Warrants, the "Warrants"), at an offering price of \$1.00 per Unit. Each Series A Warrant was exercisable at any time beginning on the date of issuance, and from time to time thereafter, through and including the first anniversary of the issuance date, unless terminated earlier as provided in the Series A Warrant. Receipt of 510(k) clearance for the Senhance System on October 13, 2017 triggered the acceleration of the expiration date of the Series A Warrants to October 31, 2017 (see Note 16). As such, all of the Series A Warrants were exercised

prior to the expiration date. Each Series B Warrant may be exercised at any time beginning on the date of issuance and from time to time thereafter through and including the fifth anniversary of the issuance date.

The fair value of the Series A Warrants of \$2.5 million at the date of issuance was estimated using the Black-Scholes Merton model which used the following inputs: term of 1 year, risk free rate of 1.07%, no dividends, volatility of 73.14%, and share price of \$8.45 per share based on the trading price of the Company's Common Stock. All Series A Warrants were exercised as of October 31, 2017.

The exercise prices and the number of shares issuable upon exercise of each of the Series B Warrants are subject to adjustment upon the occurrence of certain events, including, but not limited to, stock splits or dividends, business combinations, sale of assets, similar recapitalization transactions, or other similar transactions. The Series B warrants contain provisions, often referred to as "down-round protection," that leads to adjustment of the exercise price and number of underlying warrant shares if the Company issues securities, including its common stock or convertible securities or debt securities, in the future at sale prices below the then-current exercise price. As a result of this adjustment feature and after giving effect to the Company's reverse stock split at a ratio of one-for-thirteen shares effective December 11, 2019, or the Reverse Stock Split, the exercise price of all outstanding Series B Warrants has been adjusted to \$1.39 per share and the number of shares of common stock reserved for and issuable upon the exercise of outstanding Series B Warrants has been adjusted to 1,963,451 warrant shares as of December 31, 2019.

The change in fair value of all outstanding Series B warrants for the years ended December 31, 2019 and 2018 of a decrease of \$2.2 million and an increase of \$14.3 million, respectively, was included in the Company's consolidated statements of operations and comprehensive loss. The following table presents the inputs and valuation methodologies used for the Company's fair value of the Series B warrants:

| Series B                            | December 31, 2019 | December 31, 2018 |
|-------------------------------------|-------------------|-------------------|
| Fair value                          | \$2.4 million     | \$4.6 million     |
| Valuation methodology               | Monte Carlo       | Monte Carlo       |
| Term                                | 2.32 years        | 3.32 years        |
| Risk free rate                      | 1.59%             | 2.47%             |
| Dividends                           | —                 | —                 |
| Volatility                          | 109.80%           | 87.60%            |
| Share price                         | \$1.47            | \$29.38           |
| Probability of additional financing | 100% in 2020      | 100% in 2019      |

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements for contingent consideration as of December 31, 2019 and 2018:

|                          | Valuation Methodology                | Significant Unobservable Input | Weighted Average (range, if applicable) |                   |
|--------------------------|--------------------------------------|--------------------------------|---|-------------------|
|                          |                                      |                                | December 31, 2019                       | December 31, 2018 |
| Contingent consideration | Probability weighted income approach | Milestone dates                | 2020 to 2024                            | 2019 to 2022      |
|                          |                                      | Discount rate                  | 10% to 11%                              | 11.5% to 12%      |

The following table summarizes the change in fair value, as determined by Level 3 inputs for the warrants and the contingent consideration for the years ended December 31, 2019 and 2018:

|                                      | Fair Value<br>Measurement at<br>Reporting Date<br>(Level 3) |                             |
|--------------------------------------|---|-----------------------------|
|                                      | (In thousands)  |                             |
|                                      | Common stock<br>warrants                                    | Contingent<br>consideration |
| Balance at December 31, 2017         | \$ 14,090   | \$ 12,418                   |
| Payment for contingent consideration | —   | (770)                       |
| Exercise of warrants                 | (23,774)  | —                           |
| Change in fair value                 | 14,320  | (1,011)                     |
| Balance at December 31, 2018         | 4,636   | 10,637                      |
| Change in fair value                 | (2,248)   | (9,553)                     |
| Balance at December 31, 2019         | 2,388   | 1,084                       |
| Current portion                      | —   | 73                          |
| Long-term portion                    | 2,388   | 1,011                       |
| Balance at December 31, 2019         | \$ 2,388  | \$ 1,084                    |

## 6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

|                                      | December 31,<br>2019 | December 31,<br>2018 |
|--------------------------------------|----------------------|----------------------|
|                                      | (In thousands)       |                      |
| Gross accounts receivable            | \$ 2,274             | \$ 8,640             |
| Allowance for uncollectible accounts | (1,654)              | (80)                 |
| Total accounts receivable, net       | \$ 620               | \$ 8,560             |

The Company recorded \$1.6 million in bad debt expense during the year ended December 31, 2019.

## 7. Inventories

The components of inventories are as follows:

|                   | December 31,<br>2019 | December 31,<br>2018 |
|-------------------|----------------------|----------------------|
|                   | (In thousands)       |                      |
| Finished goods    | \$ 9,737             | \$ 5,439             |
| Raw materials     | 8,510                | 5,502                |
| Total inventories | \$ 18,247            | \$ 10,941            |
| Current Portion   | \$ 10,653            | \$ 10,941            |
| Long-term portion | 7,594                | —                    |
| Total inventories | \$ 18,247            | \$ 10,941            |

The Company recorded a write-down of obsolete inventory for the year-ended December 31, 2019 totaling \$7.4 million as part of a restructuring plan and a \$1.5 million charge for inventory obsolescence related to certain system components. There were no such write-downs or charges for the year ended December 31, 2018.

## 8. Other Current Assets

The following table presents the components of other current assets:

|                     | December 31,<br>2019 | December 31,<br>2018 |
|---------------------|----------------------|----------------------|
|                     | (In thousands)       |                      |
| Advances to vendors | \$ 2,534             | \$ 5,427             |
| Prepaid expenses    | 1,834                | 1,443                |
| VAT receivable      | 2,716                | 2,335                |
| Total               | <u>\$ 7,084</u>      | <u>\$ 9,205</u>      |

## 9. Property and Equipment

Property and equipment consisted of the following:

|  | December 31,<br>2019 | December 31,<br>2018 |
|--|----------------------|----------------------|
|  | (In thousands)       |                      |
| Machinery, manufacturing and demonstration equipment | \$ 10,421            | \$ 12,320            |
| Computer equipment                                   | 2,321                | 2,260                |
| Furniture  | 637                  | 639                  |
| Leasehold improvements                               | 2,295                | 2,280                |
| Total property and equipment                         | <u>15,674</u>        | <u>17,499</u>        |
| Accumulated depreciation and amortization            | (10,968)             | (11,162)             |
| Property and equipment, net                          | <u>\$ 4,706</u>      | <u>\$ 6,337</u>      |

Depreciation expense was approximately \$2.2 million and \$2.4 million for the years ended December 31, 2019 and 2018, respectively.

## 10. Goodwill, In-Process Research and Development and Intellectual Property

### Goodwill

Goodwill of \$93.8 million was recorded in connection with the Merger, as described in Note 1, goodwill of \$38.3 million was recorded in connection with the Senhance Acquisition, as described in Note 3, and goodwill of \$9.6 million was recorded in connection with the MST Acquisition, as described in Note 3. The carrying value of goodwill and the change in the balance for the years ended December 31, 2019 and 2018 is as follows:

|                                     | Goodwill       |
|-------------------------------------|----------------|
|                                     | (In thousands) |
| Balance at December 31, 2017        | 71,368         |
| Additions                           | 9,638          |
| Foreign currency translation impact | (875)          |
| Balance at December 31, 2018        | \$ 80,131      |
| Foreign currency translation impact | (1,162)        |
| Impairment                          | (78,969)       |
| Balance at December 31, 2019        | <u>\$ —</u>    |

Accumulated impairment of goodwill as of December 31, 2019 and 2018 was \$140.8 million and \$61.8 million, respectively.

The Company performs an annual impairment test of goodwill at December 31, or more frequently if events or changes in circumstances indicate that the carrying value of the Company's one reporting unit may not be recoverable. As of December 31, 2018, the Company calculated the fair value of the Company's sole reporting unit, based on the Company's market capitalization, which exceeded the carrying amount. Accordingly, no charge for goodwill impairment was required as of December 31, 2018. During the third quarter of 2019, the Company's stock price declined significantly as a result of decreased sales. As of September 30, 2019, goodwill was deemed to be fully impaired, and the Company recorded an impairment charge of \$79.0 million.

*In-Process Research and Development*

As described in Note 3, on October 31, 2018, the Company acquired the MST assets, technology and business from MST and recorded \$10.6 million of IPR&D. The estimated fair value of the IPR&D was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 15% and cash flows that have been probability adjusted to reflect the risks of product integration, which the Company believes are appropriate and representative of market participant assumptions.

The Company performed an impairment test of its IPR&D at the end of the third quarter 2019 as recent events and changes in market conditions indicated that the asset might be impaired. The impairment test consisted of a comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of the IPR&D exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. Significant judgment is applied when testing for impairment. This judgment includes developing cash flow projections, selecting appropriate discount rates, identifying relevant market comparables, and incorporating general economic and market conditions. During the third quarter of 2019, the Company concluded that the fair value determined by the market value approach was lower than the carrying value. As a result, the Company recognized a \$7.9 million impairment charge to its IPR&D. The company performed its annual impairment assessment at December 31, 2019 and no additional impairment was required.

The carrying value of the Company's IPR&D assets and the change in the balance for the years ended December 31, 2018 and 2019 is as follows:

|                                     | <b>In-Process<br/>Research and<br/>Development</b> |
|-------------------------------------|--|
|                                     | (In thousands)                                     |
| Balance at December 31, 2017        | \$ —   |
| Additions                           | 10,633   |
| Foreign currency translation impact | 114  |
| Balance at December 31, 2018        | 10,747   |
| Impairment                          | (7,912)  |
| Foreign currency translation impact | (365)  |
| Balance at December 31, 2019        | <u>\$ 2,470</u>                                    |

*Intellectual Property*

As described in Note 3, on September 21, 2015, the Company acquired all of the assets related to the Senhance System and recorded \$17.1 million of IPR&D. The estimated fair value of the IPR&D was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 45% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions. On October 13, 2017, upon regulatory approval and the ability to commercialize the products associated with the IPR&D assets, the assets were deemed definite-lived, reclassified to intellectual property and are now being amortized based on their estimated useful lives.

