



April 2021

To our stockholders:

As we approach this year's annual meeting, I want to provide you with a short update.

## **2020 in Review**

Despite the uncertainty that existed during the majority of 2020 as a result of the global pandemic, we made significant progress towards the ongoing acceptance and development of the Senhance® Surgical System, its digital laparoscopic capabilities, and the applicability of the platform across surgical specialties and geographies. While we did not achieve all of the goals we set out at the beginning of the year before the pandemic set in, we accomplished a tremendous amount, which we expect will pay dividends for years to come.

Key highlights from the year included:

- Throughout 2020, we initiated ten clinical programs: three in the US, four in Europe, and three in Asia.
- In the third quarter, we established the first Senhance System training center in the Asia-Pacific region in Japan at the Saitama Medical University International Medical Center in the Greater Tokyo Area.
- We received regulatory approval in Russia, allowing for the Senhance Surgical System sale and utilization throughout the Russian Federation
- We received 510(k) clearance for the Intelligent Surgical Unit™ (ISU™) that enables machine vision capabilities on the Senhance System. In September of 2020, we announced the first surgical procedures successfully completed using the ISU.
- We received CE Mark approval for an expanded indication to treat pediatric patients. During the fourth quarter of 2020, we announced the first pediatric surgical cases with the Senhance System.
- We submitted an application for 510(k) approval for an expanded General Surgery indication for use for the Senhance System to the FDA and received clearance in early 2021.
- During 2020, there were 15 peer-reviewed clinical papers published providing further support of the clinical utility of the Senhance System across gynecology, general surgery, urology and colorectal procedures demonstrating the utility breadth and the complexity of procedures being performed.

## **A Productive Start to 2021**

The first quarter of 2021 has been a busy, productive, and transformative period for the Company. The most visible event this year has been the Investor Day in February where we announced our corporate rebranding and introduced a new category of surgery, which we call Performance-Guided Surgery™. The rebranding included a corporate name change, from TransEnterix, Inc. to Asensus Surgical, Inc.



The new name reflects the company's broader vision of shaping the future of surgery through the integration of computer vision and machine learning with surgical robotics. Our new mission is to elevate robotic surgery in order to drive predictable outcomes, optimize resources and costs, and collaborate with hospital systems that strive to implement innovative healthcare strategies.

We believe that by digitizing the interface between the surgeon and patient, we can unlock the clinical intelligence to pioneer a new era of surgery, Performance-Guided Surgery. We envision a future of surgery in which we can use machine learning, advanced visualization, data analytics, and augmented intelligence to dramatically improve critical decision-making, drive predictability, and level the playing field by gathering, analyzing, and presenting information and insights to empower surgeons of all levels of experience with deeper situational knowledge.

From an operational and financial perspective, we have already achieved a number of key milestones in 2021:

- In March, we received expanded 510(k) clearance for the Senhance System which allows for indication expansion in general surgery in the United States.
- In February, we announced a partnership arrangement with Amsterdam Skills Centre to launch a Senhance surgical training center in the Netherlands establishing the second European surgical training site for Senhance Digital Laparoscopy.
- During January and February, we closed two equity financings, totaling approximately \$111 million in gross proceeds in aggregate, extending our cash runway into 2024
- In January, we received a CE Mark for the Intelligent Surgical Unit™(ISU™), enabling machine vision capabilities in Europe.

## Looking Ahead

We are very excited about the future at Asensus, and what it means for the future of digital surgery. With Performance-Guided Surgery, we are bringing our capabilities to the entire surgical paradigm from pre-operative planning to post-operative analysis, unlocking the clinical intelligence to enable consistently superior outcomes and a new standard of surgery.

Thank you all for your continued support.

Best Regards,

A handwritten signature in black ink, appearing to read "Anthony Fernando".

Anthony Fernando  
President and Chief Executive Officer

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

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**FORM 10-K**

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

**For the fiscal year ended December 31, 2020**

**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**

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**ASENSUS SURGICAL, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

**1 TW Alexander Drive, Suite 160, Durham, NC 27703**  
(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:**

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange where registered</b>
<b>Common Stock</b> <b>\$0.001 par value per share</b>	<b>ASXC</b>	<b>NYSE American</b>

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

**None**  
(Title of class)

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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 type="checkbox"/>
Non-accelerated filer	<input checked="" 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 has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

On June 30, 2020, 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 \$29.2 million.

The number of shares outstanding of the registrant’s common stock as of March 9, 2021 was 232,589,352.

**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 2021 Annual Meeting of Stockholders.

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**ASENSUS SURGICAL, INC.  
ANNUAL REPORT ON FORM 10-K**

**DECEMBER 31, 2020**

**Table of Contents**

		<b><u>Page</u></b>
<b><u>PART I</u></b>		
ITEM 1.	<u>BUSINESS</u>	<u>1</u>
ITEM 1.A.	<u>RISK FACTORS</u>	<u>17</u>
ITEM 1.B.	<u>UNRESOLVED STAFF COMMENTS</u>	<u>31</u>
ITEM 2.	<u>PROPERTIES</u>	<u>32</u>
ITEM 3.	<u>LEGAL PROCEEDINGS</u>	<u>32</u>
ITEM 4.	<u>MINE SAFETY DISCLOSURES</u>	<u>32</u>
<b><u>PART II</u></b>		
ITEM 5.	<u>MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>33</u>
ITEM 7.	<u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>34</u>
ITEM 7.A.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>50</u>
ITEM 8.	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>51</u>
ITEM 9.	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>91</u>
ITEM 9.A.	<u>CONTROLS AND PROCEDURES</u>	<u>91</u>
ITEM 9.B.	<u>OTHER INFORMATION</u>	<u>91</u>
<b><u>PART III</u></b>		
ITEM 10.	<u>DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE</u>	<u>92</u>
ITEM 11.	<u>EXECUTIVE COMPENSATION</u>	<u>92</u>
ITEM 12.	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>92</u>
ITEM 13.	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	<u>93</u>
ITEM 14.	<u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	<u>93</u>
<b><u>PART IV</u></b>		
ITEM 15.	<u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	<u>94</u>
ITEM 16.	<u>FORM 10-K SUMMARY</u>	<u>96</u>

## 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 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 implement our Performance-Guided Surgery strategy and grow our business as a result;
- 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 February 2021, we changed our name from TransEnterix, Inc. to Asensus Surgical, Inc. In this Annual Report we refer to Asensus Surgical, Inc. and its subsidiaries collectively as the “Company,” “it,” “we,” “our” or “us.” The Company’s subsidiaries are: Asensus Surgical US, Inc., SafeStitch LLC, Asensus International, Inc.; Asensus Surgical Italia S r.l.; Asensus Surgical Europe S.à.R.L.; TransEnterix Taiwan Ltd; TransEnterix Japan KK, Asensus Surgical Israel Ltd., Asensus Surgical Netherlands B.V., and Asensus Surgical Canada, Inc.

## PART I

### ITEM 1. BUSINESS

#### Overview

In February 2021, we changed our name from TransEnterix, Inc. to Asensus Surgical, Inc. We are a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery™ by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. This builds upon the foundation of Digital Laparoscopy with the Senhance® Surgical System powered by the Intelligent Surgical Unit™ (ISU™) to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare.

Our mission is focused on leveraging robotic technologies, augmented intelligence and machine learning capabilities to: reduce variability in surgery, drive more predictable outcomes, optimize resources and costs, and work with hospital systems that strive to employ innovative healthcare strategies. By leveraging advanced digital technologies, we aim to enable surgeons to take the best surgical practices and techniques from everywhere and enable them to leverage it anywhere to help improve outcomes, reduce variability, control the unexpected, reduce costs, reduce cognitive and physical fatigue of surgeons, and provide patients with the best care possible. We believe that by digitizing the interface between the surgeon and patient, we can unlock the clinical intelligence to pioneer a new era of surgery, which we are calling Performance-Guided Surgery.

Historical advances in surgery have largely focused on bringing tools and techniques into the operating room to reduce the invasiveness of procedures. When we introduced Digital Laparoscopy, our intention was to help surgeons minimize surgical variability in a cost-effective manner. The next logical step in the progression is looking for ways to deliver clinical intelligence and analytics which we believe can be enabled by what we refer to as Performance-Guided Surgery.

Performance-Guided Surgery builds upon our foundation of Digital Laparoscopy by adding machine vision, augmented intelligence, and deep learning capabilities through all surgical phases to help guide improved decision making, enriched collaboration, and enhanced predictability for all surgeons (independent of skill level and experience). Our Performance-Guided Surgery strategy is composed of the following framework:

- Pre-operative - in what we call “intelligent preparation,” our machine learning models will take data from all of the procedures done utilizing our current Senhance System with the ISU, such as tracking surgical motion and team interaction, to create a large and constantly improving database of surgeries and their outcomes to enable surgeons to best inform their approach and surgical setup.
- Intra-operative – we believe the Senhance System provides perceptive real-time guidance for intra-operative tasks, allowing any surgeon performing a procedure with the Senhance System to perform multiple tasks and benefit from the collective knowledge and rules-based performance of thousands of other successful Senhance-based procedures. Not only will this provide the surgeon with a pathway to better outcomes, we believe it will ultimately help reduce the cognitive load of the surgeons.
- Future use post-operative – finally, by tapping into the vast amount of data captured during procedures, surgeons and operating room staff will be able to get actionable assessments of their performance giving them the information needed to improve performance over time. We intend on building a new standard of analytics to improve not only the skills of all surgeons but moving towards best-practice-sharing that bridges the global surgeon community.

We continue the market development for and commercialization of the Senhance Surgical System, or Senhance System, which digitizes laparoscopic minimally invasive surgery, or MIS, by providing a computer controller interface in the Senhance System. 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 mm microlaparoscopic instruments, eye-sensing camera control and fully-reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy.

We believe that outcomes of minimally invasive surgery will be enhanced through Digital Laparoscopy, 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 current 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 commercially available in Europe, the United States, Japan, Taiwan, Russia 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 510(k) clearance from the FDA for use of the Senhance System in general laparoscopic surgical procedures and laparoscopic gynecologic surgery in a total of 31 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal, hiatal and paraesophageal hernia, sleeve gastrectomy and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, we have received regulatory approval and reimbursement for 98 laparoscopic procedures.
- The Senhance System received its registration certificate by the Russian medical device regulatory agency, Roszdravnadzor, in December 2020, allowing for its sale and utilization throughout the Russian Federation.



Our focus over the last few years has been on seeking regulatory approvals and clearances for the Senhance System and related product offerings and instruments and pursuing commercialization of our products. The following chart describes our success in achieving regulatory clearances and approvals to date.

Product/Indications	FDA Clearance	CE Mark	Other Approvals
<b>Senhance System</b>	October 2017	January 2012	Taiwan – April 2018 Japan – May 2019 Russian Federation – December 2020
<b>Indications for Use of Senhance System</b>			
• Initial general surgery indications for laparoscopic colorectal and gynecologic surgery procedures	October 2017	N/A	
• Extended to cholecystectomy and inguinal hernia repair	May 2018	N/A	
• Extended to hiatal and paraesophageal hernia, and sleeve gastrectomy	March 2021	N/A	
• General surgery indications	General laparoscopic surgical procedures and laparoscopic gynecologic surgery in a total of 31 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal, hiatal and paraesophageal hernia, sleeve gastrectomy and laparoscopic cholecystectomy (gallbladder removal)	For adult and pediatric laparoscopic abdominal and pelvic surgery, as well as limited thoracic surgeries excluding cardiac and vascular surgery	Japan – regulatory approval and reimbursement for 98 laparoscopic procedures – July 2019
• Pediatric indications	N/A	February 2020	
<b>Instruments and Other Products</b>			
• 3 mm diameter instruments	October 2018	April 2019	
• Senhance ultrasonic system	January 2019	September 2018	Japan - October 2020
• 3 and 5 mm hooks	5mm July 2019 3mm November 2019	December 2019	Japan - December 2020
• Senhance articulating system	N/A	September 2018	
• Intelligent Surgical Unit, or ISU	March 2020	January 2021	Japan - December 2020

In 2020, we obtained regulatory clearance for the Senhance ultrasonic system in both Taiwan and Japan. We also received clearance for the ISU in both the U.S. and Japan. Finally, in the EU, we expanded our claims for the Senhance System to include pediatric patients, allowing accessibility to more surgeons and patients, as well as expanding our potential market to include pediatric hospitals in Europe. We anticipate the robotic precision provided by the Senhance System, coupled with the already available 3 mm instruments will prove to be an effective tool in surgery with smaller patients. As of February 15, 2021, two hospitals have installed the Senhance System for pediatric use.

The 3 mm instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. The Senhance 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 the EU in November 2019 and we are evaluating our pathway forward to launch such a system in the United States with a planned submission for U.S. clearance in the first half of 2021.

We received FDA clearance in January 2020 for the ISU. We believe it is the only FDA-cleared device for machine vision technology in abdominal robotic surgery. On September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. In January 2021, we received CE Mark for the ISU.

We have also focused on expanding the indications for use of the Senhance System. As of March 2021, the Senhance System is cleared for use in general laparoscopic surgical procedures and laparoscopic gynecologic surgery in a total of 31 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal, hiatal and paraesophageal hernia, sleeve gastrectomy and laparoscopic cholecystectomy (gallbladder removal). We continue to make additional submissions for clearance or approval for enhancements to the Senhance System and related instruments and accessories, including additional filings and approvals sought in Japan.

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.

## **2020 Market Development Activities**

In 2020 we refocused our resources and efforts 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 are focusing on markets with high utilization of laparoscopic techniques, including Japan, Western Europe and the United States. Our focus is 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. We are not currently focusing on revenue targets, especially in the United States.

### *2020 Senhance Surgical System Placements*

Throughout 2020, we installed ten Senhance Systems, three in the U.S., four in Europe, and three in Asia, and initiated nine clinical programs.

In December 2020, we announced that Southern Surgical Hospital, a hospital based in Louisiana, has signed an agreement to initiate a Senhance Digital Laparoscopic program. This will represent the third Senhance Surgical program initiated in the state of Louisiana since 2018 (May 2018 - LSU Health's University Medical Center New Orleans, January 2020 - Ochsner Baptist Medical Center). LSU Health, in addition to utilizing a Senhance System in their Digital Laparoscopy program, is home to one of the Senhance System training centers in the southeast United States.

### *Training Sites*

In September 2020, we established the first training center for the Senhance System in the Asia-Pacific region in Japan at the Saitama Medical University International Medical Center in the Greater Tokyo Area. The Asia-Pacific region has been a major contributor of new system placements and surgical cases utilizing the Senhance Surgical System and the Asia-Pacific laparoscopy device market is expected to grow from \$1.26 billion in 2019 to \$1.87 billion by 2024, according to Market Data Forecast, Inc. The training center is expected to drive increased utilization of our eight system installations in the Asia-Pacific region and encourage further adoption of our technology in additional hospitals.

In February 2021, we announced an agreement with the Amsterdam Skills Centre (ASC) establishing the second European surgical training site for Senhance System Digital Laparoscopy. This site will serve surgeons and staff throughout Europe with basic and advanced training on the Senhance System. The ASC will also provide Asensus with a world-class facility to engage European surgeons in technology and clinical development studies.

We now have six global training sites, including three in the United States at the AdventHealth Nicholson Center in Celebration, Florida, at LSU Health's University Medical Center New Orleans, and at Pittsburgh CREATES – University of Pittsburgh.

#### *Procedure Volumes*

In 2020, surgeons performed over 1,450 procedures utilizing the Senhance System, representing a 10% decrease over the previous year, which was less than our goal as a result of the impact of the COVID-19 pandemic on elective surgeries and hospital operations. These procedures included general surgery, gynecology, urology, colorectal and bariatric surgical cases.

#### *Foundational Sites*

As of December 31, 2020, we had 11 foundational sites, up from seven at the start of 2020. Foundational sites are hospitals that are performing clinical procedures with the Senhance System at an annualized rate of greater than 100 procedures per year.

#### **Clinical Validation**

During 2020, there were 15 peer-reviewed clinical papers published providing further support of the clinical utility of the Senhance Surgical System across gynecology, general surgery, urology and colorectal procedures demonstrating the utility breadth and the complexity of procedures being performed.

#### **Impact of COVID-19**

The COVID-19 pandemic had a significant impact on us in 2020 and continues to have a significant impact on our operations, primarily due to the temporary cessation of elective surgical procedures in many markets, and the challenges and restrictions caused by stay-at-home orders, social distancing requirements and travel restrictions. Our business and customers were negatively impacted by the COVID-19 pandemic, which suspended many elective surgical procedures globally, curtailed travel and necessarily diverted the attention of hospital customers. A variety of travel restrictions have caused delays in product installation and training activities. Since the second quarter of 2020, we have seen elective surgical procedures recommence in the United States, Europe and Japan, but not, to date, to the levels seen before the COVID-19 pandemic. This has significantly impacted our ability to implement our market development activities to place our Senhance Systems, provide training, and increase the use of the Senhance Systems in place. Given the dynamic nature of this health emergency, the full impact of the COVID-19 pandemic on ongoing business, results of operations and overall financial performance cannot be reasonably estimated at this time.

#### **Recent Financing Transactions**

During 2020 and in 2021 to date, the Company engaged in a number of equity financing transactions to fund its operations and extend its cash reach to provide capital to progress its strategy. These financings included:

- *March 2020 Offering of Units.* On March 10, 2020, the Company closed a firm commitment underwritten public offering, or the March 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 consisted 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 consisted 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 were immediately separable. In addition, the underwriter for the March 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. All shares of Series A Preferred Stock were converted into 7.9 million shares of common stock prior to June 30, 2020. The net proceeds to the Company were \$13.4 million.

- *July 2020 Offering of Common Stock.* On July 6, 2020, the Company completed an underwritten public offering, or the July 2020 Public Offering, and sold an aggregate of 42,857,142 shares of its common stock, including the underwriter's full exercise of an over-allotment option, at the public offering price per of \$0.35 per share, generating net proceeds of approximately \$13.6 million after deducting underwriter discounts, commissions and expenses.
- *2020 ATM Offering.* In November 2020, the Company commenced an at-the-market offering of up to \$40 million of shares of the Company's common stock, or the 2020 ATM Offering. The 2020 ATM Offering was conducted under the Controlled Equity Offering Sales Agreement, dated August 12, 2019, or the 2019 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor. The Company sold an aggregate of 35,440,830 shares of its common stock at the public offering price of \$1.05 per share, generating approximately \$37.4 million in gross proceeds and approximately \$36.2 million in net proceeds under the 2020 ATM Offering beginning in the fourth quarter of 2020 through January 2021. On January 26, 2021, the Company terminated the 2020 ATM Offering.
- *Warrant Exercises.* The units the Company offered and sold in the March 2020 Offering included 25,367,646 Series C Warrants, each to purchase one share of common stock at an exercise price of \$0.68 per share and a one-year term, and 25,367,646 Series D Warrants, each to purchase one share of common stock at an exercise price of \$0.68 per share and a five-year term. As of the date of this Annual Report, all Series C Warrants have been exercised or expired with aggregate proceeds to the Company of \$17.2 million and 24,094,899 Series D Warrants have been exercised with aggregate proceeds to the Company of \$16.4 million. The Series C Warrants expired on March 10, 2021.
- *Registered Direct Offering.* On January 12, 2021, the Company entered into a securities purchase agreement, or the 2021 Purchase Agreement, with the purchasers named therein, pursuant to which we sold, in a registered direct offering 25,000,000 shares of common stock at a purchase price per share of \$1.25 for aggregate gross proceeds of \$31.25 million, and net proceeds of \$28.8 million, or the 2021 Registered Direct Offering.
- *2021 Public Offering.* On January 26, 2021, the Company entered into an underwriting agreement, or 2021 Underwriting Agreement, relating to the issuance and sale of 23,083,333 shares of the Company's common stock at a public offering price of \$3.00 per share, or the January 2021 Offering. On February 1, 2021, the underwriter exercised in full its option to purchase 3,462,499 additional shares of common stock at the same offering price to the public, less underwriting discounts and commissions. The Company raised approximately \$79.6 million in gross proceeds and approximately \$73.5 million in net proceeds through the January 2021 Offering.

Following such financing transactions, the Company has cash and cash equivalents, including restricted cash, of \$169.5 million as of February 1, 2021, and believes it has sufficient capital to fund operations for more than 12 months.

## 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 by providing a computer controller interface for the surgeon to manipulate surgical instruments and move the visualization system. 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.

The historical advances in surgery have largely focused on bringing tools and techniques into the operating room to reduce the invasiveness of procedures. When we introduced Digital Laparoscopy, our intention was to help surgeons minimize surgical variability in a cost-effective manner. The next step in the progress is looking for ways to deliver superior outcomes which we believe can be enabled by what we refer to as Performance-Guided Surgery.

Factors plaguing the healthcare industry that amplifies the urgency for Performance-Guided Surgery:

- Value-based care is shifting a greater responsibility for poor quality and inefficiency to hospitals and physicians;
- COVID-19 exposed the shocking financial frailty of the hospital system as well as capacity and resource constraints, which must be bolstered and requires an acceleration of innovation; and
- Patients are presenting with more complex conditions and treating them becomes more complicated. The absolute number of patients seeking care is increasing, and many more patients have multiple chronic conditions than they did a generation, or even a decade ago.

These factors make it the ideal time to integrate advanced technology in the operating room.

## **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. In March 2021, we received 510(k) clearance from the FDA for indication expansion in general surgery allowing for sleeve gastrectomy, and hiatal and paraesophageal hernia repair.

The Senhance System is commercially available in the United States, Europe, Japan, Taiwan, Russia 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, which provides the surgeon with additional depth and spatial relation of organs; and a 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;
- *Intelligent Surgical Unit or ISU*: enables machine vision capabilities providing the ability to recognize certain objects and locations in the surgical field. This new capability enhances visualization and camera control over currently available surgical technologies, and provides the foundation for additional augmented intelligence capabilities. Additionally, the ISU improves surgical team collaboration by seamlessly sharing the surgeon's console view in real-time across the entire operating room. Future augmented intelligence features may include 3D point-to-point measurement and anatomical structure identification, further enhancing the digital laparoscopic experience with Senhance;
- *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.

#### *Instruments and Other Products*

##### Instruments

We successfully obtained FDA clearance and CE Mark for a number of instruments, including, most recently, our 3 mm diameter instruments, and our 3 mm and 5 mm hooks. The 3 mm instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. We currently offer approximately 70 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.

##### Other Products

The Senhance 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 submission for U.S. clearance in the first half of 2021.

In January 2020, we submitted a 510(k) submission to the FDA for our ISU that is designed to enable machine vision capabilities on the Senhance System. Such ISU was developed using the MST image analytics technology that we retained. On March 13, 2020, the Company announced that it had received FDA clearance for the Intelligent Surgical Unit. On September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. In January 2021, we received CE Mark for the ISU.

#### *Indications for Use*

We continue to work on expanding the indications for use of the Senhance System and our instruments and other products. The most notable recent advances are:

- We received CE Mark approval for an expanded indication to treat pediatric patients. During the fourth quarter of 2020, we announced the first pediatric surgical cases with Senhance Surgical System at Maastricht University Medical Center+ in the Netherlands.
- In 2020, we submitted an application to the FDA for 510(k) clearance for expanded General Surgery indications for use for the Senhance System. In March 2021 we received such clearance for hiatal and paraesophageal hernia, and sleeve gastrectomy procedures.

#### **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 in the first half of 2021.

##### *Augmented Intelligence 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 machine vision and augmented intelligence assets, including 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 are harnessing MST's image analytics technology to accelerate and drive meaningful Senhance System developments and allow us to expand the Senhance System to add augmented, intelligent vision capability.

## **Business Strategy**

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

We believe that:

- our Performance-Guided Surgery framework, which focuses on leveraging robotic technologies, augmented intelligence and machine learning capabilities will assist in reducing variability in surgery, drive more predictable outcomes, optimize resources and costs, and resonate with hospital systems that seek to employ innovative healthcare strategies;
- 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, our strategy to lease the Senhance System to additional hospitals will increase our placements and use of our systems;
- 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 mm instruments for the Senhance System help to increase adoption of our products in the laparoscopic surgery market;
- leveraging haptic feedback, 3 mm 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.

During the first half of 2021, we expect to achieve the following regulatory milestones:

- file for FDA 510(k) clearance for articulating instruments; and
- file for FDA 510(k) clearance for the next generation ISU features.

During the first half of 2021, we expect to publish clinical papers in peer reviewed journals on the following subjects:

- health economic studies comparing Senhance Digital Laparoscopy, laparoscopy, and robotic surgery;
- clinical performance when utilizing the Senhance System; and
- operating room efficiency and surgeon ergonomics when utilizing the Senhance System.

## **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 February 28, 2021, we have six training centers, including in Milan, Italy, at the Amsterdam Skills Centre in the Netherlands, at the AdventHealth Nicholson Center in Celebration, Florida, at LSU Health's University Medical Center New Orleans, at Pittsburgh CREATES – University of Pittsburgh, and at the Saitama Medical University International Medical Center in the Greater Tokyo Area, Japan. As of December 31, 2020, we have three research and development centers, including in Research Triangle Park, North Carolina, in Milan, Italy and in Yokne'am Illit, Israel.

We are dependent on growing the number of hospital customers and increasing the number of customers with installed Senhance Systems was a focus in 2020. Throughout 2020, we installed ten Senhance Systems, three in the U.S., four in Europe, and three in Asia, and initiated nine clinical programs. We also focused on growing the number of foundational sites, adding four in 2020. Foundational sites are hospitals that are performing clinical procedures with the Senhance System at an annualized rate of greater than 100 procedures per year.

## **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, 2020, the Company's patent portfolio includes approximately 51 United States patents, over 100 patents issued outside the United States, and more than 150 patent applications filed in the United States and internationally. We own all right, title and interest in all but the 38 of our patents and patent applications that are exclusively licensed to us and the 25 patents and patent applications that are non-exclusively licensed to us.

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 120 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 Asensus Surgical 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., Memic Innovative Surgery Ltd., 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. We believe the Senhance System can be distinguished from other currently available robotic systems on the basis of (1) overall attractiveness to laparoscopic surgeons due to its ability to provide robotic benefits while leveraging their laparoscopic training and experience, (2) the additions we have made, including the ISU, (3) lower per procedure costs and (4) increasing indications for use, including pediatric indications. We further expect the Senhance System to differentiate in its ability to provide the surgeon with valuable tactile feedback and clinical intelligence to help guide better outcomes. 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. Asensus Surgical 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 was replaced by the updated European Medical Device Regulation, or 2017/745 (MDR), after a three-year transition period. The COVID-19 pandemic prompted a one-year extension of the implementation of the transition timeline. However, any of our products that were certified to comply with the MDD have been or 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 place new requirements regarding labeling, post-market surveillance, and technical documentation on all medical device manufacturers. In addition, Notified Bodies underwent 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. With the recent change in federal administration, 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, Africa, and the Commonwealth of Independent States, 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.

## Human Capital

### *Company Culture*

Our employees are passionate about the work they do and thrive in a collaborative environment that fosters creative solutions to complex problems. The Company fosters a significant amount of collaboration and synergy among employees. Team members at any level are encouraged to provide suggestions and input to enable the Company's success.

### *Employee Demographics*

As of December 31, 2020, we had 138 employees, including 128 full-time employees, of whom 47 were in the R&D department, 12 were in Quality and Regulatory Affairs, 28 were in marketing and sales, 23 were in Corporate Administration, and 18 were in Customer Care. As of December 31, 2020, approximately 33% of the Company's workforce were female and minorities represented approximately 19% of the Company's workforce. As of December 31, 2020, approximately 58% of the Company's employees were located in the United States and 42% were outside of the United States. In 2020, we hired 24 full-time employees.

### *Diversity, Equity & Inclusion, or DEI*

We believe in contributing to a society that welcomes diverse voices and values differences in lived experiences, culture, religion, age, gender identity, sexual orientation, race, ethnicity, and neurodiversity. We are committed to ensuring this same environment for our employees – a culture where individuals feel safe, heard, and respected. We celebrate the uniqueness of our global workforce, especially in a company of our size, and appreciate that only through inclusion, ongoing learning, and partnership can we succeed.

In 2020, we created an internal webpage dedicated to diversity, equity and inclusion (or DEI) resources for our employees, kicked off a DEI committee and partnered with a DEI alliance to further evolve our DEI efforts.

### *COVID-19 Pandemic*

Throughout the COVID-19 pandemic, employee safety is of top priority. Most of our employees globally have been working from home since the beginning of the pandemic, except for those with a business need to engage in work onsite. Ongoing safety measures were put into place at each of our locations including implementing pre-screening and social distancing requirements in addition to providing PPE. We also created a Global Prevention Team to monitor the impact of the pandemic on our global workforce and to carry out our ongoing planning and response efforts. We increased our employee communications to ensure frequent connections while working remotely across the company including regular all-hands meetings and employee newsletters.

### *Health & Wellness*

Throughout 2020, health and wellness was a key focus of the Company, especially in light of the pandemic. Many of our employee communications focused on the physical and mental health of our employees. We remain committed to providing our workforce with flexible remote working schedules to suit their personal needs through this challenging time. We also continue to benchmark all of our health insurance offerings to ensure plan competitiveness.

### *People Strategy*

Our People Strategy is to create and maintain a culture of high performance and accountability through the attraction, retention and development of expert talent. We compete for top talent with effective recruitment strategies, well defined roles and attractive total compensation packages. We keep talent engaged through appreciation, communication and creation of a great work environment. We support employee growth professionally and personally through formal and informal opportunities and leadership support.

### *Compensation*

In addition to competitive base salaries, we offer incentive-based compensation programs tied to the performance of key objectives. We also provide compensation in the form of restricted stock unit grants and/or stock options.

### **Corporate Information**

On February 23, 2021, we changed our corporate name to Asensus Surgical, Inc. Effective March 10, 2021, our principal executive offices are located at 1 TW Alexander Drive, Suite 160, Durham, NC 27703. The Company was originally incorporated on August 19, 1988 as a Delaware corporation.

The active subsidiaries of the Company are Asensus Surgical US, Inc., SafeStitch LLC, Asensus International, Inc.; Asensus Surgical Italia S.r.l.; Asensus Surgical Europe S.à.R.L.; TransEnterix Taiwan Ltd; TransEnterix Japan KK; Asensus Surgical Israel Ltd., Asensus Surgical Netherlands B.V., and Asensus Surgical Canada, Inc.

### **Available Information**

The Company maintains a website at [www.asensus.com](http://www.asensus.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 28, 2020, 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**

Our risk factors are grouped into the following categories: (1) Risks Related to the Operation of our Business; (2) Risks Related to Our Status as a Public Company; (3) Risks Related to Protection of our Intellectual Property; (4) Risks Related to the Regulation of our Business; and (5) General Risk Factors.

#### **Risks Related to the Operation of our Business**

##### ***We have a history of operating losses, and we may not be able to achieve or sustain profitability.***

We have a limited operating history. We are not profitable and have incurred losses since our inception. Our accumulated deficit was \$722.9 million and our working capital was \$23.7 million as of December 31, 2020. We believe that cash on hand, including proceeds from our capital raising transactions in 2020 and 2021 and the Series C Warrant and Series D Warrant exercises are sufficient to fund our operations more than 12 months, but cannot assure you that our cash needs will not change over time.