The components of gross intellectual property, accumulated amortization, and net intellectual property as of December 31, 2019 and 2018 are as follows:

|                                  | December 31, 2019     |                          |                                     |                     | December 31, 2018     |                          |                                     |                     |
|----------------------------------|-----------------------|--------------------------|-------------------------------------|---------------------|-----------------------|--------------------------|-------------------------------------|---------------------|
|                                  | (In thousands)        |                          |                                     |                     | (In thousands)        |                          |                                     |                     |
|                                  | Gross Carrying Amount | Accumulated Amortization | Foreign currency translation impact | Net Carrying Amount | Gross Carrying Amount | Accumulated Amortization | Foreign currency translation impact | Net Carrying Amount |
| Developed technology             | \$ 66,413             | \$ (36,918)              | \$ (1,208)                          | \$ 28,287           | \$ 66,413             | \$ (27,174)              | \$ 119                              | \$ 39,358           |
| Technology and patents purchased | 400                   | (112)                    | 21                                  | 309                 | 400                   | (72)                     | 30                                  | 358                 |
| Total intellectual property      | \$ 66,813             | \$ (37,030)              | \$ (1,187)                          | \$ 28,596           | \$ 66,813             | \$ (27,246)              | \$ 149                              | \$ 39,716           |

The weighted average remaining useful life of the developed technology and technology and patents purchased was 2.8 years and 7.3 years, respectively as of December 31, 2019.

The estimated future amortization expense of intangible assets as of December 31, 2019 is as follows:

|            | Year ending<br>December 31, 2019 |
|------------|----------------------------------|
|            | (In thousands)                   |
| 2020       | \$ 10,328                        |
| 2021       | 10,328                           |
| 2022       | 7,757                            |
| 2023       | 42                               |
| 2024       | 42                               |
| Thereafter | 99                               |
| Total      | \$ 28,596                        |

## 11. Income Taxes

The components for the income tax expense (benefit) are as follows for the years ended December 31 (in thousands):

|                          | 2019       | 2018       |
|--------------------------|------------|------------|
| Current income taxes     |            |            |
| Federal                  | \$ —       | \$ —       |
| State                    | —          | —          |
| Foreign                  | 100        | —          |
| Deferred income taxes    |            |            |
| Federal                  | —          | —          |
| State                    | —          | —          |
| Foreign                  | (3,224)    | (3,377)    |
| Total income tax benefit | \$ (3,124) | \$ (3,377) |

The United States and foreign components of loss from operations before taxes are as follows for the years ended December 31 (in thousands):

|   | 2019         | 2018        |
|---|--------------|-------------|
| United States                           | \$ (91,935)  | \$ (44,744) |
| Foreign                                 | (65,390)     | (20,410)    |
| Total loss from operations before taxes | \$ (157,325) | \$ (65,154) |



Significant components of the Company's deferred tax assets consist of the following at December 31 (in thousands):

|  | 2019              | 2018              |
|--|-------------------|-------------------|
| <b>Noncurrent deferred tax assets:</b>           |                   |                   |
| Stock-based compensation                         | \$ 3,665          | \$ 2,281          |
| Accrued expenses and other                       | 1,007             | 795               |
| Research credit carryforward                     | 6,776             | 6,182             |
| Fixed assets                                     | 345               | 392               |
| Capitalized start-up costs and other intangibles | 3,618             | 1,859             |
| Net operating loss carryforwards                 | 113,410           | 74,566            |
|  | <u>128,821</u>    | <u>86,075</u>     |
| Valuation allowance                              | (123,108)         | (81,337)          |
| Net noncurrent deferred tax asset                | 5,713             | 4,738             |
| <b>Noncurrent deferred tax liabilities</b>       |                   |                   |
| Fixed assets and other                           | (1,445)           | (686)             |
| Purchase accounting intangibles                  | (5,660)           | (8,772)           |
| Net noncurrent deferred tax liability            | (7,105)           | (9,458)           |
| Net deferred tax liability                       | <u>\$ (1,392)</u> | <u>\$ (4,720)</u> |

At December 31, 2019 and 2018, the Company has provided a full valuation allowance against its net deferred tax assets in the U.S., Luxembourg, Swiss, and Asian tax jurisdictions, since realization of these benefits is not more likely than not. The valuation allowance increased approximately \$41.8 million from the prior year. At December 31, 2019, the Company had U.S. federal net operating loss carryforwards of \$337.6 million. Of this amount, \$254.5 million begin to expire in 2027, while the remaining \$83.1 million carry forward indefinitely. At December 31, 2019, the Company had U.S. state net operating loss carryforwards of \$287.5 million. Of this amount, \$282.8 million begin to expire in 2022, while the remaining \$4.7 million carry forward indefinitely. At December 31, 2019, the Company had federal research credit carryforwards in the amount of \$6.8 million. These carryforwards begin to expire in 2027. The utilization of the federal net operating loss carryforwards and credit carryforwards will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

At December 31, 2019, the Company had foreign operating loss carryforwards in Italy of approximately \$23.1 million, which can be carried forward indefinitely; foreign operating loss carryforwards in Luxembourg of approximately \$95.1 million, which will begin to expire in 2035; foreign operating loss carryforwards in Switzerland of approximately \$42.3 million, which begin to expire in 2023; and foreign operating loss carryforwards in Japan of approximately \$2.0 million, which begin to expire in 2028.

The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2019, the Company had gross unrecognized tax benefits of approximately \$1.5 million. Of the total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next twelve months. Furthermore, the Company does not expect any cash settlement with the taxing authorities as a result of these unrecognized tax benefits as the Company has sufficient unutilized carryforward attributes to offset the tax impact of these adjustments.

The following is a tabular reconciliation of the Company's change in gross unrecognized tax positions at December 31 (in thousands):

|  | 2019            | 2018            |
|--|-----------------|-----------------|
| Beginning balance  | \$ 1,363        | \$ 1,202        |
| Gross increases for tax positions related to current periods | 149             | 161             |
| Gross increases for tax positions related to prior periods   | —               | —               |
| Ending balance   | <u>\$ 1,512</u> | <u>\$ 1,363</u> |

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company has analyzed its filing positions in all significant federal, state, and foreign jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. With few exceptions, the Company is no longer subject to United States Federal, state, and local tax examinations by tax authorities for years before 2016, although carryforward attributes that were generated prior to 2016 may still be adjusted upon examination by the taxing authorities if they either have been or will be used in a future period. No income tax returns are currently under examination by taxing authorities.

Taxes computed at the then-current statutory federal income tax rate of 21% are reconciled to the provision for income taxes as follows for the years ended December 31:

|   | 2019              |                      | 2018              |                      |
|---|-------------------|----------------------|-------------------|----------------------|
|   | Amount            | % of Pretax Earnings | Amount            | % of Pretax Earnings |
| United States federal tax at statutory rate             | \$ (33,038)       | 21.0 %               | \$ (13,682)       | 21.0 %               |
| State taxes (net of deferred benefit)                   | (4,778)           | 3.0 %                | (1,080)           | 1.7 %                |
| Nondeductible expenses                                  | 709               | (0.5)%               | (1,320)           | 2.0 %                |
| Change in fair market value of contingent consideration | (2,342)           | 1.5 %                | (256)             | 0.4 %                |
| Warrant remeasurement and financing costs               | (551)             | 0.4 %                | 3,630             | (5.6)%               |
| Research & Development credits                          | (743)             | 0.5 %                | (803)             | 1.2 %                |
| Change in unrecognized tax benefits                     | 149               | (0.1)%               | 161               | (0.2)%               |
| Foreign tax rate differential                           | 2,590             | (1.6)%               | (96)              | 0.1 %                |
| Goodwill impairment                                     | (6,638)           | 4.2 %                | —                 | —                    |
| Change in enacted tax rates and other, net              | (253)             | 0.2 %                | 252               | (0.3)%               |
| Change in valuation allowance                           | 41,771            | (26.6)%              | 9,817             | (15.1)%              |
| Income tax benefit                                      | <u>\$ (3,124)</u> | <u>2.0 %</u>         | <u>\$ (3,377)</u> | <u>5.2 %</u>         |

U.S. shareholders are subject to tax on global intangible low-taxed income (GILTI) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, *Accounting for Global Intangible Low-Taxed Income*, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred. As of December 31, 2019, no GILTI tax has been recorded.

In a referendum held on May, 19 2019, Swiss voters adopted the Federal Act on Tax Reform and AVS Financing (TRAF). TRAF introduces major changes in the Swiss tax system by abolishing certain current preferential tax regimes and replacing them with new measures that are in line with international standards. The referendum did not have a material impact on the Company's 2019 tax provision. The Company will continue to evaluate the impact of these provisions in future periods as the enactment process is completed.

## 12. Accrued Expenses

The following table presents the components of accrued expenses:

|                              | December 31,<br>2019 | December 31,<br>2018 |
|------------------------------|----------------------|----------------------|
|                              | (In thousands)       |                      |
| Compensation and benefits    | \$ 5,061             | \$ 6,243             |
| Restructuring costs          | 882                  | —                    |
| Consulting and other vendors | 308                  | 895                  |
| Other                        | 242                  | 539                  |
| Lease Liability              | 1,112                | —                    |
| Royalties                    | 148                  | 498                  |
| Legal and professional fees  | 474                  | 432                  |
| Deferred rent                | —                    | 391                  |
| Taxes and other assessments  | 326                  | 365                  |
| Interest                     | —                    | 256                  |
| <b>Total</b>                 | <b>\$ 8,553</b>      | <b>\$ 9,619</b>      |

### 13. Notes Payable

On May 23, 2018, the Company and its domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement (the “Hercules Loan Agreement”) with several banks and other financial institutions or entities from time to time party to the Loan Agreement (collectively, the “Lender”) and Hercules Capital, Inc., as administrative agent and collateral agent (the “Agent”). Under the Hercules Loan Agreement, the Lender agreed to make certain term loans to the Company in the aggregate principal amount of up to \$40.0 million. Funding of the first \$20.0 million tranche occurred on May 23, 2018 (the “Initial Funding Date”). On October 23, 2018, the Lender funded the second tranche of \$10.0 million under the Hercules Loan Agreement. The Company was entitled to make interest-only payments until December 1, 2020, and at the end of the interest-only period, the Company would have been required to repay the term loans over an eighteen-month period based on an eighteen-month amortization schedule, with a final maturity date of June 1, 2022. The term loans were required to be repaid if the term loans were accelerated following an event of default.