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.

***The coronavirus (COVID-19) pandemic has negatively impacted our operations.***

We have facilities located in the United States, Israel, Japan, and Italy. All of our facilities are in locations that are subject to, or have been subject to, stay-at-home or shelter-in-place orders. Our Senhance Systems are manufactured at a contract manufacturing facility in Milan. With the quarantines in Northern Italy, the assembly of new units was disrupted earlier in 2020. A variety of travel restrictions, caused delays in our product installation and training activities in the 2020 to date, particularly in April and May, and are expected to continue. Elective surgeries were halted in the United States and Europe and only limited procedures were being done in Japan at the height of stay-at-home requirements in these jurisdictions. Although such procedures have commenced in some locations, the limited procedures have significantly impacted our ability to place our Senhance Systems, provide training, and increase the use of the Senhance Systems in place. It is uncertain whether elective surgeries will be negatively impacted or halted again in the future by a resurgence of COVID-19 cases in any of these jurisdictions.

In addition, we are aware that the FDA clearance process has been impacted by the COVID-19 pandemic, resulting in delays in the clearance process. We anticipate such delays may continue.

The global spread of COVID-19 and the various attempts to contain it continue to create significant volatility, uncertainty and economic disruption. The full extent to which the COVID-19 pandemic and the various responses to it impacts our business, operations and financial results continues to depend on numerous factors that we may not be able to accurately predict, including: the duration and scope of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the availability and cost to access the capital markets; the decline in elective surgery procedures during 2020 and into 2021; the effect on our customers and customer demand for Senhance Systems and the ability to provide training services; and disruptions or restrictions on our employees' ability to work and travel. In addition, any preventative or protective actions that governments implement or that we take in respect of COVID-19, such as travel restrictions or stay-at-home orders, may interfere with the ability of our employees, vendors and contract manufacturers to perform their respective responsibilities and obligations relative to the conduct of our business. Such results could have a material adverse effect on our operations, business, financial condition, results of operations, or cash flows.

We believe the COVID-19 pandemic will continue to negatively impact our operations and our ability to implement our market development efforts, which will have a negative effect on our financial condition.

***Our new strategic focus, on delivering tools and assistance to provide Performance-Guided Surgery opportunities, may not result in the growth of our business in the timeline we envision or at all.***

On February 23, 2021, we announced a new strategic focus on providing clinical intelligence to surgeons to provide Performance-Guided Surgery opportunities. We believe that the Senhance System, which digitizes the interface between the surgeon and the patient in laparoscopic surgery can also be used, with our augmented intelligence offerings, to provide real-time clinical data throughout the entire surgical experience, to assist in removing elements and factors that contribute to surgical variability and reduce complications. Our efforts to communicate and implement this strategy with hospitals, surgery centers and surgeons may take longer than we anticipate, may not be as successful as we contemplate and may not result in a meaningful increase in our business or financial condition.

***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, registered for sale in the Russian Federation, 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 and 2020. We have determined to focus our energies on market development and increased usage of the Senhance Systems that have been purchased and placed, as well as on our Performance-Guided Surgery strategy. 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, leading us to refocus our energies on entering into placement and leasing arrangements with hospitals, which has had an impact on our revenue.***

Purchase of a surgical robotic system such as the Senhance System represents a capital purchase by hospitals and other potential customers, which is a time-intensive process involving adoption by surgeons and approval of the capital purchase by administration. 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. In 2020 we placed ten Senhance Systems under this program. We cannot assure you that these lease arrangements will lead to longer term placements or result in 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, the Russian Federation 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.

***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 and increase volatility in our stock price.

***In order to compete successfully within the surgical robotics industry, we need to continue to evolve the Senhance System, including the innovations associated with 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 assets we acquired from Medical Surgery Technologies, Ltd. in 2018. Our focus currently is on harnessing the image technology acquired in the MST acquisition to advance the intelligence of the Senhance System through the ISU to provide meaningful real-time data to surgeons. We have developed and received CE Mark for articulating instruments in Europe. We are developing articulating instruments and will seek FDA 510(k) clearance in the US. These assets are also vital to our Performance-Guided Surgery strategy. If we fail to continue 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.

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

The medical device industry is highly competitive, and we face significant competition from many 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, the Commonwealth of Independent States, 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., Memic Innovative Surgery Ltd., 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.

***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, Asia and the Russian Federation, 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 may require substantial additional funding to advance our current plans.***

We are focused on our market development efforts and commercialization of the Senhance System and other products, as well as research and development activities for advancements for the Senhance System and our other products. We intend to advance multiple additional products through clinical and pre-clinical development in the future. We may need to raise additional capital in the future in order to fund these priorities and achieve our business objectives. We cannot assure you that we will be successful in obtaining additional financing in the future 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 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.

***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.

**Risks Related to Our Status as a Public Company**

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

The market price of our common stock has been, and may continue to be, volatile, and the market price of our common stock could 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, 2020, the market price of our common stock fluctuated from a high of \$43.29 per share to a low of \$0.28 per share, after giving effect to the one-for-thirteen reverse stock split we effected on December 11, 2019. Our stock price was below \$1.00 per share from early March 2020 through January 2021. 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 lease placements or commercial sales of our products;
- the announcement of new products or product enhancements or collaborations 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;
- 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 may need to raise substantial additional capital in order to continue our operations and achieve our business objectives. 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.

***We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.***

At the present time, we intend to use available funds to finance our operations. Accordingly, while payments of dividends is within the discretion of our board of directors, no cash dividends on our common stock have been declared or paid by us, and we have no intention of paying any such dividends in the foreseeable future. Any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

## **Risks Related to Protection of our Intellectual Property**

***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 Asensus Surgical Italia S.r.l. 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.

### **Risks Related to Regulation of our Business**

***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 2021 after a four-year transition period, imposes 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.

***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.

### **General Risk Factors**

***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 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**

Effective March 10, 2021, our principal corporate office is located at 1 TW Alexander Drive, Suite 160, Durham, North Carolina. We lease this facility, which consists of 27,807 square feet, for a ten year and five month term ending in August 2031.

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 "ASXC," which changed from "TRXC" on March 5, 2021.

As of March 9, 2021, there were approximately 151 record holders of our common stock (counting all shares held in single nominee registration as one stockholder).

#### **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, 2020.

## 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

Asensus Surgical is a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery by unlocking the clinical intelligence to enable consistently superior outcomes and a new standard of surgery. This builds upon the foundation of Digital Laparoscopy with the Senhance® Surgical System powered by the Intelligent Surgical Unit to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. 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 mm microlaparoscopic instruments, eye-sensing camera control and fully-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, Russia 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 general laparoscopic surgical procedures and laparoscopic gynecologic surgery in a total of 31 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal, hiatal and paraesophageal hernia, sleeve gastrectomy and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, the Company has received regulatory approval and reimbursement for 98 laparoscopic procedures.
- The Senhance System received its registration certificate by the Russian medical device regulatory agency, Roszdravnadzor, in December 2020, allowing for its sale and utilization throughout the Russian Federation.

On February 23, 2021, we changed our name from TransEnterix, Inc. to Asensus Surgical, Inc. as part of our strategy to utilize the Senhance System and ISU capabilities, along with our other augmented intelligence related offerings and instrumentation to unlock clinical intelligence to enable consistently superior outcomes and a new standard of surgery we are calling Performance-Guided Surgery. We believe our product offerings, and our digitization of the interface between the surgeon and the patient allows us to assist the surgeon in all aspects of laparoscopic surgery including:

- Pre-operative - in what we call "intelligent preparation," our machine learning models will take data from all of the procedures done utilizing our current Senhance System with the ISU, such as tracking surgical motion and team interaction, to create a large and constantly improving database of surgeries and their outcomes to enable surgeons to best inform their approach and surgical setup.
- Intra-operative – we believe the Senhance System provides perceptive real-time guidance for intra-operative tasks, allowing any surgeon performing a procedure with the Senhance System to perform multiple tasks and benefit from the collective knowledge and rules-based performance of thousands of other successful Senhance-based procedures. Not only will this provide the surgeon with a pathway to better outcomes, we believe it will ultimately help reduce the cognitive load of the surgeons.
- Future use post-operative – finally, by tapping into the vast amount of data captured during procedures, surgeons and operating room staff will be able to get actionable assessments of their performance giving them the information needed to improve performance over time. We intend on building a new standard of analytics to improve not only the skills of all surgeons but moving towards best-practice-sharing that bridges the global surgeon community.



We received FDA clearance in January 2020 for our Intelligent Surgical Unit, or ISU. We believe it is the only FDA-cleared device for machine vision technology in abdominal robotic surgery. On September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. In January 2021, we received CE Mark for the ISU.

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

In 2020, we obtained regulatory clearance for the Senhance ultrasonic system in both Taiwan and Japan. We also received clearance for the ISU in both the U.S. and Japan. Finally, in the EU, we expanded our claims for the Senhance System to include pediatric patients, allowing accessibility to more surgeons and patients, as well as expanding our potential market to include pediatric hospitals in Europe. We anticipate the robotic precision provided by the Senhance System, coupled with the already available 3 mm instruments will prove to be an effective tool in surgery with smaller patients. As of February 15, 2021, two hospitals have installed the Senhance System for pediatric use.

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, 2020, we had an accumulated deficit of \$722.9 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.

## Financing Transactions

### *January 2021 Public Offering*

On February 1, 2021, the Company completed an underwritten public offering of 26,725,832 shares of its common stock, including the underwriter's full exercise of an over-allotment option, at the public offering price of \$3.00 per share, generating net proceeds of approximately \$73.5 million.

### *Registered Direct Purchase Agreement*

On January 12, 2021, the Company sold in a registered direct offering 25,000,000 shares of common stock at a purchase price per share of \$1.25 for aggregate gross proceeds of \$31.25 million, and net proceeds of \$28.8 million.

### *At-the-Market Offerings*

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, and commenced an at-the-market offering, or the 2019 ATM Offering pursuant to which the Company could 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. Pursuant to the 2019 Sales Agreement, sales of the common stock were made under the Company's previously filed and currently effective shelf 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. Under the 2019 ATM Offering, the Company raised gross proceeds of \$7.2 million 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 during the year ended December 31, 2020. The 2019 ATM Offering was completed in February 2020.

On October 9, 2020, the Company filed a prospectus supplement relating to an "at the market" offering with Cantor pursuant to which the Company could sell from time to time, at its option, up to an aggregate of \$40.0 million of shares of the Company's common stock, through Cantor as sales agent, pursuant to the 2019 Sales Agreement, or the "2020 ATM Offering". The 2020 ATM Offering was conducted under the Company's effective shelf registration statement on Form S-3, which was declared effective by the SEC on February 10, 2020. The aggregate compensation paid to Cantor was 3.0% of the aggregate gross proceeds from each sale of the Company's common stock.

The following table summarizes the total sales under the 2019 ATM Offering and 2020 ATM Offering for the period indicated (in thousands except for share and per share amounts):

	2019 ATM Offering For the year ended December 31, 2019	2019 ATM Offering For the year ended December 31, 2020	2020 ATM Offering For the year ended December 31, 2020
Total shares of common stock sold	1,374,686	6,687,846	16,320,793
Average price per share	\$ 5.23	\$ 1.73	\$ 0.58
Gross proceeds	\$ 7,193	\$ 11,558	\$ 9,264
Commissions earned by Cantor	\$ 212	\$ 347	\$ 278
Net Proceeds	\$ 6,981	\$ 11,211	\$ 8,986

From January 1, 2021 through the termination date of January 26, 2021, the Company has raised, under the 2020 ATM Offering, additional gross proceeds of \$28.1 million through the sale of 19,120,037 shares of common stock.

### *Public Offerings of Securities*

On July 6, 2020, the Company completed an underwritten public offering, or the July 2020 Public Offering, and sold an aggregate of 42,857,142 shares of its common stock, including the underwriter's full exercise of an over-allotment option, at the public offering price per of \$0.35 per share, generating net proceeds of approximately \$13.6 million after deducting underwriter discounts, commissions and expenses.

On March 10, 2020, the Company closed a firm commitment underwritten public offering, or the March 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 consisted 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 consisted 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 had 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 were immediately separable. In addition, the underwriter for the March 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. All shares of Series A Preferred Stock were converted into 7.9 million shares of common stock prior to June 30, 2020. The net proceeds to the Company were \$13.4 million.

On September 4, 2019, the Company entered into an underwriting agreement with an underwriter. Subject to the terms and conditions of the underwriting agreement, the Company sold, in a firm commitment underwritten offering, 2,153,846 shares of the Company's common stock. The Company raised \$18.8 million in gross proceeds under this offering.

### ***Paycheck Protection Program***

The CARES Act was passed in the United States and signed into law on March 7, 2020 and was amended on June 5, 2020 through the enactment of the Paycheck Protection Program Flexibility Act. On April 27, 2020, Asensus Surgical US, Inc., a wholly owned subsidiary of the Company, received funding under a promissory note dated April 18, 2020 (the "Promissory Note"), evidencing an unsecured non-recourse loan in the principal amount of \$2,815,200 under the PPP provisions of the CARES Act. The PPP is administered by the U.S. Small Business Administration (the "SBA"). The Promissory Note was made through City National Bank of Florida, a national banking association (the "Lender"). The Company elected to account for the PPP loan as debt and included the principal amount within notes payable on the consolidated balance sheet.

The Promissory Note has a two-year term, maturing on April 27, 2022, and bears interest at 1.00% per annum. If the Promissory Note is not forgiven, payments can be deferred until 10 months after the end of the Company's covered period, which is the 24-week period beginning on the date the Company received the PPP loan proceeds from the Lenders (the "Covered Period"). The Promissory Note contains customary events of default relating to, among other things, payment defaults, and breach of representations and warranties, or other provisions of the Promissory Note. The Promissory Note may be forgiven partially or fully if the proceeds are used for covered payroll, rent and utility costs incurred during the Covered Period and if at least 60% of the proceeds are used for covered payroll costs. All or a portion of the Promissory Note may be forgiven by the SBA upon application by the Company and documentation of expenditures in accordance with the SBA requirements.

Any forgiveness of the Promissory Note will be subject to approval by the SBA and the Lender. The Company recognizes that its restructuring activities unrelated to COVID-19 led to a decrease in the number of employees and, the Company may not be able to comply with the available safe harbor and savings provisions of the CARES Act, therefore, not all of the Promissory Note may be eligible for forgiveness. The Company submitted its application for forgiveness of the Promissory Note in full to the Lender on February 10, 2021.

### ***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. No other shares were issued to Lincoln Park under the purchase agreement, and it was terminated in June 2020.

### ***Hercules Loan Agreement***

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”). The Hercules Loan Agreement was modified on two separate occasions in 2019.

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.

## **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 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.

### **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 Asensus 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 Asensus Surgical 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, 2020, the Company has paid all Cash Consideration due under the second and fourth tranches. The third tranche, consisting of €15.0 million, has not yet been paid and is subject to certain sales revenue milestones.

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.

## **Results of Operations**

### **Revenue**

In 2020, our revenue consisted of Senhance System leasing, instruments, accessories, and services for Senhance Systems sold in Europe, Asia and the U.S. in prior periods. 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.

Product, instrument, and accessory revenue for the year ended December 31, 2020 decreased to \$1.6 million compared to \$7.1 million for the year ended December 31, 2019. The \$5.5 million decrease is due to the 2020 revenue being derived primarily from system leasing arrangements, versus 2019 revenue driven by the sale of four Senhance Systems, as well as instruments and accessories. Services revenue for the year ended December 31, 2020 increased to \$1.6 million from \$1.4 million for the year ended December 31, 2019 due to the increase in the number of Senhance Systems under service contracts.