Effective April 30, 2019, the Hercules Loan Agreement was amended (the “Hercules Amendment”) to eliminate the availability of the Tranche III Loan facility, add a new Tranche IV Loan facility of up to \$20.0 million, revise certain financial covenants and make other changes. The availability of advances under the Tranche IV Loan was not milestone-based, rather the Company could request advances in minimum \$5.0 million increments at any time during the period from July 1, 2019 through December 31, 2020, subject to the funding discretion of the Lender. The monthly trailing six month net revenue financial covenant was amended to be tested quarterly and to change the projected net revenue percentage to be met for the six months ending on the last day of each fiscal quarter. If such quarterly financial covenant was not achieved as of the last day of any fiscal quarter, as tested on the thirtieth day after quarter end, the Company must have complied with the waiver conditions in the Hercules Amendment from such test date until the next quarterly test date. The Hercules Amendment was executed by the parties on May 7, 2019. The Amendment was treated as a debt modification for accounting purposes.

In connection with the entry into the AutoLap Sale Agreement with respect to the AutoLap assets, the Company commenced discussions with the Agent in order to obtain the required consent of the Agent and the Lender with respect to the sale of the AutoLap assets. In connection with obtaining such consent, the Company entered into the Consent and Second Amendment to the Loan and Security Agreement on July 10, 2019 (the “Hercules Second Amendment”). Under the Hercules Second Amendment, in consideration for the consent to the sale of, and the release of the Lender’s security interest on, the AutoLap assets, the Company reduced its indebtedness under the Hercules Loan Agreement by repaying \$15.0 million of the \$30.0 million of outstanding indebtedness thereunder, without any prepayment penalties, amendment fee or acceleration of the end of term charges, and received adjustments to the quarterly financial covenants and related waiver conditions to reflect the decreased outstanding indebtedness. The Amendment was treated as a debt modification for accounting purposes. Under the Hercules Second Amendment, the applicable waiver condition for fiscal year 2019 was changed to maintenance of unrestricted cash equal to \$7.0 million.

The term loans bore interest at a rate equal to the greater of (i) 9.55% per annum (the “Fixed Rate”) and (ii) the Fixed Rate plus the prime rate (as reported in The Wall Street Journal) minus 5.00%. On the Initial Funding Date, the Company was obligated to pay a facility fee of \$0.4 million, recorded as a debt discount. The Company also incurred other debt issuance costs totaling \$1.1 million in conjunction with its entry into the Hercules Loan Agreement. In addition, the Company was permitted to prepay the term loans in full at any time, with a prepayment fee of 3.0% of the outstanding principal amount of the loan in the first year after the Initial Funding Date, 2.0% if the prepayment occurred in the second year after the Initial Funding Date and 1.0% thereafter. Upon prepayment of the term loans in full or repayment of the terms loans at the maturity date or upon acceleration, the Company

was required to pay a final fee of 6.95% of the aggregate principal amount of term loans funded. The final payment fee was accreted to interest expense over the life of the term loan and included within notes payable on the consolidated balance sheet.

The Company's obligations under the Hercules Loan Agreement were guaranteed by all current and future material foreign subsidiaries of the Company and were secured by a security interest in all of the assets of the Company and their current and future domestic subsidiaries and all of the assets of their current and future material foreign subsidiaries, including a security interest in the intellectual property. The Hercules Loan Agreement contained customary representations and covenants that, subject to exceptions, restricted the Company's and its subsidiaries' ability to do the following, among other things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that were not related to its existing business. Under the terms of the Hercules Loan Agreement, the Company was required to maintain cash and/or investment property in accounts which perfected the Agent's first priority security interest in such accounts in an amount equal to the lesser of (i) (x) 120% of the then-outstanding principal balance of the term loans, including accrued interest and any other fees payable under the agreement to the extent accrued and payable plus (y) an amount equal to the then-outstanding accounts payable of the Company on a consolidated basis that were more than 90 days past due and (ii) 80% of the aggregate cash of the Company and its consolidated subsidiaries. The Agent was granted the option to invest up to \$2.0 million in any future equity offering broadly marketed by the Company to investors on the same terms as the offering to other investors.

On November 4, 2019, the Company entered into a payoff letter with the Agent pursuant to which the Company terminated the Hercules Loan Agreement, as amended. The Company determined it was in the best interests of the Company to pay down the debt and terminate the Hercules Agreement to simplify the Company's balance sheet and provide additional flexibility as the Board of Directors continues to explore strategic and financial alternatives for the Company. Under the payoff letter, the Company repaid all amounts owed under the Hercules Loan Agreement totaling approximately \$16.4 million, which included end of term fees of \$1.4 million, and Hercules released all security interests held on the assets of the Company and its subsidiaries, including, without limitation, on the intellectual property assets of the Company. The Company recognized a loss of \$1.0 million on the extinguishment of notes payable, which is included in interest expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

In connection with its entrance into the Hercules Loan Agreement, the Company repaid its existing loan and security agreement (the "Innovatus Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"). The Company recognized a loss of \$1.4 million on the extinguishment of notes payable which was included in interest expense on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2018. The Company paid \$0.7 million in final payment obligations and \$0.3 million in prepayment fees under the Innovatus Loan Agreement upon repayment.

Under the Innovatus Loan Agreement, entered into on May 10, 2017, Innovatus agreed to make certain term loans in the aggregate principal amount of up to \$17.0 million. Funding of the first \$14.0 million tranche occurred on May 10, 2017.

The Innovatus Loan Agreement allowed for interest-only payments for up to twenty-four months at a fixed rate equal to 11% per annum, of which 2.5% could be paid in-kind and added to the outstanding principal amount of the term loans until the earlier of (i) the first anniversary following the funding date and (ii) the Company's failure to achieve an Interest-Only Milestone. At the end of the interest-only period, the Company would be required to repay the term loans over a two-year period, based on a twenty-four (24) month amortization schedule, with a final maturity date of May 10, 2021.

In connection with the Innovatus funding, the Company paid a facility fee of \$0.2 million on the date of funding of the first tranche and incurred additional debt issuance costs of approximately \$1.2 million, recorded as a debt discount. In addition, the Company issued warrants to Innovatus to purchase shares of the Company's common stock that will expire five years from such issue date. The warrants issued in connection with funding of the first tranche entitle Innovatus to purchase up to 95,750 shares of the Company's common stock at an exercise price of \$13.00 per share. The Company estimated the fair value of the warrants to be \$0.3 million. The value of the warrants was classified as equity and recorded as a discount to the loan. The debt discount was amortized as interest expense using the effective interest method over the life of the loan. As of December 31, 2018, the unamortized debt discount was \$0.

#### **14. Stock-Based Compensation**

The Company's stock-based compensation plans include the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, previously named the TransEnterix, Inc. 2007 Incentive Compensation Plan, or the Plan, as well as options outstanding under the TransEnterix, Inc. Stock Option Plan, or the 2006 Plan. As part of the Merger, options outstanding, whether vested or unvested, under the 2006 Plan were adjusted by the Exchange Ratio of approximately 0.0887, and assumed by the Company concurrent with the closing of the Merger.

The Plan was initially approved by the majority of the stockholders on November 13, 2007. The Plan was amended on June 19, 2012 to increase the number of shares of common stock available for issuance to 76,923 and was amended on October 29, 2013 to (a) increase the number of shares of common stock authorized for issuance under the Plan from 76,923 shares of common stock to 380,000 shares of common stock, (b) increase the per-person award limitations for options or stock appreciation rights from 15,385 to 76,923 shares and for restricted stock, deferred stock, performance shares and/or other stock-based awards from 7,692 to 38,462 shares, and (c) change the name of the Plan to reflect the Merger-related change. The Plan was again amended on May 7, 2015 to (i) increase the number of shares reserved for issuance under the Plan to 918,462 shares; (ii) extend the term of the Plan until May 7, 2025; and (iii) make other changes and updates to the Plan and was further amended in October 2015 to add French Sub-Plan amendments applicable to awards made to France-based employees. The Plan was further amended on June 8, 2016 to (a) approve an increase in the number of shares reserved for issuance under the Plan to 1,456,923 shares and (b) establish maximum equity award limits for initial awards and annual awards to non-employee directors. The Plan was subsequently amended as of May 25, 2017, increasing the number of shares of Common Stock authorized under the Plan to 1,995,385. The Plan was again amended on May 24, 2018, increasing the number of shares of Common Stock authorized under the Plan to 3,149,231. The Plan was again amended in October 2018 to add an Israeli Sub-Plan applicable to awards made to Israel-based employees. The Plan was again amended on April 24, 2019, to increase the number of shares of Common Stock authorized under the Plan to 4,072,308 and to make other changes.

The October 2013, May 2015, June 2016, May 2017, May 2018, and April 2019 amendments were approved by the Board of Directors and stockholders; the French Sub-Plan and Israeli Sub-Plan were approved by the Board of Directors. Under the Plan, which is administered by the Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock and/or deferred stock to employees, officers, directors, consultants and vendors. The exercise price of stock options or stock appreciation rights may not be less than the fair market value of the Company's shares at the date of grant. Additionally, no stock options or stock appreciation rights granted under the Plan may have a term exceeding ten years.

The 2006 Plan was adopted and approved by stockholders in September 2006 and provided for the granting of up to 6,154 stock options to employees, directors, and consultants. Under the 2006 Plan, both employees and non-employees were eligible for such stock options. In 2009, the 2006 Plan was amended to increase the total options pool to 85,389. In 2011, the 2006 Plan was amended to increase the total options pool to 259,861. The amendments were approved by the Board of Directors and stockholders. The Board of Directors had the authority to administer the plan and determine, among other things, the exercise price, term and dates of the exercise of all options at their grant date. Under the 2006 Plan, options become vested generally over four years, and expire not more than 10 years after the date of grant. As part of the Merger, options outstanding under the 2006 Plan were adjusted by the Conversion Ratio, and remain in existence as options of TransEnterix.

During the years ended December 31, 2019 and 2018, the Company recognized approximately \$11.5 million and \$9.0 million, respectively, of stock-based compensation expense, including stock options and restricted stock units.

The Company recognizes as expense, the grant-date fair value of stock options and other stock based compensation issued to employees and non-employee directors over the requisite service periods, which are typically the vesting periods. The Company uses the Black-Scholes-Merton model to estimate the fair value of its stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies as well as the Company's historical volatility. The expected term of options granted by the Company has been determined based upon the simplified method, because the Company does not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero. The Company estimates forfeitures based on the historical experience of the Company and adjusts the estimated forfeiture rate based upon actual experience.

The fair value of options granted were estimated using the Black-Scholes-Merton option pricing model based on the assumptions in the table below:

|                          | Year ended December 31, |               |
|--------------------------|-------------------------|---------------|
|                          | 2019                    | 2018          |
| Expected dividend yield  | 0%                      | 0%            |
| Expected volatility      | 81% - 92%               | 73% - 75%     |
| Risk-free interest rate  | 1.39% - 2.66%           | 2.35% - 3.02% |
| Expected life (in years) | 5.5 - 6.1               | 5.5 - 6.1     |

The following table summarizes the Company's stock option activity, including grants to non-employees, for the year ended December 31, 2019:

|  | Number of<br>Shares | Weighted-<br>Average<br>Exercise Price | Weighted-<br>Average<br>Remaining<br>Contractual<br>Term (Years) |
|--|---------------------|--|--|
| Options outstanding at December 31, 2018 | 1,529,964           | \$ 31.45                               | 7.82   |
| Granted                                  | 623,272             | 29.79                                  |  |
| Forfeited                                | (248,834)           | 33.13                                  |  |
| Cancelled                                | (43,525)            | 38.67                                  |  |
| Exercised                                | (29,919)            | 18.00                                  |  |
| Options Outstanding December 31, 2019    | 1,830,958           | \$ 30.71                               | 7.36   |

The following table summarizes information about stock options outstanding at December 31, 2019:

|   | Number of<br>Shares | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (Years) |
|---|---------------------|---------------------------------------|---|
| Exercisable at December 31, 2019                | 926,498             | \$ 32.48                              | 6.14  |
| Vested or expected to vest at December 31, 2019 | 1,763,300           | \$ 30.75                              | 7.28  |

Stock options outstanding, exercisable, and vested or expected to vest at December 31, 2019 had no intrinsic value based on the closing market price of the Company's common stock at December 31, 2019.

The total intrinsic value of options exercised during 2019 and 2018 was approximately \$0.2 million and \$9.3 million, respectively. Proceeds from options exercised during 2019 and 2018 were approximately \$0.5 million and \$7.1 million, respectively.

The Company granted 623,272 and 669,662 options to employees and non-employees during the years ended December 31, 2019 and 2018, respectively, with a weighted-average grant date fair value of \$21.23 and \$20.67, respectively.

As of December 31, 2019, the Company had future employee stock-based compensation expense of approximately \$19.6 million related to unvested share awards, which is expected to be recognized over an estimated weighted-average period of 2.5 years.

## 15. Restricted Stock Units

In 2018 and 2019, the Company issued Restricted Stock Units ("RSUs") to certain employees which vest over three years. The RSUs vest on defined vesting dates, subject to the continuous service with the Company at the applicable vesting event. Vesting can be accelerated upon a change in control under the Plan if the RSUs are not assumed by the successor company, and will be accelerated for certain executive officers under existing employment agreements if any such executive officer has a termination of employment in connection with a change in control event. When vested, the RSUs represent the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The fair value of each RSU is estimated based upon the closing price of the Company's common stock on the grant date. Share-based compensation expense related to RSUs is recognized over the requisite service period as adjusted for estimated forfeitures.

The following is a summary of the RSU activity for the years ended December 31, 2019 and 2018:

|                            | Number of<br>Restricted<br>Stock Units<br>Outstanding | Weighted<br>Average<br>Grant<br>Date Fair<br>Value |
|----------------------------|---|--|
| Unvested December 31, 2017 | 338,055   | \$ 14.95   |
| Granted                    | 170,403   | 28.66  |
| Vested                     | (123,539)   | 17.44  |
| Forfeited                  | (2,821)   | 17.71  |
| Unvested December 31, 2018 | 382,098   | \$ 20.24   |
| Granted                    | 192,987   | 31.42  |
| Vested                     | (85,153)  | 25.98  |
| Forfeited                  | (46,005)  | 21.38  |
| Unvested December 31, 2019 | 443,927   | \$ 23.88   |

As of December 31, 2019 and 2018, the Company recorded approximately \$3.2 million and \$2.9 million, respectively, in compensation expense for the RSUs. As of December 31, 2019, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$5.5 million, which is expected to be recognized over a weighted average period of approximately 1.4 years.

## 16. Warrants

On March 22, 2013, SafeStitch entered into a stock purchase agreement with approximately 17 investors (the "2013 PIPE Investors") pursuant to which the 2013 PIPE Investors purchased an aggregate of approximately 186,092 shares of common stock at a price of \$16.25 per share for aggregate consideration of approximately \$3.0 million. Included in this private placement was the issuance of warrants to purchase approximately 93,046 common shares, representing one warrant for every two common shares purchased, with an exercise price of \$21.45 per share and five years expiration. Among the 2013 PIPE Investors purchasing shares were related parties who purchased 98,462 shares and received 49,231 warrants. There were approximately 92,277 warrants outstanding that were assumed as of the Merger. During the years ended December 31, 2018 and 2017, 61,538 and 18,462, respectively of these warrants were exercised. During the year ended December 31, 2018, the remaining 7,354 warrants expired.

On January 17, 2012, TransEnterix Surgical entered into an original Loan Agreement with Silicon Valley Bank ("SVB") and Oxford Financial LLC (the "Prior Lenders"). Pursuant to such agreement, TransEnterix Surgical issued preferred stock warrants to the Prior Lenders on January 17, 2012 and December 21, 2012, respectively, to purchase shares of TransEnterix Surgical preferred stock. The preferred stock warrants expire ten years from the issue date. The preferred stock warrants were remeasured immediately prior to the Merger. As of the Merger, the preferred stock warrants converted to common stock warrants, adjusted based on a Merger exchange ratio of approximately 0.0887, and the preferred stock warrant liability was reclassified to additional paid-in capital. These warrants are exercisable for an aggregate of approximately 21,506 shares of common stock, with an exercise price of \$18.85 per share. During the year ended December 31, 2013, 10,753 of these warrants were exercised in a cashless transaction for 8,674 shares of common stock. During the year ended December 31, 2018, the remaining 10,753 of these warrants were exercised in a cashless transaction for 8,065 shares of common stock.

On September 26, 2014, the Company entered into an amendment to the SVB Loan Agreement with the Prior Lenders. In connection with the first tranche borrowings under such amendment, the Company issued 2,948 common stock warrants to the Prior Lenders to purchase shares of the Company's common stock, with an exercise price of \$52.20 per share. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and were amortized using the effective interest method from issuance to the maturity of the term loans. None of these warrants were exercised during the years ended December 31, 2019. During the year ended December 31, 2018, 2,145 of these warrants were exercised in a cashless transaction for 660 shares of common stock.

On August 14, 2015, in connection with an amendment to the SVB Loan Agreement and first tranche borrowings thereunder, the Company issued 8,684 common stock warrants to the Prior Lenders to purchase shares of the Company's common stock, with an exercise price of \$40.30 per share. The warrants expire seven years from their respective issue date. The Company concluded that the warrants are considered equity instruments. The warrants were recognized at the relative fair value on the issuance date as a debt discount and were amortized using the effective interest method from issuance to the maturity of the note. None of these warrants were exercised during the years ended December 31, 2019. During the year ended December 31, 2018, 5,211 of these warrants were exercised in a cashless transaction for 2,426 shares of common stock.

On April 28, 2017, the Company sold 24.9 million Units, each consisting of approximately 0.077 shares of the Company's Common Stock, a Series A Warrant to purchase approximately 0.077 shares of Common Stock with an exercise price of \$13.00 per share, and a Series B Warrant to purchase approximately 0.058 shares of Common Stock with an exercise price of \$13.00 per share at an offering price of \$1.00 per Unit. Each Series A Warrant was exercisable at any time beginning on the date of issuance, and from time to time thereafter, through and including the first anniversary of the issuance date, unless terminated earlier as provided in the Series A Warrant. Receipt of 510(k) clearance for the Senhance System on October 13, 2017, triggered the acceleration of the expiration date of the Series A Warrants to October 31, 2017. As such, all of the Series A Warrants were exercised prior to the expiration date. Each Series B Warrant may be exercised at any time beginning on the date of issuance and from time to time thereafter through and including the fifth anniversary of the issuance date.

The exercise prices and the number of shares issuable upon exercise of each of the Series B Warrants are subject to adjustment upon the occurrence of certain events, including, but not limited to, stock splits or dividends, business combinations, sale of assets, similar recapitalization transactions, or other similar transactions. The Series B warrants contain provisions, often referred to as "down-round protection," that leads to adjustment of the exercise price and number of underlying warrant shares if the Company issues securities, including its common stock or convertible securities or debt securities, in the future at sale prices below the then-current exercise price. As a result of this adjustment feature and after giving effect to the Company's reverse stock split at a ratio of one-for-thirteen shares effective December 11, 2019, or the Reverse Stock Split, the exercise price of all outstanding Series B Warrants has been adjusted to \$1.39 per share and the number of shares of common stock reserved for and issuable upon the exercise of outstanding Series B Warrants has been adjusted to 1,963,451 underlying warrant shares as of December 31, 2019.

The exercisability of the Series B Warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.99% of the Common Stock. If, at any time Series B Warrants are outstanding, any fundamental transaction occurs, as described in the Series B Warrants and generally including any consolidation or merger into another corporation, the consummation of a transaction whereby another entity acquires more than 50% of the Company's outstanding voting stock, or the sale of all or substantially all of its assets, the successor entity must assume in writing all of the obligations to the Series B Warrant holders. Additionally, in the event of a fundamental transaction, each Series B Warrant holder will have the right to require the Company, or its successor, to repurchase the Series B Warrants for an amount of cash equal to the Black-Scholes value of the remaining unexercised portion of such Series B Warrants. During the years ended December 31, 2018 and 2017, 542,478 and 684,131, respectively, Series B Warrants were exercised. There were no Series B Warrants exercised during the year ended December 31, 2019.