We expect to experience variability in the number and trend, and average selling price or leasing price of our products 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, 2020 decreased to \$2.3 million as compared to \$16.4 million for the year ended December 31, 2019. This \$14.1 million decrease over the prior year period was primarily the result of decreased materials cost of \$11.6 million, which includes an inventory write-down in the amount of \$7.4 million under our restructuring plan during the year ended December 31, 2019. Also contributing to the decrease were lower personnel costs totaling \$1.6 million, decreased facility costs totaling \$0.3 million, decreased freight costs of \$0.3 million, decreased travel costs of \$0.2 million, and decreased supplies cost of \$0.2 million.

Service cost for the year ended December 31, 2020 decreased to \$2.9 million as compared to \$4.3 million for the year ended December 31, 2019. This \$1.4 million decrease over the prior year period was primarily related to \$1 million in reduced supplies costs, \$0.3 million in reduced travel expenses for field service engineers driven by the COVID-19 pandemic, and \$0.1 million in reduced other costs. Cost of revenue exceeds revenue primarily due to part replacements under maintenance plans, which are expensed when incurred, along with salaries for the field service teams.

## **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 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, 2020 decreased 26% to \$16.6 million as compared to \$22.5 million for the year ended December 31, 2019. The \$5.9 million decrease primarily relates to decreased personnel costs of \$3.7 million driven by a reduced headcount under our restructuring plan, decreased technology fees of \$0.6 million, decreased supplies costs of \$0.6 million, decreased travel costs of \$0.5 million, decreased consulting costs of \$0.4 million, decreased facility costs of \$0.1 million, and decreased other costs of \$0.2 million offset by \$0.2 million in increased 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, tradeshow, marketing clinical studies and consulting expenses. We expect sales and marketing expenses to remain level 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, 2020 decreased 53% to \$13.1 million compared to \$28.0 million for the year ended December 31, 2019. The \$14.9 million decrease was primarily related to decreased personnel related costs of \$7.5 million, decreased travel of \$3.7 million, decreased consulting costs of \$2.1 million, decreased supplies expense of \$0.9 million, decreased facilities costs of \$0.3 million, decreased depreciation expense of \$0.2 million, and decreased other costs of \$0.1 million. These decreases were primarily the result of the restructuring plan implemented in the fourth quarter of 2019 together with reductions in travel and cancellation of tradeshow beginning in the first quarter of 2020 in response to the COVID-19 pandemic.

## **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, 2020 decreased 24% to \$14.2 million compared to \$18.8 million for the year ended December 31, 2019. The \$4.6 million decrease was primarily due to decreased personnel costs of \$2.4 million, decreased bad debt expense of \$1.6 million, decreased consulting and outside services costs of \$0.3 million, decreased supplies expense of \$0.2 million, decreased travel costs of \$0.2 million, and decreased other costs of \$0.4 million offset by increased facilities costs of \$0.5 million. In 2019, the Company recorded the bad debt charge due to uncertainty regarding collectability on a 2018 system sale in North Africa.

## **Restructuring**

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. Payments under the restructuring plan concluded in 2020.

During March 2020, we continued our restructuring with additional headcount reductions which resulted in \$0.9 million related to severance costs which were paid in 2020.

### **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.

### **Amortization of Intangible Assets**

Amortization of intangible assets for the year ended December 31, 2020 increased to \$10.8 million compared to \$10.3 million for the year ended December 31, 2019. The \$0.5 million increase was primarily the result of a higher Euro to Dollar exchange rate.

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

The Company historically tested 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 does not have any goodwill on its consolidated balance sheet as of December 31, 2020 and 2019. 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 during the year ended December 31, 2019. No such impairment was recognized for the year ended December 31, 2020.

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

The change in fair value of contingent consideration in connection with the Senhance Acquisition was a \$2.9 million increase for the year ended December 31, 2020 compared to a decrease of \$9.6 million for the year ended December 31, 2019. The net \$12.5 million increase was primarily due to changes in the Company's fair value measurement of a discounted cash flow model using significant unobservable inputs including the probability of achieving the potential milestone, future Euro-to-USD exchange rates, and an estimated discount rate associated with the risks of the expected cash flows attributable to the milestone.



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

The change in fair value of Series B Warrants issued in April 2017 was an increase of \$0.3 million for the year ended December 31, 2020 compared to a decrease of \$2.2 million for the year ended December 31, 2019. The net \$2.5 million increase in change in fair value of warrant liabilities for the year ended December 31, 2020 over the year ended December 31, 2019 includes re-measurement associated with the warrants exercised during the year ended December 31, 2020 and 2019, and the outstanding warrants at December 31, 2020. 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.

## **Interest Income**

There was no interest income for the year ended December 31, 2020, compared to \$0.6 million for the year ended December 31, 2019. The decrease of \$0.6 million was due to less cash and short-term investments on hand during the year ended December 31, 2020 earning less interest.

## **Interest Expense**

There was insignificant interest expense for the year ended December 31, 2020, compared to \$4.6 million for the year ended December 31, 2019. The Company incurred a \$1.0 million loss on extinguishment of debt, classified as interest expense, during the year ended December 31, 2019 which did not recur during the year ended December 31, 2020.

## **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 Asensus Surgical Italia as a result of the acquisition of the Senhance System. We recognized \$1.5 million and \$3.1 million of income tax benefit for the years ended December 31, 2020 and 2019, respectively.

## **Liquidity and Capital Resources**

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 has not established sufficient sales revenues to cover its operating costs and may require additional capital to proceed with its operating plan. The Company had an accumulated deficit of \$722.9 million as of December 31, 2020 and working capital of \$23.7 million as of December 31, 2020.

The Company has raised additional capital through equity offerings, including raising net proceeds of \$73.5 million in the January 2021 public offering, \$28.8 million in the January 2021 registered direct offering, \$36.2 million in the 2020 ATM Offering, \$13.5 million in the March 2020 public offering and an additional \$13.6 million in net proceeds in the July 2020 public offering (see Note 17). Also Series B, C and D warrants have been exercised in 2020 and 2021 for aggregate proceeds to the Company of \$33.7 million. Additionally, in April 2020 the Company secured a non-recourse loan in the principal amount of \$2.8 million under the Paycheck Protection Program (the "PPP") provisions of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), as amended that may be forgiven under certain circumstances, although forgiveness is not assured. Management's plan to obtain additional 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. However, management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. The Company believes the COVID-19 pandemic will continue to negatively impact its operations and ability to implement its market development efforts, which will have a negative effect on its financial condition.

At December 31, 2020, the Company had cash and cash equivalents, excluding restricted cash, of approximately \$16.4 million. Based on the Company's expected cash requirements, the Company believes its cash on hand at December 31, 2020 combined with the net proceeds of the January 2021 public offering, the January 2021 registered direct offering, the 2020 ATM Offering, and the Series B, C and D Warrant exercises will be sufficient to fund our operations for at least the next 12 months.

During 2020, we had 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 registered 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 under such registration statements approximately \$294.5 million since 2017. The first effective shelf registration statement expired in May 2020, and the second was completed in February, 2021. As of the date of this Annual Report, the Company has no effective 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.

## Consolidated Cash Flow Data

	Years Ended December 31,	
	2020	2019
(in millions)		
Net cash (used in) provided by		
Operating activities	\$ (46.7)	\$ (73.5)
Investing activities	(0.0)	67.6
Financing activities	53.4	(5.6)
Effect of exchange rate changes on cash and cash equivalents	0.3	0.4
Net increase in cash, cash equivalents and restricted cash	\$ 7.0	\$ (11.1)

### Operating Activities

For the year ended December 31, 2020, net cash used in operating activities of \$46.7 million consisted of a net loss of \$59.3 million and cash used for working capital of \$10.7 million, offset by non-cash items of \$23.3 million. The non-cash items primarily consisted of \$10.8 million of net amortization of intangible assets, \$7.9 million of stock-based compensation expense, \$2.9 million change in fair value of contingent consideration, \$2.9 million of depreciation, \$1.5 million deferred income tax benefit, and \$0.3 million change in fair value of warrant liabilities. The decrease in cash from changes in working capital included \$7.2 million increase in inventories, \$2.6 million decrease in accrued expenses, \$2.3 million decrease in other current and long term assets, \$1.8 million decrease in accounts payable, \$0.9 million decrease in other long term liabilities, \$0.4 million increase in accounts receivable, and \$0.1 million decrease in deferred revenue. For the year ended December 31, 2019, net 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.

### **Investing Activities**

For the year ended December 31, 2020, net cash used in investing activities was \$0 million. 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.

### **Financing Activities**

For the year ended December 31, 2020, net cash provided by financing activities was \$53.4 million. The net change primarily related to \$13.5 million in proceeds from the issuance of common stock, preferred stock, and warrants under the March 2020 Public Offering, \$13.6 million in proceeds from the issuance of common stock under a July 2020 underwritten public offering, \$20.2 million in proceeds from additional issuances of common stock, \$3.3 million from the exercise of warrants, and \$2.8 million from the receipt of funding under a Promissory Note under the PPP provisions of the CARES Act.

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 under the Hercules Loan Agreement 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.

### **Operating Capital and Capital Expenditure Requirements**

We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, commercial activities and the enhancement and protection of our intellectual property. We obtained financing for these activities over the past four months, but cannot assure you that additional financing will not be required in the future to support our operations. We intend to be use financing opportunities strategically to continue to strengthen our financial position.

Cash and cash equivalents held by our foreign subsidiaries totaled \$2.3 million at December 31, 2020, 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.

### **Contractual Obligations and Commercial Commitments**

The following table summarizes our contractual obligations as of December 31, 2020 (in millions):

	<b>Payments due by period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1 to 3 years</b>	<b>3 to 5 years</b>	<b>Thereafter</b>
Operating leases	\$ 1.4	\$ 0.9	\$ 0.5	\$ 0.0	\$ —
License, supply and vendor agreements	\$ 5.7	\$ 3.6	\$ 1.1	\$ 1.0	\$ —
Total contractual obligations	<u>\$ 7.1</u>	<u>\$ 4.5</u>	<u>\$ 1.6</u>	<u>\$ 1.0</u>	<u>\$ —</u>

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, 2020, 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 acquisitions 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.

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.

## **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. As of March 31, 2020, all IPR&D asset development was completed and reclassified to intellectual property.

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 include a five-year service period; 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.

Our System sale arrangements generally contain multiple products and services. For these consolidated 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 consolidated 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 may include a combination of the following performance obligations: System(s), System components, instruments, accessories, and System service.

For arrangements that contain multiple performance obligations, revenue is allocated to each performance obligation based on its relative estimated standalone selling price. When available, standalone selling prices are based on observable prices at which the Company separately sells the products or services; however, due to limited sales to date, standalone selling prices are not 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 estimated standalone selling prices and updates these estimates if necessary.

We enter into lease arrangements with certain qualified customers. Revenue related to arrangements including lease elements are allocated to lease and non-lease elements based on their relative standalone selling prices. Lease elements generally include a System, while non-lease elements generally include service, instruments, and accessories. For some lease arrangements, the customers are provided with the right to purchase the leased System at some point during or at the end of the lease term. In some arrangements lease payments are based on the usage of the System.

In determining whether a transaction should be classified as a sales-type or operating lease, we consider the following terms at lease commencement: (1) whether title of the System transfers automatically or for a nominal fee by the end of the lease term, (2) whether the present value of the minimum lease payments equals or exceeds substantially all of the fair value of the leased System, (3) whether the lease term is for the major part of the remaining economic life of the leased System, (4) whether the lease grants the lessee an option to purchase the leased System that the lessee is reasonably certain to exercise, and (5) whether the underlying System is of such a specialized nature that it is expected to have no alternative use to the Company at the end of the lease term. As of September 30, 2020, all such arrangements have been classified as operating leases.

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 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.
- *Lease arrangements.* Revenue related to lease elements from operating lease arrangements is generally recognized on a straight-line basis over the lease term or based upon System usage and is presented as product revenue.
- *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.
- *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, 2020, 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 2020 or 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

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>52</u>
Consolidated Financial Statements:	
<u>Consolidated Balance Sheets as of December 31, 2020 and 2019</u>	<u>54</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and 2019</u>	<u>55</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2020 and 2019</u>	<u>56</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019</u>	<u>57</u>
<u>Notes to Consolidated Financial Statements</u>	<u>58</u>

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

Stockholders and Board of Directors  
Asensus Surgical, Inc.  
Durham, North Carolina

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

We have audited the accompanying consolidated balance sheets of Asensus Surgical, Inc. (the “Company”) as of December 31, 2020 and 2019, 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, 2020 and 2019, 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.

### **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 Public Company Accounting Oversight Board (United States) (“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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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.

### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

### *Inventories Valuation*

Inventories totaled approximately \$18.8 million at December 31, 2020, including approximately \$8.8 million classified as long-term. As described in Note 2 to the Company's consolidated financial statements, inventories are stated at the lower of cost or net realizable value. Management considers forecasted demand in relation to inventories on hand, competitiveness of product offerings, and product life cycles when estimating net realizable value.

We identified management's estimation of the net realizable value of inventories as a critical audit matter. The Company's limited sales history requires management to make significant judgments and assumptions with respect to future demand for the Company's products and product life cycles that affect the estimation of the net realizable value of inventories. Auditing such assumptions required a high degree of auditor judgment and an increased auditor effort.

The primary procedures we performed to address this critical audit matter included:

- Assessing the reasonableness of management's forecasted demand for instruments and accessories, included in finished goods inventories, by (i) comparing forecasts to historical sales of the Company's identical products, (ii) evaluating the reasonableness of the period over which forecasted sales are expected to occur, and (iii) performing a lookback analysis to compare the Company's historical estimates of future demand to actual sales results for the same period.
- Assessing the reasonableness of management's forecasted consumption of raw materials inventories by (i) comparing to production plans obtained from the Company's supply chain personnel, and (ii) evaluating forecasted demand and expectations with respect to changes in product life cycles and potential for obsolescence of the Company's finished products.
- Testing management's estimation of the net realizable value of Senhance Systems, included in finished goods inventories, by evaluating the Company's assumptions with respect to future sales quantities and selling prices in new and emerging markets as well as the Company's assumptions with respect to expected terms of its future arrangements related to the Senhance Systems.

/s/ BDO USA, LLP

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

Raleigh, North Carolina  
March 11, 2021

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

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 16,363	\$ 9,598
Accounts receivable, net	1,115	620
Inventories	10,034	10,653
Other current assets	6,501	7,084
Total Current Assets	<u>34,013</u>	<u>27,955</u>
Restricted cash	1,166	969
Inventories, net of current portion	8,813	7,594
Property and equipment, net	10,342	4,706
Intellectual property, net	22,267	28,596
In-process research and development	-	2,470
Net deferred tax assets	307	-
Other long term assets	1,350	2,489
Total Assets	<u><u>\$ 78,258</u></u>	<u><u>\$ 74,779</u></u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,965	\$ 3,579
Accrued expenses	6,301	8,553
Deferred revenue - current portion	789	818
Notes payable - current portion	1,228	-
Contingent consideration - current portion	-	73
Total Current Liabilities	<u>10,283</u>	<u>13,023</u>
Long Term Liabilities:		
Deferred revenue - less current portion	-	27
Contingent consideration - less current portion	3,936	1,011
Notes payable - less current portion	1,587	-
Warrant liabilities	255	2,388
Net deferred tax liabilities	-	1,392
Other long term liabilities	628	1,403
Total Liabilities	<u>16,689</u>	<u>19,244</u>
Commitments and Contingencies (Note 21)		
Stockholders' Equity:		
Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2020 and December 31, 2019; 116,231,072 and 20,691,301 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	116	21
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Additional paid-in capital	781,397	720,484
Accumulated deficit	(722,912)	(663,600)
Accumulated other comprehensive income (loss)	2,968	(1,370)
Total Stockholders' Equity	<u>61,569</u>	<u>55,535</u>
Total Liabilities and Stockholders' Equity	<u><u>\$ 78,258</u></u>	<u><u>\$ 74,779</u></u>

*See accompanying notes to consolidated financial statements.*

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

	<b>Year ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenue:		
Product	\$ 1,612	\$ 7,104
Service	1,563	1,427
Total revenue	<u>3,175</u>	<u>8,531</u>
Cost of revenue:		
Product	2,254	16,439
Service	2,912	4,292
Total cost of revenue	<u>5,166</u>	<u>20,731</u>
Gross loss	<u>(1,991)</u>	<u>(12,200)</u>
Operating Expenses:		
Research and development	16,621	22,468
Sales and marketing	13,064	28,014
General and administrative	14,137	18,758
Amortization of intangible assets	10,801	10,301
Change in fair value of contingent consideration	2,924	(9,553)
Restructuring and other charges	851	1,374
Goodwill impairment	-	78,969
Intangible assets impairment	-	7,912
Loss from sale of SurgiBot assets, net	-	97
Gain from sale of AutoLap assets, net	-	(15,965)
Total Operating Expenses	<u>58,398</u>	<u>142,375</u>
Operating Loss	<u>(60,389)</u>	<u>(154,575)</u>
Other Income (Expense):		
Change in fair value of warrant liabilities	(336)	2,248
Interest income	35	582
Interest expense	(19)	(4,613)
Other expense, net	(119)	(967)
Total Other Expense, net	<u>(439)</u>	<u>(2,750)</u>
Loss before income taxes	(60,828)	(157,325)
Income tax benefit	1,516	3,124
Net loss	<u>(59,312)</u>	<u>(154,201)</u>
Deemed dividend related to beneficial conversion feature of preferred stock	(412)	-
Deemed dividend related to conversion of preferred stock into common stock	(299)	-
Net loss attributable to common stockholders	<u>(60,023)</u>	<u>(154,201)</u>
Comprehensive loss:		
Net loss	(59,312)	(154,201)
Foreign currency translation gain (loss)	4,338	(2,708)
Comprehensive loss	<u>\$ (54,974)</u>	<u>\$ (156,909)</u>
Net loss per common share attributable to common stockholders - basic and diluted	<u>\$ (0.85)</u>	<u>\$ (8.69)</u>
Weighted average number of shares used in computing net loss per common share - basic and diluted	<u>70,809</u>	<u>17,737</u>

*See accompanying notes to consolidated financial statements.*

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

	<u>Common Stock</u>		<u>Preferred Stock</u>		<u>Treasury Stock</u>					
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Total Stockholders' Equity</u>
<b>Balance, December 31, 2018</b>	<b>16,642</b>	<b>\$ 17</b>	<b>-</b>	<b>\$ -</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 676,572</b>	<b>\$ (509,406)</b>	<b>\$ 1,338</b>	<b>\$ 168,521</b>
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 of MST	370	-	-	-	-	-	6,599	-	-	6,599
Exercise of stock options and warrants	38	-	-	-	-	-	538	-	-	538
Award of restricted stock units	70	-	-	-	-	-	-	-	-	-
Return of common stock to pay withholding taxes on restricted stock	-	-	-	-	15	-	(499)	-	-	(499)
Cancellation of treasury stock	-	-	-	-	(15)	-	-	-	-	-
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>	<b>20,691</b>	<b>\$ 21</b>	<b>-</b>	<b>\$ -</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 720,484</b>	<b>\$ (663,600)</b>	<b>\$ (1,370)</b>	<b>\$ 55,535</b>
Stock-based compensation							7,911			7,911
Issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs	14,122	14	7,937	79	-	-	13,384	-	-	13,477
Issuance of common stock, net of issuance costs	66,241	66	-	-	-	-	33,780	-	-	33,846
Conversion of preferred stock to common stock	7,937	8	(7,937)	(79)	-	-	71	-	-	-
Exchange of shares for Series B Warrants	2,041	2	-	-	-	-	2,468	-	-	2,470
Exercise of warrants	4,913	5	-	-	-	-	3,335	-	-	3,340
Award of restricted stock units	286	-	-	-	-	-	-	-	-	-
Return of common stock to pay withholding taxes on restricted stock	-	-	-	-	28	-	(36)	-	-	(36)
Cancellation of treasury stock	-	-	-	-	(28)	-	-	-	-	-
Other comprehensive income	-	-	-	-	-	-	-	-	4,338	4,338
Net loss	-	-	-	-	-	-	-	(59,312)	-	(59,312)
<b>Balance, December 31, 2020</b>	<b>116,231</b>	<b>\$ 116</b>	<b>-</b>	<b>\$ -</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 781,397</b>	<b>\$ (722,912)</b>	<b>\$ 2,968</b>	<b>\$ 61,569</b>

*See accompanying notes to consolidated financial statements.*

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

	<b>Year ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Operating Activities:		
Net loss	\$ (59,312)	\$ (154,201)
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 from sale of SurgiBot assets, net	-	97
Goodwill and intangible assets impairment	-	86,881
Depreciation	2,898	2,166
Amortization of intangible assets	10,801	10,301
Amortization of debt discount and debt issuance costs	-	1,513
Amortization of short-term investment discount	-	(327)
Stock-based compensation	7,911	11,508
Interest expense on deferred consideration - MST acquisition	-	756
Deferred tax benefit	(1,516)	(3,224)
Bad debt expense	-	1,634
Write down of inventory	-	8,931
Change in fair value of warrant liabilities	336	(2,248)
Change in fair value of contingent consideration	2,924	(9,553)
Loss on extinguishment of debt	-	1,006
Changes in operating assets and liabilities:		
Accounts receivable	(447)	6,083
Interest receivable	-	26
Inventories	(7,198)	(16,404)
Other current and long term assets	2,296	(655)
Accounts payable	(1,758)	(668)
Accrued expenses	(2,645)	(1,180)
Deferred revenue	(105)	(959)
Other long term liabilities	(860)	998
Net cash and cash equivalents used in operating activities	(46,675)	(73,484)
Investing Activities:		
Proceeds from sale of AutoLap assets	-	15,965
Purchase of short-term investments	-	(12,883)
Proceeds from maturities of short-term investments	-	65,000
Purchase of property and equipment	(3)	(437)
Net cash and cash equivalents (used in) provided by investing activities	(3)	67,645
Financing Activities:		
Proceeds from issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs	13,478	-
Proceeds from issuance of common stock, net of issuance costs	33,847	25,777
Proceeds from notes payable, net of issuance costs	2,815	-
Payment of note payable	-	(31,425)
Taxes paid related to net share settlement of vesting of restricted stock units	(36)	(499)
Payment of contingent consideration	(74)	-
Proceeds from exercise of stock options and warrants	3,340	538
Net cash and cash equivalents provided by (used in) financing activities	53,370	(5,609)
Effect of exchange rate changes on cash and cash equivalents	270	364
Net increase in cash, cash equivalents and restricted cash	6,962	(11,084)
Cash, cash equivalents and restricted cash, beginning of period	10,567	21,651
Cash, cash equivalents and restricted cash, end of period	\$ 17,529	\$ 10,567

Supplemental Disclosure for Cash Flow Information:

Interest paid	\$	-	\$	2,187
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Supplemental Schedule of Non-cash Investing and Financing Activities:

Transfer of inventories to property and equipment	\$	8,113	\$	486
Exchange of common stock for Series B Warrants	\$	2,470	\$	-
Transfer of in-process research and development to intellectual property	\$	2,425	\$	-
Deemed dividend related to beneficial conversion feature of preferred stock	\$	412	\$	-
Deemed dividend related to conversion of preferred stock into common stock	\$	299	\$	-
Issuance of common stock - MST acquisition	\$	-	\$	6,600
Proceeds from sale of AutoLap assets exchanged for settlement of Company obligations	\$	-	\$	1,000
Transfer of property and equipment to inventories	\$	-	\$	323
Conversion of preferred stock to common stock	\$	79	\$	-

*See accompanying notes to consolidated financial statements.*



## Asensus Surgical, Inc.

### Notes to Consolidated Financial Statements

#### 1. Organization and Capitalization

In February 2021, TransEnterix, Inc. changed the name of the company to Asensus Surgical, Inc. Asensus Surgical, Inc. (the "Company") is a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery™ by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. 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 mm microlaparoscopic instruments, eye-sensing camera control and fully-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, Russia 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 general laparoscopic surgical procedures and laparoscopic gynecologic surgery in a total of 31 indicated procedures, including benign and oncologic procedures, laparoscopic inguinal, hiatal and paraesophageal hernia, sleeve gastrectomy and laparoscopic cholecystectomy (gallbladder removal) surgery.
- In Japan, the Company has received regulatory approval and reimbursement for 98 laparoscopic procedures.
- The Senhance System received its registration certificate by the Russian medical device regulatory agency, Roszdravnadzor, in December 2020, allowing for its sale and utilization throughout the Russian Federation.

In 2020, the Company obtained regulatory clearance for the Senhance ultrasonic system in both Taiwan and Japan. On March 13, 2020 the Company announced that it received FDA clearance for the 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 September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. On January 19, 2021, the Company announced that it received CE Mark for the ISU. Finally, in the EU, the Company expanded its claims for the Senhance System to include pediatric patients, allowing accessibility to more surgeons and patients, as well as expanding its potential market to include pediatric hospitals in Europe. The Company anticipates the robotic precision provided by the Senhance System, coupled with the already available 3 mm instruments will prove to be an effective tool in surgery with smaller patients. As of February 15, 2021, two hospitals have installed the Senhance System for pediatric use.

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.

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 future minimum royalties payable beginning at the earlier of receipt of Chinese regulatory approval or March 2023. In estimating the consideration in this transaction, the Company applied the guidance on constraining estimates of variable consideration. The Company reassesses the estimate every reporting period and the variable consideration will be adjusted when it is deemed no longer constrained. 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 Asensus International, Inc. (“Asensus 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”). On February 24, 2021, TransEnterix Italia changed its name to Asensus Surgical Italia S.r.l. 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. On February 23, 2021, TransEnterix, Inc. changed its name to Asensus Surgical, Inc. On February 25, 2021, TransEnterix Surgical changed its name to Asensus Surgical US, Inc.

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

## **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. 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.

**Liquidity**

The Company had an accumulated deficit of \$722.9 million, working capital of \$23.7 million, and cash and cash equivalents, excluding restricted cash, of \$16.4 million as of December 31, 2020. The Company has not established sufficient sales revenues to cover its operating costs and requires additional capital to proceed with its operating plan.

The Company believes the COVID-19 pandemic will continue to negatively impact its operations and ability to implement its market development efforts, which will have a negative effect on its financial condition. At December 31, 2020, the Company had cash and cash equivalents, excluding restricted cash, of approximately \$16.4 million. Subsequent to December 31, 2020, the Company has raised additional capital through equity offerings, including raising net proceeds of \$73.5 million in the January 2021 public offering, \$28.8 million in the January 2021 registered direct offering, and \$28.1 million in the 2020 ATM Offering. Also Series B, C and D warrants have been exercised in 2021 for aggregate proceeds to the Company of \$30.4 million. While the Company believes that its existing cash and cash equivalents at December 31, 2020 and the proceeds from the January 2021 public offering and registered direct offering, ATM offering, and exercise of the warrants will be sufficient to sustain operations for at least the next 12 months from the issuance of these financial statements, the Company will need to obtain additional financing to proceed with its business plan. Management's plan to obtain additional 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. However, management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans.

**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 impairment considerations for intangible assets, fair value estimates related to 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.

The COVID-19 pandemic has caused significant social and economic restrictions that have been imposed in the United States and abroad, which has resulted in significant volatility in the global economy and led to reduced economic activity. In the preparation of these financial statements and related disclosures, the Company has assessed the impact that COVID-19 has had on its estimates, assumptions, forecasts, and accounting policies. The Company continues to monitor closely the COVID-19 pandemic impact on its estimates, assumptions and forecasts used in the preparation of its financial statements. As the COVID-19 situation is unprecedented and ever evolving, future events and effects related to COVID-19 cannot be determined with precision, and actual results could significantly differ from estimates or forecasts.

**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, 2020 and 2019 includes \$1.2 million and \$1.0 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.

**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 provided reserves for potential credit losses and recorded a bad debt charge totaling \$0 million during the year ended December 31, 2020 and \$1.6 million during the year ended December 31, 2019. The Company had 7 customers who constituted 68% of the Company's net accounts receivable at December 31, 2020. The Company had eight customers who constituted 85% of the Company's net accounts receivable at December 31, 2019. The Company had nine customers who accounted for 55% of revenue in 2020 and six customers who accounted for 82% of revenue in 2019.

### **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. The allowance for doubtful accounts was \$1.8 million and \$1.7 million as of December 31, 2020 and December 31, 2019, respectively.

### **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**

#### *Definite-Lived Intangible Assets - Intellectual Property*

Intellectual property consists of purchased patent rights and developed technology acquired as part of a business acquisition. Developed technology includes reclassified IPR&D assets related to (i) the Senhance System acquired in 2015 and reclassified in 2017 and (ii) MST acquired in 2018 and reclassified in 2020. 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 periodically evaluates intellectual property for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To determine the recoverability, 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 assets, then such assets are written down to their fair value. No impairment of intellectual property was identified during the year ended December 31, 2020 and 2019.

#### *Indefinite-Lived Intangible Assets – 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. To determine the recoverability, the Company evaluates the probability that future estimated discounted 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 assets, then such assets are written down to their fair value.

The Company reclassifies IPR&D assets to intellectual property when development is complete, which generally occurs upon regulatory approval when the Company is able to commercialize products. The completed IPR&D assets are then classified as definite-lived intangible assets (developed technology) 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 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. 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 and 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. As of December 31, 2020, all IPR&D asset development was completed and reclassified to intellectual property.

As of December 31, 2020, there were no remaining IPR&D assets.

#### *Goodwill*

Goodwill of \$93.8 million was recorded in connection with a September 2013 merger transaction, goodwill of \$38.3 million was recorded in connection with the Senhance Acquisition and goodwill of \$9.6 million was recorded in connection with the MST Medical Surgical Technologies, Ltd. Acquisition (see Note 3). During the third quarter of 2019, the Company's stock price declined significantly as a result of decreased sales and goodwill was deemed to be fully impaired, resulting in an impairment charge of \$79.0 million.

As of December 31, 2020, there was no remaining Goodwill asset.

### **Property and Equipment**

Property and equipment consists primarily of operating lease Senhance System assets, 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:

	<u>Years</u>
Operating lease assets – Senhance System leasing	5
Machinery, manufacturing, and demonstration equipment	3 - 5
Computer equipment	3
Furniture	5
Leasehold improvements	Lesser of lease term or 3 to 10

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 property and equipment 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 did not identify any impairment during the years ended December 31, 2020 and 2019.

### **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.

### **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, 2020 and 2019 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 risks similar to other similarly sized companies in the medical device industry. These risks include, without limitation: potential negative impacts on the Company's operations caused by the COVID-19 pandemic; the Company's ability to continue as a going concern; the historical lack of profitability; the Company's ability to raise additional capital; the success of its market development efforts, 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 United Kingdom, 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's revenue consists of product revenue resulting from the sale and lease 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 include a five-year service period; 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's System sale arrangements generally contain multiple products and services. For these consolidated 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 consolidated 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 may include a combination of the following performance obligations: System(s), System components, instruments, accessories, and System service.

For arrangements that contain multiple performance obligations, revenue is allocated to each performance obligation based on its relative estimated standalone selling price. When available, standalone selling prices are based on observable prices at which the Company separately sells the products or services; however due to limited sales to date, standalone selling prices generally 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 estimated standalone selling prices and updates these estimates if necessary.