On May 10, 2017, in connection with the entry into the Innovatus Loan Agreement, the Company issued warrants to Innovatus to purchase shares of the Company's common stock. The warrants are issued on the funding date of each tranche and will expire five (5) years from such issue date. The warrants issued in connection with funding of the first tranche will entitle Innovatus to purchase up to 95,750 shares of the Company's common stock at an exercise price of \$13.00 per share. None of these warrants were exercised as of December 31, 2019.

On September 12, 2017, the Company entered into a service agreement with a third party vendor. In connection with the service agreement, the Company issued 73,076 common stock warrants ("Service Warrants") to purchase shares of the Company's common stock, with an exercise price of \$13.00 per share. The Service Warrants vest as follow: (a) twenty-five percent (25%) on the date of execution of the services agreement; (b) fifty percent (50%) upon completion of hiring the sales team; and (c) the remaining twenty-five percent (25%) upon achieving cumulative product revenue of \$15.0 million. The Service Warrants expire ten years from their issue date. The Company concluded that the Service Warrants are considered equity instruments. The fair value of the Service Warrants on the issuance date was determined using a Black-Scholes Merton model. The fair value of the remaining Service Warrants was updated each reporting period and the expense was recorded over the service period. The initial expense of \$0.6 million and additional expense of \$0.3 million was recognized during the year ended December 31, 2017. In February 2018, the Company terminated its relationship with the vendor and accelerated the full vesting of the Service Warrants in accordance with the service agreement. The remaining expense of \$0.3 million was recognized during the year ended December 31, 2018. During the year ended December 31, 2019 and 2018, 15,385 and 50,000 of these warrants were exercised, respectively.



|                                  | Number of<br>Warrant Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (in years) | Weighted<br>Average<br>Fair Value |
|----------------------------------|-----------------------------|--|--|-----------------------------------|
| Outstanding at December 31, 2017 | 1,012,513                   | \$ 14.04                                 | 4.5  | \$ 5.07                           |
| Exercised                        | (672,125)                   | 14.17                                    | 0  | —                                 |
| Expired                          | (7,354)                     | 21.45                                    | 0  | —                                 |
| Outstanding at December 31, 2018 | 333,034                     | \$ 13.39                                 | 3.7  | \$ 3.38                           |
| Exercised                        | (15,385)                    | 13.00                                    | 0  | —                                 |
| Reserved for future issuance     | 1,753,523                   | 1.39                                     | 2.2  | 1.22                              |
| Outstanding at December 31, 2019 | 2,071,172                   | \$ 2.05                                  | 2.4  | \$ 1.34                           |

The aggregate intrinsic value of the common stock warrants in the above table was \$0.2 million and \$5.3 million at December 31, 2019 and 2018, respectively. The aggregate intrinsic value is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the estimated fair market value of the applicable stock as of the respective dates.

## 17. Purchase Agreement and Offerings

On August 12, 2019, the Company entered into a Controlled Equity Offering Sales Agreement (the “2019 Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”) pursuant to which the Company may sell from time to time, at its option, up to an aggregate of \$25.0 million, shares of the Company’s common stock, through Cantor, as sales agent (the “2019 ATM Offering”). Pursuant to the Sales Agreement, sales of the Common Stock were made under the Company’s previously filed and currently effective Registration Statement on Form S-3. The aggregate compensation payable to Cantor was 3.0% of the aggregate gross proceeds from each sale of the Company’s common stock.

On September 4, 2019, the Company entered into an Underwriting Agreement (the “Underwriting Agreement”) with Cantor (the “Underwriter”). Subject to the terms and conditions of the Underwriting Agreement, the Company agreed to sell to the Underwriter, in a firm commitment underwritten offering, 2,153,846 shares of the Company’s common stock (the “Firm Commitment Offering”). In addition, the Company granted the Underwriter a 30-day option to purchase 323,077 of additional shares of common stock. The 30-day option was not exercised.

The following table summarizes the total sales under the ATM Offering and Firm Commitment Offering for the period indicated (in thousands except for share and per share amounts):

|                                   | ATM Offering       |  | Firm Commitment Offering |  | Total             |
|-----------------------------------|--------------------|--|--------------------------|--|-------------------|
|                                   | For the year ended |  | For the year ended       |  | December 31, 2019 |
|                                   | December 31, 2019  |  | December 31, 2019        |  | December 31, 2019 |
| Total shares of common stock sold | 1,374,686          |  | 2,153,846                |  | 3,528,532         |
| Average price per share           | \$ 5.23            |  | \$ 8.73                  |  | \$ 7.37           |
| Gross proceeds                    | \$ 7,193           |  | \$ 18,796                |  | \$ 25,989         |
| Commissions earned by Cantor      | 212                |  | —                        |  | 212               |
| Net Proceeds                      | \$ 6,981           |  | \$ 18,796                |  | \$ 25,777         |

On December 28, 2018, the Company entered into an At-the-Market Equity Offering Sales Agreement (the “2018 Sales Agreement”) with Stifel, Nicolaus & Company, Incorporated (“Stifel”) as sales agent, pursuant to which the Company could sell through Stifel, from time to time, up to \$75.0 million in shares of common stock in an at-the-market offering. The Company was to pay Stifel a commission of approximately 3% of the aggregate gross proceeds received from all sales of common stock under the 2018 Sales Agreement. Effective August 12, 2019, the Company terminated the 2018 Sales Agreement. The Company sold no shares of its common stock under the Stifel Sales Agreement.

On April 28, 2017, the Company sold 24.9 million units, each consisting of approximately 0.077 shares of the Company’s common stock, a Series A warrant to purchase approximately 0.077 shares of Common Stock with an exercise price of \$13.00 per share,

and a Series B warrant to purchase approximately 0.058 shares of common stock with an exercise price of \$13.00 per Unit for aggregate gross proceeds of \$24.9 million in an underwritten firm commitment public offering. Net proceeds after issuance costs were \$23.2 million, assuming no exercise of the warrants. The closing of the public offering occurred on May 3, 2017.

## 18. Restructuring

During the fourth quarter of 2019, the Company announced the implementation of a restructuring plan to reduce operating expenses as the Company continues the global market development of the Senhance platform. Under the restructuring plan, the Company reduced headcount primarily in the sales and marketing functions and determined that the carrying value of its inventory exceeded the net realizable value due to a decrease in expected sales. The restructuring charges amounted to \$8.8 million, of which \$7.4 million was an inventory write down and was included in cost of product revenue and \$1.4 million related to employee severance costs and was included as restructuring and other charges in the consolidated statements of operations and comprehensive loss, for the year ended December 31, 2019. Future payments under the restructuring plan are expected to conclude in 2020 and total \$0.9 million. During the year ended December 31, 2019, the activity related to the Company's restructuring liability, which is included in accrued expenses in the consolidated balance sheet, was as follows:

|                                      | <b>Restructuring Liability</b> |       |
|--------------------------------------|--------------------------------|-------|
|                                      | (In thousands)                 |       |
| Balance at December 31, 2018         | \$                             | —     |
| Amount charged to operating expenses |                                | 1,374 |
| Cash payments                        |                                | (492) |
| Balance at December 31, 2019         | \$                             | 882   |

## 19. Basic and Diluted Net Loss per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed giving effect to all dilutive potential common shares that were outstanding during the period. Diluted potential common shares consist of incremental shares issuable upon exercise of stock options, warrants and restricted stock units. No adjustments have been made to the weighted average outstanding common shares figures for the years ended December 31, 2019 or 2018 as the assumed exercise of outstanding options, warrants and restricted stock units would be anti-dilutive.

Potential common shares not included in calculating diluted net loss per share are as follows:

|                                  | <b>December 31</b> |             |
|----------------------------------|--------------------|-------------|
|                                  | <b>2019</b>        | <b>2018</b> |
| Stock options                    | 1,830,958          | 1,529,964   |
| Stock warrants                   | 2,071,172          | 333,034     |
| Nonvested restricted stock units | 443,927            | 382,098     |
| Total                            | 4,346,057          | 2,245,096   |

## 20. Related Person Transactions

A member of the Company's Board of Directors is an executive officer of Synecor, LLC. Various research and development services were purchased by the Company from Synecor, LLC and its wholly owned subsidiary Synchrony Labs LLC. These purchases were approved by the Audit Committee and totaled approximately \$0 and \$24,000 for the years ended December 31, 2019 and 2018, respectively.

A member of the Company's Board of Directors is an executive officer of Sofar S.p.A. Various equipment was purchased by the Company from Sofar S.p.A. and totaled approximately \$26,000 and \$0 for the years ended December 31, 2019 and 2018, respectively.

In March 2018, TransEnterix Europe entered into a Service Supply Agreement with 1 Med S.A. for certain regulatory consulting services. Andrea Biffi, a current member of the Company's Board of Directors, owns a non-controlling interest in 1 Med S.A. Expenses under the Service Supply Agreement were approximately \$12,000 and \$71,000 for the years ended December 31, 2019 and 2018, respectively.

## 21. Commitments and Contingencies

### *Contingent Consideration*

As discussed in Note 3, in September 2015, the Company completed the Senhance Acquisition using a combination of cash, stock and potential post-acquisition milestone payments. These milestone payments may be payable in the future, depending on the achievement of certain commercial milestones. On December 30, 2016, the Company entered into an Amendment to restructure the terms of the Second Tranche of the Cash Consideration. Under the Amendment, the Second Tranche was restructured to reduce the contingent cash consideration by €5.0 million in exchange for the issuance of 286,360 shares of the Company's common stock with an aggregate fair market value of €5.0 million. As of December 31, 2019, the fair value of the contingent consideration was \$1.1 million.

### *Legal Proceedings*

When determining the estimated probable loss or range of losses, significant judgment is required to be exercised in order to estimate the amount and timing of the loss to be recorded. Estimating an amount or range of possible losses resulting from litigation proceedings is inherently difficult and requires an extensive degree of judgment, particularly where the matters involve indeterminate claims for monetary damages, are in the early stages of the proceedings, and are subject to appeal. In addition, because most legal proceedings are resolved over extended periods of time, potential losses are subject to change due to, among other things, new developments, changes in legal strategy, the outcome of intermediate procedural and substantive rulings and other parties' settlement posture and their evaluation of the strength or weakness of their case against the Company. For these reasons, the Company is currently unable to predict the ultimate timing or outcome of, or reasonably estimate the possible losses or a range of possible losses resulting from, the matters described above. Based on information currently available, the Company does not believe that any reasonably possible losses arising from currently pending legal matters will be material to the Company's results of operations or financial condition. However, in light of the inherent uncertainties involved in such matters, an adverse outcome in one or more of these matters could materially and adversely affect the Company's financial condition, results of operations or cash flows in any particular reporting period.