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.
- 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.

The following table presents revenue disaggregated by type and geography:

	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
	(in thousands)	
<b>U.S.</b>		
Systems	\$ 282	\$ 90
Instruments and accessories	187	108
Services	380	338
Total U.S. revenue	<u>849</u>	<u>536</u>
<b>Outside of U.S. ("OUS")</b>		
Systems	490	5,459
Instruments and accessories	653	1,447
Services	1,183	1,089
Total OUS revenue	<u>2,326</u>	<u>7,995</u>
<b>Total</b>		
Systems	772	5,549
Instruments and accessories	840	1,555
Services	1,563	1,427
Total revenue	<u>\$ 3,175</u>	<u>\$ 8,531</u>

The Company recognizes sales by geographic area based on the country in which the customer is based. Operating lease revenue from Senhance System Leasing (see discussion below) is included as Systems in the above table and was approximately \$0.7 million and \$0 million for the years ended December 31, 2020 and 2019, respectively.

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 \$3.1 million and \$3.7 million as of December 31, 2020 and 2019, respectively.

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 \$0.1 million and \$0.2 million as of December 31, 2020 and 2019, 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 for the years ended December 31, 2020 and 2019, that was included in the deferred revenue balance at the beginning of each reporting period was \$0.6 million and \$1.0 million, respectively. Revenue for the year ended December 31, 2019 also included \$1.3 million from a System sold in 2017 for which revenue was deferred until its first clinical use, which occurred in the second quarter of 2019. The aggregate amount of transaction price allocated to performance obligations that remain unsatisfied as of December 31, 2020 was \$3.1 million, which is expected to be recognized as revenue over one to three years.

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 and such costs are expensed as incurred.

### **Senhance System Leasing**

The Company enters into lease arrangements with certain qualified customers. Revenue related to arrangements including lease elements are allocated to lease and non-lease elements based on their relative standalone selling prices. Lease elements generally include a Senhance System, while non-lease elements generally include training and proctoring services, instruments, and accessories. For some lease arrangements, the customers are provided with the right to purchase the leased System at some point during and/or at the end of the lease term. In some arrangements lease payments are based on the usage of the System.



In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following terms at lease commencement: (1) whether title of the Senhance System transfers automatically or for a nominal fee by the end of the lease term, (2) whether the present value of the minimum lease payments equals or exceeds substantially all of the fair value of the leased System, (3) whether the lease term is for the major part of the remaining economic life of the leased System, (4) whether the lease grants the lessee an option to purchase the leased System that the lessee is reasonably certain to exercise, and (5) whether the underlying System is of such a specialized nature that it is expected to have no alternative use to the Company at the end of the lease term. All such arrangements through December 31, 2020 are classified as operating leases.

Revenue related to lease elements from operating lease arrangements is generally recognized on a straight-line basis over the lease term or based upon System usage and is presented as product revenue. Revenue related to lease elements from operating lease arrangements was approximately \$0.7 million and \$0 million for the years ended December 31, 2020 and 2019, respectively.

### **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 years ended December 31, 2020 and 2019, the Company recorded \$0 and \$1.5 million of expenses, respectively, 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.

### **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 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 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 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 its historical experience and adjust the estimated forfeiture rate based upon actual experience.

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 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 \$7.9 million and \$11.5 million for the years ended December 31, 2020 and 2019, 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. The Company has elected to account for global intangible low-taxed income (“GILTI”) as a period expense in the year the tax is incurred.

The Company recognizes the financial statement benefit of an income tax position only after determining that the relevant taxing authority would more likely than not sustain the position following audit. For tax positions meeting the more likely than not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require application of significant judgment. The Company is subject to U.S. federal and various state, local and foreign jurisdictions. Due to the Company's net operating loss carryforwards, the Company may be subject to examination by authorities for all previously filed income tax returns.

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 for the 2020 or 2019 tax provisions. The Company will continue to evaluate the impact of these provisions in future periods as the enactment process is completed.

On March 27, 2020, the CARES Act was signed into law in response to the COVID-19 pandemic. The CARES Act, as amended on June 5, 2020 through the enactment of the Paycheck Protection Program Flexibility Act, provides numerous tax provisions and stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses, temporary changes to the prior and future limitations on interest deductions, and technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property. The Company continues to evaluate the provisions of the CARES Act, as amended, relating to income taxes which may result in adjustments to certain deferred tax assets and liabilities.

### **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 27% and 19% of the Company's total consolidated assets are located within the U.S. as of December 31, 2020 and 2019, respectively. The remaining assets are mostly located in Europe and are primarily related to the Company's facility in Italy, and include intellectual property, in-process research and development, other current assets, property and equipment, cash, accounts receivable, other long-term assets and inventory of \$56.8 million and \$60.5 million as of December 31, 2020 and 2019, respectively. Total assets outside of the United States amounted to 73% and 81% of total consolidated assets at December 31, 2020 and 2019, respectively. Long-lived assets in the U.S. were 11% and 8%, Italy were 48% and 63%, and Switzerland were 41% and 27%, as of December 31, 2020 and 2019, respectively. The Company recognizes sales by geographic area based on the country in which the customer is based. For the years ended December 31, 2020 and 2019, 27% and 6%, respectively, of net revenue were generated in the United States; while 53% and 39%, respectively, were generated in Europe; and 20% and 55% were generated in Asia.

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

In August 2018, the FASB issued Accounting Standards Update ("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 Company adopted this ASU effective January 1, 2020 and the adoption did not have a material impact on the consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740, Income Tax and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 will be effective for public business entities for annual reporting periods beginning after December 15, 2020, and interim periods within those periods, with early adoption permitted. The guidance is not expected to have a material impact on the Company's financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which is designed to provide financial statement users with more information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. When determining such expected credit losses, the guidance requires companies to apply a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance is effective on a modified retrospective basis for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The guidance is not expected to have a material impact on the Company's financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06 *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (subtopic 815-40)* guidance on the accounting for convertible debt instruments and contracts in an entity's own equity. The guidance simplifies the accounting for convertible instruments by reducing the various accounting models that can require the instrument to be separated into a debt component and equity component or derivative component. Additionally, the guidance eliminated certain settlement conditions previously required to be able to classify a derivative in equity. The new guidance is effective on a modified or full retrospective basis for fiscal years beginning after December 15, 2023, including interim periods with those fiscal years. The Company is currently evaluating the impact on the consolidated financial statements upon adoption.

The Company has evaluated all other issued and unadopted ASUs and believes the adoption of these standards will not have a material impact on its consolidated statements of operations and comprehensive loss, balance sheets, or statements of cash flows.

### 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 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 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 the Company’s 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 Additional Consideration Shares were released from the lock-up restrictions on February 7, 2020.

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 February 25, 2021, TransEnterix International changed its name to Asensus International.

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 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, 2020, the Company had paid all installments of the fourth tranche.

The Third Tranche payments will be accelerated in the event that (i) the Company or Asensus 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, 2020 and 2019 at their estimated fair value.

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

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

	December 31, 2020	December 31, 2019
	(In thousands)	
Cash	\$ 6,679	\$ 9,596
Money market	9,684	2
Total cash and cash equivalents	\$ 16,363	\$ 9,598
Restricted cash	1,166	969
Total	<u>\$ 17,529</u>	<u>\$ 10,567</u>

Restricted cash at December 31, 2020 and 2019 includes \$1.2 million and \$1.0 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, 2020 and 2019.

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, other current assets, accounts payable, and certain accrued expenses at December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, using quoted prices in active markets for identical assets (Level 1); significant other observable inputs (Level 2); and significant unobservable inputs (Level 3):

December 31, 2020				
(In thousands)				
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets measured at fair value				
Cash and cash equivalents	\$ 16,363	\$ —	\$ —	\$ 16,363
Restricted cash	1,166	—	—	1,166
Total Assets measured at fair value	<u>\$ 17,529</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 17,529</u>
Liabilities measured at fair value				
Contingent consideration	\$ —	\$ —	\$ 3,936	\$ 3,936
Warrant liabilities	—	—	255	255
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,191</u>	<u>\$ 4,191</u>
December 31, 2019				
(In thousands)				
Description	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets measured at fair value				
Cash and cash equivalents	\$ 9,598	\$ —	\$ —	\$ 9,598
Restricted cash	969	—	—	969
Total Assets measured at fair value	<u>\$ 10,567</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,567</u>
Liabilities measured at fair value				
Contingent consideration	\$ —	\$ —	\$ 1,084	\$ 1,084
Warrant liabilities	—	—	2,388	2,388
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,472</u>	<u>\$ 3,472</u>

The Company's financial liabilities consisted of contingent consideration 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 increase in fair value of the contingent consideration of \$2.9 million for the year ended December 31, 2020 was primarily due to a lower discount rate, stronger Euro versus the U.S. dollar, and the passage of time. The decrease in fair value of the contingent consideration of \$9.6 million for the year ended December 31, 2019 was primarily due to 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. The Company uses a probability-weighted income approach for estimating the fair value of the contingent consideration. The significant unobservable inputs used in this approach include estimates of amounts and timing of stated milestones and the discount rate.

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. All of the Series A Warrants were exercised prior to the expiration date of October 31, 2017. 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 \$0.35 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 567,660 warrant shares as of December 31, 2020.

The change in fair value of all outstanding Series B warrants for the years ended December 31, 2020 and 2019 of an increase of \$0.3 million and a decrease of \$2.2 million, respectively, was included in the Company’s consolidated statements of operations and comprehensive loss. The increase in fair value of the Series B warrants of \$0.3 million for the year ended December 31, 2020 was primarily due to a lower discount rate, increased volatility, and the passage of time. The increase in fair value of the Series B warrants of \$2.2 million for the year ended December 31, 2019 was primarily due to a lower discount rate, increased volatility, and the passage of time. 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, 2020	December 31, 2019
Fair value (million)	\$ 0.3	\$ 2.4
Valuation methodology	Black-Scholes-Merton	Monte Carlo
Term (years)	1.32	2.32
Risk free rate	0.10%	1.59%
Dividends	—	—
Volatility	150.97%	109.80%
Share price	\$ 0.63	\$ 1.47
Probability of additional financing	N/A	100% in 2020

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, 2020 and 2019:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)	
			December 31, 2020	December 31, 2019
Contingent consideration	Probability weighted income approach	Milestone dates	2024 to 2029	2020 to 2024
		Discount rate	9.5% to 15.75%	10% to 11%

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, 2020 and 2019:

	<b>Fair Value Measurement at Reporting Date (Level 3)</b>	
	(In thousands)	
	Common stock warrants	Contingent consideration
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
Exchange of warrants for common stock	(2,469)	—
Payment for contingent consideration	—	(74)
Change in fair value	336	2,924
Balance at December 31, 2020	255	3,936
Current portion	—	—
Long-term portion	255	3,936
Balance at December 31, 2020	\$ 255	\$ 3,936

## 6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
	(In thousands)	
Gross accounts receivable	\$ 2,917	\$ 2,274
Allowance for uncollectible accounts	(1,802)	(1,654)
Total accounts receivable, net	\$ 1,115	\$ 620

The Company recorded \$1.6 million in bad debt expense during the year ended December 31, 2019. No bad debt expense was incurred during the year ended December 31, 2020.

## 7. Inventories

The components of inventories are as follows:

	<b>December 31, 2020</b>	<b>December 31, 2019</b>
	(In thousands)	
Finished goods	\$ 10,749	\$ 9,737
Raw materials	8,098	8,510
Total inventories	\$ 18,847	\$ 18,247
Current Portion	\$ 10,034	\$ 10,653
Long-term portion	8,813	7,594
Total inventories	\$ 18,847	\$ 18,247

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, 2020.



## 8. Other Current Assets

The following table presents the components of other current assets:

	December 31, 2020	December 31, 2019
	(In thousands)	
Advances to vendors	\$ 1,925	\$ 2,534
Prepaid expenses	1,706	1,834
VAT receivable	2,870	2,716
Total	<u>\$ 6,501</u>	<u>\$ 7,084</u>

## 9. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2020	December 31, 2019
	(In thousands)	
Machinery, manufacturing and demonstration equipment	\$ 10,153	\$ 9,711
Operating lease assets - Senhance System leasing	9,203	710
Computer equipment	2,297	2,321
Furniture	640	637
Leasehold improvements	2,309	2,295
Total property and equipment	24,602	15,674
Accumulated depreciation and amortization	(14,260)	(10,968)
Property and equipment, net	<u>\$ 10,342</u>	<u>\$ 4,706</u>

Depreciation expense was approximately \$2.9 million and \$2.2 million for the years ended December 31, 2020 and 2019, 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 year ended December 31, 2019 is as follows:

	Goodwill (In thousands)
Balance at December 31, 2018	\$ 80,131
Foreign currency translation impact	(1,162)
Impairment	(78,969)
Balance at December 31, 2019	<u>\$ —</u>

The Company performed an annual impairment test of goodwill at December 31, or more frequently if events or changes in circumstances indicated that the carrying value of the Company's one reporting unit may not be recoverable. 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. As of December 31, 2020, all IPR&D asset development was completed and reclassified to intellectual property.

The carrying value of the Company's IPR&D assets and the change in the balance for the years ended December 31, 2019 and 2020 is as follows:

	<b>In-Process Research and Development</b>
	(In thousands)
Balance at December 31, 2018	\$ 10,747
Impairment	(7,912)
Foreign currency translation impact	(365)
Balance at December 31, 2019	2,470
Impairment	—
Foreign currency translation impact	(45)
Transfer of in-process research and development to intellectual property	(2,425)
Balance at December 31, 2020	<u>\$ —</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.

As described above, on March 13, 2020, upon regulatory approval and the ability to commercialize the products associated with the IPR&D assets in the United States, the remaining MST 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, 2020 and 2019 are as follows:

	<b>December 31, 2020</b>				<b>December 31, 2019</b>			
	(In thousands)				(In thousands)			
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Foreign currency translation impact</b>	<b>Net Carrying Amount</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Foreign currency translation impact</b>	<b>Net Carrying Amount</b>
Developed technology	\$ 68,838	\$ (51,734)	\$ 4,872	\$ 21,976	\$ 66,413	\$ (36,918)	\$ (1,208)	\$ 28,287
Technology and patents purchased	400	(168)	59	291	400	(112)	21	309
Total intellectual property	<u>\$ 69,238</u>	<u>\$ (51,902)</u>	<u>\$ 4,931</u>	<u>\$ 22,267</u>	<u>\$ 66,813</u>	<u>\$ (37,030)</u>	<u>\$ (1,187)</u>	<u>\$ 28,596</u>

The weighted average remaining useful life of the developed technology and technology and patents purchased was 2.2 years and 6.3 years, respectively as of December 31, 2020.

The estimated future amortization expense of intangible assets as of December 31, 2020 is as follows:

	<b>Year ending December 31, 2020</b>
	(In thousands)
2021	\$ 11,634
2022	8,833
2023	430
2024	430
2025	430
Thereafter	510
Total	<u>\$ 22,267</u>

## 11. Income Taxes

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

	<b>2020</b>	<b>2019</b>
Current income taxes		
Federal	\$ —	\$ —
State	—	—
Foreign	169	100
Deferred income taxes		
Federal	—	—
State	—	—
Foreign	(1,685)	(3,224)
Total income tax expense (benefit)	<u>\$ (1,516)</u>	<u>\$ (3,124)</u>

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

	<b>2020</b>	<b>2019</b>
United States	\$ (34,398)	\$ (91,935)
Foreign	(26,430)	(65,390)
Total loss from operations before taxes	<u>\$ (60,828)</u>	<u>\$ (157,325)</u>

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

	<b>2020</b>	<b>2019</b>
Deferred tax assets:		
Stock-based compensation	\$ 4,253	\$ 3,665
Accrued expenses and other	906	1,007
Research credit carryforward	7,209	6,776
Fixed assets	385	345
Capitalized start-up costs and other intangibles	2,686	3,618
Net operating loss carryforwards	<u>122,193</u>	<u>113,410</u>
	137,632	128,821
Valuation allowance	<u>(132,928)</u>	<u>(123,108)</u>
Net deferred tax asset	4,704	5,713
Deferred tax liabilities		
Fixed assets and other	(1,590)	(1,445)
Purchase accounting intangibles	<u>(2,807)</u>	<u>(5,660)</u>
Net deferred tax liability	<u>(4,397)</u>	<u>(7,105)</u>
Net deferred tax asset (liability)	<u>\$ 307</u>	<u>\$ (1,392)</u>

At December 31, 2020 and 2019, the Company has provided a full valuation allowance against its net deferred assets in the U.S., Canada, Italy, Luxembourg, Swiss, and Taiwan tax jurisdictions, since realization of these benefits is not more likely than not. The valuation allowance increased approximately \$9.8 million from the prior year. At December 31, 2020, the Company had U.S. federal net operating loss carryforwards of \$364.3 million. Of this amount, \$254.5 million begin to expire in 2027, while the remaining \$109.8 million carry forward indefinitely. At December 31, 2020, the Company had U.S. state net operating loss carryforwards of \$296.2 million. Of this amount, \$289.3 million begin to expire in 2022, while the remaining \$6.8 million carry forward indefinitely. At December 31, 2020, the Company had federal research credit carryforwards in the amount of \$7.2 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, 2020, the Company had foreign operating loss carryforwards in Italy of approximately \$24.5 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; and foreign operating loss carryforwards in Switzerland of approximately \$61.9 million, which begin to expire in 2023.

The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2020, the Company had gross unrecognized tax benefits of approximately \$1.6 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):

	<b>2020</b>	<b>2019</b>
Beginning balance	\$ 1,512	\$ 1,363
Gross increases for tax positions related to current periods	108	149
Gross increases for tax positions related to prior periods	—	—
Ending balance	<u>\$ 1,620</u>	<u>\$ 1,512</u>

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2020 and 2019, 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 2017, although carryforward attributes that were generated prior to 2017 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:

	<b>2020</b>		<b>2019</b>
	<b>Amount</b>	<b>Percent of Pretax Earnings</b>	<b>Amount</b>
United States federal tax at statutory rate	\$ (12,774)	21.0%	\$ (33,038)
State taxes (net of deferred benefit)	(1,768)	2.9%	(4,778)
Nondeductible expenses	719	(1.2%)	709
Change in fair market value of contingent consideration	717	(1.2%)	(2,342)
Warrant remeasurement and financing costs	82	(0.1%)	(551)
Research & Development credits	(542)	0.9%	(743)
Change in unrecognized tax benefits	108	(0.2%)	149
Foreign tax rate differential	1,589	(2.6%)	2,590
Goodwill and investment impairments	—	(0%)	(6,638)
Change in enacted tax rates and other, net	533	(0.9%)	(253)
Change in valuation allowance	9,820	(16.1%)	41,771
Income tax benefit	<u>\$ (1,516)</u>	<u>2.5%</u>	<u>\$ (3,124)</u>

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. Pursuant to the Internal Revenue Code, as amended (the "Code") Sections 382 and 383, annual use of a company's NOL and research and development credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not completed such an analysis pursuant to Sections 382 and 383. Due to the existence of the valuation allowance, further changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate. With few exceptions, the Company is no longer subject to United States Federal, state, and local tax examinations by tax authorities for years before 2017, although carryforward attributes that were generated prior to 2017 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.

## 12. Accrued Expenses

The following table presents the components of accrued expenses:

	December 31, 2020	December 31, 2019
	(In thousands)	
Compensation and benefits	\$ 4,541	\$ 5,061
Restructuring costs	—	882
Consulting and other vendors	66	308
Other	177	242
Lease Liability	686	1,112
Royalties	147	148
Legal and professional fees	314	474
Taxes and other assessments	351	326
Interest	19	—
Total	<u>\$ 6,301</u>	<u>\$ 8,553</u>

## 13. Notes Payable

### *Paycheck Protection Program*

The CARES Act was passed in the United States and signed into law on March 7, 2020 and was amended on June 5, 2020 through the enactment of the Paycheck Protection Program Flexibility Act. On April 27, 2020, Asensus Surgical US, Inc., a wholly owned subsidiary of the Company, received funding under a promissory note dated April 18, 2020 (the “Promissory Note”), evidencing an unsecured non-recourse loan in the principal amount of \$2,815,200 under the PPP provisions of the CARES Act. The PPP is administered by the U.S. Small Business Administration (the “SBA”). The Promissory Note was made through City National Bank of Florida, a national banking association (the “Lender”). The Company accounted for the PPP loan as debt and included the principal amount within notes payable on the consolidated balance sheet.

The Promissory Note has a two-year term, maturing on April 27, 2022, and bears interest at 1.00% per annum. The Promissory Note may be forgiven partially or fully if the proceeds are used for covered payroll, rent and utility costs incurred during the Covered Period and if at least 60% of the proceeds are used for covered payroll costs. All or a portion of the Promissory Note may be forgiven by the SBA upon application by the Company and documentation of expenditures in accordance with the SBA requirements. If the Promissory Note is not forgiven, payments can be deferred until 10 months after the end of the Company’s covered period, which is the 24-week period beginning on the date the Company received the PPP loan proceeds from the Lenders (the “Covered Period”). The Promissory Note contains customary events of default relating to, among other things, payment defaults, and breach of representations and warranties, or other provisions of the Promissory Note. The Promissory Note is classified as long term except for the portion to be paid within twelve months of the year end, which is classified as current.

Any forgiveness of the Promissory Note will be subject to approval by the SBA and the Lender. The Company recognizes that its restructuring activities unrelated to COVID-19 led to a decrease in the number of employees and, the Company may not be able to comply with the available safe harbor and savings provisions of the CARES Act, therefore, not all of the Promissory Note may be eligible for forgiveness. The Company submitted its application for forgiveness of the Promissory Note in full to the Lender on February 10, 2021.

### *Hercules Loan Agreement*

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”). The Hercules Loan Agreement was modified on two separate occasions in 2019.

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.

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

The Company’s stock-based compensation plans include the Asensus Surgical, Inc. Amended and Restated Incentive Compensation Plan, previously named the TransEnterix, Inc. Amended and Restated Incentive Compensation Plan and prior to that 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 Plan was again amended on June 8, 2020, to increase the number of shares of Common Stock authorized under the Plan to 10,072,308 and to make other changes. The Plan was amended in October 2020 to include the Canadian Sub-Plan.

The October 2013, May 2015, June 2016, May 2017, May 2018, April 2019 and June 2020 amendments were approved by the Board of Directors and stockholders; the French Sub-Plan, the Israeli Sub-Plan, and the Canadian 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.

On August 11, 2020, the Compensation Committee of the Board of Directors approved awards to a newly hired executive officer of non-qualified stock options to acquire 150,000 shares of the Company's common stock with an exercise price equal to the closing price on the date of grant, 30,000 time-based restricted stock units and 20,000 performance-based restricted stock units, each as inducement grants made outside of the stockholder-approved incentive compensation plan in accordance with NYSE American Company Guide Section 711(a).

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 the Company.

During the years ended December 31, 2020 and 2019, the Company recognized approximately \$7.9 million and \$11.5 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,	
	2020	2019
Expected dividend yield	0%	0%
Expected volatility	82% - 126%	81% - 92%
Risk-free interest rate	0.2% - 1.69%	1.39% - 2.66%
Expected life (in years)	3.8 - 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, 2020:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)
Options outstanding at December 31, 2019	1,830,958	\$ 30.71	7.36
Granted	3,005,964	0.54	
Forfeited	(293,102)	19.08	
Cancelled	(181,948)	35.57	
Exercised	-	-	
Options Outstanding December 31, 2020	4,361,872	\$ 10.49	6.05

The following table summarizes information about stock options outstanding at December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Exercisable at December 31, 2020	1,282,678	\$ 27.71	4.81
Vested or expected to vest at December 31, 2020	4,141,694	\$ 10.89	6.05

Stock options outstanding, exercisable, and vested or expected to vest at December 31, 2020 had no intrinsic value based on the closing market price of the Company's common stock at December 31, 2020.

The total intrinsic value of options exercised during 2020 and 2019 was approximately \$0 million and \$0.2 million, respectively. Proceeds from options exercised during 2020 and 2019 were approximately \$0 million and \$0.5 million, respectively.

The Company granted 3,005,964 and 623,272 options to employees and non-employees during the years ended December 31, 2020 and 2019, respectively, with a weighted-average grant date fair value of \$0.53 and \$21.23, respectively.

As of December 31, 2020, the Company had future employee stock-based compensation expense of approximately \$4.2 million related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 1.8 years.

## 15. Restricted Stock Units

In 2019 and 2020, 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, 2020 and 2019:

	<b>Number of Restricted Stock Units Outstanding</b>	<b>Weighted Average Grant Date Fair Value</b>
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
Granted	3,112,382	0.67
Vested	(354,808)	19.38
Forfeited	(242,402)	6.54
Unvested December 31, 2020	2,959,099	\$ 1.41

As of December 31, 2020 and 2019, the Company recorded approximately \$1.7 million and \$3.2 million, respectively, in compensation expense for the RSUs. As of December 31, 2020, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$1.5 million, which is expected to be recognized over a weighted average period of approximately 1.1 years.

## 16. Warrants

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, 2020 or 2019.

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, 2020 or 2019.

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.

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. The Series B Warrants are liability classified.

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. As a result, the warrant liability decreased by \$2.5 million and the additional paid in capital increased by the same amount.

As a result of the March 2020 Public Offering and adjustment feature, the exercise price of all outstanding Series B Warrants has been adjusted to \$0.35 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 567,660 underlying warrant shares as of December 31, 2020. The remaining Series B Warrants were exercised in full in February 2021.

On March 10, 2020, the Company closed an underwritten public offering under which it issued, as part of units and the exercise of an over-allotment option, 25,367,646 Series C Warrants, each to acquire one share of common stock at an exercise price of \$0.68 per share, and 25,367,646 Series D Warrants, each to acquire one share of common stock at an exercise price of \$0.68 per share. See Note 17 for a description of the public offering. As of March 9, 2021, 25,235,970 Series C Warrants and 24,094,899 Series D Warrants have been exercised.

The Series C Warrants and Series D Warrants are equity classified. The fair value of the Series C Warrants and Series D Warrants on the issuance date was determined using a Black-Scholes Merton model. The unit proceeds were then allocated to the Common Stock, Series A Preferred Stock, Series C Warrants, and Series D Warrants, respectively, based on their relative fair values. As a result, the Company determined that a beneficial conversion feature was created by the difference between the effective conversion price of the preferred stock and the fair value of the Company's Common Stock as of the issuance date. The Company therefore recorded a beneficial conversion feature of \$0.4 million as a deemed dividend included in additional paid-in capital and an immediate charge to earnings available to common stockholders for the year ended December 31, 2020.

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, 2020 or 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. 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. There were no exercises of these warrants in 2020. During the year ended December 31, 2019, 15,385 of these warrants were exercised.

	<b>Number of Warrant Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (in years)</b>	<b>Weighted Average Fair Value</b>
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
Granted	50,735,292	0.68	2.4	0.19
Exercised	(4,911,764)	0.68	0	—
Exchanged	(2,040,757)	1.24	0	—
Reserved for future issuance	644,966	0.35	1.3	0.45
Outstanding at December 31, 2020	46,498,909	\$ 0.71	2.4	\$ 0.20

The aggregate intrinsic value of the common stock warrants in the above table was \$0.2 million at each of December 31, 2020 and 2019. 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. Equity Offerings

### At-the-Market Offerings

On August 12, 2019, the Company entered into a Controlled Equity Offering Sales Agreement (the “2019 Sales Agreement”), with Cantor Fitzgerald & Co., (“Cantor”), and commenced an at-the-market offering (the “2019 ATM Offering”) pursuant to which the Company could 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. Sales of the common stock under the 2019 ATM Offering were made under the Company’s previously filed and currently effective shelf 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. Under the 2019 ATM Offering, the Company raised gross proceeds of \$7.2 million 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 during the year ended December 31, 2020.

On October 9, 2020, the Company filed a prospectus supplement relating to an at-the-market offering with Cantor pursuant to which the Company may could from time to time, at its option, up to an aggregate of \$40.0 million of shares of the Company’s common stock, through Cantor as sales agent, pursuant to the 2019 Sales Agreement (the “2020 ATM Offering”). Sales of the common stock were made on the Company’s shelf registration statement on Form S-3, which was declared effective by the SEC on February 10, 2020. The aggregate compensation payable to Cantor was 3.0% of the aggregate gross proceeds from each sale of the Company’s common stock.

The following table summarizes the total sales under the 2019 ATM Offering and 2020 ATM Offering for the period indicated (in thousands except for share and per share amounts):

	2019 ATM Offering For the year ended December 31, 2019	2019 ATM Offering For the year ended December 31, 2020	2020 ATM Offering For the year ended December 31, 2020
Total shares of common stock sold	1,374,686	6,687,846	16,320,793
Average price per share	\$ 5.23	\$ 1.73	\$ 0.58
Gross proceeds	\$ 7,193	\$ 11,558	\$ 9,264
Commissions earned by Cantor	\$ 212	\$ 347	\$ 278
Net Proceeds	\$ 6,981	\$ 11,211	\$ 8,986
From January 1, 2021 through the termination date of January 26, 2021, the Company has raised, under the 2020 ATM Offering, additional gross proceeds of \$28.1 million through the sale of 19,120,037 shares of common stock.			

### Public Offerings of Securities

On March 10, 2020, the Company closed the March 2020 Public Offering 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 and purchased 3,308,823 Series C Warrants and 3,308,823 Series D Warrants.

The shares of Series A Preferred Stock rank on par with the shares of the common stock, in each case, as to dividend rights and distributions of assets upon liquidation, dissolution or winding up of the Company. With certain statutory exceptions, as described in the Series A Preferred Stock Certificate of Designation, the shares of Series A Preferred Stock have no voting rights. Each share of Series A Preferred Stock was convertible at any time at the holder's option into one share of common stock, which conversion ratio was subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations and other similar transactions as specified in the Series A Preferred Stock Certificate of Designation. All of the shares of Series A Preferred Stock were converted to common stock by the holders by June 30, 2020. Upon conversion, the Company recorded \$0.3 million as a deemed dividend as an immediate charge to earnings available to common stockholders for the year ended December 31, 2020. In accordance with the Series A Preferred Stock Certificate of Designation, the shares of Series A Preferred Stock regained the status of authorized and unissued shares of preferred stock.

The net proceeds to the Company from the March 2020 Public Offering were approximately \$13.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. All shares of Series A Preferred Stock were converted into 7.9 million shares of common stock prior to June 30, 2020. Approximately 4.9 million Series C Warrants were exercised during the year ended December 31, 2020, generating net proceeds of \$3.3 million. The Class A Units, the Class B Units, the Series A Preferred Stock, the Series C Warrants and the Series D Warrants (together with the shares of common stock underlying the shares of Series A Preferred Stock and such warrants) were offered under the Company's previously filed Registration Statement on Form S-3, which registration statement expired in May 2020. The Company filed a new registration statement on Form S-1 covering the exercise of the outstanding Series C Warrants and Series D Warrants, which was declared effective by the SEC on May 27, 2020.

On July 6, 2020, the Company completed an underwritten public offering of 42,857,142 shares of its common stock, including the underwriter's full exercise of an over-allotment option, at the public offering price per share of \$0.35 per share, generating net proceeds of approximately \$13.6 million. Following the offering, the exercise price of the outstanding Series B Warrants was adjusted to \$0.35 per share and the number of shares of common stock underlying such warrants increased to 567,660 shares (see Note 16).