No liability or related charge was recorded to earnings in the Company's consolidated financial statements for legal contingencies for the years ended December 31, 2019 and 2018.

### *Operating Leases*

On November 2, 2009, TransEnterix Surgical entered into an operating lease for its corporate offices for a period of five years commencing in April 2010. On June 12, 2014, the Company entered into a lease amendment extending the term of the lease for a period of 3 years and 2 months commencing on May 1, 2015 and expiring on June 30, 2018, with an option to renew for an additional three years. On January 8, 2018, the Company entered into a lease amendment extending the term of the lease for a period of eighteen months commencing on July 1, 2018 and expiring on December 31, 2019, with an option to renew for an additional five years. On June 10, 2019, the Company entered into a lease amendment extending the term of the lease for an additional twelve months commencing on January 1, 2020 and expiring on December 31, 2020, with no option to renew. On October 25, 2013, the Company entered into an operating lease for its warehouse for a period of four years and four months commencing in January 2014, with an option to renew for an additional six years. On December 27, 2017, the Company entered into an agreement to terminate this lease effective January 31, 2018. On May 12, 2016, TransEnterix Italia entered into an operating lease for research and development and demonstration facilities for a period of six years commencing in July 2016. On April 15, 2019, TransEnterix Israel entered into an operating lease for research and development facilities for a period of five years commencing in April 2019. On April 25, 2018, TransEnterix Japan entered into an operating lease for office space for a period of five years commencing in April 2018. On July 1, 2018, TransEnterix Europe S.à.R.L entered into an operating lease for office space for a period of five years commencing in July 2018. Rent expense was approximately \$1.4 million and \$1.2 million for the years ended December 31, 2019 and 2018, respectively.

### *License and Supply Agreements*

As discussed in Note 3, in September 2015, the Company completed the Senhance Acquisition. As part of this transaction, the Company assumed certain license and supply agreements. Commitments under these agreements amount to approximately \$5.5 million in 2020, \$0.6 million in 2021, \$0.6 million in 2022, \$0.6 million in 2023, \$0.6 million in 2024, and \$1.1 million thereafter until termination in 2027.

The Company has placed orders with various suppliers for the purchase of certain tooling, supplies and contract engineering and research services. Each of these orders has a duration or expected completion within the next twelve months.

## 22. Subsequent Events

### *Series B Warrant Exchange*

On February 24, 2020, the Company entered into a Series B Warrants Exchange Agreement (the "Exchange Agreement") with holders of its Series B Warrants. Under the terms of the Exchange Agreement, each Series B Warrant was canceled in exchange for 0.61 shares of common stock. The Warrant holders participating in the exchange held 3,373,900 of the 3,638,780 Series B Warrants then outstanding, and received an aggregate of 2,040,757 shares of common stock, leaving 264,880 Series B Warrants outstanding to acquire 160,226 shares of common stock. The number of shares of common stock subject to the outstanding Series B Warrants increased to 292,178 shares as a result of the adjustment made following the 2020 Public Offering.

### *Lincoln Park Capital Purchase Agreement*

On February 10, 2020, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC, an Illinois limited liability company, pursuant to which the Company has the right to sell to Lincoln Park up to an aggregate of \$25,000,000 in shares of common stock over the 36-month term of the Purchase Agreement, subject to certain limitations and conditions set forth in the Purchase Agreement. In consideration for entering into the Purchase Agreement, the Company issued to Lincoln Park 343,171 shares of common stock as commitment shares on February 10, 2020. No shares have been sold to Lincoln Park under the Purchase Agreement to date.

### *Public Offering of Securities*

On March 10, 2020, the Company closed an underwritten public offering (the "2020 Public Offering") with Ladenburg Thalmann & Co. Inc. as underwriter and sold an aggregate of 14,121,766 Class A Units at a public offering price of \$0.68 per Class A Unit and 7,937,057 Class B Units at a public offering price of \$0.68 per Class B Unit. Each Class A Unit consists of one share of the Company's common stock, one warrant to purchase one share of common stock that expires on the first anniversary of the date of issuance (collectively, the "Series C Warrants"), and one warrant to purchase one share of common stock that expires on the fifth anniversary of the date of issuance (collectively, the "Series D Warrants"). Each Class B Unit consists of one share of Series A Convertible Preferred Stock, par value \$0.01 per share (the "Series A Preferred Stock"), convertible into one share of common stock, a Series C Warrant to purchase one share of Common Stock and a Series D Warrant to purchase one share of Common Stock. The Class A Units and Class B Units have no stand-alone rights and were not certificated or issued as stand-alone securities. The shares of common stock, Series A Preferred Stock, Series C Warrants and Series D Warrants are immediately separable. In addition, the underwriter for the public offering exercised an overallotment option allowing them to purchase 3,308,823 Series C Warrants and 3,308,823 Series D Warrants.

The net proceeds to the Company from the 2020 Public Offering were approximately \$13.4 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

### *At-The-Market Offering*

The following table summarizes the total sales under the 2019 Sales Agreement for the period commencing January 1, 2020 through the date of this filing (in thousands except for per share amounts):

|                                   |    |        |
|-----------------------------------|----|--------|
| Total shares of common stock sold |    | 6,688  |
| Average price per share           | \$ | 1.73   |
| Gross proceeds                    | \$ | 11,558 |
| Commissions earned by Cantor      | \$ | 347    |
| Net Proceeds                      | \$ | 11,211 |

### *Restructuring*

During March 2020, the Company continued the restructuring efforts with additional headcount reductions which resulted in \$0.8 million related to severance costs. These 2020 severance costs are primarily expected to be paid in 2020 and 2021.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## **ITEM 9.A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2019. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, due to the material weakness in our internal control over financial reporting described below, our disclosure controls and procedures were ineffective.

### **Management's Report on Internal Control Over Financial Reporting**

We are responsible for establishing and maintaining adequate internal control over financial reporting. As defined in the securities laws, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the acquisitions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

For the year ended December 31, 2019, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, management (with the participation of our principal executive officer and principal financial officer) conducted an evaluation of the effectiveness of our internal control over financial reporting, based on the original framework established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management concluded that, as of December 31, 2019, our internal control over financial reporting was not effective because a material weakness existed in our internal controls related to the Company's income tax process. Specifically, we did not maintain effective controls over the documentation and review relating to the income tax accounting and disclosures for the significant components of deferred tax assets and liabilities related to a foreign non-recurring transaction. The Company's management has concluded that this control deficiency constitutes a material weakness as of December 31, 2019.

Based on this finding, management is implementing a remediation plan to address the control deficiency that led to the material weakness. The remediation plan includes enhancing specific review procedures over the income tax provision and related disclosures, including strengthening the Company's documentation standards, technical oversight and training.

The Company's independent registered public accounting firm, BDO USA, LLP, audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2019. BDO USA, LLP's report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019 is set forth herein and contains an adverse opinion.

### **Changes in Internal Controls Over Financial Reporting**

Except for the material weakness identified above, there were no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9.B. OTHER INFORMATION**

As part of the Company's restructuring program initiated in November 2019 and continued into the first quarter of 2020, the Company determined that it would eliminate the role of Chief Commercial Officer effective March 31, 2020. Eric Smith, the current Chief Commercial Officer is party to an Employment Agreement, dated August 15, 2018 with the Company (the "Employment Agreement"). The elimination by the Company of the Chief Commercial Officer role is a termination without cause by the Company under the Employment Agreement, entitling Mr. Smith to receive, for nine months following the date of termination a monthly amount equal to one-twelfth of his annual base salary in effect as of March 13, 2020, plus the target bonus for 2020, and continued provision of health care benefits for nine months. In addition, the short-term retention bonus awarded to Mr. Smith in November 2019 vested and was earned as of March 6, 2020 and will be paid to Mr. Smith by April 30, 2020. Mr. Smith is providing the Company a release of claims and will continue to be subject to the non-competition, non-solicitation and confidentiality and inventions disclosure provisions of the Employment Agreement. The Company and Mr. Smith are entering into a Separation and Release Agreement to memorialize these understandings.

**PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.**

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2020.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2020.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2020.

**Securities Authorized for Issuance Under Equity Compensation Plans.**

The Company currently has one equity compensation plan under which it makes awards, the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, (the "Plan"). The Plan was originally approved by the Board of Directors of the Company, or the Board, and adopted by the majority of our stockholders on November 13, 2007. The Plan was subsequently amended, approved by the Board, and approved by stockholders as follows:

| No. | Amendment Purpose  | Date of Stockholders' approval |
|-----|--|--------------------------------|
| 1   | increase the number of shares of common stock authorized under the Plan to 918,462 shares, and to make other changes | May 7, 2015                    |
| 2   | increase the number of shares reserved for issuance under the Plan to 1,456,923 shares, and to make other changes    | June 8, 2016                   |
| 3   | increase the number of shares reserved for issuance under the Plan to 1,995,385 shares                               | May 25, 2017                   |
| 4   | increase the number of shares reserved for issuance under the Plan to 3,149,231 shares                               | May 24, 2018                   |
| 5   | increase the number of shares reserved for issuance under the Plan to 4,072,308 shares, and to make other changes    | April 24, 2019                 |

The Plan is used for plan-based awards for officers, other employees, consultants, advisors and non-employee directors. In connection with the 2013 merger transaction with SafeStitch Medical, Inc., or the Merger, we assumed all of the options that were issued and outstanding immediately prior to the Merger as issued by TransEnterix Surgical, and adjusted based on the Merger at the exchange ratio, which are now exercisable for approximately 32,590 shares of common stock. Such options were granted under the TransEnterix, Inc. 2006 Stock Plan (the "2006 Plan") which was assumed by the Company in the Merger. The 2006 Plan is maintained solely for the purpose of the stock options granted under such 2006 Plan that remain outstanding; no future awards are authorized to be made under the 2006 Plan.

The following table gives information about the Company's common stock that may be issued upon the exercise of options and other equity awards as of December 31, 2019:

| <u>Plan Category</u>   | <u>Number of securities to be issued upon exercise of outstanding options (1)</u> | <u>Weighted average exercise price of outstanding options</u> | <u>Number of securities remaining available for future issuance (2)</u> |
|--|---|---|---|
| Equity compensation plans approved by security holders         | 2,242,295   | 30.84   | 1,340,527   |
| Equity compensation plans not approved by security holders (3) | 32,590  | 23.71   | 0   |
| Total  | 2,274,885   |   | 1,340,527   |

- (1) Includes 1,798,368 shares underlying outstanding stock options awarded under the Plan and 443,927 restricted stock units awarded under the Plan.
- (2) These shares are all available for future awards under the Plan.
- (3) Represents 32,590 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2020.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

The information required by this item is incorporated by reference from the information contained in our Proxy Statement for the Annual Meeting of Shareholders expected to be filed with the SEC on or prior to April 29, 2020.



**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

- (a). (1) The following consolidated financial statements are filed as a part of this Annual Report:

|   | Page               |
|---|--------------------|
| Consolidated Financial Statements :   |                    |
| <a href="#">Reports of Independent Registered Public Accounting Firm</a>  | <a href="#">50</a> |
| <a href="#">Consolidated Balance Sheets as of December 31, 2019 and 2018</a>  | <a href="#">53</a> |
| <a href="#">Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018</a> | <a href="#">54</a> |
| <a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018</a>              | <a href="#">55</a> |
| <a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018</a>                        | <a href="#">56</a> |

- (2) Consolidated Financial Statement Schedules: The information required by this item has been omitted in this report because they are not applicable, not required under these instructions, or included in the consolidated financial statements or related notes thereto contained in Item 8 of this Annual Report.

- (3) Exhibits: The following exhibits are filed as part of, or incorporated by reference into, this Annual Report.

| Exhibit No. | Description   |
|-------------|---|
| 2.1         | <a href="#">Membership Interest Purchase Agreement, dated September 18, 2015, by and among Sofar S.p.A., Vulcanos S.r.l., the Registrant and TransEnterix International, Inc. filed as Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on September 21, 2015 and incorporated by reference herein).</a> |
| 2.1(a)      | <a href="#">Amendment to Membership Interest Purchase Agreement by and among TransEnterix, Inc., TransEnterix International, Inc., and Sofar, S.p.A., dated December 30, 2016 (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on January 5, 2017 and incorporated by reference herein).</a>  |
| 3.1         | <a href="#">Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).</a>  |
| 3.1.1       | <a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on April 1, 2014 and incorporated herein by reference).</a>  |
| 3.1.2       | <a href="#">Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TransEnterix, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on December 11, 2019 and incorporated herein by reference).</a>  |
| 3.1.3       | <a href="#">Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Preferred Stock (filed as Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on March 6, 2020 and incorporated herein by reference).</a>  |
| 3.2         | <a href="#">Amended and Restated Bylaws of TransEnterix, Inc. (filed as Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on December 9, 2013 and incorporated by reference herein).</a>  |
| 4.1         | <a href="#">Specimen Certificate for Common Stock of TransEnterix, Inc. (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-3, File No. 333-236200, filed with the SEC on January 31, 2020 and incorporated by reference herein).</a>  |
| 4.2         | <a href="#">Form of Warrant to Purchase Common Stock for warrants issued to Oxford Finance LLC and Silicon Valley Bank (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on September 30, 2014 and incorporated by reference herein).</a>   |
| 4.3         | <a href="#">Form of Series B Warrant (filed as Exhibit 4.2 to our Current Report on Form 8-K, filed with the SEC on April 28, 2017 and incorporated by reference herein).</a>   |
| 4.4         | <a href="#">Form of Warrant to Purchase Stock for warrants issued to Innovatus Life Sciences Lending Fund I, LP (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on May 10, 2017 and incorporated by reference herein).</a>  |
| 4.5         | <a href="#">Form of Service Warrant to purchase common stock for warrants issued to third party vendor (filed as Exhibit 4.4 to our Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2017 and incorporated by reference herein).</a>  |
| 4.6         | <a href="#">Form of Common Stock Purchase Warrant (Series C and Series D Warrants) (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on March 6, 2020 and incorporated herein by reference).</a>  |

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 4.7                | <a href="#">Form of Warrant Agency Agreement by and between the Registrant and Continental Stock Transfer &amp; Trust Company (filed as Exhibit 4.2 to our Current Report on Form 8-K, filed with the SEC on March 6, 2020 and incorporated herein by reference).</a>  |
| 4.8*               | <a href="#">Description of Listed Securities</a>   |
| 10.1 +             | <a href="#">Employment Agreement, dated March 6, 2018, and effective as of March 1, 2018, by and between the Registrant and Anthony Fernando (filed as Exhibit 10.7 to our Annual Report on Form 10-K, filed with the SEC on March 8, 2018 and incorporated by reference herein).</a>  |
| 10.2 +             | <a href="#">Employment Agreement, dated August 15, 2018, and effective as of August 31, 2018, by and between the Registrant and Eric Smith.</a>  |
| 10.3.1 +           | <a href="#">Amended and Restated Employment Agreement, dated March 6, 2018, and effective as of March 1, 2018, by and between the Registrant and Todd M. Pope (filed as Exhibit 10.5 to our Annual Report on Form 10-K, filed with the SEC on March 8, 2018 and incorporated by reference herein).</a>   |
| 10.3.2 +           | <a href="#">Separation Agreement and General Release, dated November 8, 2019, by and between the Registrant and Todd M. Pope (filed as Exhibit 10.6 to our Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2019 and incorporated herein by reference).</a>   |
| 10.4.1 +           | <a href="#">Employment Agreement, dated March 6, 2018, and effective as of March 1, 2018, by and between the Registrant and Joseph P. Slattery (filed as Exhibit 10.6 to our Annual Report on Form 10-K, filed with the SEC on March 8, 2018 and incorporated by reference herein).</a>  |
| 10.4.2+            | <a href="#">Transition Agreement, dated October 17, 2019, by and between the Registrant and Joseph P. Slattery (filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2019 and incorporated herein by reference).</a>   |
| 10.5 +             | <a href="#">TransEnterix, Inc. 2006 Stock Plan, as amended on November 29, 2011 (filed as Exhibit 4.4 to the Registrant's Registration Statement on Form S-8 (File No. 333-191011), filed with the SEC on September 5, 2013 and incorporated by reference herein).</a>   |
| 10.6 +             | <a href="#">TransEnterix, Inc. Amended and Restated Incentive Compensation Plan, as amended and restated effective April 24, 2019 (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on April 26, 2019 and incorporated by reference herein).</a>  |
| 10.7 +             | <a href="#">Form of Employee Stock Option Agreement pursuant to the Plan (filed as Exhibit 10.15 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 5, 2014 and incorporated by reference herein).</a>  |
| 10.8 +             | <a href="#">Form of Employee Stock Option Agreement (performance stock options) pursuant to the Plan (filed as Exhibit 10.16 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 5, 2014 and incorporated by reference herein).</a>  |
| 10.9 +             | <a href="#">Form of Non-Employee Stock Option Agreement pursuant to the Plan (filed as Exhibit 10.17 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 5, 2014 and incorporated by reference herein).</a>  |
| 10.10 +            | <a href="#">Form of Restricted Stock Unit Agreement pursuant to the Plan (filed as Exhibit 10.18 to our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 5, 2014 and incorporated by reference herein).</a>  |
| 10.11 ++           | <a href="#">License Contract between the European Union and Vulcanos S.r.l. (now known as TransEnterix Italia S.r.l.), dated September 18, 2015 (filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2015 and incorporated by reference herein).</a>   |
| 10.12              | <a href="#">Amended and Restated AutoLap System Sale Agreement, dated October 15, 2019, by and between the Registrant and Great Belief International Limited (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on October 17, 2019).</a>  |
| 10.13              | <a href="#">Loan and Security Agreement, dated May 23, 2018, with the several banks and other financial institutions or entities from time to time party to the Loan Agreement as Lenders and Hercules Capital, Inc., as administrative agent and collateral agent (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2018 and incorporated by reference herein).</a>                |
| 10.13.1            | <a href="#">First Amendment to Loan and Security Agreement, dated May 7, 2019, with the several banks and other financial institutions or entities from time to time party to the Loan Agreement as Lenders and Hercules Capital, Inc., as administrative agent and collateral agent (filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on May 9, 2019 and incorporated by reference herein).</a> |

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.13.2            | <a href="#">Consent and Second Amendment to Loan and Security Agreement, dated July 10, 2019, with the several banks and other financial institutions or entities from time to time party to the Loan Agreement as Lenders and Hercules Capital, Inc., as administrative agent and collateral agent ((filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on August 8, 2019 and incorporated by reference herein).</a> |
| 10.14 +            | <a href="#">TransEnterix, Inc. Non-Employee Director Compensation Program, effective May 24, 2018 (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on May 29, 2018 and incorporated by reference herein).</a>  |
| 10.15              | <a href="#">Lock-Up Agreement, dated October 31, 2018, by and between TransEnterix, Inc. and MST Medical Surgery Technologies Ltd. (filed as Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on November 1, 2018 and incorporated by reference herein).</a>   |
| 10.16              | <a href="#">Registration Rights Agreement, dated October 31, 2018, by and between TransEnterix, Inc. and MST Medical Surgery Technologies Ltd. (filed as Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on November 1, 2018 and incorporated by reference herein).</a>   |
| 10.17              | <a href="#">Purchase Agreement by and between TransEnterix, Inc. and Lincoln Park Capital, LLC dated February 10, 2020 (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on February 10, 2020 and incorporated by reference herein).</a>   |
| 10.18              | <a href="#">Offer Letter, dated December 17, 2019, to Brett Farabaugh (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on January 3, 2020 and incorporated by reference herein).</a>  |
| 21.1 *             | <a href="#">Subsidiaries of the Registrant.</a>   |
| 23.1 *             | <a href="#">Consent of BDO USA, LLP.</a>  |
| 31.1 *             | <a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>  |
| 31.2 *             | <a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>  |
| 32.1 *             | <a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>   |
| 32.2 *             | <a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>   |
| 101.INS *          | XBRL Instance Document.   |
| 101.SCH *          | XBRL Taxonomy Extension Schema Document.  |
| 101.CAL *          | XBRL Taxonomy Extension Calculation Linkbase Document.  |
| 101.DEF *          | XBRL Taxonomy Extension Definition Linkbase Document.   |
| 101.LAB *          | XBRL Taxonomy Extension Label Linkbase Document.  |
| 101.PRE *          | XBRL Taxonomy Extension Presentation Linkbase Document.   |

+ A management contract, compensatory plan or arrangement required to be separately identified.