## Firm Commitment Offering

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.

## 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. No other shares were issued to Lincoln Park under the purchase agreement, and it was terminated in June 2020.

## 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. During the year ended December 31, 2020, the Company continued the restructuring efforts with additional headcount reductions which resulted in \$0.9 million related to severance costs. Payments under the restructuring plan concluded in 2020. During the year ended December 31, 2020, 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, 2019	\$ 882
Amount charged to operating expenses	851
Cash payments	(1,733)
Balance at December 31, 2020	<u>\$ —</u>

## 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 potential dilutive common shares that were outstanding during the period when the effect is dilutive. Potential dilutive common shares consist of incremental shares issuable upon exercise of stock options, restricted stock units, warrants and preferred stock. For the year ended December 31, 2020, the effects of the Series A Preferred Stock beneficial conversion charge and conversion are included in the calculation of net loss attributable to common stockholders. No adjustments have been made to the weighted average outstanding common shares figures for the years ended December 31, 2020 or 2019 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>2020</b>	<b>2019</b>
Stock options	4,361,872	1,830,958
Stock warrants	46,498,909	2,071,172
Nonvested restricted stock units	2,959,099	443,927
Total	<u>53,819,880</u>	<u>4,346,057</u>

## **20. Related Person Transactions**

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 \$74,000 and \$26,000 for the years ended December 31, 2020 and 2019, respectively.

In March 2018, Asensus Surgical Europe S.à.R.L 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 \$110,000 and \$12,000 for the years ended December 31, 2020 and 2019, 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. The fair value of the contingent consideration was \$3.9 million and \$1.1 million as of December 31, 2020 and 2019, respectively.

### ***Legal Proceedings***

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, 2020 and 2019.

### ***Operating Leases***

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. 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.

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 was 8.2% and 7.8% as of December 31, 2020 and December 31, 2019, respectively.

As of December 31, 2020, the right-of-use asset totaled \$1.2 million and is included within other long-term assets on the consolidated balance sheet and the lease liability totaled \$1.3 million, of which \$0.7 million is classified as current within accrued expenses and \$0.6 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, 2020 totaled \$1.5 million and are included within operating expenses in the consolidated statement of operations and comprehensive loss. The weighted average remaining lease term for operating leases as of December 31, 2020 was 1.8 years. Total cash paid for operating leases during the year ended December 31, 2020 was \$1.5 million and is included within cash flows from operating activities within the consolidated statement of cash flows.

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. 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, 2020 (in thousands):

<b>Fiscal Year</b>	
2021	\$ 883
2022	404
2023	120
2024	5
2025	—
Thereafter	—
Total minimum lease payments	\$ 1,412
Less: Amount of lease payments representing interest	(151)
Present value of future minimum lease payments	<u>\$ 1,261</u>

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

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

On November 2, 2009, Asensus Surgical US, Inc. ("Asensus Surgical US") 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. The Company's current North Carolina lease was extended for three months and expires on March 31, 2021.

In July 2020, Asensus Surgical US, entered into a lease agreement for new office, lab and warehouse space in Durham, North Carolina. The lease is expected to commence in the first quarter of 2021, has an initial lease term of 125 months following commencement, and includes tenant options to extend the lease term for up to two additional five-year periods. Monthly base rent payments begin five months after the commencement date and are subject to annual escalations. Total base rent payments over the initial 125-month term shall be approximately \$5.0 million. A proportionate share of building operating costs and ad valorem property taxes are also due monthly. In conjunction with entering into the lease, Asensus Surgical US obtained a standby letter of credit issued by Silicon Valley Bank for approximately \$0.5 million for the benefit of the landlord and has been required to increase restricted cash held with Silicon Valley Bank by \$0.5 million. The Company has executed a guaranty for the payment and performance of obligations incurred under the lease.

On May 12, 2016, Asensus Surgical Italia S.r.l. 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, Asensus Surgical Israel Ltd 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 K.K. entered into an operating lease for office space for a period of five years commencing in April 2018. On July 1, 2018, Asensus Surgical 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 \$1.5 million and \$1.4 million for the years ended December 31, 2020 and 2019, 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 \$3.5 million in 2021, \$0.5 million in 2022, \$0.5 million in 2023, \$0.5 million in 2024, and \$0.5 million thereafter until termination in 2027. Payments under these arrangements generally become due and payable only upon the achievement of certain milestones. For instances in which the achievement of these milestones is neither probable nor reasonably estimable, such contingencies are not included in the estimated amount.

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**

### **Financings**

On January 12, 2021, the Company sold, in a registered direct offering, 25,000,000 shares of common stock at a purchase price per share of \$1.25 for aggregate gross proceeds of \$31.25 million, and net proceeds of \$28.8 million.

On January 29, 2021, the Company completed an underwritten public offering of 26,725,832 shares of its common stock, including the underwriter's full exercise of an over-allotment option on February 1, 2021, at the public offering price of \$3.00 per share, generating net proceeds of approximately \$73.5 million.

As of the date of this filing Series B, C and D warrants have been exercised during 2021 for aggregate proceeds to the Company of \$30.4 million.

From January 1, 2021 through to the date of this filing the following table summarizes the total sales under the 2020 ATM Offering (in thousands except for per share amounts). The 2020 ATM Offering was terminated on January 26, 2021.

Total shares of common stock sold	19,120
Average price per share	\$ 1.47
Gross proceeds	\$ 28,100
Commissions earned by Cantor	\$ 843
Net Proceeds	\$ 27,257

### **Name change**

Effective on February 23, 2021, the Company changed its name from TransEnterix, Inc. to Asensus Surgical, Inc. On March 5, 2021, the ticker symbol of the Company's common stock on the NYSE American changed from "TRXC" to "ASXC."

## **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, 2020. 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, 2020, our disclosure controls and procedures were effective at a reasonable assurance level.

#### **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, 2020, 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 this evaluation, management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

As of December 31, 2020, we are a non-accelerated filer, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

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

There were no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **ITEM 9.B. OTHER INFORMATION**

None.

### 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 30, 2021.

#### 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 30, 2021.

#### 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 30, 2021.

##### 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
6	increase the number of shares reserved for issuance under the Plan to 10,072,307 shares, and to make other changes	June 8, 2020

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 Asensus Surgical US, Inc., 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, 2020:

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options and other equity awards (1)</b>	<b>Weighted average exercise price of outstanding options</b>	<b>Number of securities remaining available for future issuance (2)</b>
Equity compensation plans approved by security holders	7,089,363	10.76	2,076,152
Equity compensation plans not approved by security holders (3)	230,490	4.38	0
Total	7,319,853	10.50	2,076,152

(1) Includes 4,180,264 shares underlying outstanding stock options awarded under the Plan, 2,589,099 restricted stock units awarded under the Plan, and 320,000 performance-based restricted stock units awarded under the Plan.

(2) These shares are all available for future awards under the Plan.

(3) Represents 30,490 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger and 200,000 shares underlying outstanding stock options, restricted stock units, and performance-based restricted stock units issued as an employment inducement grant as an exception to the NYSE American stockholder approval rules.

#### **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 30, 2021.

#### **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 30, 2021.

## 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:

	<u>Page</u>
Consolidated Financial Statements :	
<u>Report of Independent Registered Public Accounting Firm</u>	52
<u>Consolidated Balance Sheets as of December 31, 2020 and 2019</u>	54
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and 2019</u>	55
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2020 and 2019</u>	56
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019</u>	57

(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	<u>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).</u>
2.1(a)	<u>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).</u>
3.1.1	<u>Amended and Restated Certificate of Incorporation of Asensus Surgical, Inc. (filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on February 25, 2021 and incorporated by reference herein).</u>
3.1.2	<u>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).</u>
3.2	<u>Amended and Restated Bylaws of Asensus Surgical, Inc. (filed as Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on February 25, 2021 and incorporated by reference herein).</u>
4.1 *	<u>Specimen Certificate for Common Stock of Asensus Surgical, Inc.</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
4.6	<u>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).</u>
4.7	<u>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).</u>

<b>Exhibit No.</b>	<b>Description</b>
4.8 *	<u>Description of Listed Securities</u>
10.1 +	<u>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).</u>
10.2+	<u>Employment Agreement, dated August 14, 2020, by and between TransEnterix Canada, Inc., on behalf of the Registrant, and Shameze Rampertab (filed as Exhibit 10.1 to our Current Report on Form 8-K/A, filed with the SEC on August 14, 2020 and incorporated by reference herein).</u>
10.2.1+	<u>Amendment to Employment Agreement, dated September 16, 2020, by and between TransEnterix Canada, Inc., on behalf of the Registrant, and Shameze Rampertab (filed as Exhibit 10.1.2 to our Registration Statement on Form S-8, filed with the SEC on November 6, 2020 and incorporated by reference herein).</u>
10.2.2+	<u>TransEnterix, Inc. Employment Inducement Performance Restricted Stock Unit Award Agreement, dated as of August 24, 2020, by and between the Registrant and Shameze Rampertab (filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2020 and incorporated by reference herein).</u>
10.2.3+	<u>TransEnterix, Inc. Employment Inducement Restricted Stock Unit Award Agreement, dated as of August 24, 2020, by and between the Registrant and Shameze Rampertab (filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2020 and incorporated by reference herein).</u>
10.2.4+	<u>TransEnterix, Inc. Employment Inducement Stock Option Award Agreement, dated as of August 24, 2020, by and between the Registrant and Shameze Rampertab (filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q, filed with the SEC on November 5, 2020 and incorporated by reference herein).</u>
10.3 +	<u>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).</u>
10.4 + *	<u>Asensus Surgical, Inc. Amended and Restated Incentive Compensation Plan, as amended and restated effective June 8, 2020 (the "Plan").</u>
10.4.1 + *	<u>Appendix C to the Asensus Surgical, Inc. Amended and Restated Incentive Compensation Plan.</u>
10.4.2 + *	<u>Form of Employee Stock Option Agreement pursuant to the Plan.</u>
10.4.3 + *	<u>Form of Employee Restricted Stock Unit Agreement pursuant to the Plan.</u>
10.4.4 + *	<u>Form of Employee Performance-Based Restricted Stock Unit Agreement pursuant to the Plan.</u>
10.4.5 + *	<u>Form of Non-Employee Director Stock Option Agreement pursuant to the Plan.</u>
10.4.6 + *	<u>Form of Non-Employee Director Restricted Stock Unit Agreement pursuant to the Plan.</u>
10.4.7 + *	<u>Form of Non-Employee Director Other Stock Award Agreement</u>
10.4.8 + *	<u>Form of Non-Employee Director Stock Option Grant in Lieu of Cash Retainer</u>
10.5 ++	<u>License Contract between the European Union and Vulcanos S r.l. (now known as Asensus Surgical 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).</u>
10.6	<u>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 and incorporated by reference herein).</u>
10.7	<u>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).</u>

<b>Exhibit No.</b>	<b>Description</b>
10.7.1	<u>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).</u>
10.7.2	<u>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).</u>
10.8 + *	<u>Asensus Surgical, Inc. Non-Employee Director Compensation Program, effective July 1, 2020</u>
10.9	<u>Form of Series B Warrants Exchange Agreement dated February 24, 2020, among TransEnterix, Inc. and the Series B Warrant holders signatory thereto (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 25, 2020 and incorporated by reference herein).</u>
10.10	<u>Promissory Note, dated April 18, 2020, by and between TransEnterix, Inc. and City National Bank, a national banking association (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 28, 2020 and incorporated by reference).</u>
10.11	<u>Form of Securities Purchase Agreement dated January 12, 2021, by and among the Registrant and the Purchasers (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 14, 2021 and incorporated by reference).</u>
21.1 *	<u>Subsidiaries of the Registrant.</u>
23.1 *	<u>Consent of BDO USA, LLP.</u>
31.1 *	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).</u>
31.2 *	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).</u>
32.1 *	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2 *	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS *	Inline XBRL Instance Document.
101.SCH *	Inline XBRL Taxonomy Extension Schema Document.
101.CAL *	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF *	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB *	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (included in Exhibit 101).
+	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 11, 2021

**Asensus Surgical, 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 Asensus Surgical, Inc., hereby severally constitute and appoint Anthony Fernando and Shameze Rampertab, 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.

<b>Signature</b>	<b>Title(s)</b>	<b>Date</b>
<u>/s/ Anthony Fernando</u> Anthony Fernando	President, Chief Executive Officer and a Director (principal executive officer)	March 11, 2021
<u>/s/ Shameze Rampertab</u> Shameze Rampertab	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 11, 2021
<u>/s/ Paul A. LaViolette</u> Paul A. LaViolette	Chairman of the Board and a Director	March 11, 2021
<u>/s/ Andrea Biffi</u> Andrea Biffi	Director	March 11, 2021
<u>/s/ Jane H. Hsaio</u> Jane H. Hsaio, Ph.D.	Director	March 11, 2021
<u>/s/ David B. Milne</u> David B. Milne	Director	March 11, 2021
<u>/s/ Richard C. Pfenniger, Jr.</u> Richard C. Pfenniger, Jr.	Director	March 11, 2021
<u>/s/ William N. Starling, Jr.</u> William N. Starling, Jr.	Director	March 11, 2021



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**Asensus Surgical, Inc. Board of Directors**  
**As of April 22, 2021**

**Paul A. LaViolette – Chairman (1)(2)(3)**

*Managing Partner and COO, SV Health Investors*

**Andrea Biffi**

*CEO, SOFAR, S.p.A.*

**David B. Milne (1)(2)**

*Former Managing Partner, SV Health Investors*

**Anthony Fernando**

*President and CEO, Asensus Surgical, Inc.*

**Jane H. Hsiao, Ph.D., MBA**

*Vice-Chairman and Chief Technical Officer, OPKO Health, Inc.*

**Richard C. Pfenniger, Jr. (2)(3)**

*Former Chairman and CEO, Continucare Corporation*

**William N. Starling (3)**

*CEO, Synecor, LLC*

- 
- (1) Member of Corporate Governance and Nominating Committee
  - (2) Member of Audit Committee
  - (3) Member of Compensation Committee

**Asensus Surgical, Inc. Executive Officers**  
**As of April 22, 2021**

**Anthony Fernando**

*President and Chief Executive Officer*

**Shameze Rampertab**

*Executive Vice President and Chief Financial Officer*

**STOCK AND INVESTOR INFORMATION**

**Corporate Offices -**

*1 TW Alexander Drive, Suite 160  
Durham, NC 27703  
(919) 765-8400  
(919) 765-8459*

**Common Stock -**

*Asensus Surgical, Inc. Common Stock, par value \$0.001, is traded on the NYSE American under the symbol "ASXC"*

**Independent Auditors -**

*BDO USA, LLP  
421 Fayetteville Street, Suite 300  
Raleigh, NC 27601*

**Transfer Agent -**

*Continental Stock Transfer & Trust Company  
1 State Street 30th Floor  
New York, NY 10004-1561*

**At the written request of each record owner or beneficial owner of our securities, we will provide, without charge, a copy of the Asensus Surgical, Inc. Annual Report on Form 10-K for the year ended December 31, 2020 or any exhibit thereto not included herein. Requests should be sent to Secretary, Asensus Surgical, Inc., 1 TW Alexander Drive, Suite 160, Durham, NC 27703; or by email at [corporatesecretary@asensus.com](mailto:corporatesecretary@asensus.com).**

*Except for the historical matters contained herein, statements made in this report are forward looking and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. Investors are cautioned that forward looking statements involve risks and uncertainties that may affect our business and prospects, including economic, competitive, governmental, technological, and other factors discussed in this report and in our filings with the Securities and Exchange Commission, including without limitation, the Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 11, 2021.*