++ Confidential treatment has been granted for certain portions of the agreement pursuant to a confidential treatment request filed with the Commission on November 9, 2015. Such provisions have been filed separately with the Commission.

\* Filed herewith.

#### **ITEM 16. FORM 10-K SUMMARY.**

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

March 16, 2020

**TransEnterix, Inc.**

By: /s/ Anthony Fernando

Anthony Fernando  
 President, Chief Executive Officer  
 and a Director  
 (principal executive officer)

**POWER OF ATTORNEY**

We, the undersigned officers and directors of TransEnterix, Inc., hereby severally constitute and appoint Anthony Fernando and Brett Farabaugh, our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution in him for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

| <u>Signature</u>  | <u>Title(s)</u>   | <u>Date</u>    |
|---|---|----------------|
| <u>/s/ Anthony Fernando</u><br>Anthony Fernando                   | President, Chief Executive Officer and a Director<br>(principal executive officer)                | March 16, 2020 |
| <u>/s/ Brett Farabaugh</u><br>Brett Farabaugh                     | Interim Chief Financial Officer<br>(principal financial officer and principal accounting officer) | March 16, 2020 |
| <u>/s/ Paul A. LaViolette</u><br>Paul A. LaViolette               | Chairman of the Board and a Director  | March 16, 2020 |
| <u>/s/ Andrea Biffi</u><br>Andrea Biffi                           | Director  | March 16, 2020 |
| <u>/s/ Jane H. Hsaio</u><br>Jane H. Hsaio, Ph.D.                  | Director  | March 16, 2020 |
| <u>/s/ William N. Kelley</u><br>William N. Kelley, M.D.           | Director  | March 16, 2020 |
| <u>/s/ David B. Milne</u><br>David B. Milne                       | Director  | March 16, 2020 |
| <u>/s/ Richard C. Pfenniger, Jr.</u><br>Richard C. Pfenniger, Jr. | Director  | March 16, 2020 |
| <u>/s/ William N. Starling, Jr.</u><br>William N. Starling, Jr.   | Director  | March 16, 2020 |

## DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the common stock of TransEnterix, Inc. (“us,” “our,” “we,” or the “Company”), which is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation, as amended, including by the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the “Certificate of Designation, and with the amended and restated certificate of incorporation, as amended the “Certificate of Incorporation”) and amended and restated by-laws (“Bylaws”), which are incorporated as exhibits to this Annual Report on Form 10-K and are incorporated herein by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws, and the applicable provisions of the Delaware general corporate law for additional information.

### Authorized Shares of Capital Stock

Our authorized capital stock consists of 750,000,000 shares of common stock, par value \$0.001 per share (the “Common Stock”), and 25,000,000 shares of preferred stock, par value \$0.01 per share (the “Preferred Stock”).

As of March 12, 2020, there were 46,089,766 shares of Common Stock issued and outstanding and 5,675,293 shares of Series A Convertible Preferred Stock (the “Series A Preferred”) issued and outstanding. All of the shares of the Common Stock currently issued and outstanding are fully-paid and non-assessable.

### Common Stock

#### *Listing*

The Common Stock is listed on the NYSE American under the symbol “TRXC.”

#### *Dividend Rights*

Subject to the prior rights of the holders of any shares of Preferred Stock which may be issued in the future, the holders of the Common Stock are entitled to receive dividends from our funds legally available therefor when, as and if declared by our Board of Directors (“Board”). The Series A Preferred is entitled to dividends only if declared and paid on the Common Stock.

#### *Voting Rights*

Holders of the Common Stock are entitled to one vote per share on all matters which they are entitled to vote upon at meetings of stockholders or upon actions taken by written consent pursuant to Delaware corporate law. The holders of the Common Stock do not have cumulative voting rights, which mean that the holders of a plurality of the outstanding shares of Common Stock can elect all of our directors.

#### *Liquidation and Dissolution*

In the event of our liquidation, dissolution or winding-up, the holders of the Common Stock are entitled to share ratably in all of our assets available for distribution to holders of the Common Stock, subject to the liquidation preferences, if any, of any then-outstanding Preferred Stock. The holders of Series A Preferred will be treated equally with the holders of Common Stock in any liquidation, dissolution or winding-up of the Company.

#### *No Preemptive or Similar Rights*

Holders of the Common Stock do not have any preemptive, subscription, redemption or conversion rights.

#### *Transfer Agent*

The transfer agent for the Common Stock is Continental Stock Transfer & Trust Company.

#### *Relationship to Preferred Stock*

The Board has the authority, without further action by the holders of the outstanding Common Stock, to issue Preferred Stock from time to time in one or more classes or series, to fix the number of shares constituting any class or series and the stated value thereof, if different from the par value, as to fix the terms of any such series or class, including dividend rights, dividend rates, conversion or exchange rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price and the liquidation preference of such class or series. Any or all of these rights may be greater than the rights of our Common Stock. Our Board may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely

affect the voting power or other rights of the holders of our Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. The Certificate of Designation sets forth the rights of the Series A Preferred.

## **Registration Rights**

We entered into a Registration Rights Agreement, dated February 10, 2020 (the “Registration Rights Agreement”), with Lincoln Park Capital Fund (“LPC”), pursuant to which we agreed to file a prospectus supplement to register for resale the shares of Common Stock held by LPC. Under the terms of the Registration Rights Agreement, we are required to use commercially reasonable efforts to keep the registration statement and prospectus current and available for the resale of all of the shares of Common Stock held by LPC at all times for up to a possible maximum of forty-two months.

## **Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, our Bylaws and Delaware Law**

### *Delaware Statute*

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to such date, our Board approves either the business combination or the transaction that resulted in the stockholder’s becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owns at least 85% of our outstanding voting stock, excluding shares held by directors, officers and certain employee stock plans; or
- on or after the consummation date, the business combination is approved by our Board and by the affirmative vote at an annual or special meeting of stockholders holding at least two-thirds of our outstanding voting stock that is not owned by the interested stockholder.

For purposes of Section 203, a “business combination” includes, among other things, a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an “interested stockholder” is generally a person who, together with affiliates and associates of such person:

- owns 15% or more of outstanding voting stock; or
- is an affiliate or associate of ours and was the owner of 15% or more of our outstanding voting stock at any time within the prior three years.

### *Certificate of Incorporation and Bylaw Provisions*

Our Certificate of Incorporation and Bylaws include provisions that, among others, could have the effect of delaying, deferring or discouraging potential acquisition proposals and could delay or prevent a change of control of the Company. The provisions in our Certificate of Incorporation and Bylaws that may have such effect include:

- Preferred Stock. As noted above, our Board, without stockholder approval, has the authority under our certificate of incorporation to issue Preferred Stock with rights superior to the rights of the holders of the Common Stock. As a result, we could issue Preferred Stock quickly and easily, which could adversely affect the rights of holders of the Common Stock and could be issued with terms calculated to delay or prevent a change of control or make removal of management more difficult.
- Stockholder Meetings. Under our Certificate of Amendment and Bylaws, special meetings of our stockholders may be called only by the vote of a majority of the entire Board or the chairman of the Board. Our stockholders may not call a special meeting of the stockholders.
- Requirements for Advance Notification of Stockholder Nominations and Proposals. Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our Board or a committee thereof.

**Exhibit 21.1****SUBSIDIARIES**

| <b>Name of Subsidiary</b>        | <b>Jurisdiction of Incorporation</b> |
|----------------------------------|--------------------------------------|
| TransEnterix Surgical, Inc.      | Delaware                             |
| SafeStitch LLC                   | Virginia                             |
| TransEnterix International, Inc. | Delaware                             |
| TransEnterix Italia, S.r.l.      | Italy                                |
| TransEnterix Europe Sàrl         | Luxemburg                            |
| TransEnterix Asia PTE Ltd.       | Singapore                            |
| TransEnterix Taiwan Ltd          | Taiwan                               |
| TransEnterix Netherlands B.V.    | Netherlands                          |
| TransEnterix Israel LTD          | Israel                               |
| TransEnterix Japan K.K.          | Japan                                |

Consent of Independent Registered Public Accounting Firm

TransEnterix, Inc.  
Morrisville, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (No. 333-209485, No. 333-209486, No. 333-217865, No. 333-222103, No. 333-224049, No. 333-236200 and No. 333-236337) and Form S-8 (No. 333-161291, No. 333-190184, No. 333-191011, No. 333-193234, No. 333-197908, No. 333-203950, No. 333-211972, No. 333-219111, No. 333-225231 and No. 333-231078) of TransEnterix, Inc. of our reports dated March 16, 2020, relating to the consolidated financial statements, and the effectiveness of TransEnterix, Inc.'s internal control over financial reporting, which appear in this Form 10-K. Our report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern. Our report on the effectiveness of internal control over financial reporting expresses an adverse opinion on the effectiveness of TransEnterix, Inc.'s internal control over financial reporting as of December 31, 2019.

/s/ BDO USA, LLP

Raleigh, North Carolina  
March 16, 2020



## CERTIFICATIONS

I, Anthony Fernando, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of TransEnterix, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 16, 2020

By: /s/ Anthony Fernando

Anthony Fernando

President and Chief Executive Officer (Principal Executive Officer)

## CERTIFICATIONS

I, Brett Farabaugh, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of TransEnterix, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 16, 2020

By: /s/ Brett Farabaugh

Brett Farabaugh

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Interim Chief Financial Officer

(principal financial officer and principal accounting officer)

**CERTIFICATIONS PURSUANT  
TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-K of TransEnterix, Inc. for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TransEnterix, Inc.

By: /s/ Anthony Fernando

Anthony Fernando  
President and Chief Executive Officer  
(Principal Executive Officer)

March 16, 2020

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of TransEnterix, Inc. or the certifying officers.

**CERTIFICATION PURSUANT  
TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Annual Report on Form 10-K of TransEnterix, Inc. for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

By:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TransEnterix, Inc.

By: /s/ Brett Farabaugh

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Brett Farabaugh

Interim Chief Financial Officer

(principal financial officer and principal accounting officer)

March 16, 2020

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of TransEnterix, Inc. or the certifying officers.